# ASCO Daily News®

FRIDAY · JUNE 1, 2018

REGISTRATION


## INSIDE



### Tip of the Day

**Stay Engaged During the Sessions**

**New this year, use Interact, *powered by SYNC*, to view speaker slides on your personal device in real time, take notes on slides during sessions, and post questions to session faculty.**

# 2018 ASCO Annual Meeting: Delivering Discoveries, Expanding the Reach of Precision Medicine

Every year, the ASCO Annual Meeting attracts the best and brightest in oncology to McCormick Place convention center in Chicago, where more than 39,000 attendees from around the world gather to network and hear the latest innovations in cancer care. There is no better forum to learn about and discuss the important issues and ongoing controversies in cancer care across a variety of disease sites, treatment approaches, and disciplines.

The theme for this year's meeting, selected by 2017-2018 ASCO President Bruce E. Johnson, MD, FASCO, sets an exciting tone for the presentation of advances in the field of cancer care. "Delivering Discoveries: Expanding the Reach of Precision Medicine" highlights the importance of making precision medicine accessible to every patient with cancer.

"Precision medicine is transforming cancer care in profound ways and is a focus of this year's Meeting," Dr. Johnson said. "I firmly believe that the number of patients who benefit from precision medicine will continue to increase as treatments become more effective."

Don't get overwhelmed by the extraordinary size and scope of the Annual Meeting. In this article, we highlight the Meeting's can't-miss events, tips for connecting with colleagues, and new features for 2018.

"The Annual Meeting is one of a kind," David R. Spigel, MD, 2018 ASCO Annual Meeting Education Committee chair, said. "There is something for everyone who is dedicated to improving the lives of people facing cancer. It can be a bit overwhelming because there is so much outstanding content to choose from. My best advice is to take your time, choose what interests you most each day, and go enjoy, participate, and learn—and bring that excitement back to your community and share it with others."

### 2018 Scientific Program Highlights

This year, 6,450 abstracts were submitted for consideration by the Scientific Program Committee. The committee, which is composed of 180 members across 24 tracks, puts these abstracts through an intensive review process and curates them carefully into thematic scientific sessions, meant to inform and educate attendees on the latest advances in cancer care. This year, approximately 2,515 abstracts were selected for presentation in Oral Abstract Sessions, Clinical Science Symposia, and Posters, plus more than 3,350 for online publication.

"The scientific program promises to highlight the emerging role of precision medicine, not only in research to conquer cancer but

*See ASCO Annual Meeting, Page 17*

# Spotlight on Innovation in Precision Medicine

**SESSION PREVIEW**

The 2018 ASCO Annual Meeting will feature a diverse range of sessions focusing on the theme, "Delivering Discoveries: Expanding the Reach of Precision Medicine." The theme will highlight the effects of precision medicine on patients with cancer who could benefit from innovative treatment options.

### Growth of Precision Medicine

Precision medicine is a growing area of interest in health care. In 2015, President Barack Obama announced the allocation of $215 million for research efforts that can accelerate biomedical discoveries.[1] This included $70 million for the National Cancer Institute to aid in increased efforts for identifying genomic drivers of cancer and to apply new knowledge to develop more effective treatments.

More recently, the National Institutes of Health launched its All of Us research program, a part of the Precision Medicine Initiative that aims to gather data from more than 1 million people in the United States in order to expedite health research breakthroughs.[2]

ASCO has also shown its commitment to expanding the reach of precision medicine by launching its Targeted Agent and Profiling Utilization Registry (TAPUR) study in 2016. TAPUR is designed to identify signals of activity of commercially available, targeted anticancer drugs in patients with advanced cancer whose tumors harbor one or more genomic variants known to be a drug target. In late 2017, ASCO announced further expansion of the study, which now includes more than 500 patients and 16 therapies.[3]

### Precision Medicine Informatics

"Precision medicine is the ability to use a patient's features, be they molecular, clinical, or histopathologic, to tailor a treatment regimen that would be most beneficial for them," said James Lin Chen, MD, of The Ohio State University. "Precision medicine has fundamentally shifted the way we think about cancer treatment. If you look at guideline-based treatment, we were trying to find regimens that treat the majority of patients. With precision medicine, we are trying to find the best tailored therapy for a representative set of patients with whom your patient belongs."

In today's oncology arena, there is a tremendous amount of information that a practicing oncologist needs to know, Dr. Chen said, adding that the amount of available information is far more than can be found in a synopsis using a literature search on PubMed. Instead, oncologists must learn to embrace informatics as a means to rapidly find the most appropriate treatment for each patient. This is the main focus of "The Informatics of Precision Cancer Medicine," an Education Session on June 1 chaired by Dr. Chen.*

According to Dr. Chen, there has been an explosion of data in oncology. During his presentation on the health information

*See Precision Medicine, Page 4*

Dr. Bruce E. Johnson

## A Note From the ASCO President

Precision medicine is transforming cancer care in profound ways and is a focus of this year's Meeting. I firmly believe that the number of patients who benefit from precision medicine will continue to increase as treatments become more effective. Thank you for joining me in Chicago to participate in a unique global exchange of information about how to drive progress and expand the reach of precision medicine to all of our patients.

*See ASCO President, Page 3*

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# New Annual Meeting Workshops Offer Hands-On Training

On June 1, ASCO Annual Meeting attendees will have the opportunity to participate in four workshops, each including interactive, didactic teaching along with hands-on experiences. Participants will work in small groups to learn practical take-home skills and tools to implement in their practices. All workshops are limited in size, and space is available on a first-come, first-served basis.

### Talking With Patients About Risk and Uncertainty

**1 PM-3:15 PM, S405**

Dame Dr. Lesley Fallowfield

Dr. Valerie A. Jenkins

This new workshop is co-chaired by Dame Lesley Fallowfield, BSc, DPhil, FMedSci, and Valerie A. Jenkins, BSc, DPhil. "Not only will attendees learn specific strategies for explaining risk and uncertainty to patients," Dr. Jenkins said, "but the workshop aims to help participants identify their own tolerances to risk and uncertainty and recognize how these may influence the way they convey information to patients."

In 2017, Dame Dr. Fallowfield and Dr. Jenkins developed an education program focused on helping physicians talk with patients about risk and uncertainty in the context of genomic test results through a grant from the Breast Cancer Research Foundation. The program includes videos of doctors speaking with patients about risk and simulated patient/physician group exercises, some of which will be delivered at the ASCO workshop.

"Cancer treatment has become very complex, and one almost needs a degree in molecular biology to understand the pros and cons as to why one treatment is being recommended over another," Dame Dr. Fallowfield said. "Physicians need to help patients understand the data that demonstrate side effects, recurrence risk, efficacy, and impact of recurrence in terms of survival."

### Genomics for Oncologists 101

**1 PM-5 PM, S105ab**

Dr. Richard L. Haspel

Dr. Ramaswamy Govindan

Also new this year is a workshop intended for all oncology health care providers to understand how to order genomic testing and how to interpret the results. "The overarching purpose of the workshop is to get a practical look at how to do genomic testing in cancer," Co-chair Richard L. Haspel, MD, PhD, said. Dr. Haspel collaborated with Co-chair Ramaswamy Govindan, MD, to create the first-ever ASCO workshop intended to give oncology participants experience using actual genomics tools to work on a clinical case that they would see in practice.

To allow for an interactive approach, the workshop is in a team-based learning format. After a short pre-activity lecture, participants work in teams of four or five following a case scenario. The teams use online genomics tools to search databases to find what kind of genomic testing they want to order, and then gauge the clinical significance of genetic variants. "It's very practical. It's not just about gaining knowledge, but developing the skills for treating [patients with cancer]," Dr. Govindan said. Participants will learn how to understand the genetic reports, what the results mean, and what to do with the information.

After the team activity, participants will hear a post-exercise lecture and discuss their findings with the larger group. The end result is to help physicians find appropriate treatments and identify the most appropriate active clinical trials if their patient has a variant of a gene.

### Developing a Survivorship Clinic

**3:45 PM-6 PM, S405**

Dr. Kevin C. Oeffinger

Dr. Eva Grunfeld

Workshop Co-chairs Kevin C. Oeffinger, MD, and Eva Grunfeld, MD, DPhil, will be hosting a new practical program on how to develop a survivorship clinic.

Currently, there are more than 15 million cancer survivors in the United States.[1] "People are recognizing that survivorship is much more than simply checking to make sure the cancer did not return," Dr. Oeffinger said. "Although that is important in the first 2 to 3 years, it becomes less so over time."

Other aspects of survivorship care become important including screening for second cancers, screening for late effects of cancer therapy, helping with psychosocial problems or financial challenges, and helping people get back to an active lifestyle through rehabilitation and exercise intervention.

In the first half of the workshop, participants will learn specifics about how to establish a survivorship program at both the community oncology setting and at an academic setting. The second portion of the workshop will introduce participants to a novel approach developed at the University of Toronto that integrates survivorship care with general preventive care. Participants will be introduced to the BETTER approach with hands-on application of the BETTER tools. The BETTER Coalition aims to improve chronic disease prevention and screening in the primary care setting.

The goal of the workshop is to give participants practical solutions on several fronts, including a needs assessment to choose what might be the best model for their organizations, the myriad types of challenges faced when starting a survivorship clinic and how to overcome them, and how to measure the success of their program.

### Grant Writing for Young Researchers

**1 PM-5 PM**

For more than 10 years, ASCO has offered "Grant Writing for Young Researchers," which reviews the specifics of grant-writing for funding. In this three-part workshop, participants will first hear several 15-minute talks on a variety of topics including grant writing pearls, how to work with a statistician, how to choose a mentor, and what to do when your application is rejected.

During the second phase, participants will observe a mock grant selection review similar in methodology to the National Institutes of Health and research foundation awards. "We will evaluate a grant application just as we do in our own grant selection committee for ASCO's Conquer Cancer Foundation Young Investigator and Career Development Awards," said Conquer Cancer's Scientific Review Officer Dean Frohlich, MD, who will act as the grant selection chair.

The third portion of the workshop will be a small-group, roundtable discussion with experienced grant writers where participants can move between tables. ●

**–Alice McCarthy**

**Reference:**

1. National Cancer Institute: Division of Cancer Control and Population Sciences. Statistics. cancercontrol.cancer.gov/ocs/statistics/statistics.html. Accessed April 3, 2018.

### ASCO President

*Continued from page 1*

We drive progress by delivering care that is truly personalized—by considering each person's unique genetics, environment, and lifestyle to prevent cancer in patients at high risk, and when not possible, to diagnose early and treat cancer effectively. With exciting advances in immunotherapy treatments, we are seeing an uptick in remissions and longer survival rates in some cancer types that had been refractory to other conventional treatments. Improved genetic tests can identify individuals' cancer susceptibility earlier, while informing plans for our patients who want to grow their families.

> "Precision medicine is transforming cancer care in profound ways and is a focus of this year's Meeting."
>
> –DR. BRUCE E. JOHNSON

This Meeting couldn't happen without all of our dedicated volunteers, and I especially thank the leaders of the Scientific Program and Education Committees, Ann H. Partridge, MD, MPH, FASCO, and David R. Spigel, MD, respectively, who have selected the top research scientists and educators to participate and share the latest in oncology advances.

This Meeting wouldn't happen without our welcomed attendees each year who bring a depth of knowledge that is shared across meeting rooms, as well as in small settings where long-lasting professional connections are made.

ASCO is the leading organization of oncology professionals in the world, and I am honored and proud to serve as its volunteer leader. Thank you for joining me as we learn and share the latest innovations in the field of oncology, to the benefit of those we care about most—our patients. ●

**–Bruce E. Johnson, MD, FASCO**
**2017-2018 ASCO President**
**Dana-Farber Cancer Institute**

### CANCER.NET: COMPREHENSIVE FAMILY CAREGIVER SUPPORT

Cancer.Net, ASCO's patient education website, provides patients, caregivers, families, and friends the oncologist-approved information they need. The caregiving section was recently revised and updated with expert guidance from family caregivers and oncology professionals, so you know the information is relevant and essential. When your patients and their loved ones need to learn more about caregiving, send them to cancer.net/caregiving. ●

# Attend ASCO Voices for an Innovative Presentation Experience

This year's Annual Meeting is raising the curtain on a new session type: ASCO Voices. This noncompete session will feature presentations no longer than 7 minutes each and will bring a variety of perspectives to the stage to share stories on oncology, medicine, and the world. From big ideas to personal passions, ASCO Voices will present stories that differ significantly from the remainder of session types available at Annual Meeting.

The key difference? ASCO Voices presenters will not use slides or podiums. Data and figures will not play into the talks—only the presenter, the stage, and the story will stand before the audience. The talks will be compelling, thought-provoking, and enjoyable.


Dr. Monica Morrow

ASCO Voices presentations will cover a range of stories. Trevor John Bayliss, MD, will present "Heroes, Mentors, and Hope"; Edmond Ang, MRCP, will present "Chemoboy"; Nina Shah, MD, and Rachna T. Shroff, MD, will give a joint presentation titled, "Did You Ever Know That You're My Hero? An Unexpected Gift From Our Career in Oncology"; Monica Morrow, MD, FASCO, will present "Surgery is Never Elegant When Women Are in the Operating Room"; and Patrick J. Loehrer Sr., MD, FASCO, will present "The Call."

Dr. Morrow is looking forward to speaking in this new format. "The Annual Meeting is packed with data presentations, which is how we traditionally provide and receive information," she said. "ASCO Voices offers a more personal look at oncology practice in the broadest context, with no podium or slides to hide behind. It's a great way to get to know other ASCO members, and it will be fun to listen to."


ASCO Voices will take place June 2, Arie Crown Theater, 12 PM-1 PM. For up-to-date program information, refer to your ASCO iPlanner app. ●

**–Caroline Hopkins**

## Precision Medicine

*Continued from page 1*

technology needs of oncologists and tumor boards, he will explain that the use of genomics is not the only growing aspect of precision medicine, and he will draw a distinction between personalized medicine and precision medicine.

"We have to move from the idea that a computer is going to tell us that Person A should get this treatment and Person B should get this treatment based on exact biomarkers to a system where a computer will show us possible treatments based on 'patients like my patient,'" Dr. Chen said.

The informatics session will also include presentations from Subha Madhavan, PhD, of the Georgetown University Medical Center, on enabling genomic interoperability through minimum variant level data; Somasundaram Subramaniam, MD, MS, of the Swedish Cancer Institute, on precision medicine in the community practice; and Kimberly Shoenbill, MD, MS, of the UNC School of Medicine, on the ethical, legal, and social implications of genomics information in electronic health records.

"Precision medicine can be overwhelming, but there are mechanisms being developed such as virtual tumor boards and decision support software that can be helpful," Dr. Chen said. "Precision medicine should be part of our daily practice, and help is on the way."

## Genomics in Breast Cancer

Another Education Session on June 1 will discuss "Incorporating Genomics Into the Care of Patients With Advanced Breast Cancer." Chaired by Philippe L. Bedard, MD, FRCPC, of the Princess Margaret Cancer Centre, in Toronto, Canada, the session will discuss tools available in the clinic to understand the heterogeneity of breast cancer and what genomic advances are coming in the future that may be relevant to the practicing oncologist.


Dr. Philippe L. Bedard

According to Dr. Bedard, it has long been recognized that breast cancers are heterogeneous. Traditionally, breast cancer has been treated according to subtype: hormone receptor–positive or –negative disease, HER2-positive or -negative disease, or triple-negative disease. Each subtype has a different natural history, and each is treated differently in the clinic.

"They are treated as distinct diseases," Dr. Bedard said. "What we are starting to recognize is that within each broader subtype, there are more distinct molecular subsets that represent a smaller percentage of the patient population."

The challenge now is to develop and test new drugs in these molecular subtypes or diseases with rare mutations, he said.

Lajos Pusztai, MD, PhD, of Yale Cancer Center, will open the Education Session with a presentation outlining why oncologists should care about the molecular evolution in breast cancer. Mark E. Burkard, MD, PhD, of the University of Wisconsin School of Medicine and Public Health, will focus his presentation on how to read a molecular report. "There are a variety of different labs that have developed tests and commercial assays that can be ordered, and sometimes patients even arrange for their own testing," Dr. Bedard said. "Practicing oncologists need to know what considerations are relevant when reading these reports."

In the final presentation of the session, Dr. Bedard will focus on what considerations are relevant for clinical trials of new cancer drugs, what some of the new alterations are, and how they may be relevant to specific classes of drugs. For example, researchers have known about *PI3K* mutations for quite some time, he said. They represent 30% to 40% of patients with hormone receptor–positive disease. First-generation PI3K inhibitors had mixed results, but there are some new inhibitors that are more isoform selective or mutant specific that are showing promising results. "They potentially may be the next big area of drug development that will introduce new options for the treatment of patients with these mutations," Dr. Bedard said. "There is a new wave of treatments coming that is likely to make an impact in the clinic."

## Role of Data

A third session turning its focus to precision medicine is the Education Session, "Precision Medicine for a Single Patient: What Does It Really Mean and How Do We Do It?" on June 3, chaired by Victoria Meucci Villaflor, MD, of Northwestern University.


Dr. Victoria Meucci Villaflor

During the session, Dr. Villaflor will discuss some of the challenges and opportunities associated with delivering precision medicine to patients with cancer. For instance, one challenge of precision medicine is the large amount of data available today and our ability to condense those data to determine if they apply to the patient sitting in front of us.

"Case in point is we know that c-Kit can be targeted by oral medications such as imatinib. Patients who have c-Kit alterations in gastrointestinal stromal tumors or chronic myeloid leukemia can be treated with a targeted agent, whereas patients who have salivary gland tumors with the same c-Kit alteration do not necessarily respond to the same type of medicine," Dr. Villaflor said. "Although you may have specific findings among different groups of patients, not everybody necessarily responds to the same type of treatment, meaning there are probably other factors operating within the tumor microenvironment that may not allow the tumors to be driven by that specific mutation or allow for resistance."

Dr. Villaflor is hopeful for more widespread use of precision medicine due to successes in areas like lung cancer and melanoma. Patients with *EGFR*-mutated, *ALK*-translocated lung cancers have amazing response and survival rates with use of appropriate *EGFR* or *ALK* tyrosine-kinase inhibitors. "These options afford our patients better treatment options and better quality of life," she said.

Additionally, work has been done using genomics to predict dosing of drugs. "All in all, with the collection of data studies and improved knowledge, there may come a point in time when we are able to better predict which drugs will treat the disease best with the least side effects," Dr. Villaflor said.

Dr. Villaflor will be joined in the session by Matthew Meyerson, MD, PhD, of the Dana-Farber Cancer Institute, who will discuss the role of big data and informatics in precision medicine, and Amy E. McKee, MD, of the U.S. Food and Drug Administration, who will discuss the challenges associated with the use of "small data" such as small trials or off-label use in regulatory science.

"There is so much we don't know at this point and so much we can ascertain with data sharing in an effort to drive science forward," Dr. Villaflor said.

Precision medicine is going to progress even further in the coming years, she said.

"We have only hit the tip of the iceberg," Dr. Villaflor said. "We have to work together as a scientific community to try to move science forward and see how well we can elucidate what is going on with many molecular, protein, genetic, and immune alterations in each type of malignant disease to learn how to better treat and even prevent cancers." ●

**–Leah Lawrence**

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1. ASCO in Action. ASCO Commends President Obama for Precision Medicine Initiative. asco.org/advocacy-policy/asco-in-action/asco-commends-president-obama-precision-medicine-initiative. Published January 30, 2015. Accessed March 1, 2018.
2. ASCO in Action. National Institutes of Health Launches New Precision Medicine Initiative. asco.org/advocacy-policy/asco-in-action/national-institutes-health-launches-new-precision-medicine-initiative. Published October 11, 2017. Accessed March 1, 2018.
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**Program information updated as of March 1. For session time and location information, please refer to the ASCO iPlanner on the Attendee Resource Center (am.asco.org/arc).*

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**Reference: 1**. Xofigo® (radium Ra 223 dichloride) injection [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; February 2018.

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The latest edition of *ASCO-SEP*®, ASCO's self-evaluation program in oncology, is available for purchase from ASCO University®. *ASCO-SEP* is a comprehensive resource designed to help providers assess their level of knowledge in the various areas of oncology and provides current understanding of cancer, its treatment, and the supportive care needed to optimize the quality of life for people with cancer.

The program includes 22 chapters and a companion mock exam with answer rationales covering the full range of topics in oncology, including major cancer types, epidemiology and cancer prevention, strategies for cancers in elderly patients, clinical trial design and statistics, molecular biology, and an overview of biologic therapy. Purchase of this publication comes with an eBook version.

*ASCO-SEP 6th Edition* features a new chapter on Genetic Testing for Hereditary Cancer Syndromes and an expanded chapter on Principles of Immuno-Oncology and Biologic Therapy. In addition, *ASCO-SEP* features more than 190 all new self-assessment questions from the 22 chapters and a Mock Exam with more than 120 new self-assessment questions not found in the book. Questions feature practical scenarios, predominantly in a patient case-based format, and provide detailed rationales and supporting references. Upon successful completion of both the *ASCO-SEP* book self-assessment questions and the Mock Exam, participants may request CME, ABIM MOC, Nursing, and Pharmacy credit through online courses.

### New This Year: Pharmacy and Nursing Credit Opportunities

Oncology professionals can receive up to 55.5 *AMA PRA Category 1 Credits*™ for CME and 55.5 MOC points upon successful completion of the online activities in the print publication, with additional credits available upon completion of the Mock Exam.

The certificate and credit types available upon completion of the evaluation and request for credit include: CME certificate, ABIM MOC Points, Continuing Nursing Education Certificate, Continuing Pharmacy Education certificate, certification of participation, and certificate of completion for continuing education.

*ASCO-SEP* and complementary educational products are all available on university.asco.org/sep. ASCO members receive substantial discounts on all materials. ●

# Opening Session to Feature Distinguished Guests

*ASCO President Dr. Bruce E. Johnson, Dr. Norman Sharpless, and Dr. Scott Gottlieb among speakers*


Dr. Bruce E. Johnson


Dr. Norman Sharpless


Dr. Scott Gottlieb

Each year, the Annual Meeting Opening Session includes distinguished speakers that capture the themes that permeate the Meeting, provide context for its scientific and educational programming, and honor those who have made significant contributions to ASCO and the entire oncology field.

The 2018 Opening Session on June 2 will consist of the Conquer Cancer Top Donor Recognition Awards; ASCO President Bruce E. Johnson, MD, FASCO's Presidential Address; the presentation of the 2018 Fellows of the American Society of Clinical Oncology (FASCO) recipients; the David A. Karnofsky Memorial Award and Lecture from Ralph R. Weichselbaum, MD; remarks from the Director of the National Cancer Institute (NCI) of the National Institutes of Health Norman Sharpless, MD; and remarks from U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD.

### Speakers

***Dr. Norman Sharpless***

NCI Director Dr. Sharpless was sworn in as the 15th director of the NCI on October 17, 2017. Prior to his appointment, Dr. Sharpless served as the director of the UNC Lineberger Comprehensive Cancer Center, a position he held since January 2014. In addition to serving as NCI director, Dr. Sharpless continues his research in understanding the biology of the aging process that promotes the conversion of normal self-renewing cells into dysfunctional cancer cells.

Dr. Sharpless is looking forward to attending the Annual Meeting. "The NCI is committed to supporting research focused on optimizing cancer care, so I am excited about the opportunity to attend the ASCO Annual Meeting and speak directly to those physicians and oncology professionals on the frontlines of making breakthrough discoveries," Dr. Sharpless said.

"I see the ASCO Annual Meeting as an important step toward expanding the delivery of state-of-the-art cancer care to all people, thereby helping reduce the burden of cancer in the United States and worldwide."

***Dr. Scott Gottlieb***

FDA Commissioner Dr. Gottlieb was sworn in as the 23rd Commissioner of Food and Drugs on May 11, 2017. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs and in advising roles for both the FDA and the Centers for Medicare and Medicaid Services. He also served as a resident fellow at the American Enterprise Institute and served as a clinical assistant professor at the New York University School of Medicine, where he practiced medicine as a hospitalist physician. ●

**–Caroline Hopkins**

# Education Session to Review Lifestyle Changes for Cancer Prevention

It is well known that maintaining a healthy weight, limiting alcohol consumption, and taking precautions against sun exposure can reduce the risk of developing certain cancers and improve treatment outcomes in patients diagnosed with specific cancers.

ASCO has released policy positions on alcohol consumption and indoor tanning and is encouraging its members to address lifestyle behaviors including diet and exercise in their clinics and communities.[1,2]

During an Education Session on June 3*, "Lifestyle Modifications for Primary and Secondary Cancer Prevention: Diet, Exercise, Sun Safety, and Alcohol Reduction," speakers will review the latest data and provide attendees with practical tips on communicating these lifestyle risk factors to their patients.

### Alcohol Consumption and Cancer Risk

Session Chair Noelle K. LoConte, MD, of the University of Wisconsin School of Medicine and Public Health, will discuss data showing the association between alcohol consumption and certain types of cancer, the need for additional research, and policy strategies for controlling alcohol consumption.


Dr. Noelle K. LoConte

"Alcohol is considered a definitive carcinogen by the International Agency for Research on Cancer, which assesses the cancer risk of environmental carcinogens. Alcohol has been associated with seven types of cancer, the most common being head and neck," Dr. LoConte said.

Research shows that the risk of cancer is higher for heavy drinkers, including binge drinkers who may not meet the criteria for alcoholism or alcohol abuse. However, even moderate drinking can increase the risk of developing certain cancers, such as breast cancer.[3]

Dr. LoConte, who is a member of ASCO's Cancer Prevention Committee, will discuss the position statement, "Alcohol and Cancer: A Statement of the American Society of Clinical Oncology," which was recently published in the *Journal of Clinical Oncology*.[1]

> "Alcohol has been associated with seven types of cancer, the most common being head and neck."
>
> –DR. NOELLE K. LOCONTE

"This is the first time ASCO has formally taken a stand in favor of various alcohol policy strategies to prevent and control cancer," she said. "Examples include raising taxes on alcohol sales and reducing the density of alcohol outlets by restricting sales and liquor licenses. We also recommend reducing youth exposure to alcohol marketing, which is pervasive and effective. Research shows that youth who drink are more likely to become adults who drink heavily."

ASCO also has taken a formal position opposing "pinkwashing," which typically occurs when institutions serve alcohol by dyeing it pink to fundraise for cancer causes.[4] "As frontline providers who are treating patients with alcohol-related cancers, we need to take alcohol exposure as seriously as the sun or other harmful substances," Dr. LoConte said.

### Melanoma Prevention Strategies

This year alone in the United States, more than 90,000 people will be diagnosed with melanoma, the most lethal form of skin cancer.[5] An estimated 95% of all melanomas are attributed to UV radiation exposure from either the sun or indoor tanning beds.[6]

*See Lifestyle Changes, Page 7*

## Lifestyle Changes

*Continued from page 6*

During his presentation, Jeffrey E. Gershenwald, MD, of The University of Texas MD Anderson Cancer Center, will highlight key accomplishments in skin cancer prevention in the past decade including ASCO's joint statement on indoor tanning, "The Surgeon General's Call to Action to Prevent Skin Cancer," and 17 states and the District of Columbia with laws banning indoor tanning salons from admitting minors.[7]

He will also discuss recent studies exploring melanoma risk and sunscreen use, decreasing trends in melanoma incidence rates among younger adults, scaling up educational campaigns aimed at children and adults, and multicomponent community-wide efforts.

"One of the messages I want to deliver is the importance of starting sun safety behaviors in early childhood," Dr. Gershenwald said. "Research shows that having five or more sunburns as a child or initiating indoor tanning at an early age greatly increases the risk of melanoma later in life. Evidence is mounting that risk reduction strategies can have a clinical impact."

He will also highlight several sun safety educational campaigns aimed at school children as early as pre-kindergarten, such as Ray and the Sunbeatables: A Sun Safety Curriculum, an evidence-based program developed by MD Anderson.

"As part of our Melanoma Moon Shot initiative, we recently digitalized Ray and the Sunbeatables, which enables us to offer this program on a national and international basis," he said. "We also just launched a new third to fifth grade curriculum, Be Sunbeatable, in collaboration with Scholastic, which will be available in schools across the United States."

search shows that a healthy diet and regular physical activity can help overweight or obese individuals improve their body composition and metabolic health, which may improve their survival."

> "A healthy lifestyle can improve the survival rates of patients diagnosed with cancer."
>
> –DR. CYNTHIA A. THOMSON

During her presentation, Dr. Thomson will discuss the key role diet and physical activity play in both cancer prevention and survivorship, review the current guidelines and the link between obesity and cancer, and recommend actions oncologists can take.

Dr. Cynthia A. Thomson

"A healthy lifestyle can improve the survival rates of patients diagnosed with cancer. For example, patients with a healthy lifestyle and

### Diet and Physical Activity for Cancer Prevention

In the United States, being overweight or obese are risk factors for developing cancers of the liver, colon, rectum, gallbladder, and others.[8,9]

"We know that obesity changes hormones and increases the risk of insulin resistance, inflammation, diabetes, and cardiovascular disease," Cynthia A. Thomson, PhD, RDN, of the University of Arizona Cancer Center, said. "The research shows that a healthy diet and regular physical activity can help overweight or obese individuals improve their body composition and metabolic health, which may improve their survival."

During her presentation, Dr. Thomson will discuss the key role diet and physical activity play in both cancer prevention and survivorship, review the current guidelines and the link between obesity and cancer, and recommend actions oncologists can take.

"A healthy lifestyle can improve the survival rates of patients diagnosed with cancer. For example, patients with a healthy lifestyle and body weight before a cancer diagnosis tend to have a better prognosis. After a cancer diagnosis, changing lifestyle behaviors and controlling body weight can still improve a patient's survival rate," Dr. Thomson said.

Dr. Thomson will also examine workforce issues such as whether there are enough registered dieticians and physical therapists specializing in oncology care to counsel patients. "Although national cancer guidelines have emphasized diet and physical activity for the past 20 years, too few patients with cancer are receiving appropriate dietary and physical activity counseling from qualified professionals specializing in oncology care," she said.

Besides referrals for diet and activity counseling, oncologists can take simple steps to encourage healthy behaviors in their patients. "Just writing a prescription for eating five vegetables daily and 30 minutes of daily walking can be very impactful," Dr. Thomson said. ●

**–Christine Lehmann, MA**

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**Program information updated as of February 23. For session time and location information, please refer to the ASCO iPlanner on the Attendee Resource Center (am.asco.org/arc).*

# Exploring Precision Medicine in Primary Brain Tumors

## SESSION PREVIEW

The Education Session "Precision Medicine for Primary Central Nervous System Tumors: Are We There Yet?" on June 2* will highlight the novel, clinically actionable mutations that have been identified in gliomas, craniopharyngiomas, and meningiomas.

During the session, presenters will "summarize recent advances in our understanding of the molecular landscape of gliomas, craniopharyngiomas, and meningiomas and will discuss the diagnostic and therapeutic implications of these findings," session Chair Priscilla Kaliopi Brastianos, MD, of Massachusetts General Hospital and Harvard Medical School, said. "We hope this will be an enriching talk for trainees, physicians, and allied health professionals who have an interest in primary brain tumors.


Dr. Priscilla Kaliopi Brastianos

"The progress in primary brain tumors is exciting," Dr. Brastianos said. The identification of these mutations "has truly opened up new potential treatment options for patients. Based on these findings, the efficacy of new targeted agents is currently being investigated in clinical trials and, if successful, may change treatment paradigms in these tumors," she said.

Other presenters during the session include Howard Colman, MD, PhD, of Huntsman Cancer Institute, and Martin J. van den Bent, MD, PhD, of the Erasmus MC Cancer Institute, in the Netherlands.

### Genetic Driver Mutations in Brain Tumors

Improved sequencing techniques over the past several decades have resulted in an increased understanding of the cancer genome. The discovery of genetic driver mutations in brain tumors has subsequently been integrated into the diagnostic process and has led to implementation of targeted treatment strategies in affected patients by directing them to clinical trials. These targeted therapies can block the growth and spread of cancer by interfering with specific molecules involved in the growth, progression, and spread of cancer.

Speakers during the Education Session will outline research and clinical trials that have led to discovery of the driver mutations in gliomas and how these discoveries are affecting diagnosis and treatment.

In low-grade gliomas, MGMT-promoter methylation status, *IDH*-mutation status, upregulation of the PI3K/AKT/mTOR-pathway, and *BRAF* mutations have shifted the focus of treatment toward agents that target these associated alterations. When the MGMT-promoter methylation status is considered, for example, alkylating and methylating chemotherapy can be considered targeted treatments. Targeting DNA-repair mechanisms using PARP inhibitors and agents that target the *IDH*-mutant enzyme and gene fusion are promising for treating patients with glioblastoma who have those genetic alterations.

Upregulation of the PI3K/mTOR pathway has been identified as playing

### SUBMIT AN ASCO DATA REQUEST

ASCO's recently established Center for Research and Analytics (CENTRA) is accepting data research requests. Through CENTRA, requests can be made for data from ASCO sources, such as the annual Practice Census; CancerLinQ Discovery®; Quality Oncology Practice Initiative (QOPI®); survey data collected by ASCO for other purposes; byproducts from ASCO meetings including abstracts, articles, slides, posters, and presentations; and ASCO journal articles, beyond what is searchable online. CENTRA also will facilitate requests for data sets that will become available from ASCO's Targeted Agent and Profiling Utilization Registry (TAPUR) Study, following initial publications.

For a full list of available data and/or to submit a request, go to asco.org or stop by ASCO Central. ●

a major role in glioblastoma, but it may also be relevant in lower-grade gliomas, according to the presenters. The discovery of *IDH* mutations as a key driver for a subset of gliomas has drastically altered the understanding of gliomas. After the *IDH* mutations were discovered in gliomas, frequent *IDH* mutations were identified in several other tumor types, including acute myeloid leukemia, cholangiocarcinoma, and certain sarcomas.

The presentations will look at the pathogenic role of *IDH* mutations, which were discovered more than a decade ago. Even though clinical progress has been disappointing, inhibitors of the IDHmt protein remain promising and warrant further study.

## Craniopharyngiomas and Precision Medicine

Craniopharyngiomas comprise 1% to 3% of all brain tumors in the United States.[1] These locally aggressive, low-grade epithelial neoplasms start in the suprasellar region of the brain and can result in devastating symptoms in affected patients. Not only is intervention challenging, but the clinical management of patients can be impeded by the lack of standardized clinical practice guidelines and effective systemic therapies. Speakers during the Education Session will review recent research that has identified highly recurrent driver mutations of craniopharyngiomas and the implications of this research for targeted therapy.

Promising response rates have been noted with *BRAF*-inhibitor therapy in patients with *BRAF V600E*–mutant melanomas, gangliogliomas, pleomorphic xanthoastrocytomas, and hairy cell leukemias. Because of the success in those patients, patients with papillary craniopharyngiomas may benefit from these treatment options and can be enrolled in clinical trials, according to Dr. Brastianos. Presenters will outline the "spectacular results" that have already been achieved in several published case reports, she said. Case reports[2,3] have found similar successful response rates in patients with papillary craniopharyngiomas who were treated with a combination of *BRAF* and *MEK* inhibitors, Dr. Brastianos said.

A phase II clinical trial (NCT03224767), led by Dr. Brastianos, is investigating the role of dual *BRAF* and MEK inhibition in patients with newly diagnosed and recurrent papillary craniopharyngiomas. Patients in the trial will be treated with vemurafenib and cobimetinib. The trial will also analyze papillary craniopharyngioma tissue pre- and post-treatment with whole-exome and RNA sequencing to identify genetic alterations that may evolve during treatment. That analysis will hopefully help refine therapeutic strategies, she explained.

## Meningiomas and Targeted Therapy

Most meningiomas have been treated with surgical resection, but the treatment can be challenging and is associated with

*See Primary Brain Tumors, Page 10*

## Primary Brain Tumors

*Continued from page 9*

high morbidity in some anatomical locations. Not all patients can be successfully treated with surgical resection alone, and the recurrence rate after 5 years can range up to 95% for World Health Organization grade 3 disease.[4,5] Systemic therapies in recurrent grade 2-3 meningiomas in recent years have led to disappointing results, Dr. Brastianos said.

Presentations will review the latest research in whole-genome and whole-exome sequencing in meningioma tissue samples. This research has found relatively simple genomes with fewer copy number alterations, translocations/rearrangements, and mutations than are usually observed in other tumors in adult patients.

A phase II trial (NCT02523014), also led by Dr. Brastianos, is analyzing the activity of *SMO*, *AKT*, and *NF2* inhibitors in recurrent or progressive meningiomas that have the *SMO*, *AKT*, or *NF2* mutation. Other driver mutations have also been described.

Other research has suggested that there may be a role for immunotherapy in grade 1-3 meningiomas, as PD-L1 expression was found to be increased in anaplastic meningiomas. The mechanisms that have been identified may contribute to an immunosuppressive microenvironment and to aggressive phenotype of this tumor subtype.[6] A phase II trial (NCT03279692) is now recruiting patients to look at the role of pembrolizumab in recurrent or residual high-grade meningiomas, she said. ●

**–Kathy Holliman, MEd**

**Program information updated as of February 23. For session time and location information, please refer to the ASCO iPlanner on the Attendee Resource Center (am.asco.org/arc).*

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### JOIN THE ASCO BOOK CLUB

Join the discussion as Damon Tweedy, MD, author of the *New York Times* bestseller *Black Man in a White Coat*, shares insights about race and bias in medicine. The session will be held on June 2, 4:45 PM-6:00 PM, S100bc. ●

# 2018 ASCO Annual Meeting Networking Guide

With more than 35,000 oncology professionals from around the world gathering to discuss state-of-the-art treatment modalities, new therapies, and ongoing controversies in the field, the ASCO Annual Meeting is an unparalleled opportunity for attendees to advance their work through networking.

ASCO offers a number of programs and events throughout the week that are specifically designed to encourage attendees to connect. The following networking lounges, spaces, events, and social media opportunities are available throughout the Annual Meeting.

The Women's Networking Center provides an intimate, informal setting for women to network and discuss work–life challenges.

## Women's Networking Center

The Women's Networking Center provides a unique opportunity for female attendees to attend interactive panel discussions and network in an intimate, informal setting. The primary goal of the Women's Networking Center is to advocate for women in oncology and to help close the gender gap through professional development discussions. The ASCO Professional Development Committee has worked to develop panel discussions and informal talks that offer something for every woman, regardless of work setting, specialty, or years of experience. Women's Mentoring Office Hours are available within the Women's Networking Center as well, providing an opportunity for attendees to engage in 30-minute, one-on-one mentoring conversations with women in the oncology field.

*See Networking Guide, Page 32*

The following table compares the incidence of common (≥10%) treatment-emergent adverse reactions for patients receiving SUTENT versus placebo.

**Adverse Reactions Reported in S-TRAC in ≥10% of Patients With RCC Who Received SUTENT and More Commonly Than in Patients Given Placebo***

| | Adjuvant treatment of RCC | | | |
|---|---|---|---|---|
| | SUTENT (N=306) | | PLACEBO (N=304) | |
| Adverse Reaction | All Grades % | Grade 3-4 % | All Grades % | Grade 3-4 % |
| **Any Adverse Reaction** | 99 | 60 | 88 | 15 |
| **Constitutional** | | | | |
| Fatigue/Asthenia | 57 | 8 | 34 | 2 |
| Localized edema[a] | 18 | <1 | <1 | 0 |
| Pyrexia | 12 | <1 | 6 | 0 |
| **Gastrointestinal** | | | | |
| Mucositis/Stomatitis[b] | 61 | 6 | 15 | 0 |
| Diarrhea | 57 | 4 | 22 | <1 |
| Nausea | 34 | 2 | 15 | 0 |
| Dyspepsia | 27 | 1 | 7 | 0 |
| Abdominal pain[c] | 25 | 2 | 9 | <1 |
| Vomiting | 19 | 2 | 7 | 0 |
| Constipation | 12 | 0 | 11 | 0 |
| **Cardiac** | | | | |
| Hypertension[d] | 39 | 8 | 14 | 1 |
| Edema/Peripheral edema | 10 | <1 | 7 | 0 |
| **Dermatology** | | | | |
| Hand-foot syndrome | 50 | 16 | 10 | <1 |
| Hair color changes | 22 | 0 | 2 | 0 |
| Rash[e] | 24 | 2 | 12 | 0 |
| Skin discoloration/Yellow skin | 18 | 0 | 1 | 0 |
| Dry skin | 14 | 0 | 6 | 0 |
| **Neurology** | | | | |
| Altered taste[f] | 38 | <1 | 6 | 0 |
| Headache | 19 | <1 | 12 | 0 |
| **Musculoskeletal** | | | | |
| Pain in extremity | 15 | <1 | 7 | 0 |
| Arthralgia | 11 | <1 | 10 | 0 |
| **Endocrine** | | | | |
| Hypothyroidism/TSH increased | 24 | <1 | 4 | 0 |
| **Metabolism/Nutrition** | | | | |
| Anorexia/Decreased appetite | 19 | <1 | 5 | 0 |
| **Hemorrhage/Bleeding** | | | | |
| Bleeding events, all sites[g] | 24 | <1 | 5 | <1 |

*Common Terminology Criteria for Adverse Events (CTCAE), version 3.0.
Abbreviations: ARs=adverse reactions; N=number of patients; RCC=renal cell carcinoma.
[a]Includes edema localized, face edema, eyelid edema, periorbital edema, swelling face, and eye edema.
[b]Includes mucosal inflammation, stomatitis apthous ulcer, mouth ulceration, tongue ulceration, oropharyngeal pain and oral pain.
[c]Includes abdominal pain, abdominal pain lower, and abdominal pain upper.
[d]Includes hypertension, blood pressure increased, blood pressure systolic increased, blood pressure diastolic increased, and hypertensive crisis.
[e]Includes dermatitis, dermatitis psoriasiform, exfoliative rash, genital rash, rash, rash erythematous, rash follicular, rash generalized, rash macular, rash maculopapular, rash papular, and rash pruritic.
[f]Includes ageusia, hypogeusia, and dysgeusia.
[g]Includes epistaxis, gingival bleeding, rectal hemorrhage, hemoptysis, anal hemorrhage, upper gastrointestinal hemorrhage, hematuria.

Grade 4 adverse reactions in patients on SUTENT included hand-foot syndrome (1%), fatigue (<1%), abdominal pain (<1%), stomatitis (<1%), and pyrexia (<1%). Grade 4 adverse reactions in patients on placebo included asthenia (<1%) and hypertension (<1%).

Grade 3-4 laboratory abnormalities that occurred in ≥2% of patients receiving SUTENT include neutropenia (13%), thrombocytopenia (5%), leukopenia (3%), lymphopenia (3%), elevated alanine aminotransferase (2%), elevated aspartate aminotransferase (2%), hyperglycemia (2%), and hyperkalemia (2%).

**Venous Thromboembolic Events.** In patients treated with SUTENT (N=7527) for GIST, advanced RCC, adjuvant treatment of RCC and pNET, 3.5% of patients experienced a venous thromboembolic event; 2.2% Grade 3-4.

**Reversible Posterior Leukoencephalopathy Syndrome.** There have been reports (<1%), some fatal, of patients presenting with seizures and radiological evidence of reversible posterior leukoencephalopathy syndrome (RPLS). Patients with seizures and signs/symptoms consistent with RPLS, such as hypertension, headache, decreased alertness, altered mental functioning, and visual loss, including cortical blindness, should be controlled with medical management including control of hypertension. Temporary suspension of SUTENT is recommended; following resolution, treatment may be resumed at the discretion of the treating healthcare provider.

**Pancreatic Function.** Pancreatitis was observed in 5 patients (1%) receiving SUTENT for treatment-naïve RCC compared to 1 patient (<1%) receiving IFN-α. In a trial of patients receiving adjuvant treatment for RCC, 1 patient (<1%) on SUTENT and none on placebo experienced pancreatitis. Pancreatitis was observed in 1 patient (1%) receiving SUTENT for pNET and 1 patient (1%) receiving placebo.

**Postmarketing Experience.** The following adverse reactions have been identified during post-approval use of SUTENT. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

***Blood and lymphatic system disorders:*** hemorrhage associated with thrombocytopenia*. Suspension of SUTENT is recommended; following resolution, treatment may be resumed at the discretion of the treating healthcare provider.

***Gastrointestinal disorders:*** esophagitis.

***Hepatobiliary disorders:*** cholecystitis, particularly acalculous cholecystitis.

***Immune system disorders:*** hypersensitivity reactions, including angioedema.

***Infections and infestations:*** serious infection (with or without neutropenia)*. The infections most commonly observed with SUTENT treatment include respiratory, urinary tract, skin infections, and sepsis/septic shock.

***Musculoskeletal and connective tissue disorders:*** fistula formation, sometimes associated with tumor necrosis and/or regression*; myopathy and/or rhabdomyolysis with or without acute renal failure*. Patients with signs or symptoms of muscle toxicity should be managed as per standard medical practice.

***Renal and urinary disorders:*** renal impairment and/or failure*.

***Respiratory disorders:*** pulmonary embolism*.

***Skin and subcutaneous tissue disorders:*** pyoderma gangrenosum, including positive dechallenges.

***Vascular disorders:*** arterial thromboembolic events*. The most frequent events included cerebrovascular accident, transient ischemic attack, and cerebral infarction.

*including some fatalities.

**DRUG INTERACTIONS**

**CYP3A4 Inhibitors.** Strong CYP3A4 inhibitors such as ketoconazole may **increase** sunitinib plasma concentrations. Selection of an alternate concomitant medication with no or minimal enzyme inhibition potential is recommended. Concurrent administration of SUTENT with the strong CYP3A4 inhibitor, ketoconazole, resulted in 49% and 51% increases in the combined (sunitinib + primary active metabolite) $C_{max}$ and $AUC_{0-\infty}$ values, respectively, after a single dose of SUTENT in healthy volunteers. Coadministration of SUTENT with strong inhibitors of the CYP3A4 family (e.g., ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole) may increase sunitinib concentrations. Grapefruit may also increase plasma concentrations of sunitinib. A dose reduction for SUTENT should be considered when it must be coadministered with strong CYP3A4 inhibitors *[see Dosage and Administration]*.

**CYP3A4 Inducers.** CYP3A4 inducers such as rifampin may **decrease** sunitinib plasma concentrations. Selection of an alternate concomitant medication with no or minimal enzyme induction potential is recommended. Concurrent administration of SUTENT with the strong CYP3A4 inducer, rifampin, resulted in a 23% and 46% reduction in the combined (sunitinib + primary active metabolite) $C_{max}$ and $AUC_{0-\infty}$ values, respectively, after a single dose of SUTENT in healthy volunteers. Coadministration of SUTENT with inducers of the CYP3A4 family (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort) may decrease sunitinib concentrations. St. John's Wort may decrease sunitinib plasma concentrations unpredictably. Patients receiving SUTENT should not take St. John's Wort concomitantly. A dose increase for SUTENT should be considered when it must be coadministered with CYP3A4 inducers *[see Dosage and Administration]*.

**In Vitro Studies of CYP Inhibition and Induction.** In vitro studies indicated that sunitinib does not induce or inhibit major CYP enzymes. The in vitro studies in human liver microsomes and hepatocytes of the activity of CYP isoforms CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, CYP3A4/5, and CYP4A9/11 indicated that sunitinib and its primary active metabolite are unlikely to have any clinically relevant drug-drug interactions with drugs that may be metabolized by these enzymes.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

Risk Summary. Based on animal reproduction studies and its mechanism of action, SUTENT can cause fetal harm when administered to a pregnant woman. There are no available data in pregnant women to inform a drug-associated risk. In animal developmental and reproductive toxicology studies, oral administration of sunitinib to pregnant rats and rabbits throughout organogenesis resulted in teratogenicity (embryolethality, craniofacial and skeletal malformations) at 5.5 and 0.3 times the AUC in patients administered the recommended daily doses (RDD), respectively *[see Data]*. Advise pregnant women or females of reproductive potential of the potential hazard to a fetus.

The background risk of major birth defects and miscarriage for the indicated populations are unknown. However, the estimated background risk in the United States (U.S.) general population of major birth defects is 2%-4% and of miscarriage is 15%-20% of clinically recognized pregnancies.

Data

*Animal Data.* In a female fertility and early embryonic development study, female rats were administered oral sunitinib (0.5, 1.5, 5 mg/kg/day) for 21 days prior to mating and for 7 days after mating. Embryolethality was observed at 5 mg/kg/day (approximately 5 times the AUC in patients administered the RDD of 50 mg/day).

In embryo-fetal developmental toxicity studies, oral sunitinib was administered to pregnant rats (0.3, 1.5, 3, 5 mg/kg/day) and rabbits (0.5, 1, 5, 20 mg/kg/day) during the period of organogenesis. In rats, embryolethality and skeletal malformations of the ribs and vertebrae were observed at the dose of 5 mg/kg/day (approximately 5.5 times the systemic exposure [combined AUC of sunitinib + primary active metabolite] in patients administered the RDD). No adverse fetal effects were observed in rats at doses ≤3 mg/kg/day (approximately 2 times the AUC in patients administered the RDD). In rabbits, embryolethality was observed at 5 mg/kg/day (approximately 3 times the AUC in patients administered the RDD), and craniofacial malformations (cleft lip and cleft palate) were observed at ≥1 mg/kg/day (approximately 0.3 times the AUC in patients administered the RDD of 50 mg/day).

Sunitinib (0.3, 1, 3 mg/kg/day) was evaluated in a pre- and postnatal development study in pregnant rats. Maternal body weight gains were reduced during gestation and lactation at doses ≥1 mg/kg/day (approximately 0.5 times the AUC in patients administered the RDD). At 3 mg/kg/day (approximately 2 times the AUC in patients administered the RDD), reduced neonate body weights were observed at birth and persisted in the offspring of both sexes during the preweaning period and in males during postweaning period. No adverse developmental effects were observed at doses ≤1 mg/kg/day.

**Lactation.** There is no information regarding the presence of sunitinib and its metabolites in human milk. Sunitinib and its metabolites were excreted in rat milk at concentrations up to 12-fold higher than in plasma. Because of the potential for serious adverse reactions in breastfed infants from SUTENT, advise a lactating woman not to breastfeed during treatment with SUTENT and for at least 4 weeks after the last dose.

Data

*Animal Data.* In lactating female rats administered 15 mg/kg, sunitinib and its metabolites were excreted in milk at concentrations up to 12-fold higher than in plasma.

**Females and Males of Reproductive Potential.** Based on animal reproduction studies and its mechanism of action, SUTENT can cause fetal harm when administered to a pregnant woman.

Pregnancy Testing

Females of reproductive potential should have a pregnancy test before treatment with SUTENT is started.

*In the Journals*

# Using the Internet for Nonpharmacologic Symptom Management in Breast Cancer

**"Pilot Study of an Internet-based Self-Management Program for Symptom Control in Patients With Early Stage Breast Cancer"**

***Journal:*** *JCO Clinical Cancer Informatics*
***DOI:*** 10.1200/CCI.17.00106

## Abstract

***Purpose:*** Many breast cancer survivors experience an array of chronic symptoms, including pain, insomnia, and fatigue. Few effective therapies have been identified. Behavioral management programs to address similar symptom clusters in other chronic conditions have been shown to be effective. The objective was to determine the effect of an internet-based lifestyle and behavioral self-management program on cancer-related symptoms.

***Patients and Methods:*** Women with stage 0-III breast cancer who reported insomnia, pain, or fatigue as their primary symptom of concern during the 7 days prior to enrollment were enrolled. Local therapies and/or chemotherapy were completed at least 3 months prior to enrollment. Patients were assessed at baseline and after 8 weeks, and completed the PROMIS-29 Profile and Patient Global Impression of Change (PGIC) questionnaire electronically. Change in each of the eight symptom domains was assessed.

***Results:*** Fifty patients enrolled. In the 45 patients with both baseline and 8-week PROMIS data, statistically significant improvements in anxiety, sleep, fatigue, activity level, and pain severity were reported. Of the 35 patients who responded to the PGIC, 62.9% reported improvement in their primary symptom. Those who reported fatigue as their primary symptom reported greatest overall benefit in multiple symptom improvement, including improvements in fatigue, anxiety, pain severity, pain interference, and participation in social activities.

***Conclusion:*** These findings suggest that this lifestyle and behavioral management may improve multiple symptoms in breast cancer survivors when delivered via the internet. Randomized studies are warranted to evaluate the efficacy of the online intervention compared to standard symptom management approaches, and to identify patients most likely to benefit.



## Author Perspective

*Lynn Henry, MD, PhD, FACP,*
*University of Utah*

**Q: What did your study reveal about symptom improvement using the internet?**

**Dr. Henry:** Traditionally, nonpharmacologic symptom management has employed methods such as cognitive behavioral therapy that are typically administered in person, in individual or group settings. More recently, data have emerged that support use of cognitive-behavioral therapy administered through the telephone or the internet to ease symptoms such as insomnia and pain. In our small pilot study, we specifically examined use of a cognitive behavioral therapy–based intervention (PROSPECT) administered through the internet for the management of pain, insomnia, and fatigue in breast cancer survivors. Our intervention is not strictly an educational intervention, but rather it is intended to provide users with tools, such as relaxation, pacing, goal-setting, and communication, to improve their behavior and lifestyle.


Dr. Lynn Henry

We were able to demonstrate improvement in multiple symptoms with use of the intervention for 8 weeks, especially in patients with fatigue. We also assessed acceptability of the intervention and found that most patients felt it was acceptable and convenient to use. By administering this intervention using the internet, it is accessible to patients who may not have the time or the financial capability to attend individual or group sessions or who may live far from the treating facility. It also means that more patients are able to access the intervention, since it doesn't require that the facility have trained staff to administer it.

*See Internet-Based Self-Management, Page 13*

# Self-Assessment Resources From ASCO University®

Increasing evidence shows that self-assessment is an important approach for meaningful learning. Often, learners—including oncologists—believe that they know where their knowledge gaps are, but this isn't really the case.

"We don't know what we don't know," said Jamie Von Roenn, MD, FASCO, ASCO's vice president of Education, Science, and Professional Development.

That's why Dr. Von Roenn thinks it's important that oncologists take advantage of the ASCO University® self-assessment resources. Self-assessment not only helps identify knowledge gaps, but research shows that it also helps learners retain new knowledge. "Well-formulated test questions actually educate the learner, and assessment drives learning," Dr. Von Roenn said. "Testing for learning is more effective for retention than re-reading or studying the same material for an equal amount of time."

ASCO University offers several self-assessment resources for oncologists. These self-assessment resources, available for purchase from the ASCO University Bookstore, feature up-to-date and practice-relevant questions written by ASCO expert faculty and edited by course planners for clarity and focus. All questions provide not only the correct answer but also an answer rationale including references that support the best answer.


Dr. Jamie Von Roenn

### ASCO University Personalized Learning Dashboard

The ASCO University Personalized Learning Dashboard was designed for learners who want a more individualized approach.

Learners begin the self-assessment by designating their media preferences for videos, text-based articles, audio podcasts, or eLearning courses. Then they test their current knowledge through a 60-question assessment. Finally, two scores—an actual score based on right and wrong answers and an adjusted score that takes into account confidence levels—generate the learner's dashboard, indicating knowledge gaps and allowing the user to choose from a list of

*See Self-Assessment Resources, Page 31*

### Internet-Based Self-Management

*Continued from page 12*

**Q: How can your study serve to build upon this method going forward? How might it be incorporated into a cancer care plan?**

**Dr. Henry:** We plan to test this intervention in larger controlled trials in order to better assess the impact in populations of patients with cancer. Ideally, an intervention such as this could be available to patients on a cancer center's website or in a mobile app, and patients could access the intervention intermittently as they work to develop and reinforce their tools for behavior and lifestyle management. At the University of Utah, we are currently testing the intervention in combination with exercise in patients with metastatic cancer.

**Q: Have you seen any significant changes in treatment decisions in the wake of your study?**

**Dr. Henry:** Our pilot was designed to provide initial data about the efficacy of the intervention, which is required information for planning subsequent, well-controlled trials. Because there is the potential that patients' symptoms could improve on their own over time, or simply because the investigators were interacting more with the participating patients compared to usual clinical care, it is possible that the intervention itself did not provide the benefit. Therefore, well-designed, randomized trials that validate the findings are necessary before the intervention can be widely adopted.

**Q: What surprised you about these results?**

**Dr. Henry:** The results were somewhat surprising because we expected to find more of an effect in patients with pain, since the intervention that PROSEPCT was adapted from was originally developed for management of fibromyalgia, a chronic pain condition. It is possible that the sample size was too small or that the improvement in pain takes longer than the 8-week duration of the study. Another possibility is that the underlying reason for pain in enrolled subjects was likely quite heterogeneous (surgery, neuropathy, and aromatase inhibitor therapy), and the intervention may have had differential effects depending on the etiology of the pain. ●

# 2018 Cancer Survivorship Symposium Highlights Need for Collaboration, Continued Research

The 2018 Cancer Survivorship Symposium took place on February 16 and 17 in Orlando, Florida. This unique Symposium provided attendees with information about survivorship issues that are relevant to both oncologists and primary care physicians.

It is no secret that the number of cancer survivors continues to grow in the United States and throughout the world. By 2040, it is estimated that the number of cancer survivors in the United States will increase to approximately 26 million.[1]


Dr. Carol A. Rosenberg

"Survivorship is still the frontier of the cancer care continuum," said Symposium Steering Committee Chair Carol A. Rosenberg, MD, FACP. Now in its third year, the Symposium has hit its stride and is cultivating a more collaborative process for all stakeholders in the cancer survivorship care continuum, said Dr. Rosenberg, who is also the director of the Living in the Future Cancer Survivorship Program at NorthShore University HealthSystem.

"The 2016 and 2017 meetings were notable for beginning a conversation among health professionals and stakeholders with different perspectives," Dr. Rosenberg said. "The 2018 Symposium really built on the success of the first two."

The 2018 Symposium highlighted a variety of relevant abstracts that tackled issues related to both the implementation of improved survivorship care programs and some of the late effects experienced by cancer survivors.

## Practical Considerations

"With the cancer survivor at the center, this Symposium brings together the many health care professions charged with providing care to this special group of patients with unique health care concerns and needs," said Program Committee Chair Bryan A. Bognar, MD, MPH, FACP, vice dean for educational affairs at the University of South Florida, Morsani College of Medicine. "The passion and dedication of this group is unrivaled."

Oral Abstract Session A opened with a study that evaluated the impact of survivorship transition models on health system resources and costs (Abstract 1).[2] This Canadian study, presented by Soo Jin Seung, MD, compared health care usage and cost among women with breast cancer who participated in a survivorship care program with early transition to primary care follow-up versus those who did not. The study showed that early transition of care resulted in fewer oncology visits, fewer diagnostic scans, and the same number of primary care visits. This equated to a cost savings, despite a large initial investment in the development of the survivorship care transition program.

"The study demonstrated that breast cancer survivors who participated in a transition program through a survivorship process used fewer health system resources and had lower health system costs," Dr. Rosenberg said. "This provides real-world evidence to inform the transition policies for breast cancer survivors."

A second presentation turned the focus from costs to the health system toward costs to the patient with cancer (Abstract 145).[3] Theresa A. Hastert, PhD, of the Karmanos Cancer Center and Wayne State University School of Medicine, presented results of a study that looked at the association between material and behavioral financial hardship and health-related quality of life among 1,000 patients diagnosed with breast, colorectal, lung, or prostate cancers. The study showed that 46.4% of patients experienced some kind of material financial hardship (defined as cancer-related debt, the need to borrow money from friends or family, the use of assets to pay for cancer care, or a loss in income). Behavioral financial hardship (defined as skipping doses of medication to save money, not going to the doctor because of cost, or refusing treatment because of cost) was less common at approximately 18% incidence. The study showed that both material and behavioral financial hardships were inversely associated with health-related quality of life.


Program Committee Chair Dr. Bryan A. Bognar delivers the Welcome Address during the Cancer Survivorship Symposium.

## Survivorship Care

The other two abstracts in Oral Abstract Session A focused on the implementation and success of survivorship care programs. Paul B. Jacobsen, PhD, of the National Cancer Institute, presented the results of a systematic review that evaluated whether survivorship care plans positively affected health outcomes and health care delivery (Abstract 2).[4] Findings from existing research showed that survivorship care plans generally had no effect on psychological, physical, and functional well-being.

"Although existing research provides minimal evidence that survivorship care plans impact psychological, physical, and functional well-being, that is most likely because of the heterogeneity in the study designs, lack of risk-based investigation, and lack of focus on adoption of survivorship care plan recommendations as an outcome measurement. Findings were positive for outcomes such as amount of information received, satisfaction with care, cancer-related contact with a primary care physician, adherence to cardiomyopathy screening, and physician implementation of recommended survivorship care," Dr. Rosenberg said. "We need to provide a nuanced interpretation of these studies, because the dose of survivorship care planning was not equal in the investigations examined. As we look to future survivorship research, our goal should be to determine which form of survivorship care is best for which patient at what time and better distinguish between proximal and distal outcomes measured."


Panelists discuss presentations during Oral Abstract Session A.

Finally, Genevieve Chaput, MD, of McGill University, in Montreal, presented results from a study that Dr. Bognar called one of the most interesting and important abstracts of the meeting (Abstract 20).[5] The study evaluated the success of a primary care provider education workshop focused on teaching primary care physicians about cancer survivorship.[5] The workshop discussed different issues that patients with a cancer history may have. When the benefit of the workshop was assessed, the researchers found that not every primary care physician necessarily needs formal training. Primary care physicians with no survivorship training may be able to care for survivors at low risk for cancer-related late and long-term effects; however, survivorship education should be delivered to all primary care physicians to ensure optimal care delivery.

"This [abstract] provided a wonderful example of providing frontline survivorship care education to primary care physicians," Dr. Bognar said. "It is a model that can easily be replicated in many other settings."

## Physical Late Effects

Abstracts presented during Oral Abstract Session B focused more on some of the late effects experienced by cancer survivors.

David Baraghoshi, MD, of the Huntsman Cancer Institute, presented data from a study that looked at the long-term risk of cardiovascular disease among survivors of colorectal cancer (Abstract 113).[6] The study compared outcomes in 1,749 cancer survivors and 6,480 members of the general population and found that survivors had a significantly increased risk for cardiovascular disease more than 10 years after their cancer diagnoses.

"It is important to note from this abstract that increased risk was more prevalent in older survivors and those who were obese or had other comorbidities, but another important consideration is that increased risk for cardiovascular disease may also be attributable to lifestyle risk factors that are shared by people with colorectal cancer and cardiovascular disease," Dr. Rosenberg said.

A second study also evaluated late cardiovascular disease risk (Abstract 114).[7] Flora Van Leeuwen, PhD, of the Netherlands Cancer Institute, in Amsterdam, reported the results of a study to assess cardiovascular risk in women with treatment-induced primary ovarian insufficiency as a result of Hodgkin lymphoma.[7] The retrospective study included 944 women who had 5 or more years of survival after Hodgkin lymphoma. Cardiovascular outcomes were assessed with a questionnaire. Approximately one-third of participants had premature ovarian insufficiency, and the median age of menopause was 34 years. However, results showed that premature ovarian insufficiency and age at menopause did not affect cardiovascular disease risk, which implies that ovarian hormone insufficiency may not explain increased cardiovascular risk in naturally menopausal women.


Attendees listen to scientific presentations during Oral Abstract Session B.

## Psychosocial Effects

After-effects of cancer treatment are not always physical but can be psychological as well. For example, during

See Cancer Survivorship Symposium, Page 15

# Association of Northern California Oncologists Supports YIA for a Northern California Researcher

The Association of Northern California Oncologists (ANCO), an ASCO affiliate, is among the newest nonprofit supporters of ASCO's Conquer Cancer Foundation. ANCO is generously funding a 2018 Young Investigator Award (YIA) for a qualified northern California applicant working on mentored clinical and/or translational cancer research. The recipient of the ANCO YIA will be announced at the Conquer Cancer grants and awards ceremony during the ASCO Annual Meeting.

Since 1984, the YIA program has been encouraging and promoting high-quality clinical cancer research by providing funds to promising investigators during the transition from a fellowship program to a faculty appointment, an especially vulnerable time for young scientists who are on the cusp of starting their careers.

"ANCO chose to support a YIA because we recognize the importance of investing in young physicians at the beginning of their careers, especially those doing research that will help tackle this disease," Jose Luis Gonzalez, ANCO executive director, said. "We are very excited and hopeful that we will get many qualified applications, and that Conquer Cancer will have a hard time choosing one."

"Conquer Cancer appreciates the generous support of ANCO and the opportunity to work together as partners advancing high-quality cancer research taking place in northern California through the YIA program," Nancy R. Daly, MS, MPH, Conquer Cancer's executive vice president and chief philanthropic officer, said.

ASSOCIATION OF NORTHERN CALIFORNIA ONCOLOGISTS

ANCO dates back to 1990 when a group of physicians in northern California created the organization as a way to have more influence on the practice of oncology regarding the payers in the region. Since then, ANCO membership has grown to include more than 500 physicians from academic institutions and private practice. There are no geographical boundaries for ANCO, but most members work in private practice or at the major centers in the area, including Kaiser Permanente, Stanford University, the University of California, Davis, or the University of California, San Francisco. ANCO members must be board certified or board eligible in one of the oncologic subspecialties. Membership benefits extend to the entire organization including hematologists, oncologists, nurses, advanced practice providers, patients, and the cancer community at large.

The three main services ANCO offers are advocacy, education, and information dissemination. An active and engaged state or regional affiliate of ASCO, ANCO works with ASCO before Congress and the Centers for Medicare and Medicaid Services on cancer issues. At the state level, ANCO works closely with the Medical Oncology Association of Southern California to influence and offer legislation affecting cancer care in California. ANCO helps societies like ASCO mobilize grassroots advocacy when issues impacting the practice of oncology arise. The association also meets with insurance companies on behalf of its members to discuss topics such as coverage policies and claims adjudication. ANCO is currently involved in an ongoing effort to pass legislation in California that would regulate development and implementation of clinical care pathways in cancer care by private insurance companies.

ANCO offers a robust portfolio of clinical and professional educational programs for its members, including ASCO Annual Meeting Highlights, San Antonio Breast Cancer Symposium Highlights, and Hematologic Malignancies Updates, to name a few. ANCO also organizes an annual professional education meeting for its members to discuss topics of current relevance such as MACRA and MIPS participation.


Mr. Jose Luis Gonzalez

"People love coming to our ASCO Annual Meeting Highlights, particularly private practice physicians who are not typically able to take several days off to attend the ASCO Annual Meeting. These meetings distill all the major research advances presented at the ASCO Annual Meeting that may impact their practice in the next year and also provide valuable networking opportunities and the chance for interaction between private practice physicians and their academic colleagues," Mr. Gonzalez said.

ANCO cosponsored the 18th Multidisciplinary Management of Cancers: A Case-Based Approach, which took place March 16-18 at the Silverado Resort and Spa in Napa, California. Over the course of 3 days, faculty from three northern California academic medical centers presented the most current information on multidisciplinary approaches in clinical oncology using tumor board cases from a variety of diagnoses. The conference was designed for physicians, nurses, pharmacists, and other health care professionals who work with patients with cancer.

To learn more about ANCO programs and membership benefits, visit anco-online.org. To learn more about the Young Investigator Award, visit CONQUER.org/YIA. ●

## Cancer Survivorship Symposium

*Continued from page 14*

Oral Abstract Session B, Nosayaba Osazuwa-Peters, BDS, MPH, of the Saint Louis University School of Medicine, presented data that evaluated suicide risk among survivors of head and neck cancer (Abstract 146).[8] The retrospective study used data from the National Cancer Institute's Surveillance, Epidemiology, and End Results Program database regarding patients with the top 20 cancers diagnosed between 2000 and 2014. During that time, 4,513 suicides were documented in the study group. Dr. Osazuwa-Peters reported that the study identified a significantly elevated risk of suicide across all cancer sites compared with the general population. The risk was especially high in patients with head and neck cancer and pancreatic cancer, which indicates that cancer survivors should be candidates for suicide-related psychosocial surveillance.

Finally, Sarah C. Reed, MSW, MPH, PhD, of the Jane Addams College of Social Work, presented research on the prevalence of fear of cancer recurrence in a U.S. population–based sample of cancer survivors (Abstract 147).[9] Approximately 11% of patients reported a high fear of cancer recurrence. Although high fear levels were not associated with depressive symptoms or psychological distress, they were associated with significantly worse mental health status. According to Dr. Reed, this suggests that fear of cancer recurrence may be distinct from depression and distress.

Overall, Dr. Bognar said that he hoped the Symposium and its presentations provided attendees with "an appreciation of the unique health care concerns and needs for the cancer survivor and the attendee's special role in working with a team of specialists who are all passionate about filling those needs." ●

**–Leah Lawrence**

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***ASCO Daily News***
The Official Newspaper of the
2018 ASCO Annual Meeting
Vol. 21, No. 1
Friday, June 1

*ASCO Daily News*, the official newspaper of the 2018 ASCO Annual Meeting, is published by the American Society of Clinical Oncology as a service to all who attend.

Ipatasertib (GDC-0068, RG7440): An investigational, ATP-competitive Akt inhibitor

# Currently Enrolling in Prostate Cancer

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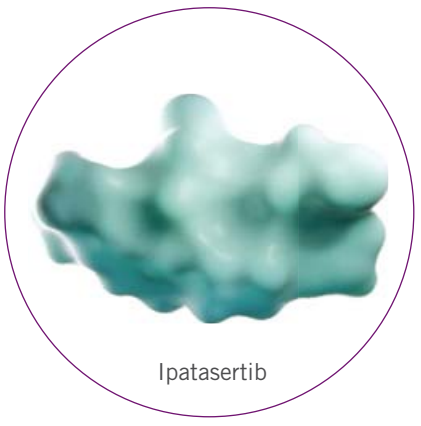
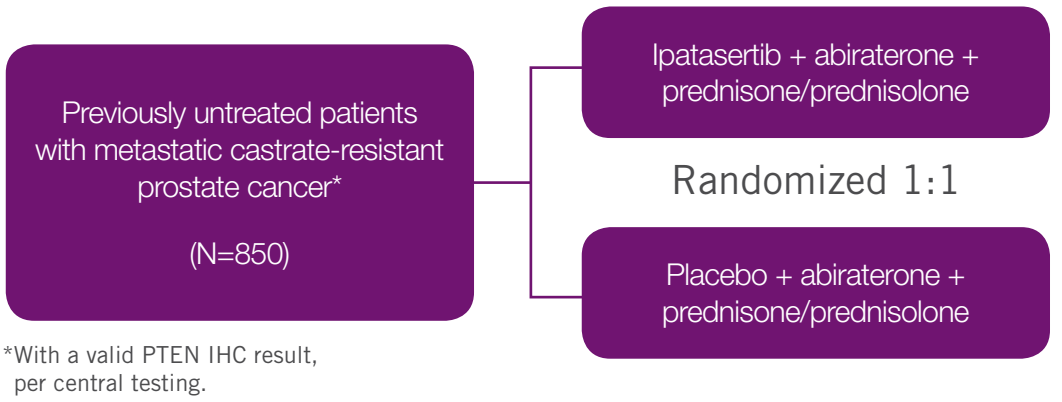


Ipatasertib




*With a valid PTEN IHC result, per central testing.

### Study Endpoints

**Primary Outcome Measure:**

- Investigator-assessed rPFS in PTEN-loss patients evaluated against the ITT patient population†

**Selected Secondary Outcome Measures:**

- Time to pain progression
- Time to initiation of cytotoxic chemotherapy
- Overall survival
- Objective response rate
- Investigator-assessed rPFS in patients with PTEN-loss tumors by next-generation sequencing

†PTEN loss assessed by IHC.

### Selected Eligibility Criteria

- Previously untreated adult males with asymptomatic or mildly symptomatic mCRPC
- Progressive disease during or after ADT with GnRH analog or bilateral orchiectomy
- Consent to provide tissue for PTEN-loss testing
- No prior treatment with chemotherapy for the treatment of castrate-resistant prostate cancer
- No diabetic patients requiring insulin
- ECOG performance status of 0 or 1

### Find out if your patients are eligible for enrollment. For more information:

Visit: **www.IPATential150.com**

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ClinicalTrials.gov Identifier: NCT03072238; Sponsor Study Identifier: CO39303.

ADT=androgen deprivation therapy; ECOG=Eastern Cooperative Oncology Group; GnRH=gonadotropin-releasing hormone; IHC=immunohistochemistry; ITT=intent-to-treat; PTEN=phosphatase and tensin homolog; rPFS=radiographic progression-free survival.

**This compound and the combination of agents and their uses are investigational and have not been approved by the US Food and Drug Administration. Efficacy and safety have not been established. The information presented should not be construed as a recommendation for use. The relevance of findings in preclinical studies to humans is currently being evaluated.**

Information is consistent with ClinicalTrials.gov as of April 24, 2017.

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## ASCO Annual Meeting

*Continued from page 1*

in our day-to-day care of patients," Ann H. Partridge, MD, MPH, FASCO, 2018 ASCO Annual Meeting Scientific Program Committee chair, said. "Discovering new ways to treat different cancers, and how to get the best treatments to all patients who might benefit from them, is critical."

### Plenary Session

The Plenary Session will showcase abstract presentations of the top practice-changing science, with commentary from expert discussants, preceded by the Science of Oncology Award and Lecture.

The Plenary Session will be presented in the North Building, Hall B1, on June 3, from 1 PM to 4 PM. Attendees can also watch the session via live simulcast in the East Building, Hall D1, and on ASCO TVs located throughout McCormick Place.

Topics discussed during this year's Plenary Session will include adjuvant therapy in breast cancer, metastatic renal cell carcinoma, rhabdomyosarcoma, and immuno-oncology in lung cancer.

### Clinical Science Symposia

Another standout in the Scientific Program are the Clinical Science Symposia, which are designed to address a cross-cutting theme or hot topic in oncology while integrating abstracts from multiple tracks. Led by experts in the field, these symposia are composed of a presentation and discussion of three to four relevant abstracts. The following Clinical Science Symposia are can't-miss sessions for this year's Annual Meeting:

- "Tumor Genomics: Finding the Target, Hitting the Target" will be held on June 2, and chaired by Suzanne George, MD, of the Dana-Farber Cancer Institute.
- "Compelling Combinations: Raising the Bar With Immunotherapy" will be held on June 3, and chaired by David C. Smith, MD, of the University of Michigan.
- "The Arrival of Biosimilars" will be held on June 4, and chaired by Colin Weekes, MD, PhD, of the Dana-Farber Cancer Institute.

### Unique Educational Experiences

The ASCO Annual Meeting offers a variety of session types designed to teach, engage, and bring the field together. In addition to presenting the latest research in cancer care, the Annual Meeting will also offer these one-of-a-kind sessions and workshops.

Dr. Bruce E. Johnson

In putting together the educational sessions for this year's Annual Meeting, the Education Committee was guided by the presidential theme and established its own theme, "Broadening Our View: Navigating Results and Breakthroughs in Cancer Care." With this theme in mind, the educational sessions at the Meeting were developed to improve understanding and application of research results, address what both providers and patients need most from precision medicine, highlight how care decisions are approached, and educate attendees so that they can help their patients.

"Keeping pace with advances across oncology is harder than ever. The entire education program was designed to help address this primary challenge," Dr. Spigel said. "This year's program is focused on the issues we face as a community, the data we have, and the next questions to solve."

### ASCO Voices

Wanting to share and explore different perspectives of oncology, medicine, and the world, ASCO will introduce a new kind of presentation, ASCO Voices, to its programming this year. The five speakers were selected among hundreds of applicants to deliver a short presentation to share their stories—without notes or slides.

"One of the sessions I'm most excited for this year is ASCO Voices," Dr. Partridge said. "This program is going to be interesting and engaging for the oncology community. There were so many wonderful auditions, and the speakers selected will really put together something novel and different from anything we've ever seen at the Annual Meeting."

ASCO Voices will be presented in the Arie Crown Theater on June 2 at 12 PM.

### Covering Cancer: Perspectives From the Media

New this year, ASCO is convening health reporters from top media outlets—the Associated Press, *Forbes*, NBC, STAT, and Kaiser Health News—to discuss their experiences covering cancer science, policy, and patient care. The panel, moderated by ASCO Chief Medical Officer Richard L. Schilsky, MD, FACP, FSCT, FASCO, will offer insights into how the media determine the news value of cancer research and how the evolving media landscape has changed the way cancer is covered in the news. The session will also include comments from Dr. Johnson and ASCO CEO Clifford A. Hudis, MD, FACP, FASCO. The session will be held in the Arie Crown Theater on June 2.

### ASCO Town Hall: Utilization Management in Oncology

During this event, moderator and session Chair John V. Cox, DO, FASCO, will guide speakers through a conversation that includes the vision of the American Medical Association (AMA), pathways and MACRA, pharmacy benefit managers, and what to expect from future legislation. Speakers include AMA President-Elect Barbara McAneny, MD, FASCO, MACP (the first oncologist elected to lead the nation's largest physician organization); Robin Zon, MD, FACP, FASCO; Melissa S. Dillmon, MD; and Blase N. Polite, MD, MPA, FASCO. The Town Hall session will be held on June 2.

Dr. Ann H. Partridge

### Cultivating Primary Resilience: Burnout Prevention on a Larger Scale?

Burnout is not a new concern for oncology professionals. In fact, according to a 2014 ASCO-sponsored study of burnout and career satisfaction among U.S. oncologists, 44.7% of surveyed oncologists reported feeling symptoms of burnout.[1] To emphasize the importance of taking steps to prevent burnout and maintain wellness, ASCO has dedicated a session at the Annual Meeting to help oncologists work through these feelings and build their resiliency skills. "Cultivating Primary Resilience: Burnout Prevention on a Larger Scale?" will be led by Susana Banerjee, PhD, MA, MBBS, MRCP, on June 4.

### Making Connections

When the brightest minds in oncology are all under one roof, there are unprecedented opportunities to network. Make new professional connections at some of the Annual Meeting's many networking events:

- **Trainee and Early-Career Oncologist Member Lounge**
  Designed for medical students, residents, fellows, early-career oncologists, and oncology training program directors, this lounge provides attendees with an opportunity to receive career advice and network. Attendees can meet with and learn from experienced, notable ASCO members through career development and science discussions, small-group Poster Walks, and mock job interviews.
- **Happy Hour on the Terrace**
  After a full day indoors, Happy Hour on D2 Terrace is a great place to unwind, with a landscaped deck and a sweeping view of Lake Michigan. Stop by to recount sessions with colleagues and meet other attendees looking for a break outdoors. Beverages will be available for purchase from 4 PM to 6 PM, June 1 to June 4.
- **Lakeside Lounge**
  For another stunning view of Lake Michigan, the Lakeside Lounge in the East Building in front of Halls D1 and D2 offers space to unwind or meet with colleagues between sessions. Here, attendees can charge devices, eat, watch ASCO TV, and do some shopping at a pop-up shop.

### Prayer/Meditation Room

ASCO provides a dedicated room for the purposes of meditation, quiet prayer, silent reflection, or relaxation during the Annual Meeting in room E251. The room will include clean cloths for attendees to use for kneeling as well as signage indicating East and West.

### Final Tips: New Tool, Twitter, and Getting Around

- **Interact, *powered by SYNC***
  New to the Annual Meeting after a successful debut at the thematic symposia, Interact, *powered by SYNC*, will be offered in all sessions. This platform allows attendees to view speaker slides on their personal devices in real time, take notes on slides during sessions, and pose questions to session faculty. After a session, Interact users will receive an email with a link to a PDF containing all the slides and their notes. Attendees can access Interact using the iPlanner on both their mobile device and laptop.
- **Social Media**
  Connect with @ASCO on Twitter and use #ASCO18 to keep up with the latest information during the Annual Meeting. You can also follow ASCO's Featured Voices, volunteers who have committed to leading a robust social media conversation throughout the Annual Meeting.
- **Getting Around Chicago**
  To help ease the commute to McCormick Place, ASCO provides free shuttle service to and from all of its official hotels. Chicago also has a variety of transportation options, including taxis, Metra, CTA ("L" train), Divvy Bikes, and app-based rideshares. Review the full list of transportation options in the Insider's Guide on am.asco.org.

### Nursing Mothers' Rooms

Inside room N227a (North Building, Level 2), eight private rooms are available for use by nursing mothers. The rooms are open until June 5. Each room will be equipped with a chair, table, power outlet, and refrigerator. ●

**–Carson Rolleri**

*Reprinted and adapted with permission from the May 2018 issue of* ASCO Connection.

### Reference:

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## WHY I ATTEND DR. GEORGE DANEKER JR.

George Daneker Jr., MD, is chief medical officer of Cancer Treatment Centers of America (CTCA) and began attending the ASCO Annual Meeting in the 1990s. In the following interview, Dr. Daneker shares the benefits of the Annual Meeting and advice for newer attendees.

**Q: Why are you attending the ASCO Annual Meeting this year?**
**Dr. Daneker Jr.:** Without question, ASCO is the premier clinical oncology event worldwide. It offers incredibly rich educational content, from groundbreaking presentations of the latest research to in-depth deliberations about a wide range of issues affecting patients with cancer. It also covers the bigger picture in cancer and cancer care, including how it impacts—and is impacted—by society. The conference attracts the who's who in oncology, and it's also valuable for those learning the field or studying a specific topic such as immunotherapy. Further, it's always exciting to walk through the exhibits and get a glimpse into the latest and greatest technologies and advancements coming into practice.

**Q: How do you plan your time during the Meeting? Do you have any tips for new attendees who may feel overwhelmed by all the on-site options?**
**Dr. Daneker Jr.:** The sheer number of superb sessions can truly be overwhelming. I highly recommend downloading the iPlanner app a couple of weeks ahead of time and familiarizing yourself with the program to identify sessions you plan to attend—acknowledge you can't see and do everything, and spend some time figuring out what your priorities are.

You should also be strategic and tactical. There could be three sessions you'd like to attend at any one time, so you need to carefully plan your own personal syllabus ahead of time to maximize value. Additionally, take into account the location of each session. Some conference rooms might be a 15-minute walk away. And for the most popular sessions, arrive in advance to guarantee a seat.

**Q: Apart from the science presented, what are the benefits of attending the Meeting?**
**Dr. Daneker Jr.:** The conference allows for a truly immersive educational experience. Personally, I have a hard time sitting and reading a journal for a couple of hours at the end of a busy day. At the Meeting, I turn my cell phone off (or at least silence it), and I engross myself in the content. The experience allows for the condensed exposure and rapid connection of ideas and learnings so you come out with a synergistic enhancement of your understanding of a topic, as opposed to trying to connect ideas encountered from various noncurated sources. The Plenary Session also provides a real sense of oncology as a discipline and where it is going—not only specifics about clinical trials, but bigger, macro trends that get you thinking.

I particularly enjoy the networking aspect of the conference and catching up with old friends and colleagues. I often run into people with whom I've served on committees, worked on projects, or trained with in my residency or fellowships.

I also look forward to hearing and learning from fellow physicians on key topics such as precision medicine. CTCA has a specific interest in where the field is going and what the future looks like. In turn, I'm excited to share our learnings, such as best practices that led CTCA to become a lead accruer in ASCO's TAPUR study.

**Q: Have you made any connections at the Meeting that have impacted your career?**
**Dr. Daneker Jr.:** Where do I start? The connections I've made or renewed at the Annual Meeting have influenced decisions about my fellowship and my choice of a faculty position and inspired the overall direction my career has taken in terms of clinical and scientific interest. These connections have shaped my career as a surgeon, as a researcher, and as a health care executive.

**Q: Do you have any advice for networking at the Meeting?**
**Dr. Daneker Jr.:** Don't be afraid to just walk up and say hello to *anybody*. Even the big names are open to meeting people, too. In my experience, these kinds of introductions have rarely been anything but beneficial.

**Q: This year's theme is focused on precision medicine. What do you think the Meeting will be most focused on 10 years from now?**
**Dr. Daneker Jr.:** The world of precision medicine is changing rapidly as we continue to develop clinically meaningful approaches to improve the likelihood that an individual patient's cancer will respond to precision medicine options. A decade from now, I believe we will be discussing how to leverage clinical trial and real-world evidence to inform and influence clinical decision-making at the *true* point of care. We might be asking:

1. How do we incorporate a robust oncology clinical decision–support strategy that will have been shown by that time to be of value in randomized clinical trials into routine clinical practice? And how will this essential management tool be funded?
2. How do we finally learn to incorporate lifestyle strategies (obesity management, HPV vaccination, tobacco control, stress reduction, etc.) in the cancer management paradigm as the cost of cancer care is increasingly recognized to be bankrupting the U.S. economy?

**Q: What do you always make sure to include when packing for the Meeting?**
**Dr. Daneker Jr.:** Comfortable shoes! You'll do a lot of walking around the sprawling McCormick Place venue. I also bring something to take notes on, like a tablet, and a charger. And of course, a desire to learn and forge new relationships.

**Q: Where is your favorite place in Chicago to get a drink?**
**Dr. Daneker Jr.:** For a touch of nostalgia, and when I feel like reliving my days at the University of Chicago's Business School, I go to the quintessential dive bar, Rossi's. The Langham Hotel is also a great place to get a drink in a more upscale environment. And on a Friday afternoon, The Purple Pig is a fun place to be. But to me, the *place* is not as important as the people you drink with—and of course, the drink itself. Mine's a dirty martini with a little vermouth and three blue cheese–stuffed olives.

**Q: Any other tips for attendees?**
**Dr. Daneker Jr.:** *Have fun* and be open to meeting new people. ●


George Daneker Jr., MD, is chief medical officer at Cancer Treatment Centers of America and has more than 30 years of clinical, research, and health care leadership experience.

# Oncology Professionals Hall: Educational Resources and Exhibitor Offerings

The Oncology Professionals Hall includes the Exhibit Hall, Posters, Industry Expert Theater, Food Court, and ASCO Bistro. Highlighting the most advanced treatments, products, and services in oncology, the Oncology Professionals Hall provides attendees the opportunity to meet with representatives from the health care industry, including pharmaceutical companies, scientific publishers, electronic health record vendors, and advocacy groups.

Located in front of the Oncology Professionals Hall, ASCO Central is designed to highlight all of ASCO's programs and services.

Attendees can locate Annual Meeting exhibitors in many ways: the Online Exhibitor Directory (am.asco.org), the iPlanner mobile app, at Online Exhibitor Directory stations at the entrance to the Oncology Professionals Hall, or in the printed Exhibitor Directory. The Exhibitor Directory features a detailed floor plan of the Oncology Professionals Hall, with exhibitors searchable by company name and category. It is available at Materials Pickup locations in Registration in Hall C of the North Building or by Gate 3 of the South Building, and at the Exhibits Information Desk at the entrance to the Oncology Professionals Hall. The Oncology Professionals Hall is open from June 2 to June 4, 9 AM to 5 PM.

### ASCO Central

Located in front of the Oncology Professionals Hall, ASCO Central, Booth 7004, is designed to highlight all of ASCO's programs and services.

- **Cancer.Net and Patient Information:** ASCO's patient education website, Cancer.Net, offers printed resources for your office or resource center, including *ASCO Answers* fact sheets and guides on a variety of cancer types and cancer-related topics.
- **ASCO's policy, guidelines, practice, research, and advocacy resources**: Stop by to learn about these resources, including information on TAPUR, CENTRA, and the Community Research Forum. Clinical practice guidelines serve as a reference for doctors and outline appropriate methods of treatment and care. Guidelines can

*See Oncology Professionals Hall, Page 34*

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# The BEACON CRC trial in 2nd- and 3rd-line treatment of *BRAF* V600E metastatic colorectal cancer (mCRC)

## DESIGN

- A Phase 3 trial in patients with *BRAF* V600E–mutant mCRC comparing:
  - Binimetinib + encorafenib + cetuximab
  - Encorafenib + cetuximab
  - Irinotecan-based treatment (FOLFIRI[a] or irinotecan) + cetuximab
- **Primary objective:** OS of binimetinib + encorafenib + cetuximab compared to irinotecan-based therapy + cetuximab
- **Select secondary objectives:**
  - OS of encorafenib + cetuximab compared to irinotecan-based therapy + cetuximab, and binimetinib + encorafenib + cetuximab compared to encorafenib + cetuximab
  - PFS, ORR, DoR, and time to response compared across all treatment arms

For a complete list of secondary objectives, please visit Clinicaltrials.gov using identifier: NCT02928224

[a]FOLFIRI: 5-fluorouracil bolus followed by continuous infusion + leucovorin + irinotecan.

## ENROLL A PATIENT

**EMAIL**

clinicaltrials@arraybiopharma.com

**CALL**

303-381-6604

## LEARN MORE

BEACONCRCtrial.com

**Discuss with an Array medical colleague at ASCO booth #22145**

AE, adverse event; CR, complete response; DoR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.



Trial conducted with support from Merck KGaA (support is for sites outside of North America), Ono Pharmaceutical, and Pierre Fabre.

# FDA approved for metastatic CRPC since 2012


## In the US alone, 106,000 patients have been prescribed XTANDI—and counting†[2]

†Estimate based on US sales and use data from September 2012 to December 2017.
Reference: Astellas. XTANDI. Data on File. Source: Symphony Health.[2]

## Indication and Important Safety Information

### Indication

XTANDI (enzalutamide) capsules is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

## Important Safety Information

### Contraindications

XTANDI is not indicated for women. XTANDI can cause fetal harm and potential loss of pregnancy.

### Warnings and Precautions

**Seizure** occurred in 0.5% of patients receiving XTANDI in clinical studies. In a study of patients with predisposing factors, seizures were reported in 2.2% of patients. See section 5.1 of the Prescribing Information for the list of predisposing factors. It is unknown whether anti-epileptic medications will prevent seizures with XTANDI. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

**Posterior Reversible Encephalopathy Syndrome (PRES)**
In post approval use, there have been reports of PRES in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XTANDI in patients who develop PRES.

### Adverse Reactions

The most common adverse reactions (≥ 10%) that occurred more commonly (≥ 2% over placebo) in the XTANDI patients from the two placebo-controlled clinical trials were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo. In the bicalutamide-controlled study of chemotherapy-naïve patients, the most common adverse reactions (≥ 10%) reported in XTANDI patients were asthenia/fatigue, back pain, musculoskeletal pain, hot flush, hypertension, nausea, constipation, upper respiratory tract infection, diarrhea, and weight loss.

In the placebo-controlled study of patients taking XTANDI who previously received docetaxel, Grade 3 and higher adverse reactions were reported among 47% of XTANDI patients and 53% of placebo patients. Discontinuations due to adverse events were reported for 16% of XTANDI patients and 18% of placebo patients. In the placebo-controlled study of chemotherapy-naïve patients, Grade 3-4 adverse reactions were reported in 44% of XTANDI patients and 37% of placebo patients. Discontinuations due to adverse events were reported for 6% of both study groups. In the bicalutamide-controlled study of chemotherapy-naïve patients, Grade 3-4 adverse reactions were reported in 38.8% of XTANDI patients and 37.6% of bicalutamide patients. Discontinuations due to adverse events were reported for 7.6% of XTANDI patients and 6.3% of bicalutamide patients.

## Supported by 3 randomized, controlled trials

### AFFIRM TRIAL

**1199 patients** with metastatic CRPC who were previously on docetaxel therapy were randomized to XTANDI + GnRH therapy* (n = 800) or placebo + GnRH therapy* (n = 399).[1]

### PREVAIL TRIAL

**1717 patients** with metastatic CRPC who were asymptomatic or mildly symptomatic were randomized to XTANDI + GnRH therapy* (n = 872) or placebo + GnRH therapy* (n = 845).[1,3]

### TERRAIN TRIAL

**375 patients** with metastatic CRPC who were asymptomatic or mildly symptomatic were randomized to XTANDI + GnRH therapy* (n = 184) or bicalutamide + GnRH therapy* (n = 191).[1,4]

GnRH therapy, gonadotropin-releasing hormone therapy; mCRPC, metastatic castration-resistant prostate cancer.

***Or after bilateral orchiectomy.**[1]

**Visit XtandiHCP.com to learn more about XTANDI in metastatic CRPC patients**

Lab Abnormalities: In the two placebo-controlled trials, Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and 6% of placebo patients (0.5% Grade 3-4). Grade 1-4 thrombocytopenia occurred in 6% of XTANDI patients (0.3% Grade 3-4) and 5% of placebo patients (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of XTANDI patients (0.2% Grade 3-4) and 16% of placebo patients (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients (0.1% Grade 3-4) and 2% of placebo patients (no Grade 3-4).

Infections: In the study of patients taking XTANDI who previously received docetaxel, 1% of XTANDI patients compared to 0.3% of placebo patients died from infections or sepsis. In the study of chemotherapy-naïve patients, 1 patient in each treatment group (0.1%) had an infection resulting in death.

Falls (including fall-related injuries) occurred in 9% of XTANDI patients and 4% of placebo patients in the two placebo-controlled trials. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in XTANDI patients, and included non-pathologic fractures, joint injuries, and hematomas.

Hypertension occurred in 11% of XTANDI patients and 4% of placebo patients in the two placebo-controlled trials. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of patients in each arm.

## Drug Interactions

**Effect of Other Drugs on XTANDI** Avoid strong CYP2C8 inhibitors, as they can increase the plasma exposure to XTANDI. If co-administration is necessary, reduce the dose of XTANDI.

Avoid strong CYP3A4 inducers as they can decrease the plasma exposure to XTANDI. If co-administration is necessary, increase the dose of XTANDI.

**Effect of XTANDI on Other Drugs** Avoid CYP3A4, CYP2C9, and CYP2C19 substrates with a narrow therapeutic index, as XTANDI may decrease the plasma exposures of these drugs. If XTANDI is co-administered with warfarin (CYP2C9 substrate), conduct additional INR monitoring.

**Please see adjacent pages for Brief Summary of Full Prescribing Information.**

**References: 1.** XTANDI [package insert]. Northbrook, IL: Astellas, Inc. **2.** Astellas. XTANDI. Data on File. **3.** Beer TM, Armstrong AJ, Rathkopf DE, et al; for the PREVAIL Investigators. Enzalutamide in metastatic prostate cancer before chemotherapy. N Engl J Med 2014;371(5):424-33. **4.** Shore ND, Chowdhury S, Villers A, et al. Efficacy and safety of enzalutamide versus bicalutamide for patients with metastatic prostate cancer (TERRAIN): a randomised, double-blind, phase 2 study. Lancet Oncol 2016;17(2):153-63.

astellas

Pfizer Oncology



Xtandi®
(enzalutamide)
40 mg capsules

Xtandi® (enzalutamide) 40 mg capsules

**XTANDI® (enzalutamide) capsules for oral use**
**Initial U.S. Approval: 2012**

## BRIEF SUMMARY OF PRESCRIBING INFORMATION

The following is a brief summary. Please see the package insert for full prescribing information.

## INDICATIONS AND USAGE

XTANDI is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

## CONTRAINDICATIONS

### Pregnancy

XTANDI can cause fetal harm and potential loss of pregnancy.

## WARNINGS AND PRECAUTIONS

### Seizure

Seizure occurred in 0.5% of patients receiving XTANDI in clinical studies. In these trials patients with predisposing factors for seizure were generally excluded. Seizure occurred from 31 to 603 days after initiation of XTANDI. Patients experiencing seizures were permanently discontinued from therapy and all seizure events resolved.

In a single-arm trial designed to assess the risk of seizure in patients with pre-disposing factors for seizure, 8 of 366 (2.2%) XTANDI-treated patients experienced a seizure. Three of the 8 patients experienced a second seizure during continued treatment with XTANDI after their first seizure resolved. It is unknown whether anti-epileptic medications will prevent seizures with XTANDI. Patients in the study had one or more of the following pre-disposing factors: the use of medications that may lower the seizure threshold (~ 54%), history of traumatic brain or head injury (~ 28%), history of cerebrovascular accident or transient ischemic attack (~ 24%), and Alzheimer's disease, meningioma, or leptomeningeal disease from prostate cancer, unexplained loss of consciousness within the last 12 months, past history of seizure, presence of a space occupying lesion of the brain, history of arteriovenous malformation, or history of brain infection (all < 5%). Approximately 17% of patients had more than one risk factor.

Advise patients of the risk of developing a seizure while receiving XTANDI and of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others.

Permanently discontinue XTANDI in patients who develop a seizure during treatment.

### Posterior Reversible Encephalopathy Syndrome (PRES)

There have been reports of posterior reversible encephalopathy syndrome (PRES) in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging (MRI). Discontinue XTANDI in patients who develop PRES.

## ADVERSE REACTIONS

### Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Three randomized clinical trials enrolled patients with metastatic prostate cancer that has progressed on androgen deprivation therapy (GnRH therapy or bilateral orchiectomy), a disease setting that is also defined as metastatic CRPC. Two trials were placebo-controlled (Studies 1 and 2), and one trial was bicalutamide-controlled (Study 3). In Studies 1 and 2, patients received XTANDI 160 mg or placebo orally once daily. In Study 3, patients received XTANDI 160 mg or bicalutamide 50 mg orally once daily. All patients continued androgen deprivation therapy. Patients were allowed, but not required, to take glucocorticoids.

The most common adverse reactions (≥ 10%) that occurred more commonly (≥ 2% over placebo) in the XTANDI-treated patients from the two randomized placebo-controlled clinical trials were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo.

### Study 1: XTANDI versus Placebo in Metastatic CRPC Following Chemotherapy

Study 1 enrolled 1199 patients with metastatic CRPC who had previously received docetaxel. The median duration of treatment was 8.3 months with XTANDI and 3.0 months with placebo. During the trial, 48% of patients on the XTANDI arm and 46% of patients on the placebo arm received glucocorticoids.

Grade 3 and higher adverse reactions were reported among 47% of XTANDI-treated patients and 53% of placebo-treated patients. Discontinuations due to adverse events were reported for 16% of XTANDI-treated patients and 18% of placebo-treated patients. The most common adverse reaction leading to treatment discontinuation was seizure, which occurred in 0.9% of the XTANDI-treated patients compared to none (0%) of the placebo-treated patients. Table 1 shows adverse reactions reported in Study 1 that occurred at a ≥ 2% higher frequency in the XTANDI arm compared to the placebo arm.

**Table 1. Adverse Reactions in Study 1**

| | XTANDI N = 800 | | Placebo N = 399 | |
|---|---|---|---|---|
| | Grade 1-4[a] (%) | Grade 3-4 (%) | Grade 1-4 (%) | Grade 3-4 (%) |
| **General Disorders** | | | | |
| Asthenic Conditions[b] | 50.6 | 9.0 | 44.4 | 9.3 |
| Peripheral Edema | 15.4 | 1.0 | 13.3 | 0.8 |
| **Musculoskeletal And Connective Tissue Disorders** | | | | |
| Back Pain | 26.4 | 5.3 | 24.3 | 4.0 |
| Arthralgia | 20.5 | 2.5 | 17.3 | 1.8 |
| Musculoskeletal Pain | 15.0 | 1.3 | 11.5 | 0.3 |
| Muscular Weakness | 9.8 | 1.5 | 6.8 | 1.8 |
| Musculoskeletal Stiffness | 2.6 | 0.3 | 0.3 | 0.0 |
| **Gastrointestinal Disorders** | | | | |
| Diarrhea | 21.8 | 1.1 | 17.5 | 0.3 |
| **Vascular Disorders** | | | | |
| Hot Flush | 20.3 | 0.0 | 10.3 | 0.0 |
| Hypertension | 6.4 | 2.1 | 2.8 | 1.3 |
| **Nervous System Disorders** | | | | |
| Headache | 12.1 | 0.9 | 5.5 | 0.0 |
| Dizziness[c] | 9.5 | 0.5 | 7.5 | 0.5 |
| Spinal Cord Compression and Cauda Equina Syndrome | 7.4 | 6.6 | 4.5 | 3.8 |
| Paresthesia | 6.6 | 0.0 | 4.5 | 0.0 |
| Mental Impairment Disorders[d] | 4.3 | 0.3 | 1.8 | 0.0 |
| Hypoesthesia | 4.0 | 0.3 | 1.8 | 0.0 |
| **Infections And Infestations** | | | | |
| Upper Respiratory Tract Infection[e] | 10.9 | 0.0 | 6.5 | 0.3 |
| Lower Respiratory Tract And Lung Infection[f] | 8.5 | 2.4 | 4.8 | 1.3 |
| **Psychiatric Disorders** | | | | |
| Insomnia | 8.8 | 0.0 | 6.0 | 0.5 |
| Anxiety | 6.5 | 0.3 | 4.0 | 0.0 |
| **Renal And Urinary Disorders** | | | | |
| Hematuria | 6.9 | 1.8 | 4.5 | 1.0 |
| Pollakiuria | 4.8 | 0.0 | 2.5 | 0.0 |
| **Injury, Poisoning And Procedural Complications** | | | | |
| Fall | 4.6 | 0.3 | 1.3 | 0.0 |
| Non-pathologic Fractures | 4.0 | 1.4 | 0.8 | 0.3 |
| **Skin And Subcutaneous Tissue Disorders** | | | | |
| Pruritus | 3.8 | 0.0 | 1.3 | 0.0 |
| Dry Skin | 3.5 | 0.0 | 1.3 | 0.0 |
| **Respiratory Disorders** | | | | |
| Epistaxis | 3.3 | 0.1 | 1.3 | 0.3 |

a CTCAE v4.
b Includes asthenia and fatigue.
c Includes dizziness and vertigo.
d Includes amnesia, memory impairment, cognitive disorder, and disturbance in attention.
e Includes nasopharyngitis, upper respiratory tract infection, sinusitis, rhinitis, pharyngitis, and laryngitis.
f Includes pneumonia, lower respiratory tract infection, bronchitis, and lung infection.

### Study 2: XTANDI versus Placebo in Chemotherapy-naïve Metastatic CRPC

Study 2 enrolled 1717 patients with metastatic CRPC who had not received prior cytotoxic chemotherapy, of whom 1715 received at least one dose of study drug. The median duration of treatment was 17.5 months with XTANDI and 4.6 months with placebo. Grade 3-4 adverse reactions were reported in 44% of XTANDI-treated patients and 37% of placebo-treated patients. Discontinuations due to adverse events were reported for 6% of XTANDI-treated patients and 6% of placebo-treated patients. The most common adverse reaction leading to treatment discontinuation was fatigue/asthenia, which occurred in 1% of patients on each treatment arm. Table 2 includes adverse reactions reported in Study 2 that occurred at a ≥ 2% higher frequency in the XTANDI arm compared to the placebo arm.

**Table 2. Adverse Reactions in Study 2**

| | XTANDI N = 871 | | Placebo N = 844 | |
|---|---|---|---|---|
| | Grade 1-4[a] (%) | Grade 3-4 (%) | Grade 1-4 (%) | Grade 3-4 (%) |
| **General Disorders** | | | | |
| Asthenic Conditions[b] | 46.9 | 3.4 | 33.0 | 2.8 |
| Peripheral Edema | 11.5 | 0.2 | 8.2 | 0.4 |
| **Musculoskeletal And Connective Tissue Disorders** | | | | |
| Back Pain | 28.6 | 2.5 | 22.4 | 3.0 |
| Arthralgia | 21.4 | 1.6 | 16.1 | 1.1 |
| **Gastrointestinal Disorders** | | | | |
| Constipation | 23.2 | 0.7 | 17.3 | 0.4 |
| Diarrhea | 16.8 | 0.3 | 14.3 | 0.4 |
| **Vascular Disorders** | | | | |
| Hot Flush | 18.0 | 0.1 | 7.8 | 0.0 |
| Hypertension | 14.2 | 7.2 | 4.1 | 2.3 |
| **Nervous System Disorders** | | | | |
| Dizziness[c] | 11.3 | 0.3 | 7.1 | 0.0 |
| Headache | 11.0 | 0.2 | 7.0 | 0.4 |
| Dysgeusia | 7.6 | 0.1 | 3.7 | 0.0 |
| Mental Impairment Disorders[d] | 5.7 | 0.0 | 1.3 | 0.1 |
| Restless Legs Syndrome | 2.1 | 0.1 | 0.4 | 0.0 |
| **Respiratory Disorders** | | | | |
| Dyspnea[e] | 11.0 | 0.6 | 8.5 | 0.6 |
| **Infections And Infestations** | | | | |
| Upper Respiratory Tract Infection[f] | 16.4 | 0.0 | 10.5 | 0.0 |
| Lower Respiratory Tract And Lung Infection[g] | 7.9 | 1.5 | 4.7 | 1.1 |
| **Psychiatric Disorders** | | | | |
| Insomnia | 8.2 | 0.1 | 5.7 | 0.0 |
| **Renal And Urinary Disorders** | | | | |
| Hematuria | 8.8 | 1.3 | 5.8 | 1.3 |
| **Injury, Poisoning And Procedural Complications** | | | | |
| Fall | 12.7 | 1.6 | 5.3 | 0.7 |
| Non-Pathological Fracture | 8.8 | 2.1 | 3.0 | 1.1 |
| **Metabolism and Nutrition Disorders** | | | | |
| Decreased Appetite | 18.9 | 0.3 | 16.4 | 0.7 |
| **Investigations** | | | | |
| Weight Decreased | 12.4 | 0.8 | 8.5 | 0.2 |
| **Reproductive System and Breast Disorders** | | | | |
| Gynecomastia | 3.4 | 0.0 | 1.4 | 0.0 |

a CTCAE v4.
b Includes asthenia and fatigue.
c Includes dizziness and vertigo.
d Includes amnesia, memory impairment, cognitive disorder, and disturbance in attention.
e Includes dyspnea, exertional dyspnea, and dyspnea at rest.
f Includes nasopharyngitis, upper respiratory tract infection, sinusitis, rhinitis, pharyngitis, and laryngitis.
g Includes pneumonia, lower respiratory tract infection, bronchitis, and lung infection.

### Study 3: XTANDI versus Bicalutamide in Chemotherapy-naïve Metastatic CRPC

Study 3 enrolled 375 patients with metastatic CRPC who had not received prior cytotoxic chemotherapy, of whom 372 received at least one dose of study drug. The median duration of treatment was 11.6 months with XTANDI

and 5.8 months with bicalutamide. Discontinuations with an adverse event as the primary reason were reported for 7.6% of XTANDI-treated patients and 6.3% of bicalutamide-treated patients. The most common adverse reactions leading to treatment discontinuation were back pain and pathological fracture, which occurred in 3.8% of XTANDI-treated patients for each event and in 2.1% and 1.6% of bicalutamide-treated patients, respectively. Table 3 shows overall and common adverse reactions (≥ 10%) in XTANDI-treated patients.

**Table 3. Adverse Reactions in Study 3**

| | XTANDI N = 183 | | Bicalutamide N = 189 | |
|---|---|---|---|---|
| | Grade 1-4[a] (%) | Grade 3-4 (%) | Grade 1-4[a] (%) | Grade 3-4 (%) |
| **Overall** | 94.0 | 38.8 | 94.2 | 37.6 |
| **General Disorders** | | | | |
| Asthenic Conditions[b] | 31.7 | 1.6 | 22.8 | 1.1 |
| **Musculoskeletal And Connective Tissue Disorders** | | | | |
| Back Pain | 19.1 | 2.7 | 18.0 | 1.6 |
| Musculoskeletal Pain[c] | 16.4 | 1.1 | 14.3 | 0.5 |
| **Vascular Disorders** | | | | |
| Hot Flush | 14.8 | 0.0 | 11.1 | 0.0 |
| Hypertension | 14.2 | 7.1 | 7.4 | 4.2 |
| **Gastrointestinal Disorders** | | | | |
| Nausea | 14.2 | 0.0 | 17.5 | 0.0 |
| Constipation | 12.6 | 1.1 | 13.2 | 0.5 |
| Diarrhea | 11.5 | 0.0 | 9.0 | 1.1 |
| **Infections And Infestations** | | | | |
| Upper Respiratory Tract Infection[d] | 12.0 | 0.0 | 6.3 | 0.5 |
| **Investigational** | | | | |
| Weight Loss | 10.9 | 0.5 | 7.9 | 0.5 |

a CTCAE v 4.
b Including asthenia and fatigue.
c Including musculoskeletal pain and pain in extremity.
d Including nasopharyngitis, upper respiratory tract infection, sinusitis, rhinitis, pharyngitis, and laryngitis.

**Laboratory Abnormalities**

In the two randomized placebo-controlled clinical trials, Grade 1-4 neutropenia occurred in 15% of patients treated with XTANDI (1% Grade 3-4) and in 6% of patients treated with placebo (0.5% Grade 3-4). The incidence of Grade 1-4 thrombocytopenia was 6% of patients treated with XTANDI (0.3% Grade 3-4) and 5% of patients treated with placebo (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of patients treated with XTANDI (0.2% Grade 3-4) and 16% of patients treated with placebo (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of patients treated with XTANDI (0.1% Grade 3-4) and 2% of patients treated with placebo (no Grade 3-4).

**Infections**

In Study 1, 1% of patients treated with XTANDI compared to 0.3% of patients treated with placebo died from infections or sepsis. In Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.

**Falls and Fall-related Injuries**

In the two randomized placebo-controlled clinical trials, falls including fall-related injuries, occurred in 9% of patients treated with XTANDI compared to 4% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in patients treated with XTANDI and included non-pathologic fractures, joint injuries, and hematomas.

**Hypertension**

In the two randomized placebo-controlled trials, hypertension was reported in 11% of patients receiving XTANDI and 4% of patients receiving placebo. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of patients in each arm.

**Post-Marketing Experience**

The following additional adverse reactions have been identified during post approval use of XTANDI. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

*Body as a Whole:* hypersensitivity (tongue edema, lip edema, and pharyngeal edema)
*Gastrointestinal Disorders:* vomiting
*Neurological Disorders:* posterior reversible encephalopathy syndrome (PRES)
*Skin and Subcutaneous Tissue Disorders:* rash

**DRUG INTERACTIONS**

**Drugs that Inhibit CYP2C8**

Co-administration of a strong CYP2C8 inhibitor (gemfibrozil) increased the composite area under the plasma concentration-time curve (AUC) of enzalutamide plus N-desmethyl enzalutamide by 2.2-fold. Co-administration of XTANDI with strong CYP2C8 inhibitors should be avoided if possible. If co-administration of XTANDI with a strong CYP2C8 inhibitor cannot be avoided, reduce the dose of XTANDI.

**Drugs that Induce CYP3A4**

Co-administration of rifampin (strong CYP3A4 inducer and moderate CYP2C8 inducer) decreased the composite AUC of enzalutamide plus N-desmethyl enzalutamide by 37%. Co-administration of strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine) with XTANDI should be avoided if possible. St John's wort may decrease enzalutamide exposure and should be avoided. If co-administration of a strong CYP3A4 inducer with XTANDI cannot be avoided, increase the dose of XTANDI.

**Effect of XTANDI on Drug Metabolizing Enzymes**

Enzalutamide is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. At steady state, XTANDI reduced the plasma exposure to midazolam (CYP3A4 substrate), warfarin (CYP2C9 substrate), and omeprazole (CYP2C19 substrate). Concomitant use of XTANDI with narrow therapeutic index drugs that are metabolized by CYP3A4 (e.g., alfentanil, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus and tacrolimus), CYP2C9 (e.g., phenytoin, warfarin) and CYP2C19 (e.g., S-mephenytoin) should be avoided, as enzalutamide may decrease their exposure. If co-administration with warfarin cannot be avoided, conduct additional INR monitoring.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

*Risk Summary*

XTANDI is contraindicated for use in pregnant women because the drug can cause fetal harm and potential loss of pregnancy. XTANDI is not indicated for use in females. There are no human data on the use of XTANDI in pregnant women. In animal reproduction studies, oral administration of enzalutamide in pregnant mice during organogenesis caused adverse developmental effects at doses lower than the maximum recommended human dose.

*Animal Data*

In an embryo-fetal developmental toxicity study in mice, enzalutamide caused developmental toxicity when administered at oral doses of 10 or 30 mg/kg/day throughout the period of organogenesis (gestational days 6-15). Findings included embryo-fetal lethality (increased post-implantation loss and resorptions) and decreased anogenital distance at ≥ 10 mg/kg/day, and cleft palate and absent palatine bone at 30 mg/kg/day. Doses of 30 mg/kg/day caused maternal toxicity. The doses tested in mice (1, 10 and 30 mg/kg/day) resulted in systemic exposures (AUC) approximately 0.04, 0.4 and 1.1 times, respectively, the exposures in patients. Enzalutamide did not cause developmental toxicity in rabbits when administered throughout the period of organogenesis (gestational days 6-18) at dose levels up to 10 mg/kg/day (approximately 0.4 times the exposures in patients based on AUC).

**Lactation**

*Risk Summary*

XTANDI is not indicated for use in females. There is no information available on the presence of XTANDI in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Enzalutamide and/or its metabolites were present in milk of lactating rats.

**Females and Males of Reproductive Potential**

**Contraception**

*Males*

Based on findings in animal reproduction studies, advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the final dose of XTANDI.

**Infertility**

Based on animal studies, XTANDI may impair fertility in males of reproductive potential.

**Pediatric Use**

Safety and effectiveness of XTANDI in pediatric patients have not been established.

**Geriatric Use**

Of 1671 patients who received XTANDI in the two randomized placebo-controlled clinical trials, 75% were 65 and over, while 31% were 75 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

**Patients with Renal Impairment**

A dedicated renal impairment trial for XTANDI has not been conducted. Based on the population pharmacokinetic analysis using data from clinical trials in patients with metastatic CRPC and healthy volunteers, no significant difference in enzalutamide clearance was observed in patients with pre-existing mild to moderate renal impairment (30 mL/min ≤ creatinine clearance [CrCL] ≤ 89 mL/min) compared to patients and volunteers with baseline normal renal function (CrCL ≥ 90 mL/min). No initial dosage adjustment is necessary for patients with mild to moderate renal impairment. Severe renal impairment (CrCL < 30 mL/min) and end-stage renal disease have not been assessed.

**Patients with Hepatic Impairment**

Dedicated hepatic impairment trials compared the composite systemic exposure of enzalutamide plus N-desmethyl enzalutamide in volunteers with baseline mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C, respectively) versus healthy controls with normal hepatic function. The composite AUC of enzalutamide plus N-desmethyl enzalutamide was similar in volunteers with mild, moderate, or severe baseline hepatic impairment compared to volunteers with normal hepatic function. No initial dosage adjustment is necessary for patients with baseline mild, moderate, or severe hepatic impairment.

**OVERDOSAGE**

In the event of an overdose, stop treatment with XTANDI and initiate general supportive measures taking into consideration the half-life of 5.8 days. In a dose escalation study, no seizures were reported at ≤ 240 mg daily, whereas 3 seizures were reported, 1 each at 360 mg, 480 mg, and 600 mg daily. Patients may be at increased risk of seizure following an overdose.

**NONCLINICAL TOXICOLOGY**

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of enzalutamide.

Enzalutamide did not induce mutations in the bacterial reverse mutation (Ames) assay and was not genotoxic in either the *in vitro* mouse lymphoma thymidine kinase (Tk) gene mutation assay or the *in vivo* mouse micronucleus assay.

Based on nonclinical findings in repeat-dose toxicology studies, which were consistent with the pharmacological activity of enzalutamide, male fertility may be impaired by treatment with XTANDI. In a 26-week study in rats, atrophy of the prostate and seminal vesicles was observed at ≥ 30 mg/kg/day (equal to the human exposure based on AUC). In 4-, 13-, and 39-week studies in dogs, hypospermatogenesis and atrophy of the prostate and epididymides were observed at ≥ 4 mg/kg/day (0.3 times the human exposure based on AUC).

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# 2017 Palliative and Supportive Care in Oncology Symposium Continues to Push Field Forward

The 2017 Palliative and Supportive Care in Oncology Symposium took place on October 27 and 28 in San Diego. It featured compelling research and the latest in clinical education that could be used to advance patient-centered care across the cancer continuum, according to Program Committee Chair Tracy A. Balboni, MD, MPH, of Dana-Farber Cancer Institute and Harvard Medical School.

Among the Symposium highlights was the inspiring keynote session, Dr. Balboni said.

Keynote lecturer Angelo E. Volandes, MD, MPH, of Massachusetts General Hospital, featured his impactful work in the use of video-based patient- and community-centered educational methods to improve understanding and decision-making for end-of-life care.

"Patients repeatedly expressed how these educational videos brought an understanding of their end-of-life medical decisions in a way that words alone too often fail to achieve," Dr. Balboni said.

Anthony Back, MD, of the University of Washington and Fred Hutchinson Cancer Research Center, received this year's inaugural Walther Cancer Foundation Palliative and Supportive Care in Oncology Endowed Award. During his award lecture, he called for a multilevel, multistakeholder response to the epidemic of clinician burnout.

Dr. Anthony Back (second from left) receives the inaugural Walther Cancer Foundation Palliative and Supportive Care in Oncology Endowed Award.

"He described the need for not only personal burnout prevention strategies but also comprehensive workplace strategies," Dr. Balboni said. "These include optimizing clinical workloads, strategizing to enhance systems efficiencies, systems changes to allow for clinician autonomy, attention to work-life balance, upholding shared values, and efforts to enhance community."

## Symptom Management

Dr. Balboni described the research presented during the Symposium as compelling and practical. Several sessions addressed symptom management in patients with cancer, such as nausea and fatigue.

Nausea assessment doesn't take long, according to Rudolph M. Navari, MD, PhD, FACP, of the University of Alabama at Birmingham, who presented on nausea associated with advanced cancer during General Session 3. Assessment should include simple questions about frequency, associated activities, and time of day. It is also important to establish whether nausea is associated with chemotherapy or radiation treatment, because nontreatment causes are numerous. Nontreatment-related causes include bowel obstruction, malignant ascites, concurrent medications, anxiety, and depression. After etiology is determined, use of guideline-directed treatment, followed by regular reassessment, is recommended.

Cancer-related fatigue occurs in as many as 25% to 99% of patients with cancer and persists even among survivors, said Sandra A. Mitchell, PhD, CRNP, AOCN, of the National Cancer Institute. During General Session 3, Dr. Mitchell discussed the scope of cancer-related fatigue and challenges associated with it. For example, fatigue can be difficult to distinguish from other symptoms such as depression, cognitive dysfunction, or asthenia. Fatigue may occur alone or as a component within a cluster that includes pain, depression, and sleep disturbances. Because fatigue can affect health-related quality of life and long-term survival outcomes, it is critical to individualize fatigue management plans. This often means using one or a combination of fatigue interventions, including exercise, management of concurrent symptoms, yoga, rehabilitation, psychoeducational interventions, or cognitive behavioral therapy.

Engaging patients in a palliative care program early in their treatment can alleviate many cancer-related symptoms. However, dissemination of these services is a challenge, according to Michael Hoerger, PhD, MSCR, of Tulane Cancer Center. During Oral Abstract Session A, Dr. Hoerger presented data from a study designed to describe key elements of palliative care and to assess whether variation in these elements was linked with changes in patient-related outcomes and end-of-life care (Abstract 154).[1] The study included patients with incurable lung or noncolorectal gastrointestinal cancer assigned to early palliative care integrated with oncology care. Patients with a higher percentage of palliative care visits that focused on coping had significantly improved quality of life and reduced rates of depression. When a higher percentage of visits focused on treatment decisions, patients had a higher quality of end-of-life care, including reduced odds of new chemotherapy and hospitalization in the 60 days before death.

## Palliative Care in the Elderly Population

Among the other diverse topics covered during the Symposium were sessions on palliative and supportive care issues in older adults—a topic relevant to all oncologists because there is a projected increase in the number of patients older than age 65 who will develop cancer by 2030.

According to a study presented by Wendi G. Lebrett, a medical student at University of California, San Diego, during Oral Abstract Session A, palliative care can have a substantial effect on health care costs among elderly patients with advanced cancer (Abstract 91).[2] The case-control study compared costs between Medicare beneficiaries with metastatic lung, colorectal, breast, or prostate cancers who received palliative care consultation and those who did not. Among the more than 2,500 patients studied, health care costs were balanced in the 30 days before palliative care consultation but significantly differed after. The introduction of palliative care reduced total health care costs per patient in the subsequent 120 days by 28%, or approximately $3,000 ($6,880 vs. $9,604; $p < 0.001$).

"These sessions also provided guidance in how clinicians should regularly apply geriatric assessments in cancer care decision-making in older adults," Dr. Balboni said. "They featured models in how to collaborate with our geriatric medicine colleagues in providing interdisciplinary cancer care."

During General Session 2, Aminah Jatoi, MD, of Mayo Clinic, Rochester, discussed how to approach care for vulnerable, frail patients with cancer. She gave several practical recommendations for the treatment of this patient population, including the use of clinical trials, in which older patients are often underenrolled. However, among the most important tools for care of older patients is the use of geriatric assessments, Dr. Jatoi said. Research has shown that these assessments take only 22 minutes on average but provide valuable information such as the detection of frailty issues, predicted toxicity, and predicted survival. These assessments may also help clinicians decide when not to give chemotherapy.

To further illustrate some of the particular issues faced by older adults with cancer, Noam A. VanderWalde, MD, of the University of Tennessee West Cancer Center, presented a case study of an older patient with head and neck cancer, a disease in which more than half of patients are older than age 65. The patient was a 73-year-old man who presented with left throat pain and a growth in his neck. A previous smoker, the man was divorced and lived alone, and he recently had a fall down some steps.

The patient was diagnosed with a small bilateral base of tongue tumor with positive lymph nodes and positive margins. Standard of care would be combined adjuvant radiation with concurrent chemotherapy. However, concurrent chemotherapy adds significant toxicity, Dr. VanderWalde noted. This patient received only two of six planned courses of chemotherapy, developed several adverse events, and required hospitalization for a fall that resulted from malnutrition. This hospitalization led to a 3-day delay in his radiation treatment.

These toxicities could have been predicted with the use of proper tools like geriatric assessments, Dr. VanderWalde said. Specifically, research has shown that just one fall in the prior 6 months predicted almost a 2.5-fold increased risk for grade 3 to 5 toxicity with chemotherapy. With older patients, Dr. VanderWalde concluded, it is important to weigh the risks and benefits of therapy as you determine the stage of not just the cancer but also the patient.

## Improving Patient Quality of Life

Quality of life is an important part of cancer care, whether a patient is a cancer survivor or has advanced disease.


Dr. Joseph Greer presents Abstract 175 during Oral Abstract Session B.

For example, patients with incurable cancer often have marked anxiety that is associated with poor quality of life. During Oral Abstract Session B, Joseph Greer, PhD, of Massachusetts General Hospital, presented data to show that patients with incurable cancer gained significant improvements in quality of life, anxiety, and depression with the intervention of a cognitive behavioral therapy mobile app or a mobile health education program (Abstract 175).[3] The mobile application taught skills to relax the body, reduce worry, stay focused in the present, improve communication, and plan/pace activities.

The introduction of early palliative care also can improve quality of life in patients with advanced cancer. During Oral Abstract Session B, Jamie M. Jacobs, PhD, of Massachusetts General Hospital, presented data from a study of 350 patients with newly diagnosed incurable lung or noncolorectal gastrointestinal cancer who were randomly assigned to oncology care with or without early palliative care integration (Abstract 92).[4] The study showed that early palliative care significantly improved the patients' use of active coping, such as positive reframing and acceptance. Use of these active coping strategies was associated with improved quality of life and depressive symptoms.

Adolescents and young adults with cancer also are at high risk for poor psychosocial outcomes, possibly because they do

not yet have the skills needed to navigate the burdens of illness, according to Abby R. Rosenberg, MD, MS, of Seattle Children's Hospital Cancer and Blood Disorder Center. During Oral Abstract Session B, Dr. Rosenberg presented the results of a study that examined the use of the Promoting Resilience in Stress Management (PRISM) tool, a brief manualized intervention that targets stress management, goal setting, cognitive reframing, and meaning-making (Abstract 176).[5] The study included 100 adolescents or young adults who underwent four in-person, 30- to 60-minute sessions and a facilitated family meeting. At the 6-month follow-up assessment, PRISM was associated with improved patient-reported resilience, improved cancer-specific quality of life and hope, lower psychosocial distress, and fewer cases of depression.

General Session 5 featured sexual health issues in palliative and supportive care, and it included data to describe the frequency of this important quality-of-life issue together with simple strategies to address it. The strategies included inquiries about sexual functioning, assessment of the impact on quality of life, determination of the cause of dysfunction, and provision of simple strategies to address the cause.

During this session, Areej El-Jawahri, MD, of Harvard Medical School, presented details of a pilot study that assessed the feasibility and preliminary efficacy of a sexual dysfunction intervention designed to improve sexual function in survivors of allogeneic hematopoietic stem cell transplantation (Abstract 191).[6] All patients were screened for sexual dysfunction that caused distress, and the approximately one-third who tested positive attended monthly multimodal intervention visits. After the intervention, participants had significant improvements in satisfaction and interest in sex, as well as in sexual function. In addition, the intervention led to improvement in quality of life and mood.

### Opiate Management

Another important session addressed difficult issues in opiate management such as the importance of universal screening of patients for the risk of developing substance abuse disorder before opiates are prescribed.

During General Session 4, David Copenhaver, MD, MPH, of the University of California, Davis, Medical Center, discussed who is at risk for opioid addiction and how to assess for this risk. Before patients with chronic pain begin opioid therapy, clinicians should assess for certain factors associated with increased risk for opioid misuse, including a history of sexual abuse or trauma, posttraumatic stress disorder, untreated psychiatric comorbid conditions, and issues related to past substance abuse. Several opioid screening tools, such as the Opioid Risk Tool, the Screener and Opioid Assessment for Patients With Pain tool, and the Diagnosis, Intractability, Risk, and Efficacy tool, are available to help clinicians classify patients by low, medium, or high risk for misuse or abuse.


Panelists discuss General Session 4, which addressed difficult issues in opiate management.

Dr. Copenhaver also discussed some universal precautions used in prescribing opioids, including an initial assessment of the patient, an opioid treatment agreement, informed consent, regular urine drug tests, review of prescription drug monitoring programs, and regular assessment of treatment goals and progress. Finally, if clinicians decide that opioids are necessary, Dr. Copenhaver said, they should monitor for the four As: analgesia, activity, aberrant drug-taking behaviors, and adverse effects.

Jeremy M. Hirst, MD, of the University of California, San Diego, addressed another challenge related to opiates: What should be done when a patient needs both opioids and benzodiazepines? These two drugs together are not contraindicated, but they need to be given with a "common sense approach," Dr. Hirst said. First, start each drug separately to make sure that the patient tolerates each one well. Then, conduct frequent assessments for adverse effects, including sedation and cognitive impairment. In addition to adverse effects, it is important to assess for benefit or improvement in functional status.

"Ask, 'Is this really helping or not?'" Dr. Hirst said.

Finally, if the patient is having difficulty tolerating both drugs, or if the combination does not seem to be effective, it is important to consider alternatives to benzodiazepines, such as antidepressants, or to consider "de-prescribing."

### Looking Ahead to the 2018 Symposium

All in all, the 2017 Symposium did not disappoint, Dr. Balboni said. It featured valuable networking opportunities, such as a Trainee and Early-Career Networking Luncheon and the Conversation Café, where attendees and faculty had roundtable discussions of topics that ranged from research in palliative oncology care to burnout.

"This year's Symposium pushed the field forward to address the quality-of-life needs of patients living with cancer through both education and research," Dr. Balboni said. "I hope you'll join us for next year's 2018 Symposium in San Diego, November 16 and 17, to continue to advance this field to the benefit of patients with cancer and their families." ●

**–Leah Lawrence**

### References:


1. Hoerger M, et al. *J Clin Oncol*. 2017;35 (suppl 31S; abstr 154).
2. Lebrett WG, et al. *J Clin Oncol*. 2017;35 (suppl 31S; abstr 91).
3. Jacobs JM, et al. *J Clin Oncol*. 2017;35 (suppl 31S; abstr 92).
4. Greer J, et al. *J Clin Oncol*. 2017;35 (suppl 31S; abstr 175).
5. Rosenberg AR, et al. *J Clin Oncol*. 2017;35 (suppl 31S; abstr 176).
6. El-Jawahri A, et al. *J Clin Oncol*. 2017;35 (suppl 31S; abstr 191).


*After failure of a prior systemic advanced RCC therapy,*

# MAKE THE NEXT MOVE TO INLYTA® (axitinib)

Demonstrated efficacy • Safety and tolerability profile

## EFFICACY MEASURES

From the AXIS trial: an open-label, phase 3 trial in metastatic RCC after failure of one prior systemic therapy (N=723)*

**PROGRESSION-FREE SURVIVAL (PFS):** PRIMARY ENDPOINT

### 6.7 months median PFS

**vs 4.7 months with sorafenib**

(95% CI: 6.3, 8.6 and 4.6, 5.6, respectively; HR=0.67 [95% CI: 0.54, 0.81; *P*<.0001])

**OBJECTIVE RESPONSE RATE (ORR):** SECONDARY ENDPOINT

### 19.4% ORR

**vs 9.4% with sorafenib**

(95% CI: 15.4, 23.9 and 6.6, 12.9, respectively; risk ratio: 2.06 [95% CI: 1.4, 3.0])

- The *P* value for the risk ratio is not included because it was not adjusted for multiple testing
- All responses were partial responses per RECIST criteria[1]

**OVERALL SURVIVAL (OS):** SECONDARY ENDPOINT

### 20.1 months median OS

**vs 19.2 months with sorafenib**

(95% CI: 16.7, 23.4 and 17.5, 22.3, respectively; HR=0.97 [95% CI: 0.80, 1.17; the difference between the treatment arms was not statistically significant])

*From AXIS, a multicenter, open-label, phase 3 trial of 723 patients with metastatic RCC after failure of 1st-line therapy (sunitinib-, temsirolimus-, bevacizumab-, or cytokine-containing regimen [54%, 3%, 8%, and 35% of patients in each of the treatment arms, respectively]). Patients were randomized 1:1 to either INLYTA 5 mg twice daily (n=361) or sorafenib 400 mg twice daily (n=362), with dose adjustments allowed in both groups. Primary endpoint was PFS. Secondary endpoints included ORR, OS, and safety and tolerability.[1,2]

AEs=adverse events; RCC=renal cell carcinoma; RECIST=Response Evaluation Criteria in Solid Tumors.

## TOLERABILITY CONSIDERATIONS

In the phase 3 AXIS trial*

### 91% of patients did not discontinue due to AEs

- 9% of patients discontinued INLYTA (n=34/359) due to AEs vs 13% of patients with sorafenib (n=46/355)
  - —Overall, 61% of patients receiving INLYTA discontinued treatment vs 71% receiving sorafenib[1]
  - —In both study groups, the most common reasons for discontinuation included disease progression or relapse and AEs[1]
- Fewer patients receiving INLYTA had dose modifications or temporary delay of treatment due to AEs compared with patients receiving sorafenib (55% vs 62%, respectively)

## MOST COMMON AEs

- The **most common (≥20%) adverse events (AEs)** occurring in patients receiving INLYTA (all grades, vs sorafenib) were diarrhea (55% vs 53%), hypertension (40% vs 29%), fatigue (39% vs 32%), decreased appetite (34% vs 29%), nausea (32% vs 22%), dysphonia (31% vs 14%), hand-foot syndrome (27% vs 51%), weight decreased (25% vs 21%), vomiting (24% vs 17%), asthenia (21% vs 14%), and constipation (20% vs 20%).
- The **most common (≥10%) grade 3/4 AEs** occurring in patients receiving INLYTA (vs sorafenib) were hypertension (16% vs 11%), diarrhea (11% vs 7%), and fatigue (11% vs 5%).
- The **most common (≥20%) lab abnormalities** occurring in patients receiving INLYTA (all grades, vs sorafenib) included increased creatinine (55% vs 41%), decreased bicarbonate (44% vs 43%), hypocalcemia (39% vs 59%), decreased hemoglobin (35% vs 52%), decreased lymphocytes (absolute) (33% vs 36%), increased ALP (30% vs 34%), hyperglycemia (28% vs 23%), increased lipase (27% vs 46%), increased amylase (25% vs 33%), increased ALT (22% vs 22%), and increased AST (20% vs 25%).

**INLYTA® (axitinib) is indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy.**

## IMPORTANT SAFETY INFORMATION

**Hypertension** including **hypertensive crisis** has been observed. Blood pressure should be well controlled prior to initiating INLYTA. Monitor for hypertension and treat as needed. For persistent hypertension, despite use of antihypertensive medications, reduce the dose. Discontinue INLYTA if hypertension is severe and persistent despite use of antihypertensive therapy and dose reduction of INLYTA, and discontinuation should be considered if there is evidence of hypertensive crisis.

**Arterial and venous thrombotic events** have been observed and can be fatal. Use with caution in patients who are at increased risk or who have a history of these events.

**Hemorrhagic events**, including fatal events, have been reported. INLYTA has not been studied in patients with evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. If any bleeding requires medical intervention, temporarily interrupt the INLYTA dose.

**Cardiac failure** has been observed and can be fatal. Monitor for signs or symptoms of cardiac failure throughout treatment with INLYTA. Management of cardiac failure may require permanent discontinuation of INLYTA.

**Gastrointestinal perforation and fistula**, including death, have occurred. Use with caution in patients at risk for gastrointestinal perforation or fistula. Monitor for symptoms of gastrointestinal perforation or fistula periodically throughout treatment.

**Hypothyroidism** requiring thyroid hormone replacement has been reported. Monitor thyroid function before initiation of, and periodically throughout, treatment.

No formal studies of the effect of INLYTA on **wound healing** have been conducted. Stop INLYTA at least 24 hours prior to scheduled surgery.

**Reversible Posterior Leukoencephalopathy Syndrome (RPLS)** has been observed. If signs or symptoms occur, permanently discontinue treatment.

Monitor for **proteinuria** before initiation of, and periodically throughout, treatment. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment.

**Liver enzyme elevation** has been observed during treatment with INLYTA. Monitor ALT, AST, and bilirubin before initiation of, and periodically throughout, treatment.

For patients with moderate **hepatic impairment**, the starting dose should be decreased. INLYTA has not been studied in patients with severe hepatic impairment.

Women of childbearing potential should be advised of potential hazard to the fetus and to avoid becoming **pregnant** while receiving INLYTA.

Avoid strong **CYP3A4/5 inhibitors**. If unavoidable, reduce the dose. Grapefruit or grapefruit juice may also increase INLYTA plasma concentrations and should be avoided.

Avoid strong **CYP3A4/5 inducers** and, if possible, avoid moderate CYP3A4/5 inducers.

**References: 1.** Rini BI, Escudier B, Tomczak P, et al. Comparative effectiveness of axitinib versus sorafenib in advanced renal cell carcinoma (AXIS): a randomised phase 3 trial. *Lancet.* 2011;378(9807):1931-1939. **2.** Data on file. Pfizer Inc, New York, NY.

***Please see Brief Summary of full Prescribing Information on the following pages.***

  Printed in USA/February 2018 

**INLYTA®** (AXITINIB) TABLETS FOR ORAL ADMINISTRATION

Initial U.S. Approval: 2012

**Brief Summary of Prescribing Information**

**INDICATIONS AND USAGE:** INLYTA is indicated for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy.

**DOSAGE AND ADMINISTRATION**

**Recommended Dosing.** The recommended starting oral dose of INLYTA is 5 mg twice daily. Administer INLYTA doses approximately 12 hours apart with or without food. INLYTA should be swallowed whole with a glass of water.

If the patient vomits or misses a dose, an additional dose should not be taken. The next prescribed dose should be taken at the usual time.

**Dose Modification Guidelines.** Dose increase or reduction is recommended based on individual safety and tolerability.

Over the course of treatment, patients who tolerate INLYTA for at least two consecutive weeks with no adverse reactions >Grade 2 (according to the Common Toxicity Criteria for Adverse Events [CTCAE]), are normotensive, and are not receiving anti-hypertension medication, may have their dose increased. When a dose increase from 5 mg twice daily is recommended, the INLYTA dose may be increased to 7 mg twice daily, and further to 10 mg twice daily using the same criteria.

Over the course of treatment, management of some adverse drug reactions may require temporary interruption or permanent discontinuation and/or dose reduction of INLYTA therapy *[see Warnings and Precautions]*. If dose reduction from 5 mg twice daily is required, the recommended dose is 3 mg twice daily. If additional dose reduction is required, the recommended dose is 2 mg twice daily.

Strong CYP3A4/5 Inhibitors: The concomitant use of strong CYP3A4/5 inhibitors should be avoided (e.g., ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, and voriconazole). Selection of an alternate concomitant medication with no or minimal CYP3A4/5 inhibition potential is recommended. Although INLYTA dose adjustment has not been studied in patients receiving strong CYP3A4/5 inhibitors, if a strong CYP3A4/5 inhibitor must be co-administered, a dose decrease of INLYTA by approximately half is recommended, as this dose reduction is predicted to adjust the axitinib area under the plasma concentration vs time curve (AUC) to the range observed without inhibitors. The subsequent doses can be increased or decreased based on individual safety and tolerability. If co-administration of the strong inhibitor is discontinued, the INLYTA dose should be returned (after 3–5 half-lives of the inhibitor) to that used prior to initiation of the strong CYP3A4/5 inhibitor.

Hepatic Impairment: No starting dose adjustment is required when administering INLYTA to patients with mild hepatic impairment (Child-Pugh class A). Based on the pharmacokinetic data, the INLYTA starting dose should be reduced by approximately half in patients with baseline moderate hepatic impairment (Child-Pugh class B). The subsequent doses can be increased or decreased based on individual safety and tolerability. INLYTA has not been studied in patients with severe hepatic impairment (Child-Pugh class C).

**DOSAGE FORMS AND STRENGTHS**

1 mg tablets of INLYTA: red, film-coated, oval tablets, debossed with "Pfizer" on one side and "1 XNB" on the other side.

5 mg tablets of INLYTA: red, film-coated, triangular tablets, debossed with "Pfizer" on one side and "5 XNB" on the other side.

**CONTRAINDICATIONS:** None

**WARNINGS AND PRECAUTIONS**

**Hypertension and Hypertensive Crisis.** In a controlled clinical study with INLYTA for the treatment of patients with RCC, hypertension was reported in 145/359 patients (40%) receiving INLYTA and 103/355 patients (29%) receiving sorafenib. Grade 3/4 hypertension was observed in 56/359 patients (16%) receiving INLYTA and 39/355 patients (11%) receiving sorafenib. Hypertensive crisis was reported in 2/359 patients (<1%) receiving INLYTA and none of the patients receiving sorafenib. The median onset time for hypertension (systolic blood pressure >150 mmHg or diastolic blood pressure >100 mmHg) was within the first month of the start of INLYTA treatment and blood pressure increases have been observed as early as 4 days after starting INLYTA. Hypertension was managed with standard antihypertensive therapy. Discontinuation of INLYTA treatment due to hypertension occurred in 1/359 patients (<1%) receiving INLYTA and none of the patients receiving sorafenib.

Blood pressure should be well-controlled prior to initiating INLYTA. Patients should be monitored for hypertension and treated as needed with standard anti-hypertensive therapy. In the case of persistent hypertension despite use of anti-hypertensive medications, reduce the INLYTA dose. Discontinue INLYTA if hypertension is severe and persistent despite anti-hypertensive therapy and dose reduction of INLYTA, and discontinuation should be considered if there is evidence of hypertensive crisis. If INLYTA is interrupted, patients receiving antihypertensive medications should be monitored for hypotension.

**Arterial Thromboembolic Events.** In clinical trials, arterial thromboembolic events have been reported, including deaths. In a controlled clinical study with INLYTA for the treatment of patients with RCC, Grade 3/4 arterial thromboembolic events were reported in 4/359 patients (1%) receiving INLYTA and 4/355 patients (1%) receiving sorafenib. Fatal cerebrovascular accident was reported in 1/359 patients (<1%) receiving INLYTA and none of the patients receiving sorafenib *[see Adverse Reactions]*.

In clinical trials with INLYTA, arterial thromboembolic events (including transient ischemic attack, cerebrovascular accident, myocardial infarction, and retinal artery occlusion) were reported in 17/715 patients (2%), with two deaths secondary to cerebrovascular accident.

Use INLYTA with caution in patients who are at risk for, or who have a history of, these events. INLYTA has not been studied in patients who had an arterial thromboembolic event within the previous 12 months.

**Venous Thromboembolic Events.** In clinical trials, venous thromboembolic events have been reported, including deaths. In a controlled clinical study with INLYTA for the treatment of patients with RCC, venous thromboembolic events were reported in 11/359 patients (3%) receiving INLYTA and 2/355 patients (1%) receiving sorafenib. Grade 3/4 venous thromboembolic events were reported in 9/359 patients (3%) receiving INLYTA (including pulmonary embolism, deep vein thrombosis, retinal vein occlusion and retinal vein thrombosis) and 2/355 patients (1%) receiving sorafenib. Fatal pulmonary embolism was reported in 1/359 patients (<1%) receiving INLYTA and none of the patients receiving sorafenib. In clinical trials with INLYTA, venous thromboembolic events were reported in 22/715 patients (3%), with two deaths secondary to pulmonary embolism.

Use INLYTA with caution in patients who are at risk for, or who have a history of, these events. INLYTA has not been studied in patients who had a venous thromboembolic event within the previous 6 months.

**Hemorrhage.** In a controlled clinical study with INLYTA for the treatment of patients with RCC, hemorrhagic events were reported in 58/359 patients (16%) receiving INLYTA and 64/355 patients (18%) receiving sorafenib. Grade 3/4 hemorrhagic events were reported in 5/359 (1%) patients receiving INLYTA (including cerebral hemorrhage, hematuria, hemoptysis, lower gastrointestinal hemorrhage, and melena) and 11/355 (3%) patients receiving sorafenib. Fatal hemorrhage was reported in 1/359 patients (<1%) receiving INLYTA (gastric hemorrhage) and 3/355 patients (1%) receiving sorafenib.

INLYTA has not been studied in patients who have evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. If any bleeding requires medical intervention, temporarily interrupt the INLYTA dose.

**Cardiac Failure.** In a controlled clinical study with INLYTA for the treatment of patients with RCC, cardiac failure was reported in 6/359 patients (2%) receiving INLYTA and 3/355 patients (1%) receiving sorafenib. Grade 3/4 cardiac failure was observed in 2/359 patients (1%) receiving INLYTA and 1/355 patients (<1%) receiving sorafenib. Fatal cardiac failure was reported in 2/359 patients (1%) receiving INLYTA and 1/355 patients (<1%) receiving sorafenib. Monitor for signs or symptoms of cardiac failure throughout treatment with INLYTA. Management of cardiac failure may require permanent discontinuation of INLYTA.

**Gastrointestinal Perforation and Fistula Formation.** In a controlled clinical study with INLYTA for the treatment of patients with RCC, gastrointestinal perforation was reported in 1/359 patients (<1%) receiving INLYTA and none of the patients receiving sorafenib. In clinical trials with INLYTA, gastrointestinal perforation was reported in 5/715 patients (1%), including one death. In addition to cases of gastrointestinal perforation, fistulas were reported in 4/715 patients (1%).

Monitor for symptoms of gastrointestinal perforation or fistula periodically throughout treatment with INLYTA.

**Thyroid Dysfunction.** In a controlled clinical study with INLYTA for the treatment of patients with RCC, hypothyroidism was reported in 69/359 patients (19%) receiving INLYTA and 29/355 patients (8%) receiving sorafenib. Hyperthyroidism was reported in 4/359 patients (1%) receiving INLYTA and 4/355 patients (1%) receiving sorafenib. In patients who had thyroid stimulating hormone (TSH) <5 µU/mL before treatment, elevations of TSH to ≥10 µU/mL occurred in 79/245 patients (32%) receiving INLYTA and 25/232 patients (11%) receiving sorafenib.

Monitor thyroid function before initiation of, and periodically throughout, treatment with INLYTA. Treat hypothyroidism and hyperthyroidism according to standard medical practice to maintain euthyroid state.

**Wound Healing Complications.** No formal studies of the effect of INLYTA on wound healing have been conducted.

Stop treatment with INLYTA at least 24 hours prior to scheduled surgery. The decision to resume INLYTA therapy after surgery should be based on clinical judgment of adequate wound healing.

**Reversible Posterior Leukoencephalopathy Syndrome.** In a controlled clinical study with INLYTA for the treatment of patients with RCC, reversible posterior leukoencephalopathy syndrome (RPLS) was reported in 1/359 patients (<1%) receiving INLYTA and none of the patients receiving sorafenib. There were two additional reports of RPLS in other clinical trials with INLYTA.

RPLS is a neurological disorder which can present with headache, seizure, lethargy, confusion, blindness and other visual and neurologic disturbances. Mild to severe hypertension may be present. Magnetic resonance imaging is necessary to confirm the diagnosis of RPLS. Discontinue INLYTA in patients developing RPLS. The safety of reinitiating INLYTA therapy in patients previously experiencing RPLS is not known.

**Proteinuria.** In a controlled clinical study with INLYTA for the treatment of patients with RCC, proteinuria was reported in 39/359 patients (11%) receiving INLYTA and 26/355 patients (7%) receiving sorafenib. Grade 3 proteinuria was reported in 11/359 patients (3%) receiving INLYTA and 6/355 patients (2%) receiving sorafenib.

Monitoring for proteinuria before initiation of, and periodically throughout, treatment with INLYTA is recommended. For patients who develop moderate to severe proteinuria, reduce the dose or temporarily interrupt INLYTA treatment.

**Elevation of Liver Enzymes.** In a controlled clinical study with INLYTA for the treatment of patients with RCC, alanine aminotransferase (ALT) elevations of all grades occurred in 22% of patients on both arms, with Grade 3/4 events in <1% of patients on the INLYTA arm and 2% of patients on the sorafenib arm.

Monitor ALT, aspartate aminotransferase (AST) and bilirubin before initiation of and periodically throughout treatment with INLYTA.

**Hepatic Impairment.** The systemic exposure to axitinib was higher in subjects with moderate hepatic impairment (Child-Pugh class B) compared to subjects with normal hepatic function. A dose decrease is recommended when administering INLYTA to patients with moderate hepatic impairment (Child-Pugh class B). INLYTA has not been studied in patients with severe hepatic impairment (Child-Pugh class C).

**Pregnancy.** INLYTA can cause fetal harm when administered to a pregnant woman based on its mechanism of action. There are no adequate and well-controlled studies in pregnant women using INLYTA. In developmental toxicity studies in mice, axitinib was teratogenic, embryotoxic and fetotoxic at maternal exposures that were lower than human exposures at the recommended clinical dose.

Women of childbearing potential should be advised to avoid becoming pregnant while receiving INLYTA. If this drug is used during pregnancy, or if a patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus.

**ADVERSE REACTIONS**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of INLYTA has been evaluated in 715 patients in monotherapy studies, which included 537 patients with advanced RCC. The data described reflect exposure to INLYTA in 359 patients with advanced RCC who participated in a randomized clinical study versus sorafenib.

The following risks, including appropriate action to be taken, are discussed in greater detail in other sections of the label: hypertension, arterial thromboembolic events, venous thromboembolic events, hemorrhage, gastrointestinal perforation and fistula formation, thyroid dysfunction, wound healing complications, RPLS, proteinuria, elevation of liver enzymes, and fetal development.

**Clinical Trials Experience.** The median duration of treatment was 6.4 months (range 0.03 to 22.0) for patients who received INLYTA and 5.0 months (range 0.03 to 20.1) for patients who received sorafenib. Dose modifications or temporary delay of treatment due to an adverse reaction occurred in 199/359 patients (55%) receiving INLYTA and 220/355 patients (62%) receiving sorafenib. Permanent discontinuation due to an adverse reaction occurred in 34/359 patients (9%) receiving INLYTA and 46/355 patients (13%) receiving sorafenib.

The most common (≥20%) adverse reactions observed following treatment with INLYTA were diarrhea, hypertension, fatigue, decreased appetite, nausea, dysphonia, palmar-plantar erythrodysesthesia (hand-foot) syndrome, weight decreased, vomiting, asthenia, and constipation.

The following table presents adverse reactions reported in ≥10% patients who received INLYTA or sorafenib.

**Adverse Reactions Occurring in ≥10% of Patients Who Received INLYTA or Sorafenib**

| Adverse Reaction[a] | INLYTA (N=359) | | Sorafenib (N=355) | |
|---|---|---|---|---|
| | All Grades[b] | Grade 3/4 | All Grades[b] | Grade 3/4 |
| | % | % | % | % |
| Diarrhea | 55 | 11 | 53 | 7 |
| Hypertension | 40 | 16 | 29 | 11 |
| Fatigue | 39 | 11 | 32 | 5 |
| Decreased appetite | 34 | 5 | 29 | 4 |
| Nausea | 32 | 3 | 22 | 1 |
| Dysphonia | 31 | 0 | 14 | 0 |
| Palmar-plantar erythrodysesthesia syndrome | 27 | 5 | 51 | 16 |
| Weight decreased | 25 | 2 | 21 | 1 |
| Vomiting | 24 | 3 | 17 | 1 |
| Asthenia | 21 | 5 | 14 | 3 |
| Constipation | 20 | 1 | 20 | 1 |
| Hypothyroidism | 19 | <1 | 8 | 0 |
| Cough | 15 | 1 | 17 | 1 |
| Mucosal inflammation | 15 | 1 | 12 | 1 |
| Arthralgia | 15 | 2 | 11 | 1 |
| Stomatitis | 15 | 1 | 12 | <1 |
| Dyspnea | 15 | 3 | 12 | 3 |
| Abdominal pain | 14 | 2 | 11 | 1 |
| Headache | 14 | 1 | 11 | 0 |
| Pain in extremity | 13 | 1 | 14 | 1 |
| Rash | 13 | <1 | 32 | 4 |
| Proteinuria | 11 | 3 | 7 | 2 |
| Dysgeusia | 11 | 0 | 8 | 0 |
| Dry skin | 10 | 0 | 11 | 0 |
| Dyspepsia | 10 | 0 | 2 | 0 |
| Pruritus | 7 | 0 | 12 | 0 |
| Alopecia | 4 | 0 | 32 | 0 |
| Erythema | 2 | 0 | 10 | <1 |

[a]Percentages are treatment-emergent, all-causality events

[b]National Cancer Institute Common Terminology Criteria for Adverse Events, Version 3.0

Selected adverse reactions (all grades) that were reported in <10% of patients treated with INLYTA included dizziness (9%), upper abdominal pain (8%), myalgia (7%), dehydration (6%), epistaxis (6%), anemia (4%), hemorrhoids (4%), hematuria (3%), tinnitus (3%), lipase increased (3%), glossodynia (3%), pulmonary embolism (2%), rectal hemorrhage (2%), hemoptysis (2%), deep vein thrombosis (1%), retinal-vein occlusion/thrombosis (1%), polycythemia (1%), and transient ischemic attack (1%).

The following table presents the most common laboratory abnormalities reported in ≥10% patients who received INLYTA or sorafenib.

**Laboratory Abnormalities Occurring in ≥10% of Patients Who Received INLYTA or Sorafenib**

| Laboratory Abnormality | N | INLYTA All Grades[a] % | INLYTA Grade 3/4 % | N | Sorafenib All Grades[a] % | Sorafenib Grade 3/4 % |
|---|---|---|---|---|---|---|
| **Hematology** | | | | | | |
| Hemoglobin decreased | 320 | 35 | <1 | 316 | 52 | 4 |
| Lymphocytes (absolute) decreased | 317 | 33 | 3 | 309 | 36 | 4 |
| Platelets decreased | 312 | 15 | <1 | 310 | 14 | 0 |
| White blood cells decreased | 320 | 11 | 0 | 315 | 16 | <1 |
| **Chemistry** | | | | | | |
| Creatinine increased | 336 | 55 | 0 | 318 | 41 | <1 |
| Bicarbonate decreased | 314 | 44 | <1 | 291 | 43 | 0 |
| Hypocalcemia | 336 | 39 | 1 | 319 | 59 | 2 |
| ALP increased | 336 | 30 | 1 | 319 | 34 | 1 |
| Hyperglycemia | 336 | 28 | 2 | 319 | 23 | 2 |
| Lipase increased | 338 | 27 | 5 | 319 | 46 | 15 |
| Amylase increased | 338 | 25 | 2 | 319 | 33 | 2 |
| ALT increased | 331 | 22 | <1 | 313 | 22 | 2 |
| AST increased | 331 | 20 | <1 | 311 | 25 | 1 |
| Hypernatremia | 338 | 17 | 1 | 319 | 13 | 1 |
| Hypoalbuminemia | 337 | 15 | <1 | 319 | 18 | 1 |
| Hyperkalemia | 333 | 15 | 3 | 314 | 10 | 3 |
| Hypoglycemia | 336 | 11 | <1 | 319 | 8 | <1 |
| Hyponatremia | 338 | 13 | 4 | 319 | 11 | 2 |
| Hypophosphatemia | 336 | 13 | 2 | 318 | 49 | 16 |

[a]National Cancer Institute Common Terminology Criteria for Adverse Events, Version 3.0
ALP: alkaline phosphatase; ALT: alanine aminotransferase; AST: aspartate aminotransferase

Selected laboratory abnormalities (all grades) that were reported in <10% of patients treated with INLYTA included hemoglobin increased (above the upper limit of normal) (9% for INLYTA versus 1% for sorafenib) and hypercalcemia (6% for INLYTA versus 2% for sorafenib).

**DRUG INTERACTIONS**

*In vitro* data indicate that axitinib is metabolized primarily by CYP3A4/5 and, to a lesser extent, CYP1A2, CYP2C19, and uridine diphosphate-glucuronosyltransferase (UGT) 1A1.

**CYP3A4/5 Inhibitors.** Co-administration of ketoconazole, a strong inhibitor of CYP3A4/5, increased the plasma exposure of axitinib in healthy volunteers. Co-administration of INLYTA with strong CYP3A4/5 inhibitors should be avoided. Grapefruit or grapefruit juice may also increase axitinib plasma concentrations and should be avoided. Selection of concomitant medication with no or minimal CYP3A4/5 inhibition potential is recommended. If a strong CYP3A4/5 inhibitor must be coadministered, the INLYTA dose should be reduced *[see Dosage and Administration]*.

**CYP3A4/5 Inducers.** Co-administration of rifampin, a strong inducer of CYP3A4/5, reduced the plasma exposure of axitinib in healthy volunteers. Co-administration of INLYTA with strong CYP3A4/5 inducers (e.g., rifampin, dexamethasone, phenytoin, carbamazepine, rifabutin, rifapentin phenobarbital, and St. John's wort) should be avoided. Selection of concomitant medication with no or minimal CYP3A4/5 induction potential is recommended *[see Dosage and Administration]*. Moderate CYP3A4/5 inducers (e.g., bosentan, efavirenz, etravirine, modafinil, and nafcillin) may also reduce the plasma exposure of axitinib and should be avoided if possible.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy.** Pregnancy Category D *[see Warnings and Precautions]*.

There are no adequate and well-controlled studies with INLYTA in pregnant women. INLYTA can cause fetal harm when administered to a pregnant woman based on its mechanism of action. Axitinib was teratogenic, embryotoxic and fetotoxic in mice at exposures lower than human exposures at the recommended starting dose. If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus.

Oral axitinib administered twice daily to female mice prior to mating and through the first week of pregnancy caused an increase in post-implantation loss at all doses tested (≥15 mg/kg/dose, approximately 10 times the systemic exposure (AUC) in patients at the recommended starting dose). In an embryo-fetal developmental toxicity study, pregnant mice received oral doses of 0.15, 0.5 and 1.5 mg/kg/dose axitinib twice daily during the period of organogenesis. Embryo-fetal toxicities observed in the absence of maternal toxicity included malformation (cleft palate) at 1.5 mg/kg/dose (approximately 0.5 times the AUC in patients at the recommended starting dose) and variation in skeletal ossification at ≥0.5 mg/kg/dose (approximately 0.15 times the AUC in patients at the recommended starting dose).

**Nursing Mothers.** It is not known whether axitinib is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from INLYTA, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Pediatric Use.** The safety and efficacy of INLYTA in pediatric patients have not been studied.

Toxicities in bone and teeth were observed in immature mice and dogs administered oral axitinib twice daily for 1 month or longer. Effects in bone consisted of thickened growth plates in mice and dogs at ≥15 mg/kg/dose (approximately 6 and 15 times, respectively, the systemic exposure (AUC) in patients at the recommended starting dose). Abnormalities in growing incisor teeth (including dental caries, malocclusions and broken and/or missing teeth) were observed in mice administered oral axitinib twice daily at ≥5 mg/kg/dose (approximately 1.5 times the AUC in patients at the recommended starting dose). Other toxicities of potential concern to pediatric patients have not been evaluated in juvenile animals.

**Geriatric Use.** In a controlled clinical study with INLYTA for the treatment of patients with RCC, 123/359 patients (34%) treated with INLYTA were ≥65 years of age. Although greater sensitivity in some older individuals cannot be ruled out, no overall differences were observed in the safety and effectiveness of INLYTA between patients who were ≥65 years of age and younger.

No dosage adjustment is required in elderly patients.

**Hepatic Impairment.** In a dedicated hepatic impairment trial, compared to subjects with normal hepatic function, systemic exposure following a single dose of INLYTA was similar in subjects with baseline mild hepatic impairment (Child-Pugh class A) and higher in subjects with baseline moderate hepatic impairment (Child-Pugh class B).

No starting dose adjustment is required when administering INLYTA to patients with mild hepatic impairment (Child-Pugh class A). A starting dose decrease is recommended when administering INLYTA to patients with moderate hepatic impairment (Child-Pugh class B).

INLYTA has not been studied in subjects with severe hepatic impairment (Child-Pugh class C).

**Renal Impairment.** No dedicated renal impairment trial for axitinib has been conducted. Based on the population pharmacokinetic analyses, no significant difference in axitinib clearance was observed in patients with pre-existing mild to severe renal impairment (15 mL/min ≤creatinine clearance [CLcr] <89 mL/min). No starting dose adjustment is needed for patients with pre-existing mild to severe renal impairment. Caution should be used in patients with end-stage renal disease (CLcr <15 mL/min).

**OVERDOSAGE**

There is no specific treatment for INLYTA overdose.

In a controlled clinical study with INLYTA for the treatment of patients with RCC, 1 patient inadvertently received a dose of 20 mg twice daily for 4 days and experienced dizziness (Grade 1).

In a clinical dose finding study with INLYTA, subjects who received starting doses of 10 mg twice daily or 20 mg twice daily experienced adverse reactions which included hypertension, seizures associated with hypertension, and fatal hemoptysis.

In cases of suspected overdose, INLYTA should be withheld and supportive care instituted.

**NONCLINICAL TOXICOLOGY**

**Carcinogenesis, Mutagenesis, Impairment of Fertility.** Carcinogenicity studies have not been conducted with axitinib.

Axitinib was not mutagenic in an *in vitro* bacterial reverse mutation (Ames) assay and was not clastogenic in the *in vitro* human lymphocyte chromosome aberration assay. Axitinib was genotoxic in the *in vivo* mouse bone marrow micronucleus assay.

INLYTA has the potential to impair reproductive function and fertility in humans. In repeat-dose toxicology studies, findings in the male reproductive tract were observed in the testes/epididymis (decreased organ weight, atrophy or degeneration, decreased numbers of germinal cells, hypospermia or abnormal sperm forms, reduced sperm density and count) at ≥15 mg/kg/dose administered orally twice daily in mice (approximately 7 times the systemic exposure (AUC) in patients at the recommended starting dose) and ≥1.5 mg/kg/dose administered orally twice daily in dogs (approximately 0.1 times the AUC in patients at the recommended starting dose). Findings in the female reproductive tract in mice and dogs included signs of delayed sexual maturity, reduced or absent corpora lutea, decreased uterine weights and uterine atrophy at ≥5 mg/kg/dose (approximately 1.5 or 0.3 times the AUC in patients at the recommended starting dose compared to mice and dogs, respectively).

In a fertility study in mice, axitinib did not affect mating or fertility rate when administered orally twice daily to males at any dose tested up to 50 mg/kg/dose following at least 70 days of administration (approximately 57 times the AUC in patients at the recommended starting dose). In female mice, reduced fertility and embryonic viability were observed at all doses tested (≥15 mg/kg/dose administered orally twice daily) following at least 15 days of treatment with axitinib (approximately 10 times the AUC in patients at the recommended starting dose).

**PATIENT COUNSELING INFORMATION**

**Reversible Posterior Leukoencephalopathy Syndrome.** Advise patients to inform their doctor if they have worsening of neurological function consistent with RPLS (headache, seizure, lethargy, confusion, blindness and other visual and neurologic disturbances).

**Pregnancy.** Advise patients that INLYTA may cause birth defects or fetal loss and that they should not become pregnant during treatment with INLYTA. Both male and female patients should be counseled to use effective birth control during treatment with INLYTA. Female patients should also be advised against breast-feeding while receiving INLYTA.

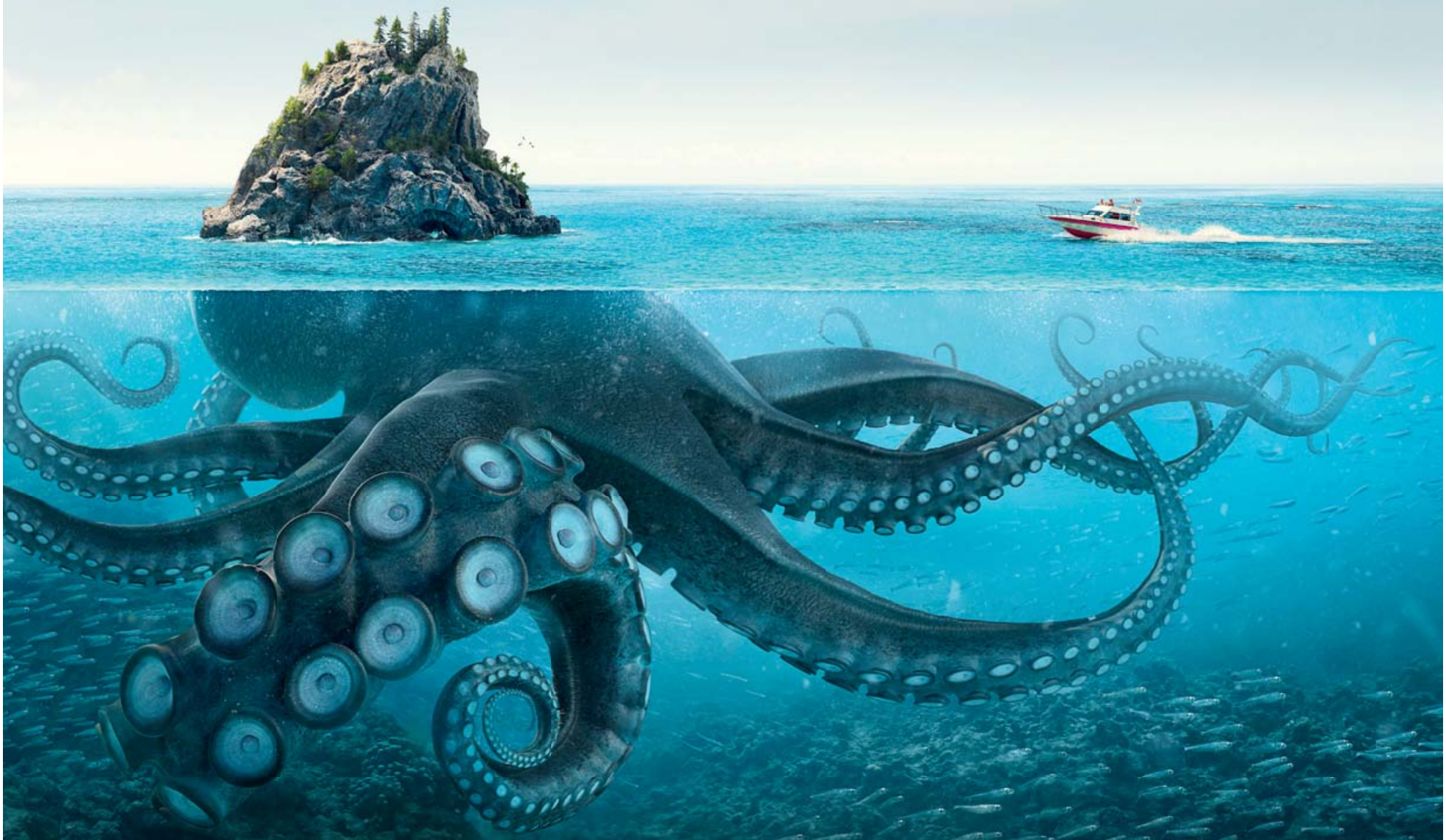
**Concomitant Medications.** Advise patients to inform their doctor of all concomitant medications, vitamins, or dietary and herbal supplements.

**Rx only**

August 2014

# THERE'S MORE TO SOME CANCERS THAN MEETS THE EYE

## TRK FUSION PROTEINS ARE A PRIMARY ONCOGENIC DRIVER ACROSS MULTIPLE TUMORS IN ADULTS AND CHILDREN[1,2]



# TRK FUSION CANCER

## LOOK BELOW THE SURFACE TO FIND OUT WHAT'S DRIVING THE TUMOR

**LEARN MORE ABOUT TRK FUSION CANCER AT TRKCANCER.COM**

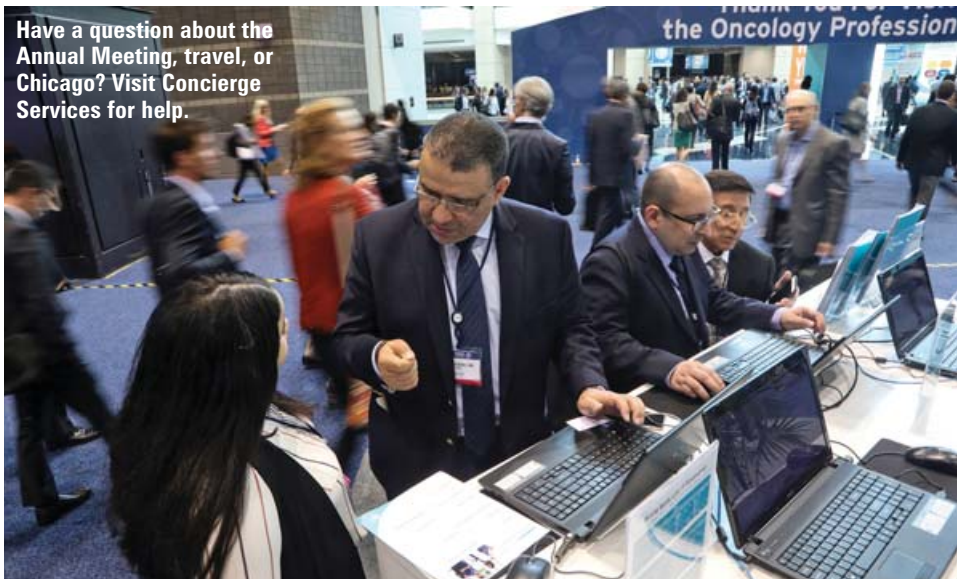
TRK, tropomyosin receptor kinase.

**References: 1**. Okimoto RA, Bivona TG. Tracking down response and resistance to TRK inhibitors. *Cancer Discov*. 2016;6(1):14-16.
**2**. Vaishnavi A, Le AT, Doebele RC. TRKing down an old oncogene in a new era of targeted therapy. *Cancer Discov*. 2015;5(1):25-34.

# Concierge Services Provides Technical Support, International Assistance, and More

Helpful staff in the Concierge Services area in the Grand Concourse Lobby of the North Building, Level 3, of McCormick Place can assist attendees with information about Chicago (including restaurant reservations, tours, and tickets to local events), travel, hotel accommodations, ASCO membership, and the ASCO University® Bookstore.

The following are services and resources that are available to attendees at Concierge Services.



Have a question about the Annual Meeting, travel, or Chicago? Visit Concierge Services for help.

### ASCO University Bookstore

Attendees can visit the ASCO University Bookstore, located in Concierge Services and as part of ASCO Central (Booth 7004) in the Oncology Professionals Hall, for the latest products from ASCO and other leading oncology publishers. Knowledgeable staff will be on hand to guide attendees through ASCO's apps and digital products, as well as to introduce ASCO University's extensive eLearning opportunities.

### Chicago Concierge

Stop by this desk to ask local Chicago representatives for dining recommendations, insight on can't-miss tours, and tickets to the best shows. You can also ask for assistance on air travel questions if you've booked your tickets through Direct Travel, ASCO's official travel agency. Staff will also be available to assist attendees who have booked their hotel through ASCO and have questions about their hotel accommodations.

### International Assistance Desk

Interpreters fluent in French, German, Italian, Japanese, Mandarin Chinese, Portuguese, and Spanish are on-site to assist international attendees with questions about currency exchange, embassy contacts, and information about the Meeting and about Chicago.

### CE and Technical Assistance Desk

Staff will be on-site to help attendees download, install, and access ASCO's suite of apps and provide general technical support. ASCO's featured apps can help you access vital information at the Meeting and on the go.

### Member Services Desk at Concierge Services

ASCO members and nonmembers can learn more about exclusive member benefits at the Member Services Desk. Members can visit the desk to pay their membership dues, sign up for a dues payment option, update their contact information for the ASCO Membership Directory, and get answers to membership-related questions. Nonmembers can learn more about ASCO membership or submit an application to join the Society. Join on-site and your first year of dues is free (certain conditions and restrictions apply).

### Discover New Ways to Engage and Contribute to ASCO

ASCO has recently launched *myConnection*, a new online community platform that provides members with the opportunity to collaborate, participate in in-depth discussions, build meaningful connections with professional peers, as well as apply for rewarding volunteer opportunities.

Visit the Member Services Desk in Concierge Services to view and participate on *myConnection* and get your complimentary headshot taken.

### Materials Pickup Locations

Attendees who registered and received their badges in advance may redeem their materials during the following hours:

***North Building, Hall C, Level 2***
- June 1, 7 AM to 6 PM
- June 2, 7 AM to 6 PM
- June 3, 7 AM to 6 PM
- June 4, 7 AM to 5 PM
- June 5, 7 AM to 12 PM

***South Building, Level 1, by Gate 3***

This location is only for attendees who have already received their badge in the mail.
- June 1, 7 AM to 6 PM
- June 2, 7 AM to 6 PM

The *2018 ASCO Educational Book* and the *Annual Meeting Proceedings* are available online via the Attendee Resource Center (am.asco.org/arc). Attendees who prefer hardcopy versions of these materials can purchase them on-site at Materials pickup locations and the ASCO University Bookstore.

### Attendee Services at Other Locations

***Annual Meeting Information Desks***

Attendees can obtain answers to general questions about the Annual Meeting at Information Desks located throughout McCormick Place.

***Bag Check***

Coat and bag check services at McCormick Place are available for all attendees.

***First Aid***

Staffed First Aid stations are located in:
- South Building, Level 2.5 Lobby, near the Business Center
- East Building, Level 1, near Arie Crown Theater

Consult on-site security personnel or staff at any Annual Meeting Information Desk to determine the location of the nearest First Aid station.

***Nursing Room***

Nursing mothers can use N277a during the Meeting. The nursing mother area will be equipped with private rooms, all with a chair, table, and power.

***Lost and Found***

The ASCO Annual Meeting Lost and Found is open 7 AM to 6 PM, June 1 through June 4, and 7 AM to 1 PM on June 5 (South Building, S101). ●

## Self-Assessment Resources

*Continued from page 13*

the recommended educational resources in those topics.

Most materials are taken from ASCO content, including journal and *ASCO Educational Book* articles, Meeting Library, ASCO University eLearning programs, and audio podcasts. At any time, learners can take a post-assessment to test their progress.

### *ASCO-SEP 6th Edition*

*ASCO-SEP,* now in its 6th edition, was designed for learners who want to take a more conventional approach to continued learning. Learners can either purchase the book individually, which includes access to the eBook, or buy a bundle that includes the book, the *ASCO-SEP* Mock Exam, and eBook access.

The *ASCO-SEP* book and eBook include 22 chapters focused on specific disease sites and oncology topics, as well as more than 190 multiple-choice questions that can be used for self-assessment. "Key Points" in each chapter facilitate review of important concepts. All of the self-assessment questions are new, so learners who have completed multiple-choice questions from previous editions will have the opportunity to review with new material.

ASCO-SEP®

The *ASCO-SEP 6th Edition* Mock Exam, included in the *ASCO-SEP* bundle, is an eLearning module on ASCO University that contains over 120 self-assessment questions that are not offered in the *ASCO-SEP* book or in any previous product.

Upon successful completion of both the *ASCO-SEP* book self-assessment questions and the Mock Exam, participants may request CME, MOC, nursing, and pharmacy credit.

### ASCO MOC App

The ASCO MOC app uses a pulsed education approach to keep the busy oncologist on track. Available for purchase from the ASCO University Bookstore and downloadable on any electronic device, the app sends questions to learners on a user-defined frequency.

After the successful completion of each course in the app, learners are eligible to claim CME credit and ABIM MOC points.

### 2018 Comprehensive Oncology Assessment

ASCO University developed a comprehensive oncology assessment to provide physicians, as well as advanced practitioners, a means to assess broad oncology knowledge as it relates to patient care and identify areas that would benefit from continued learning. The assessment contains 125 multiple-choice questions on a broad range of oncology topics, and upon successful completion, learners can claim ABIM MOC points, CME, nursing, and pharmacy credit.

### ASCO University Essentials

ASCO University offers a wealth of educational resources for oncology professionals looking stay on top of new advances. But with more than 100 interactive courses on a variety of topics, approaching the content could be daunting. Which courses should you purchase? Which certificates are you looking to obtain? Where should you focus your attention first? ASCO's comprehensive ASCO University Essentials package is designed to address these questions.

ASCO University Essentials is a one-stop source for all of ASCO University's content in the form of a yearly subscription. Rather than purchasing individual courses, ASCO members and nonmembers can pay a single fee to access the entire ASCO University eLearning catalog.

Credit: Ayano Hisa Photography

Dr. Benjamin P. Levy

"This content has been developed to appeal to a broad range of providers," Benjamin P. Levy, MD, of the Johns Hopkins Sidney Kimmel Cancer Center, said.

Dr. Levy said the content applies to all learners including academic and private practice physicians, fellows, and advanced practitioners.

#### *Learning topics*

ASCO University Essentials' eLearning courses are reviewed and updated on an ongoing basis to ensure clinical relevance and accuracy. These courses include, but are far from limited to:

- The Immuno-Oncology Program, which addresses topics such as cancer immunobiology, classes of agents, potential predictive biomarkers, clinical activity in the areas of melanoma and non–small cell lung cancer, response determination, and the management of immune-related adverse events;
- The Cancer Genetics Program, which covers topics such as quantitative risk assessment, the recognition of hereditary cancer syndromes, establishing a cancer risk–assessment service, and the ethical, legal, and social issues in cancer genetics;
- The Tumor Genomics Program, which focuses on areas such as somatic genomic alterations that drive tumor progression;
- The ASCO Tumor Board Series, which includes evidence-based, multidisciplinary bimonthly presentations that explore issues through the context of a patient case; and
- The bimonthly Molecular Oncology Tumor Board Series, which is designed to help cancer care providers with the interpretation and understanding of tumor molecular profiling tests and studies.

#### *Personalized credentials*

ASCO University Essentials also allows learners to choose which credentials they'd like to earn as they work their way through the content. Options include ABIM MOC points and CME, nursing, and pharmacy credits. By downloading the ASCO MOC mobile app—also included within the ASCO University Essentials package—learners can opt in to receive push notifications every other day with new practice questions.

A full-year subscription to ASCO University Essentials is $434 for non-ASCO members and $347 for ASCO members—significantly less than it costs to purchase both the Cancer Genetics Program and the Immuno-Oncology Program individually. Learners also have the option to sign up for a 2-week free trial subscription before purchasing the full package.

To purchase ASCO University Essentials or to learn more about all it has to offer, visit university.asco.org/essentials or email university@asco.org. ●

# Join ASCO's Diverse, Growing Community and Discover What Membership Can Do For You

ASCO is the world's leading professional organization for those who care for people with cancer. Our membership is composed of a broad constituency of nearly 45,000 oncology professionals whose roles vary widely but who all work toward a common mission: conquering cancer through research, education, prevention, and the delivery of high-quality patient care.

Our members work in all areas of oncology, from patient care and laboratory research to education and advocacy, in more than 150 countries around the globe. Nearly one-third of our members practice outside of the United States, and international membership continues to grow.

We encourage nonmembers of all career stages and specialties to consider joining ASCO and hope that current members will share the value they gain from their ASCO membership with their colleagues and refer them to join the Society. This year's Annual Meeting features special promotions for new applicants and the members who refer them:

- **New Applicants:** Apply on-site, and your first year of dues is free (certain conditions and restrictions apply).
- **Members:** Refer your colleagues, and you will receive a free gift and be entered into a drawing for a $100 ASCO University® Bookstore credit. The member who refers the most new applicants on-site will also receive a prize.


New applicants who apply for ASCO membership at the Annual Meeting receive their first year of dues for free.

To apply for ASCO membership or to learn more about what ASCO membership can do for you, please visit a Member Services Desk. We are located in:

- Concierge Services
- Oncology Professionals Hall—Booth 7004
- Registration Hall C


Stop by a Member Services Desk for information on becoming an ASCO member.

ASCO membership provides the support, resources, and solutions for all your professional needs:

- Stay on the cutting edge of scientific research and advances;
- Streamline your pursuit of continuous learning;
- Access evidence-based and data-driven quality resources;
- Obtain insight into best practices for cancer care teams; and
- Connect and exchange views with oncology experts.

Joining is easy, and membership is free for students, residents, and oncology fellows. Visit a Member Services Desk today to join or refer your colleagues. ●

## Networking Guide

*Continued from page 11*

"The Women's Networking Center has evolved into a vibrant and private space for women to learn, network, and support each other," Sonali Smith, MD, who oversees the Women's Networking Center, said. "The program attracted more than 700 women last year, and we are excited to see it grow further in 2018."

Scheduled programming in the Women's Networking Center is planned throughout the Annual Meeting. For session programming, visit the Attendee Resource Center at am.asco.org/arc.

*The Women's Networking Center is located in room S502 on the 5th level of the South Building and open from 12 PM-5 PM on June 1 and from 7:30 AM-5 PM June 2 through June 4.*

### Trainee and Early-Career Oncologist Member Lounge

The designated Trainee and Early-Career Oncologist Member Lounge provides opportunities for residents, medical students, and training program directors to advance their careers through networking. Full ASCO members enrolled in an oncology training program or within their first 3 years post-training will also find the programming valuable. Attendees can receive advice on career advancement by participating in mock job interviews and attending informal sessions on professional development topics led by prominent faculty. The Trainee and Early-Career Oncologist Member Lounge is a comfortable place to network with colleagues and enjoy complimentary refreshments.

The Trainee and Early-Career Oncologist Member Lounge connects mentees with potential mentors.

"This lounge is a fantastic place for fellows and junior faculty to use as a home base within the larger bustle of the Annual Meeting," Roberto Antonio Leon-Ferre, MD, who oversees the Trainee and Early-Career Oncologist Member Lounge, said. "In addition to providing a space for connecting with colleagues and potential mentors, the sessions offered are truly catered to the needs of junior attendees."

The lounge's schedule is available on am.asco.org and as a PDF document through the iPlanner app. For more information, visit the Attendee Resource Center at am.asco.org/arc.

*The Trainee and Early-Career Oncologist Member Lounge is located in room S501 on the 5th level of the South Building and open from 12 PM-5 PM on June 1 and from 7:30 AM-5 PM June 2 through June 4.*

### Medical Student Networking Opportunities

The ASCO Cancer Interest Group (CIG) Abstract Forum and Networking Reception are available to all medical student and internal medicine resident attendees. During the Abstract Forum, students with preselected abstracts will present their oncology research in an intimate venue to an audience of their peers and oncologists. Following the presentations, attendees can connect with other students interested in oncology during the Networking Reception.

*The CIG Abstract Forum is on June 2 from 2:30 PM-4:30 PM and located in room N229 on the 2nd level of the North Building. The Networking Reception is immediately following until 5:30 PM.*

### Publishing Lounge

ASCO's growing roster of cutting-edge publications—including the Society's flagship journal, the *Journal of Clinical Oncology*—serves readers as the most credible, authoritative, peer-reviewed resources for significant clinical oncology research and research that informs the delivery of efficient, high-quality cancer care across the globe.

The *ASCO Daily News*, the official news source of the ASCO Annual Meeting, provides readers with live coverage of the most relevant presentations from the Meeting, as well as expert commentary from oncology thought leaders.

The *ASCO Educational Book* is an NLM-indexed collection of articles written by ASCO Annual Meeting faculty and invited leaders from ASCO's other meetings. Published annually, each volume highlights the most compelling research and developments across the multidisciplinary fields of oncology and serves as an enduring scholarly resource long after the Meeting concludes.

The Publishing Lounge is a place where journal and *Educational Book* authors, *ASCO Daily News* contributors, editorial board members, and reviewers can gather to relax, take a coffee break, or network. The Publishing Lounge will also hold small events such as "meet and greets" with publication editors. Continental breakfast and light refreshments are served each day. For more information, visit the Attendee Resource Center at am.asco.org/arc.

*The Publishing Lounge is located in room S403 and is open from 1 PM-5 PM on June 1 and from 9 AM-5 PM June 2 through June 4.*

### Networking Cafés

Four Networking Cafés throughout McCormick Place offer attendees the opportunity to take a break, charge their devices, and casually connect with colleagues as they discuss the science and education taking place or watch a session live on ASCO TV. Networking Cafés offer a variety of concession options and are situated in central gathering areas of McCormick Place.

### Reserve a Table

Thirty of the tables located in the seating area behind Concierge Services in the North Building, Level 3, Grand Concourse Lobby can be reserved for 45-minute time slots for up to eight people. Table reservations are available June 1 through June 4 from 7 AM-6 PM and on June 5 from 7 AM-12 PM. Reservations will be available closer to the Meeting through am.asco.org.

*See Networking Guide, Page 34*



The Trainee and Early-Career Oncologist Member Lounge offers opportunities for residents, medical students, and training program directors to advance their work through networking.

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## Oncology Professionals Hall

*Continued from page 18*

address specific clinical situations or use of approved medical products, procedures, or tests.

- **ASCO University®:** Learn how ASCO University can meet your individual educational needs, as well as the educational needs of others at your practice. Digital education and print products from ASCO include *ASCO-SEP® 6th Edition*, MOC activities, interactive Tumor Boards, ASCO University Essentials and the Personalized Learning Dashboard, and more. Special promotions and discounts are available during the ASCO Annual Meeting.
- **ASCO Member Services:** Become an ASCO member at the Meeting, and your first year of dues is free. Renew your membership to receive a free gift, and refer your colleagues to join for a chance to receive an ASCO University Bookstore credit.
- **ASCO Journals:** Learn about ASCO's open-access publishing options and how to submit to ASCO journals. Plus, explore high-quality, practice-changing content in *Journal of Clinical Oncology*, *Journal of Global Oncology*, *Journal of Oncology Practice*, *JCO Precision Oncology*, and *JCO Clinical Cancer Informatics*.
- **ASCO's Clinical Affairs:** Clinical Affairs supports practices across the country in the areas of business analytics, performance improvement, quality certification, and practice management. Stop by to learn about the Quality Oncology Practice Initiative®, QOPI® Certification Program, and the Quality Training Program.

### Patient Advocacy Booth and Pavilion

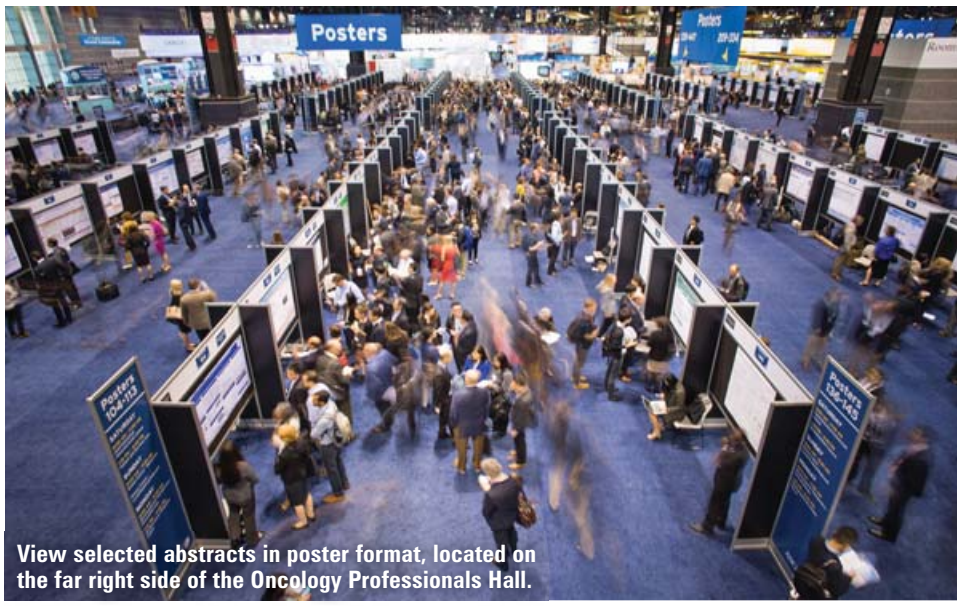
The ASCO-sponsored Patient Advocacy Booth, in Booth 3005, is designed to provide nonprofit patient advocacy organizations an opportunity to promote their programs, services, and resources to the professional oncology community. The Patient Advocacy Booth is a place where participants can display materials and where meeting attendees and patient advocates can network and exchange information.

There are also nearly 30 additional patient advocacy organizations exhibiting at the Annual Meeting, which comprise the Patient Advocacy Pavilion.

### ASCO State Oncology Societies Booth

Staff and leadership from participating societies are at the State Oncology Societies Booth, in Booth 2005, representing their organizations, interacting with attendees, and discussing the importance of local-level involvement in issues affecting oncology professionals. Attendees are encouraged to visit the Booth to receive a State Society member ribbon.


Visit the Oncology Professionals Hall to view exhibits and posters and visit the Industry Expert Theater, Food Court, and ASCO Bistro.




View selected abstracts in poster format, located on the far right side of the Oncology Professionals Hall.

### CancerLinQ™ Booth

CancerLinQ,™ in Booth 5005, aims to rapidly improve the overall quality of cancer care and is the only major cancer data initiative being developed and led by physicians. CancerLinQ will unlock real-world patient care data from millions of electronic health records and securely process and analyze the data to provide immediate quality feedback and clinical decision support to providers. Doctors will receive personalized insights on a scope that was previously unattainable, and patients will benefit by having access to high-quality care based on the most up-to-date insights and findings.

### Technology and Practice Management Pavilion

Exhibitors in the Technology and Practice Management Pavilion will highlight the latest in advanced technologies for health care professionals, such as electronic health records, database management, electronic communications, software, and other electronic products and services related to the practice of oncology.

### Posters

View selected abstracts in poster format, located on the far right side of the Oncology Professionals Hall as you enter from the Grand Concourse in the South Building, Level 3. Posters can also be accessed directly from the South Building escalators, by room S102. Poster Sessions begin on June 2 and run through June 4. Please reference the iPlanner or Meeting Program for timing.

### Food Court

The Food Court, located in the Oncology Professionals Hall, features a variety of options. Take advantage of the largest seating area in McCormick Place to network with colleagues or grab a bite to eat, featuring an all-inclusive buffet in ASCO Bistro, with fresh, healthy food options. Tickets for ASCO Bistro can be purchased online at ascobistro.com, or on-site at the entrance to the Food Court. Menus are available online. ●

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## Networking Guide

*Continued from page 32*

### Find a Colleague Directory

Use the Find a Colleague directory in the Attendee Resource Center to search for registered attendees and send direct, private emails to connect while on-site. The Find a Colleague directory will be available to all registered attendees prior to the Meeting.

### ASCO Oncology Career Fair

Job-seeking attendees may visit the ASCO Oncology Career Fair to meet with recruiters from hospitals, academic institutions, private practices, and more. Participation is open to all attendees and offers opportunities to browse general and subspecialty oncology positions, explore career development resources, and submit résumés directly to employers. The booths are located in the Oncology Professionals Hall, South Building, Hall A, and will be open June 2 and June 3 from 9 AM-5 PM.

### #ASCO18 Tweetup

The official ASCO Tweetup is an informal gathering for attendees interested in the intersection of oncology and social media to meet and mingle. The Tweetup will take place June 2 from 5:45-6:45 PM in the Plate Room food court, located in the North Hall Level 2.5.

### Lakeside Lounge

McCormick Place is nestled against Lake Michigan, and this year ASCO is giving everyone a view of the lake and a little extra sunshine. The Lakeside Lounge, located in the East Building on Level 3, is a large open area in front of Halls D1 and D2. The area will offer tables where you can take a break in between sessions or catch up on ASCO TV, as well as power strips and fast-charging stations for your device. You can grab a bite to eat at one of the many concession options both inside McCormick Place and directly outside the glass doors on the terrace. There will even be opportunities to shop at a pop-up shop. Don't miss stopping by this one-stop-shop area to rest, recharge, and refuel. ●

**–Caroline Hopkins**

# Your Social Media Guide to #ASCO18

Whether you're still learning what a tweet is or you've already built an established social media presence, there is still much to learn about taking your ASCO Annual Meeting experience online. When you keep tabs on Meeting-related social media posts, you benefit not only from important session and logistical updates, but also from real-time presentation comments, recaps, and links to supplemental articles and information. But perhaps the most valuable reason to use social media during the Annual Meeting is the host of networking opportunities it opens up. You'll form lasting connections and engage with colleagues, attendees, and leading voices in the field.

## The Basics

ASCO Annual Meeting content is available across several social media platforms, including Twitter, Facebook, LinkedIn, and Instagram. Here's how you can make the most of each:


- **Twitter:** Your most valuable channel at the Annual Meeting is Twitter. This is where presenters and attendees tend to post the most content that directly relates to the science presented. Search @ASCO and FOLLOW our account to get the latest meeting news, research, and announcements.
- **Facebook:** Search @ASCOCancer and LIKE our Facebook page to stay up to date on the latest Meeting news, research, and announcements. On Facebook, you can react to and comment on posts or share them to your own Facebook page for your friends to view. If you'd like to pass a message along to a particular Facebook friend, you have the option to send it in a private message via Facebook Messenger.

- **LinkedIn:** Similar to Facebook, you can search "American Society of Clinical Oncology (ASCO)" on LinkedIn and FOLLOW our page for the latest Meeting news, research, and announcements. If networking is one of your goals this year, be sure to send new contacts an invitation to connect on LinkedIn after the Meeting. As an ASCO member, you can also join ASCO's member-only LinkedIn discussion group.
- **Instagram:** Although ASCO does not have its own Instagram account, the Annual Meeting hashtag (#ASCO18) serves as an aggregator for Annual Meeting photographs and videos, as do the location tags for "ASCO Annual Meeting" or "McCormick Place." To view photos and videos other attendees have posted, search the hashtag or location in the "Explore" tab of your Instagram app. Instagram's "story" feature also allows you to post temporary photos or videos (videos up to 15 seconds long) that will remain accessible for 24 hours before disappearing. When you post a story and use the #ASCO18 hashtag with the text overlay feature, your story shows up in a larger, combined story that includes all stories with that same hashtag. This feature is a great way to access live updates and happenings at Annual Meeting from the attendee perspective.

## The #Hashtags

Hashtags indicate a post's specific topic. On Twitter, you can search a hashtag to find tweets related to that topic.

- The official Annual Meeting hashtag is #ASCO18.
- Using hashtags can expose your tweets to a wider audience. Even if someone doesn't follow you, they can still find your tweet if they search the hashtag you used.
- If you're discussing the Meeting, a session, or a topic, make sure to use the corresponding hashtag in your tweet so others can find it (Table 1 and Table 2).

**Table 1. ASCO Twitter Accounts and Hashtags**

| | |
|---|---|
| @ConquerCancerFd, #ConquerCancer | Conquer Cancer Foundation |
| @CancerDotNet | Cancer.Net |
| #ASCOU | ASCO University |
| @JCO_ASCO | *Journal of Clinical Oncology* |
| @JGO_ASCO | *Journal of Global Oncology* |
| @JOP_ASCO | *Journal of Oncology Practice* |

**Table 2. Common Oncology Hashtags**

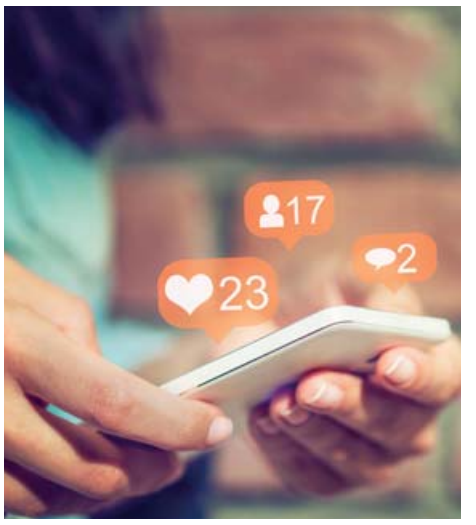
| | |
|---|---|
| #AYACSM | Adolescent and young adult cancer |
| #BCSM | Breast cancer |
| #CRCSM | Colorectal cancer |
| #GynCSM | Gynecologic cancer |
| #KCSM | Kidney cancer |
| #LCSM | Lung cancer |
| #LeuSM | Leukemia |
| #LymSM | Lymphoma |
| #MMSM | Multiple myeloma |
| #PallOnc | Palliative oncology |
| #PancSM | Pancreatic cancer |
| #PCSM | Prostate cancer |
| #PedCSM | Pediatric cancer |

## The Voices

Several ASCO members have been selected as "Featured Voices" for the ASCO Annual Meeting. These volunteers will share their expertise and impressions on Twitter throughout the Meeting—watch for their tweets as they lead this social media conversation.

Find the list of 2018 Annual Meeting Featured Voices at am.asco.org/arc/social-media or on ASCO's social media channels.

You can also follow ASCO President Bruce Johnson, MD, FASCO, @ASCOPres; ASCO CEO Clifford Hudis, MD, FACP, FASCO, @CliffordHudis; or ASCO CMO Richard Schilsky, MD, FACP, FASCO, @RSchilsky.




## Join the Conversation

During last year's Annual Meeting, more than 17,000 health care professionals, researchers, news outlets, patients, advocates, and other participants sent more than 92,000 tweets. If you're joining the conversation this year, keep the following in mind:

- Think before you tweet. Everything you tweet, retweet, or share will be seen by your friends or followers, so make sure the message is relevant, appropriate, and resonates with you.
- Don't underestimate the link. Although you may be limited to a certain number of characters on some platforms, you can always include a link to more information or a related resource in your post.
- A picture is worth 1,000 words. An image can say much more than text and is more likely to catch someone's eye in a crowded feed. Share Meeting slides, pictures with colleagues, and scenes from McCormick Place.
- Social media is a two-way conversation. Don't just share your own content; instead, take a few minutes to like, comment on, respond to, and retweet/share other users' content. This is also a great way to connect with people, broaden your network, and gain more followers.
- Join the #ASCO18 Tweetup. The official ASCO Tweetup is an informal gathering for attendees interested in the intersection of oncology and social media to meet and mingle. Join us on June 2, 5:45-6:45 PM in the Plate Room food court (North Hall Level 2.5). ●

**–Caroline Hopkins**

**JOIN US TONIGHT – Saturday Evening, June 2, 2018 – A CME Oncology Dinner Summit**

***Marriott Marquis Chicago – Great Lakes Ballroom***

*You and Your Oncology Colleagues Are Invited to Attend*
*A **CME** Oncology Dinner Summit Focused on…*

Real World, Evidence- and Case-Based Approaches
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# THERAPEUTIC ADVANCES in METASTATIC PANCREATIC ADENOCARCINOMA and RELATED CANCERS

**Focus on Evidence-Based and Sequenced Approaches to Survival Extension in Metastatic Pancreatic Adenocarcinoma**

*Which Therapies? Which Guidelines? What Formulations? In What Sequence? In Which Patient Populations? When? Why?*


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Time: 6:00 PM – 8:15 PM | Program Registration and Dinner: 5:30 PM

City: Chicago, IL | Location: **Marriott Marquis Chicago** | Address: 2121 South Prairie Avenue

Conference Room: **Great Lakes Ballroom**

**NO REGISTRATION REQUIRED TO ATTEND**

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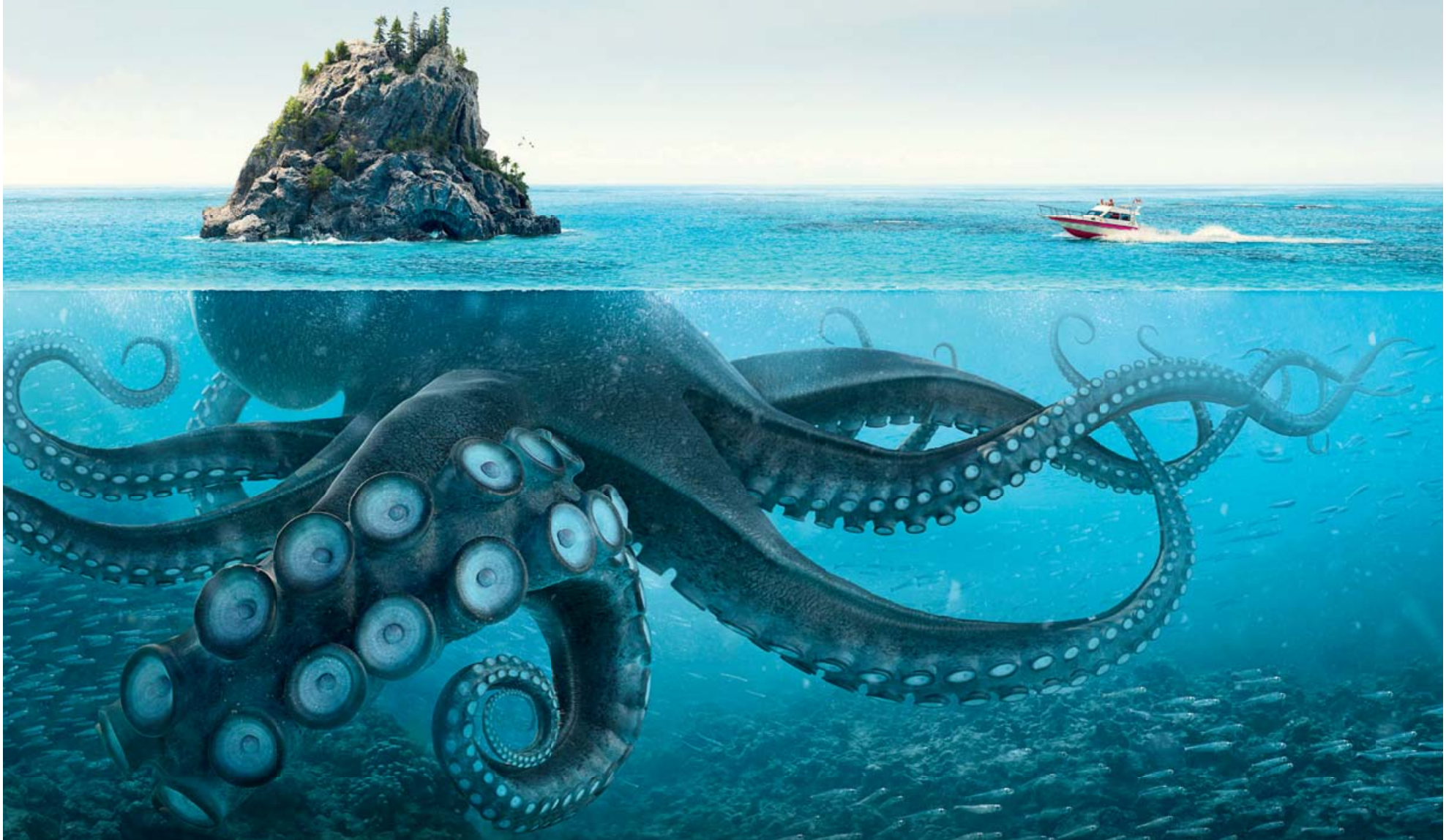
## TRK FUSION PROTEINS ARE A PRIMARY ONCOGENIC DRIVER ACROSS MULTIPLE TUMORS IN ADULTS AND CHILDREN[1,2]



# TRK FUSION CANCER

## LOOK BELOW THE SURFACE TO FIND OUT WHAT'S DRIVING THE TUMOR

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TRK, tropomyosin receptor kinase.

**References: 1**. Okimoto RA, Bivona TG. Tracking down response and resistance to TRK inhibitors. *Cancer Discov*. 2016;6(1):14-16.
**2**. Vaishnavi A, Le AT, Doebele RC. TRKing down an old oncogene in a new era of targeted therapy. *Cancer Discov*. 2015;5(1):25-34.