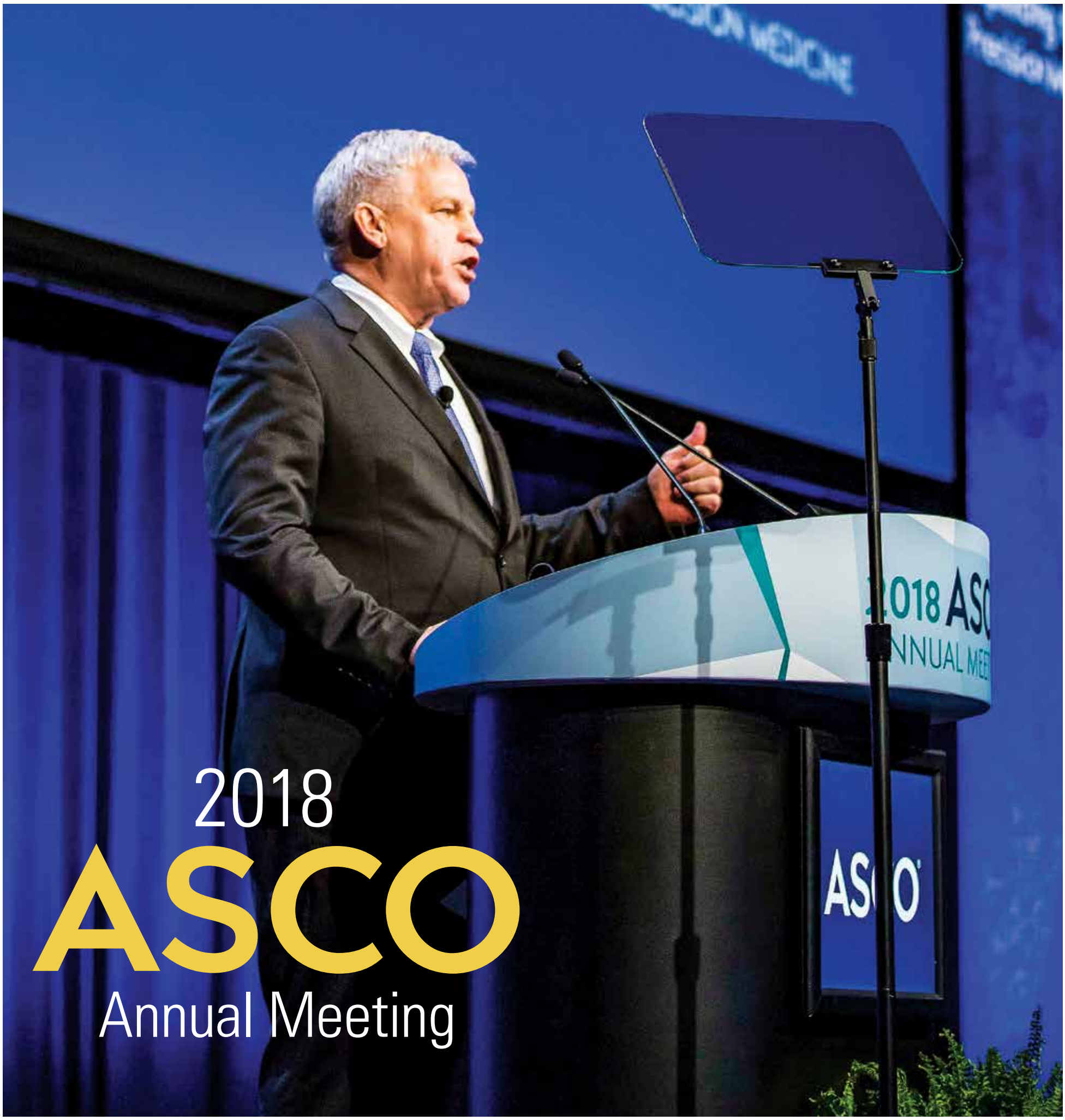
ASCO Daily News®

Evening Edition

SUNDAY • JUNE 3, 2018




## INSIDE THIS ISSUE

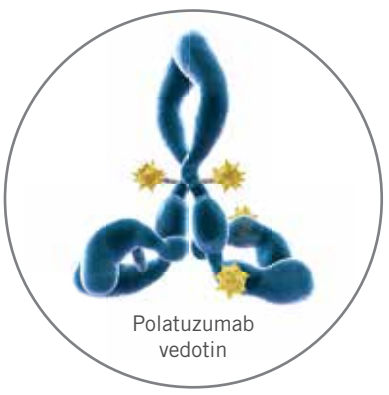
Polatuzumab vedotin (RG7596): An investigational anti-CD79b antibody-drug conjugate (ADC)[1]

# Currently Enrolling in Previously Untreated Diffuse Large B-cell Lymphoma (DLBCL)

## POLARIX — A Phase III Clinical Trial of Polatuzumab Vedotin in DLBCL

**Phase III • NCT03274492**

A Clinical Study Comparing the Efficacy and Safety of Polatuzumab Vedotin With Rituximab-Cyclophosphamide, Doxorubicin, and Prednisone (R-CHP) Versus Rituximab-Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in Participants With DLBCL




**A randomized, double-blind, placebo-controlled study**

- Previously untreated patients with DLBCL
- Age 18–80 years
- IPI 2–5
- ECOG performance status of 0–2

R

1:1
N=875

**Arm A**
Polatuzumab vedotin + R-CHP (Cycles 1–6)
→ Rituximab (Cycles 7–8)

**Arm B**
R-CHOP (Cycles 1–6)
→ Rituximab (Cycles 7–8)

### Study Endpoints

**Primary Outcome Measure:**

- PFS, defined as the time from randomization to the first occurrence of disease progression or relapse, or death*

**Selected Secondary Outcome Measures:**

- CR as assessed by FDG-PET through blinded independent central review at the end of treatment visit
- Duration of response, defined as the time from the first occurrence of a documented CR or PR to disease progression*
- EFSeff, defined as the time from randomization to the first occurrence of disease progression or relapse, or death from any cause, or other primary efficacy reason that leads to initiation of any non–protocol-specified antilymphoma treatment or residual disease*
- Overall survival
- EORTC QLQ-C30 treatment-related symptoms score
- Safety

*As assessed by the investigator through the use of Lugano Response Criteria for Malignant Lymphoma.

### Selected Eligibility Criteria

- Previously untreated participants with CD20-positive DLBCL
- LVEF ≥50% on cardiac MUGA scan or cardiac echocardiogram
- Availability of archival or freshly collected tumor tissue before study enrollment, and adequate hematologic function
- No prior treatment with cytotoxic drugs ≤5 years of screening
- No prior use of any monoclonal antibody ≤3 months of screening
- No prior use of any anti-CD20 antibody
- No prior use of any therapy for DLBCL, with the exception of nodal biopsy

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

Visit: **www.POLARIXstudy.com**

Call: Genentech Trial Information Support Line: **1-888-662-6728** (US only)

Email: **global-roche-genentech-trials@gene.com**

ClinicalTrials.gov Identifier: NCT03274492; Sponsor Study Identifier: GO39942.

CD20=cluster of differentiation 20; CR=complete response; ECOG=Eastern Cooperative Oncology Group; EFSeff=event-free survival-efficacy; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life-Core 30 Questionnaire; FDG-PET=fluorodeoxyglucose-positron emission tomography; IPI=international prognostic index; LVEF=left ventricular ejection fraction; MUGA=multigated acquisition; PFS=progression-free survival; PR=partial response.

**Reference: 1.** Roche. Product development portfolio. https://www.roche.com/research_and_development/who_we_are_how_we_work/pipeline.htm. Updated July 27, 2017. Accessed October 9, 2017.

**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 November 15, 2017.

Genentech
*A Member of the Roche Group*

BIOONCOLOGY®

# Dr. Gregory H. Reaman Receives Pediatric Oncology Award

On June 4, Gregory H. Reaman, MD, FASCO, professor of pediatrics at George Washington University School of Medicine and Health Sciences, will receive the Pediatric Oncology Award for his outstanding leadership and achievements in the field. In the following interview, Dr. Reaman discusses his career and previews his award lecture.

**Q: How has the field of pediatric oncology changed since you began?**

**Dr. Reaman:** Over the last 4 or 5 decades, it's been amazing to see how science and investigation have expanded as a result of our ability to cure cancer in an increasing number of children. Those changes have occurred in patients with many diseases, but most notably acute lymphoblastic leukemia (ALL).

However, we've recognized that the cure comes with a cost. Studying survivors who have experienced toxicities has allowed us to refine therapies for the next generation of patients with cancer. It also has permitted us to evaluate ways to prevent or mitigate those toxicities so we can maintain the same levels of cure rates and, in some cases, eliminate or decrease radiation therapy to ultimately improve survival and quality of survivorship.

It's an ongoing process that guides pediatric oncology. We've always had a responsibility to cancer survivors, and we're continuing to learn from children and their families who have agreed to participate in clinical trials. We've been able to maximize those very generous contributions from patients and families and use them to benefit current and future patients.

**Q: Why did you choose pediatric oncology?**

**Dr. Reaman:** When I was in grade school, a child in our neighborhood developed leukemia. One day he was out playing, and the next day he was in the hospital—and then we never heard anything more about him. Years later, I learned that he died. Then, as a medical student, I had an opportunity to be involved in the care of a teenager with leukemia and his family. Unfortunately, he died. I was deeply touched by the impact of his illness and death on his family. The experience was transformative for me and served to validate my interest in pediatric oncology, clarifying that caring for children with cancer requires a commitment to caring for their families.

Dr. Gregory H. Reaman

I always knew I wanted to do pediatrics but I knew if I did, I wanted to take care of sick children rather than working in general pediatrics, where most children are healthy. I considered neonatology for a while because of its fast pace, high energy, and procedure-intensive practice, but I missed the long-term relationship with patients and families.

The actual science of oncology interested me as well.

**Q: What projects are you currently working on?**

**Dr. Reaman:** Throughout my career, my research has been focused on understanding the biology and immunobiology of ALL and exploring new treatment strategies for the disease. I've also spent a lot of time and energy on clinical trial design and oversight in the Children's Oncology Group and the Children's Cancer and Leukaemia Group expanding my interest in the development of new drugs and therapies for pediatric cancer.

Today, I am focused on trying to expedite the evaluation and development of new adult drugs for use in children, when appropriate. Pediatric cancers are different from adult cancers, so many of the drugs available for adults will not work in the pediatric population.

The Research to Accelerate Cures and Equity for Children Act updates the Pediatric Research Equity Act of 2003 that required drug companies to develop their drugs for children as well as adults for certain biological products.[1] However, because children's cancers are so different from adult cancers, the law effectively eliminated cancer drugs.

The U.S. Food and Drug Administration Reauthorization Act (FDARA) of 2017, however, requires manufacturers to conduct pediatric studies of drugs whose molecular targets may be relevant to one or more pediatric cancers.[2] This has the potential to change the pediatric oncology landscape dramatically. My efforts are especially focused on developing processes and procedures for implementing these new provisions.

**Q: What future developments do you see for pediatric cancer?**

**Dr. Reaman:** We had the first chimeric antigen receptor T-cell therapy approved for relapsed pediatric ALL. I think that's the most exciting development in the treatment of childhood ALL in decades. The technology holds promise for solid tumors, particularly solid tumors that are refractory to current conventional therapy.

The other big development is being able to finally expand precision medicine to children. To date, the impact of precision medicine in oncology has been predominantly obvious in the adult space. With the passage of FDARA, there's an opportunity to exploit early developments and move them into pediatric clinical trials much earlier.

**Q: What will you discuss in your lecture?**

**Dr. Reaman:** I want to highlight the potential for children to benefit from precision medicine in the same ways that adults have. It's important to note that one of the first targeted interventions in cancer medicine was in ALL with asparaginase, a drug that eliminated an essential amino acid for leukemia cells. It is still an important part of leukemia therapy.

I plan to discuss the transition from there to the legislation that has provided the governance for pediatric drug development in general and in cancer. It hasn't been as favorable for pediatrics as it should be, but that time has, possibly, changed with this new legislation. There is hope now for more opportunities for precision medicine and novel therapeutics in oncology in the childhood cancer space. ●

–Debra Gordon

**References:**


1. U.S. Food and Drug Administration. Pediatric Product Development. www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049867.htm. Updated February 15, 2018. Accessed February 20, 2018.
2. Congress.gov. H.R.2430 – FDA Reauthorization Act of 2017. congress.gov/bill/115th-congress/house-bill/2430/text. Published August 18, 2017. Accessed February 20, 2018.


# Danielle Leach, a 'STAR' in Pediatric Cancer Advocacy, to Receive 2018 Partners in Progress Award

ASCO's Partners in Progress Award, to be presented June 4, honors an individual whose patient advocacy has impacted public awareness about cancer or resulted in additional support—either legislatively or fiscally—for cancer research, treatment, prevention, or care.

Danielle Leach, the director of advocacy and government relations at the St. Baldrick's Foundation, has been an instrumental voice in the cancer landscape for decades. For her tireless efforts and collaborative spirit, she will be receiving the 2018 Partners in Progress Award.

Danielle Leach

**Harnessing Personal Experience**

Cancer played a defining role in Ms. Leach's personal life, and the impact of her life-altering experiences has shaped her influential work. Several of Ms. Leach's loved ones were diagnosed with cancer throughout her lifetime, which illustrated to Ms. Leach the stark differences in care and access to treatment information. Through each diagnosis and ensuing treatment, she recognized gaps and inconsistencies that in many ways determined who would or would not survive their cancer.

At age 13, Ms. Leach's sister was diagnosed with rhabdomyosarcoma, which she was fortunate to survive after participating in a clinical trial. "She was one of the lucky ones," Ms. Leach said. But decades later in 2006, when Ms. Leach's son Mason was diagnosed with pediatric medulloblastoma at age 5, this

*See Partners in Progress Award, Page 4*

### Partners in Progress Award

*Continued from page 3*

was not the case. Mason died after 15 months of aggressive treatment.

During these 15 months, Ms. Leach noticed a distinct need for funding in childhood cancers. "It was incredibly frustrating to see the lack of basic research because the investment had not been there," she said. "My son and my sister received the same types of chemotherapy 25 years apart. That was unacceptable to me."

This realization impacted much of Ms. Leach's most influential work, particularly in terms of advocating for legislation and funding for research. "Not everybody gets the miracle that my sister had—what happened to Mason was unacceptable," she said. "I'm trying to change that reality for other families."

Ms. Leach sees areas for improvement across the board—the most pressing of which is collaboration. "We need to make sure every voice is present at the table," she said, explaining that the most vital aspect of her job is harnessing powerful voices across the cancer care continuum and bringing them together to translate that power into action.

#### Action and Advocacy

When Mason received his diagnosis in 2006, Ms. Leach had already spent years making waves in cancer education and advocacy. She worked with the Strang Cancer Prevention Institute, followed by the American Cancer Society in several leadership roles, ultimately traveling overseas to Bolivia and Honduras to work in cancer- and AIDS-related programming and resource development training. After Mason died, Ms. Leach went on to work with the organization Inspire as the director of partnerships, during which time she helped establish Inspire's online communities, which offer dynamic support in a moderated environment.

"There is nothing more terrifying than watching someone you love go through pain," Ms. Leach said. "Making sure that people are aware of available resources, have quality information, and feel empowered to ask questions and reach out to networks of people—that's what I strive for every day."

Continuing to turn her grief into action, Ms. Leach joined 46 other mothers of children with pediatric cancer in 2011 in shaving her head to raise money for St. Baldricks, the largest private funder of childhood cancer research grants outside the U.S. government. Heads shaved, the mothers went to Capitol Hill to advocate on behalf of kids with cancer.

Several years thereafter in 2014, Ms. Leach was brought on as the director of government relations and advocacy at St. Baldrick's, where she helped to grow a robust advocacy program. To date, she has helped bring more than 1,000 advocates to the Hill on behalf of childhood cancer and has grown St. Baldrick's advocacy network by 30% over the last 3.5 years. "St. Baldrick's is committed to advocacy and government relations so that we can strive to optimize the dollars we raise and leverage the opportunities we have for investment and collaboration in research," Ms. Leach said.

Ms. Leach is acutely aware that her contributions and the progress she has brought to the field of pediatric cancer research do not stand in isolation—collaboration continues to be the key to harnessing personal motivation across the board. "Everyone's life is touched by cancer in one way or another," she said. "We cannot talk about 'Partners in Progress' without acknowledging the role that every individual's personal experience plays in bringing about change."

#### Contributions in Partnership and Legislation

While devoting herself to a career in cancer advocacy and funding, Ms. Leach has simultaneously volunteered her expertise and persistence toward community and volunteer activities. Her past and current committee leadership positions include founder of the Mason Leach Superstar Fund, member of former Vice President Joe Biden's Cancer Moonshot Pediatric Cancer Working Group, board member for the American Childhood Cancer Organization, co-chair of the ASCO member organization Alliance for Childhood Cancer, and member of the National Cancer Institute's National Council of Research Advocates and Pediatric Solid Tumor Steering Committee.

Harnessing advocacy efforts through all of these organizations in partnership with St. Baldrick's has culminated in the most comprehensive childhood cancer bill brought to Congress: the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act. The act was initially born out of a series of policy roundtables Ms. Leach helped establish through the Alliance for Childhood Cancer. These roundtables were moderated meetings during which participants sat down with childhood cancer community members to establish priorities and courses of action. The roundtables created a roadmap for community collaboration, and the STAR Act was born out of this effort.

As established during these foundational roundtables, the primary goals of the STAR Act include advancing pediatric cancer research and child-focused cancer treatments, improving childhood cancer surveillance, and providing enhanced resources for survivors. This legislation was approved by the U.S. Senate on March 22 and is now headed to the House of Representatives, where it has been cosponsored by 383 members—more than 80% of the full House. ●

**–Caroline Hopkins and Alice McCarthy**

## WHY I ATTEND: MUHAMMAD BEG, MD

Muhammad Beg, MD, of the University of Texas Southwestern Medical Center, is a seasoned ASCO Annual Meeting attendee and current member of ASCO's Cancer Communications Committee. In the following article, Dr. Beg provides insider tips for Meeting attendees.

**Q: How do you plan your time during the Meeting?**
**Dr. Beg:** The ASCO Annual Meeting is a great opportunity to meet with colleagues and collaborators. My calendar is usually peppered with meetings with industry and advocacy group collaborators and coffee with friends and colleagues.

It helps me to look over the sessions on the iPlanner app beforehand and plan where I want to be. There is no way you can attend all the sessions, so take some time to relax, explore the Oncology Professionals Hall, and enjoy the lounges.

**Q: Apart from the science presented, what are the benefits of attending the Meeting?**
**Dr. Beg:** Networking and sharing ideas from national and international opinion leaders is always fun.

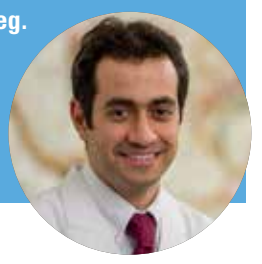
**Q: Do you have any advice for networking at the Meeting?**
**Dr. Beg:** The Poster Hall is a great place to meet people. For those looking for a job, schedule meetings at a coffee shop; it's a low-stress environment where you can get to know the other person. Be brave and say 'Hi' to someone you have always wanted to meet. What is the worst thing that can happen?

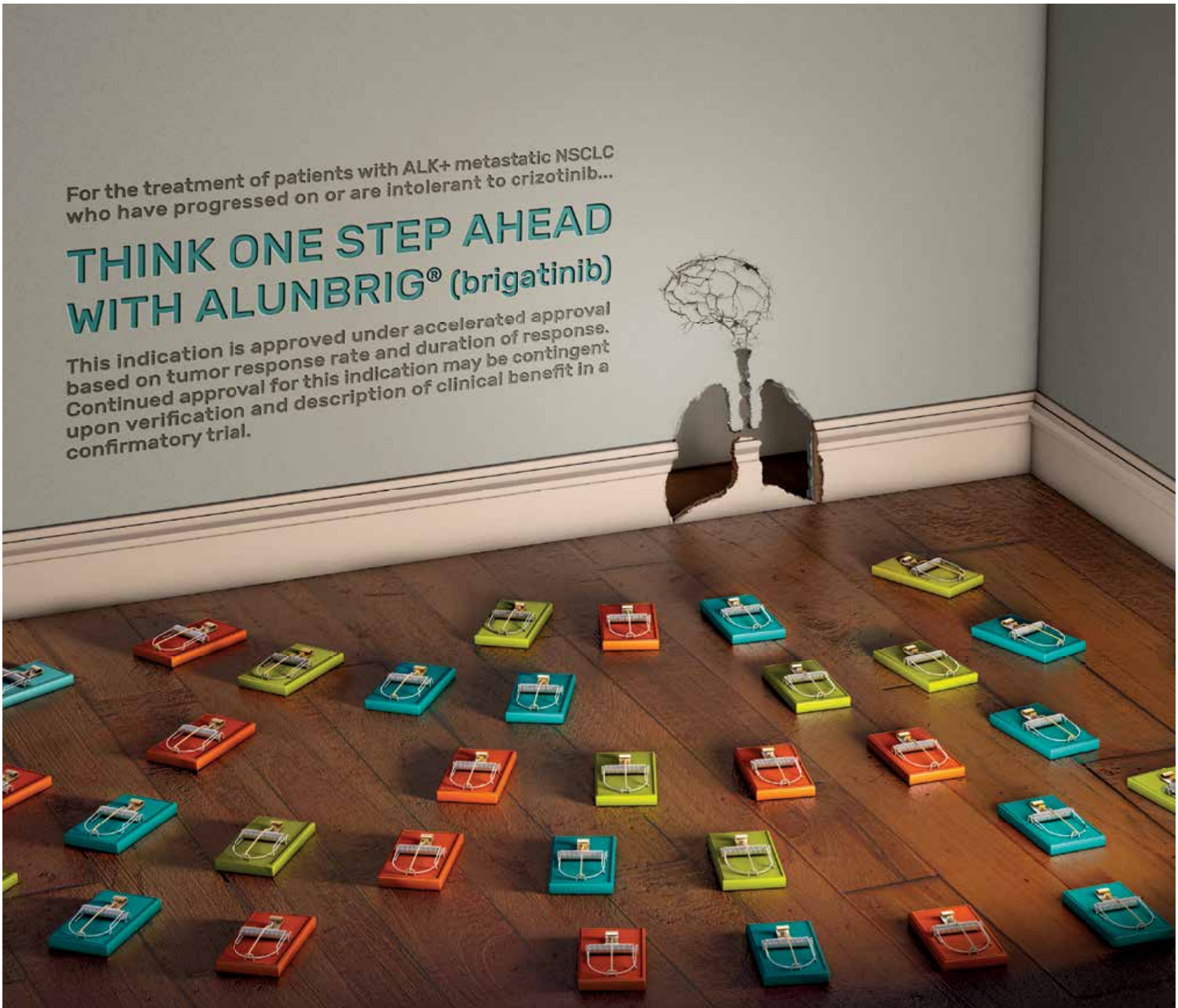
**Q: This year's theme is focused on precision medicine. What do you think the Meeting will be focused on 10 years from now?**
**Dr. Beg:** I hope the rising tide of molecular profiling, new treatments, artificial intelligence, and big data will help us give the right patient the right treatment. And importantly, I hope it will prevent us from giving the wrong treatment to the wrong patient.

**Q: Where should attendees get lunch at the convention center?**
**Dr. Beg:** The restaurants at the convention center are good, but it can be hard to get a table. I sneak away and take a car downtown if I have a break in my schedule.

**Q: Any other tips for attendees?**
**Dr. Beg:** It's the community and interaction that makes the ASCO Annual Meeting so great. You can catch up on the science later through Videos & Slides or social media. You are there to enjoy and make new friends, so have a great time. ●

**Muhammad Beg, MD, is the co-leader of the GI Oncology Group and medical director of the Clinical Research Office at the University of Texas Southwestern Medical Center. You can find him on Twitter: @ShaalanBeg.**






## INDICATION AND IMPORTANT SAFETY INFORMATION

**ALUNBRIG® (brigatinib)** is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. See accelerated approval information above.

## WARNINGS AND PRECAUTIONS

**Interstitial Lung Disease (ILD)/Pneumonitis:** Severe, life-threatening, and fatal pulmonary adverse reactions consistent with interstitial lung disease (ILD)/pneumonitis have occurred with ALUNBRIG. In Trial ALTA (ALTA), ILD/pneumonitis occurred in 3.7% of patients in the 90 mg group (90 mg once daily) and 9.1% of patients in the 90→180 mg group (180 mg once daily with 7-day lead-in at 90 mg once daily). Adverse reactions consistent with possible ILD/pneumonitis occurred early (within 9 days of initiation of ALUNBRIG; median onset was 2 days) in 6.4% of patients, with Grade 3 to 4 reactions occurring in 2.7%. Monitor for new or worsening respiratory symptoms (e.g., dyspnea, cough, etc.), particularly during the first week of initiating ALUNBRIG. Withhold ALUNBRIG in any patient with new or worsening respiratory symptoms, and promptly evaluate for ILD/pneumonitis or other causes of respiratory symptoms (e.g., pulmonary embolism, tumor progression, and infectious pneumonia). For Grade 1 or 2 ILD/pneumonitis, either resume ALUNBRIG with dose reduction after recovery to baseline or permanently discontinue ALUNBRIG. Permanently discontinue ALUNBRIG for Grade 3 or 4 ILD/pneumonitis or recurrence of Grade 1 or 2 ILD/pneumonitis.

ALK+, anaplastic lymphoma kinase-positive; NSCLC, non-small cell lung cancer.

ALUNBRIG®
BRIGATINIB
180mg | 90mg | 30mg
TABLETS

**Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.**

For patients with ALK+ metastatic NSCLC
who have progressed on or are intolerant to crizotinib

# Think One Step Ahead With ALUNBRIG® (brigatinib)

## Robust Overall Efficacy

| ALTA Efficacy Results | IRC Assessment[a] | | Investigator Assessment[a] | |
|---|---|---|---|---|
| | 90 mg once daily (n=112) | 90→180 mg once daily[b] (n=110) | 90 mg once daily (n=112) | 90→180 mg once daily[b] (n=110) |
| Overall Response Rate, (95% CI) | 48% (39-58) | 53% (43-62) | 45% (35-54) | 54% (44-63) |
| Complete Response, n (%) | 4 (3.6) | 5 (4.5) | 1 (0.9) | 4 (3.6) |
| Partial Response, n (%) | 50 (45) | 53 (48) | 49 (44) | 55 (50) |
| Duration of Response, Median in Months (95% CI) | 13.8 (7.4-NE) | 13.8 (9.3-NE) | 13.8 (5.6-13.8) | 11.1 (9.2-13.8) |

[b]180 mg once daily with a 7-day lead-in at 90 mg once daily.

Systemic follow-up data (18-month median follow-up) is consistent with 8-month median follow-up.[1]

**ALTA Study Design:** The safety and efficacy of ALUNBRIG® were evaluated in a global, two-arm, open-label, multicenter trial. The trial consisted of 222 adult patients with locally advanced or metastatic ALK+ NSCLC who had progressed on crizotinib. Patients were randomized to receive the recommended dosing regimen of 180 mg of ALUNBRIG orally once daily with a 7-day lead in at 90 mg once daily (n=110, 18 with measurable brain metastases[c]), or 90 mg of ALUNBRIG orally once daily (n=112, 26 with measurable brain metastases[c]). The major efficacy outcome measure was confirmed objective response rate (ORR) according to Response Evaluation Criteria In Solid Tumors (RECIST v1.1) as evaluated by an Independent Review Committee (IRC). Additional efficacy outcome measures included Investigator-assessed ORR, duration of response (DOR), intracranial ORR, and intracranial DOR.

## IMPORTANT SAFETY INFORMATION (continued)

### WARNINGS AND PRECAUTIONS (continued)

**Hypertension:** In ALTA, hypertension was reported in 11% of patients in the 90 mg group who received ALUNBRIG and 21% of patients in the 90→180 mg group. Grade 3 hypertension occurred in 5.9% of patients overall. Control blood pressure prior to treatment with ALUNBRIG. Monitor blood pressure after 2 weeks and at least monthly thereafter during treatment with ALUNBRIG. Withhold ALUNBRIG for Grade 3 hypertension despite optimal antihypertensive therapy. Upon resolution or improvement to Grade 1 severity, resume ALUNBRIG at a reduced dose. Consider permanent discontinuation of treatment with ALUNBRIG for Grade 4 hypertension or recurrence of Grade 3 hypertension. Use caution when administering ALUNBRIG in combination with antihypertensive agents that cause bradycardia.

**Bradycardia:** Bradycardia can occur with ALUNBRIG. In ALTA, heart rates less than 50 beats per minute (bpm) occurred in 5.7% of patients in the 90 mg group and 7.6% of patients in the 90→180 mg group. Grade 2 bradycardia occurred in 1 (0.9%) patient in the 90 mg group. Monitor heart rate and blood pressure during treatment with ALUNBRIG. Monitor patients more frequently if concomitant use of drug known to cause bradycardia cannot be avoided. For symptomatic bradycardia, withhold ALUNBRIG and review concomitant medications for those known to cause bradycardia. If a concomitant medication known to cause bradycardia is identified and discontinued or dose adjusted, resume ALUNBRIG at the same dose following resolution of symptomatic bradycardia; otherwise, reduce the dose of ALUNBRIG following resolution of symptomatic bradycardia. Discontinue ALUNBRIG for life-threatening bradycardia if no contributing concomitant medication is identified.

**Visual Disturbance:** In ALTA, adverse reactions leading to visual disturbance including blurred vision, diplopia, and reduced visual acuity, were reported in 7.3% of patients treated with ALUNBRIG in the 90 mg group and 10% of patients in the 90→180 mg group. Grade 3 macular edema and cataract occurred in one patient each in the 90→180 mg group. Advise patients to report any visual symptoms. Withhold ALUNBRIG and obtain an ophthalmologic evaluation in patients with new or worsening visual symptoms of Grade 2 or greater severity. Upon recovery of Grade 2 or Grade 3 visual disturbances to Grade 1 severity or baseline, resume ALUNBRIG at a reduced dose. Permanently discontinue treatment with ALUNBRIG for Grade 4 visual disturbances.

**Creatine Phosphokinase (CPK) Elevation:** In ALTA, creatine phosphokinase (CPK) elevation occurred in 27% of patients receiving ALUNBRIG in the 90 mg group and 48% of patients in the 90→180 mg group. The incidence of Grade 3-4 CPK elevation was 2.8% in the 90 mg group and 12% in the 90→180 mg group. Dose reduction for CPK elevation occurred in 1.8% of patients in the 90 mg group and 4.5% in the 90→180 mg group. Advise patients to report any unexplained muscle pain, tenderness, or weakness. Monitor CPK levels during ALUNBRIG treatment. Withhold ALUNBRIG for Grade 3 or 4 CPK elevation. Upon resolution or recovery to Grade 1 or baseline, resume ALUNBRIG at the same dose or at a reduced dose.

**Pancreatic Enzyme Elevation:** In ALTA, amylase elevation occurred in 27% of patients in the 90 mg group and 39% of patients in the 90→180 mg group. Lipase elevations occurred in 21% of patients in the 90 mg group and 45% of patients in the 90→180 mg group. Grade 3 or 4 amylase elevation occurred in 3.7% of patients in the 90 mg group and 2.7% of patients in the 90→180 mg group. Grade 3 or 4 lipase elevation occurred in 4.6% of patients in the 90 mg group and 5.5% of patients in the 90→180 mg group. Monitor lipase and amylase during treatment with ALUNBRIG. Withhold ALUNBRIG for Grade 3 or 4 pancreatic enzyme elevation. Upon resolution or recovery to Grade 1 or baseline, resume ALUNBRIG at the same dose or at a reduced dose.

**Hyperglycemia:** In ALTA, 43% of patients who received ALUNBRIG experienced new or worsening hyperglycemia. Grade 3 hyperglycemia, based on laboratory assessment of serum fasting glucose levels, occurred in 3.7% of patients. Two of 20 (10%) patients with diabetes or glucose intolerance at baseline required initiation of insulin while receiving ALUNBRIG. Assess fasting serum glucose prior to initiation of ALUNBRIG and monitor periodically thereafter. Initiate or optimize anti-hyperglycemic medications as needed. If adequate hyperglycemic control cannot be achieved with optimal medical management, withhold ALUNBRIG until adequate hyperglycemic control is achieved and consider reducing the dose of ALUNBRIG or permanently discontinuing ALUNBRIG.

**Embryo-Fetal Toxicity:** Based on its mechanism of action and findings in animals, ALUNBRIG can cause fetal harm when administered to pregnant women. There are no clinical data on the use of ALUNBRIG in pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with ALUNBRIG and for at least 4 months following the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose of ALUNBRIG.

## Meaningful CNS Efficacy

| Intracranial Objective Response in Patients With Measurable Brain Metastases[c] in ALTA | IRC Assessment[a] | | Follow-Up Data (18-Month Median Follow-Up[d])[1,2] | |
|---|---|---|---|---|
| | 90 mg once daily (n=26) | 90→180 mg once daily[b] (n=18) | 90 mg once daily (n=26) | 90→180 mg once daily[b] (n=18) |
| Intracranial Overall Response Rate, (95 % CI) | 42% (23-63) | 67% (41-87) | 50% (30-70) | 67% (41-87) |
| Complete Response, n (%) | 2 (7.7) | 0 | 2 (8) | 0 |
| Partial Response, n (%) | 9 (35) | 12 (67) | 11 (42) | 12 (67) |
| Duration of Intracranial Response, Median (months) (range) | NE (1.9+ - 9.2+) | 5.6 (1.9+ - 9.2+) | NR (3.7-NR) | 16.6 (3.7-16.6) |

[a]Median duration of follow-up was 8 months (range: 0.1-20.1).
[b]180 mg once daily with a 7-day lead-in at 90 mg once daily.
[c]≥10 mm in longest diameter (at baseline).
[d]Median duration of follow-up was 18-months (range:0.1-32).
CI, confidence interval; NE, not estimable; NR, not reached.

At the 8-month median follow-up, among the 23 patients who exhibited an intracranial response, 78% of patients in the 90-mg arm and 68% of patients in the 90→180-mg arm maintained a response for at least 4 months.

**ALUNBRIG is the only ALK inhibitor with a one-tablet, once-daily recommended dosing regimen that can be taken with or without food.[e]**

[e]The recommended dosing regimen is 90 mg orally once daily for the first 7 days. If tolerated during the first 7 days, increase dose to 180 mg orally once daily.

Visit **ALUNBRIG.com** to learn more.

## IMPORTANT SAFETY INFORMATION (continued)

### ADVERSE REACTIONS

Serious adverse reactions occurred in 38% of patients in the 90 mg group and 40% of patients in the 90→180 mg group. The most common serious adverse reactions were pneumonia (5.5% overall, 3.7% in the 90 mg group, and 7.3% in the 90→180 mg group) and ILD/pneumonitis (4.6% overall, 1.8% in the 90 mg group and 7.3% in the 90→180 mg group). Fatal adverse reactions occurred in 3.7% of patients and consisted of pneumonia (2 patients), sudden death, dyspnea, respiratory failure, pulmonary embolism, bacterial meningitis and urosepsis (1 patient each).

The most common adverse reactions (≥25%) in the 90 mg group were nausea (33%), fatigue (29%), headache (28%), and dyspnea (27%) and in the 90→180 mg group were nausea (40%), diarrhea (38%), fatigue (36%), cough (34%), and headache (27%).

### DRUG INTERACTIONS

**CYP3A Inhibitors:** Avoid concomitant use of ALUNBRIG with strong CYP3A inhibitors. Avoid grapefruit or grapefruit juice as it may also increase plasma concentrations of brigatinib. If concomitant use of a strong CYP3A inhibitor is unavoidable, reduce the dose of ALUNBRIG.

**CYP3A Inducers:** Avoid concomitant use of ALUNBRIG with strong CYP3A inducers.

**CYP3A Substrates:** Coadministration of ALUNBRIG with CYP3A substrates, including hormonal contraceptives, can result in decreased concentrations and loss of efficacy of CYP3A substrates.

### USE IN SPECIFIC POPULATIONS

**Pregnancy:** ALUNBRIG can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus.

**Lactation:** There are no data regarding the secretion of brigatinib in human milk or its effects on the breastfed infant or milk production. Because of the potential adverse reactions in breastfed infants, advise lactating women not to breastfeed during treatment with ALUNBRIG.

**Females and Males of Reproductive Potential:**

*Contraception:* Advise females of reproductive potential to use effective non-hormonal contraception during treatment with ALUNBRIG and for at least 4 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with ALUNBRIG and for at least 3 months after the final dose.

*Infertility:* ALUNBRIG may cause reduced fertility in males.

**Pediatric Use:** The safety and efficacy of ALUNBRIG in pediatric patients have not been established.

**Geriatric Use:** Clinical studies of ALUNBRIG did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently from younger patients. Of the 222 patients in ALTA, 19.4% were 65-74 years and 4.1% were 75 years or older. No clinically relevant differences in safety or efficacy were observed between patients ≥65 and younger patients.

**Hepatic or Renal Impairment:** No dose adjustment is recommended for patients with mild hepatic impairment or mild or moderate renal impairment. The safety of ALUNBRIG in patients with moderate or severe hepatic impairment or severe renal impairment has not been studied.

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

**References: 1.** Ahn M-J, Camidge DR, Tiseo M, et al. Oral presentation presented at: IASLC 18th World Conference on Lung Cancer; October 15-17, 2017; Yokohama, Japan. Abstract 8027. **2.** Ou S-HI, Tiseo M, Camidge DR, et al. Poster presented at the: Annual Congress of the European Society of Medical Oncology; September 8-12, 2017; Madrid, Spain. Poster 1345P.

Takeda ONCOLOGY



ALUNBRIG®
BRIGATINIB
180mg | 90mg | 30mg
TABLETS

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**
**These highlights do not include all the information needed to use ALUNBRIG safely and effectively. See full prescribing information for ALUNBRIG.**

**ALUNBRIG™ (brigatinib) tablets, for oral use**
**Initial U.S. Approval: 2017**

## 1 INDICATIONS AND USAGE

ALUNBRIG is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Interstitial Lung Disease (ILD)/Pneumonitis

Severe, life-threatening, and fatal pulmonary adverse reactions consistent with interstitial lung disease (ILD)/pneumonitis have occurred with ALUNBRIG.

In Trial ALTA (ALTA), ILD/pneumonitis occurred in 3.7% of patients in the 90 mg group (90 mg once daily) and 9.1% of patients in the 90→180 mg group (180 mg once daily with 7-day lead-in at 90 mg once daily).

Adverse reactions consistent with possible ILD/pneumonitis occurred early (within 9 days of initiation of ALUNBRIG; median onset was 2 days) in 6.4% of patients, with Grade 3 to 4 reactions occurring in 2.7%.

Monitor for new or worsening respiratory symptoms (e.g., dyspnea, cough, etc.), particularly during the first week of initiating ALUNBRIG. Withhold ALUNBRIG in any patient with new or worsening respiratory symptoms, and promptly evaluate for ILD/pneumonitis or other causes of respiratory symptoms (e.g., pulmonary embolism, tumor progression, and infectious pneumonia). For Grade 1 or 2 ILD/pneumonitis, either resume ALUNBRIG with dose reduction after recovery to baseline or permanently discontinue ALUNBRIG. Permanently discontinue ALUNBRIG for Grade 3 or 4 ILD/pneumonitis or recurrence of Grade 1 or 2 ILD/pneumonitis.

### 5.2 Hypertension

In ALTA, hypertension was reported in 11% of patients in the 90 mg group who received ALUNBRIG and 21% of patients in the 90→180 mg group. Grade 3 hypertension occurred in 5.9% of patients overall.

Control blood pressure prior to treatment with ALUNBRIG. Monitor blood pressure after 2 weeks and at least monthly thereafter during treatment with ALUNBRIG. Withhold ALUNBRIG for Grade 3 hypertension despite optimal antihypertensive therapy. Upon resolution or improvement to Grade 1 severity, resume ALUNBRIG at a reduced dose. Consider permanent discontinuation of treatment with ALUNBRIG for Grade 4 hypertension or recurrence of Grade 3 hypertension.

Use caution when administering ALUNBRIG in combination with antihypertensive agents that cause bradycardia.

### 5.3 Bradycardia

Bradycardia can occur with ALUNBRIG. In ALTA, heart rates less than 50 beats per minute (bpm) occurred in 5.7% of patients in the 90 mg group and 7.6% of patients in the 90→180 mg group. Grade 2 bradycardia occurred in 1 (0.9%) patient in the 90 mg group.

Monitor heart rate and blood pressure during treatment with ALUNBRIG. Monitor patients more frequently if concomitant use of drug known to cause bradycardia cannot be avoided.

For symptomatic bradycardia, withhold ALUNBRIG and review concomitant medications for those known to cause bradycardia. If a concomitant medication known to cause bradycardia is identified and discontinued or dose adjusted, resume ALUNBRIG at the same dose following resolution of symptomatic bradycardia; otherwise, reduce the dose of ALUNBRIG following resolution of symptomatic bradycardia. Discontinue ALUNBRIG for life-threatening bradycardia if no contributing concomitant medication is identified.

### 5.4 Visual Disturbance

In ALTA, adverse reactions leading to visual disturbance including blurred vision, diplopia, and reduced visual acuity, were reported in 7.3% of patients receiving ALUNBRIG in the 90 mg group and 10% of patients in the 90→180 mg group. Grade 3 macular edema and cataract occurred in one patient each in the 90→180 mg group.

Advise patients to report any visual symptoms. Withhold ALUNBRIG and obtain an ophthalmologic evaluation in patients with new or worsening visual symptoms of Grade 2 or greater severity. Upon recovery of Grade 2 or Grade 3 visual disturbances to Grade 1 severity or baseline, resume ALUNBRIG at a reduced dose. Permanently discontinue treatment with ALUNBRIG for Grade 4 visual disturbances.

### 5.5 Creatine Phosphokinase (CPK) Elevation

In ALTA, creatine phosphokinase (CPK) elevation occurred in 27% of patients receiving ALUNBRIG in the 90 mg group and 48% of patients in the 90 mg→180 mg group. The incidence of Grade 3-4 CPK elevation was 2.8% in the 90 mg group and 12% in the 90→180 mg group.

Dose reduction for CPK elevation occurred in 1.8% of patients in the 90 mg group and 4.5% in the 90→180 mg group.

Advise patients to report any unexplained muscle pain, tenderness, or weakness. Monitor CPK levels during ALUNBRIG treatment. Withhold ALUNBRIG for Grade 3 or 4 CPK elevation. Upon resolution or recovery to Grade 1 or baseline, resume ALUNBRIG at the same dose or at a reduced dose.

### 5.6 Pancreatic Enzyme Elevation

In ALTA, amylase elevation occurred in 27% of patients in the 90 mg group and 39% of patients in the 90→180 mg group. Lipase elevations occurred in 21% of patients in the 90 mg group and 45% of patients in the 90→180 mg group. Grade 3 or 4 amylase elevation occurred in 3.7% of patients in the 90 mg group and 2.7% of patients in the 90→180 mg group. Grade 3 or 4 lipase elevation occurred in 4.6% of patients in the 90 mg group and 5.5% of patients in the 90→180 mg group.

Monitor lipase and amylase during treatment with ALUNBRIG. Withhold ALUNBRIG for Grade 3 or 4 pancreatic enzyme elevation. Upon resolution or recovery to Grade 1 or baseline, resume ALUNBRIG at the same dose or at a reduced dose.

### 5.7 Hyperglycemia

In ALTA, 43% of patients who received ALUNBRIG experienced new or worsening hyperglycemia. Grade 3 hyperglycemia, based on laboratory assessment of serum fasting glucose levels, occurred in 3.7% of patients. Two of 20 (10%) patients with diabetes or glucose intolerance at baseline required initiation of insulin while receiving ALUNBRIG.

Assess fasting serum glucose prior to initiation of ALUNBRIG and monitor periodically thereafter. Initiate or optimize anti-hyperglycemic medications as needed. If adequate hyperglycemic control cannot be achieved with optimal medical management, withhold ALUNBRIG until adequate hyperglycemic control is achieved and consider reducing the dose of ALUNBRIG or permanently discontinuing ALUNBRIG.

### 5.8 Embryo-Fetal Toxicity

Based on its mechanism of action and findings in animals, ALUNBRIG can cause fetal harm when administered to pregnant women. There are no clinical data on the use of ALUNBRIG in pregnant women. Administration of brigatinib to pregnant rats during the period of organogenesis resulted in dose-related skeletal anomalies at doses as low as 12.5 mg/kg/day (approximately 0.7 times the human exposure by AUC at 180 mg once daily) as well as increased post implantation loss, malformations, and decreased fetal body weight at doses of 25 mg/kg/day (approximately 1.26 times the human exposure at 180 mg once daily) or higher.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with ALUNBRIG and for at least 4 months following the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose of ALUNBRIG.

## 6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the prescribing information:

- Interstitial Lung Disease (ILD)/Pneumonitis
- Hypertension
- Bradycardia
- Visual Disturbance
- Creatine Phosphokinase (CPK) Elevation
- Pancreatic Enzyme Elevation
- Hyperglycemia

### 6.1 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.

The safety of ALUNBRIG was evaluated in 219 patients with locally advanced or metastatic ALK-positive non-small cell lung cancer (NSCLC) who received at least one dose of ALUNBRIG in ALTA after experiencing disease progression on crizotinib. Patients received ALUNBRIG 90 mg once daily continuously (90 mg group) or 90 mg once daily for 7 days followed by 180 mg once daily (90→180 mg group). The median duration of treatment was 7.5 months in the 90 mg group and 7.8 months in the 90→180 mg group. A total of 150 (68%) patients were exposed to ALUNBRIG for greater than or equal to 6 months and 42 (19%) patients were exposed for greater than or equal to one year.

The study population characteristics were: median age 54 years (range: 18 to 82), age less than 65 years (77%), female (57%), White (67%), Asian (31%), Stage IV disease (98%), NSCLC adenocarcinoma histology (97%), never or former smoker (95%), ECOG Performance Status (PS) 0 or 1 (93%), and brain metastases at baseline (69%).

Serious adverse reactions occurred in 38% of patients in the 90 mg group and 40% of patients in the 90→180 mg group. The most common serious adverse reactions were pneumonia (5.5% overall, 3.7% in the 90 mg group, and 7.3% in the 90→180 mg group) and ILD/pneumonitis (4.6% overall, 1.8% in the 90 mg group and 7.3% in the 90→180 mg group). Fatal adverse reactions occurred in 3.7% of patients and consisted of pneumonia (2 patients), sudden death, dyspnea, respiratory failure, pulmonary embolism, bacterial meningitis and urosepsis (1 patient each).

In ALTA, 2.8% of patients in the 90 mg group and 8.2% of patients in the 90→180 mg group permanently discontinued ALUNBRIG for adverse reactions. The most frequent adverse reactions that led to discontinuation were ILD/pneumonitis (0.9% in the 90 mg group and 1.8% in the 90→180 mg group) and pneumonia (1.8% in the 90→180 mg group only).

In ALTA, 14% of patients required a dose reduction due to adverse reactions (7.3% in the 90 mg group and 20% in the 90→180 mg group). The most common adverse reaction that led to dose reduction was increased creatine phosphokinase for both regimens (1.8% in the 90 mg group and 4.5% in the 90→180 mg group).

Table 3 and Table 4 summarize the common adverse reactions and laboratory abnormalities observed in ALTA.

**Table 3: Adverse Reactions in ≥ 10% (All Grades*) or ≥ 2% (Grades 3-4) of Patients by Dose Group in ALTA (N=219)**

| Adverse Reactions | 90 mg once daily N=109 | | 90→180 mg once daily N=110 | |
|---|---|---|---|---|
| | All Grades (%) | Grades 3-4 (%) | All Grades (%) | Grades 3-4 (%) |
| **Gastrointestinal Disorders** | | | | |
| Nausea | 33 | 0.9 | 40 | 0.9 |
| Diarrhea | 19 | 0 | 38 | 0 |
| Vomiting | 24 | 1.8 | 23 | 0 |
| Constipation | 19 | 0.9 | 15 | 0 |
| Abdominal Pain† | 17 | 0 | 10 | 0 |
| **General Disorders And Administration Site Conditions** | | | | |
| Fatigue‡ | 29 | 1.8 | 36 | 0 |
| Pyrexia | 14 | 0 | 6.4 | 0.9 |
| **Respiratory, Thoracic And Mediastinal Disorders** | | | | |
| Cough | 18 | 0 | 34 | 0 |
| Dyspnea§ | 27 | 2.8 | 21 | 1.8‡‡ |
| ILD/Pneumonitis | 3.7 | 1.8 | 9.1 | 2.7 |
| Hypoxia | 0.9 | 0 | 2.7 | 2.7 |
| **Nervous System Disorders** | | | | |
| Headache¶ | 28 | 0 | 27 | 0.9 |
| Peripheral Neuropathy# | 13 | 0.9 | 13 | 1.8 |
| **Skin And Subcutaneous Tissue Disorders** | | | | |
| Rashᵖ | 15 | 1.8 | 24 | 3.6 |
| **Vascular Disorders** | | | | |
| Hypertension | 11 | 5.5 | 21 | 6.4 |
| **Musculoskeletal And Connective Tissue Disorders** | | | | |
| Muscle Spasms | 12 | 0 | 17 | 0 |
| Back pain | 10 | 1.8 | 15 | 1.8 |
| Myalgia** | 9.2 | 0 | 15 | 0.9 |
| Arthralgia | 14 | 0.9 | 14 | 0 |
| Pain in extremity | 11 | 0 | 3.6 | 0.9 |
| **Metabolism And Nutrition Disorders** | | | | |
| Decreased Appetite | 22 | 0.9 | 15 | 0.9 |
| **Eye Disorders** | | | | |
| Visual Disturbance†† | 7.3 | 0 | 10 | 0.9 |
| **Infections** | | | | |
| Pneumonia | 4.6 | 2.8‡‡ | 10 | 5.5‡‡ |
| **Psychiatric Disorders** | | | | |
| Insomnia | 11 | 0 | 7.3 | 0 |

*Per National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) version 4.0
†Includes abdominal distension, abdominal pain, and epigastric discomfort
‡Includes asthenia and fatigue
§Includes dyspnea and exertional dyspnea
¶Includes headache and sinus headache
#Includes peripheral sensory neuropathy and paresthesia
ᵖIncludes acneiform dermatitis, exfoliative rash, rash, pruritic rash, and pustular rash
**Includes musculoskeletal pain and myalgia
††Includes diplopia, photophobia, blurred vision, reduced visual acuity, visual impairment, vitreous floaters, visual field defect, macular edema, and vitreous detachment
‡‡Includes one Grade 5 event

**Table 4: Laboratory Abnormalities in ≥20% (All Grades*) of Patients by Regimen in ALTA (N=219)**

| Laboratory Abnormality | 90 mg once daily N= 109 | | 90→180 mg once daily N=110 | |
|---|---|---|---|---|
| | All Grades (%) | Grades 3-4 (%) | All Grades (%) | Grades 3-4 (%) |
| **Chemistry** | | | | |
| Increased aspartate aminotransferase | 38 | 0.9 | 65 | 0 |
| Hyperglycemia† | 38 | 3.7 | 49 | 3.6 |
| Increased creatine phosphokinase | 27 | 2.8 | 48 | 12 |
| Increased lipase | 21 | 4.6 | 45 | 5.5 |
| Increased alanine aminotransferase | 34 | 0 | 40 | 2.7 |
| Increased amylase | 27 | 3.7 | 39 | 2.7 |
| Increased alkaline phosphatase | 15 | 0.9 | 29 | 0.9 |
| Decreased phosphorous | 15 | 1.8 | 23 | 3.6 |
| Prolonged activated partial thromboplastin time | 22 | 1.8 | 20 | 0.9 |
| **Hematology** | | | | |
| Anemia | 23 | 0.9 | 40 | 0.9 |
| Lymphopenia | 19 | 2.8 | 27 | 4.5 |

*Per CTCAE version 4.0
†Elevated blood insulin was also observed in both regimens

## 7 DRUG INTERACTIONS

### 7.1 Drugs That May Increase Brigatinib Plasma Concentrations

Strong CYP3A Inhibitors

Coadministration of itraconazole, a strong CYP3A inhibitor, increased brigatinib plasma concentrations and may result in increased adverse reactions. Avoid the concomitant use of strong CYP3A inhibitors with ALUNBRIG, including but not limited to certain antivirals (e.g., boceprevir, cobicistat, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir), macrolide antibiotics (e.g., clarithromycin), antifungals (e.g., itraconazole, ketoconazole, posaconazole, voriconazole), and conivaptan. Avoid grapefruit or grapefruit juice as it may also increase plasma concentrations of brigatinib. If concomitant use of a strong CYP3A inhibitor cannot be avoided, reduce the dose of ALUNBRIG by approximately 50%.

### 7.2 Drugs That May Decrease Brigatinib Plasma Concentrations

Strong CYP3A Inducers

Coadministration of ALUNBRIG with rifampin, a strong CYP3A inducer, decreased brigatinib plasma concentrations and may result in decreased efficacy. Avoid the concomitant use of strong CYP3A inducers with ALUNBRIG, including but not limited to rifampin, carbamazepine, phenytoin, and St. John's Wort.

### 7.3 Drugs That May Have Their Plasma Concentrations Altered by Brigatinib

CYP3A Substrates

Brigatinib induces CYP3A in vitro and may decrease concentrations of CYP3A substrates. Coadministration of ALUNBRIG with CYP3A substrates, including hormonal contraceptives, can result in decreased concentrations and loss of efficacy of CYP3A substrates.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Risk Summary

Based on its mechanism of action and findings in animals, ALUNBRIG can cause fetal harm when administered to a pregnant woman. There are no clinical data on the use of ALUNBRIG in pregnant women. Administration of brigatinib to pregnant rats during the period of organogenesis resulted in dose-related skeletal anomalies at doses as low as 12.5 mg/kg/day (approximately 0.7 times the human exposure by AUC at 180 mg once daily) as well as increased post-implantation loss, malformations, and decreased fetal body weight at doses of 25 mg/kg/day (approximately 1.26 times the human exposure at 180 mg once daily) or greater. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, advise the patient of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

*Animal Data*

In an embryo-fetal development study in which pregnant rats were administered daily doses of brigatinib during organogenesis, dose-related skeletal (incomplete ossification, small incisors) and visceral anomalies were observed at doses as low as 12.5 mg/kg/day (approximately 0.7 times the human exposure by AUC at 180 mg once daily). Malformations observed at 25 mg/kg/day (approximately 1.26 times the human AUC at 180 mg once daily) included anasarca (generalized subcutaneous edema), anophthalmia (absent eyes), forelimb hyperflexion, small, short and/or bent limbs, multiple fused ribs, bent scapulae, omphalocele (intestine protruding into umbilicus), and gastroschisis (intestines protruding through a defect in the abdominal wall) along with visceral findings of moderate bilateral dilatation of the lateral ventricles.

### 8.2 Lactation

Risk Summary

There are no data regarding the secretion of brigatinib in human milk or its effects on the breastfed infant or milk production. Because of the potential for adverse reactions in breastfed infants, advise lactating women not to breastfeed during treatment with ALUNBRIG and for 1 week following the final dose.

### 8.3 Females and Males of Reproductive Potential

Contraception

ALUNBRIG can cause fetal harm.

*Females*

Advise females of reproductive potential to use effective non-hormonal contraception during treatment with ALUNBRIG and for at least 4 months after the final dose. Counsel patients to use a non-hormonal method of contraception since ALUNBRIG can render some hormonal contraceptives ineffective.

*Males*

Because of the potential for genotoxicity, advise males with female partners of reproductive potential to use effective contraception during treatment with ALUNBRIG and for at least 3 months after the final dose.

Infertility

Based on findings in male reproductive organs in animals, ALUNBRIG may cause reduced fertility in males.

### 8.4 Pediatric Use

The safety and efficacy of ALUNBRIG in pediatric patients have not been established.

### 8.5 Geriatric Use

Clinical studies of ALUNBRIG did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently from younger patients. Of the 222 patients in ALTA, 19.4% were 65-74 years and 4.1% were 75 years or older. No clinically relevant differences in safety or efficacy were observed between patients ≥65 years and younger patients.

### 8.6 Hepatic Impairment

No dose adjustment is recommended for patients with mild hepatic impairment (total bilirubin within upper limit of normal [ULN] and AST greater than ULN or total bilirubin greater than 1 and up to 1.5 times ULN and any AST). The pharmacokinetics and safety of ALUNBRIG in patients with moderate or severe hepatic impairment have not been studied.

### 8.7 Renal Impairment

No dose adjustment is recommended for patients with mild and moderate renal impairment [creatinine clearance ($CL_{cr}$) 30 to 89 mL/min estimated by Cockcroft-Gault)]. The pharmacokinetics and safety of ALUNBRIG in patients with severe renal impairment ($CL_{cr}$ 15 to 29 mL/min estimated by Cockcroft-Gault) have not been studied.

## 17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Inform patients of the following:

Interstitial Lung Disease (ILD)/Pneumonitis

Inform patients of the symptoms and risks of serious pulmonary adverse reactions such as ILD/pneumonitis. Advise patients to immediately report any new or worsening respiratory symptoms.

Hypertension

Advise patients of risks of hypertension and to promptly report signs or symptoms of hypertension.

Bradycardia

Advise patients to report any symptoms of bradycardia and to inform their healthcare provider about the use of heart and blood pressure medications.

Visual Disturbance

Advise patients to inform their healthcare provider of any new or worsening vision symptoms.

Creatine Phosphokinase (CPK) Elevation

Inform patients of the signs and symptoms of creatinine phosphokinase (CPK) elevation and the need for monitoring during treatment. Advise patients to inform their healthcare provider of any new or worsening symptoms of unexplained muscle pain, tenderness, or weakness.

Pancreatic Enzyme Elevation

Inform patients of the signs and symptoms of pancreatitis and the need to monitor for amylase and lipase elevations during treatment.

Hyperglycemia

Inform patients of the risks of new or worsening hyperglycemia and the need to periodically monitor glucose levels. Advise patients with diabetes mellitus or glucose intolerance that anti-hyperglycemic medications may need to be adjusted during treatment with ALUNBRIG.

Females and Males of Reproductive Potential

*Embryo-Fetal Toxicity*

Advise females and males of reproductive potential that ALUNBRIG can cause fetal harm.

- Advise females of reproductive potential to inform their healthcare provider of a known or suspected pregnancy and to use effective non-hormonal contraception during treatment with ALUNBRIG and for at least 4 months after the final dose.
- Advise males with female partners of reproductive potential to use effective contraception during treatment with ALUNBRIG and for at least 3 months after the final dose.

*Lactation*

Advise females not to breastfeed during treatment with ALUNBRIG and for at least 1 week following the final dose.

*Infertility*

Advise males of reproductive potential of the potential for reduced fertility from ALUNBRIG.

Drug Interactions

Advise patients to inform their health care provider of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, and herbal products. Inform patients to avoid grapefruit or grapefruit juice while taking ALUNBRIG.

Dosing and Administration

Instruct patients to start with 90 mg of ALUNBRIG once daily for the first 7 days and if tolerated, increase the dose to 180 mg once daily. Advise patients to take ALUNBRIG with or without food.

Missed Dose

Advise patients that if a dose of ALUNBRIG is missed or if the patient vomits after taking a dose of ALUNBRIG, not to take an extra dose, but to take the next dose at the regular time.

**Please see full Prescribing Information for ALUNBRIG at ALUNBRIG.com.**

Manufactured for:
ARIAD Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited
Cambridge, MA


01/18 MAT-US-BRG-18-00095

# ASCO's Quality Innovation Programs and Resources Improve Patient Care

Hematology-oncology and medical oncology practices in many settings and countries are improving patient care delivery using ASCO's quality programs and resources, including ASCO's Quality Oncology Practice Initiative (QOPI®). More than 900 oncology practices have participated since its creation in 2006 to help providers assess the quality of care provided to patients.

"We have QOPI measures that practices can use as benchmarking tools to compare their performance against other practices," ASCO's Vice President of Clinical Affairs Stephen S. Grubbs, MD, FASCO, said. "If practices score high on QOPI measures, they can proceed to our QOPI Certification Program. If they identify gaps in care and want to improve the quality of care, they can enroll in our Quality Training Program. Finally, they can use the QOPI Reporting Registry to report on quality measures to the Centers for Medicare and Medicaid Services [CMS]."

Quality reporting is no longer optional for practices receiving Medicare payment from CMS. Practices must report annually on six CMS-approved quality measures and sample more than half of their patient records eligible for each measure to avoid a negative adjustment of their Medicare fee schedule, Dr. Grubbs said. As of 2018, the QOPI Reporting Registry, a joint project with the American Society for Radiation Oncology (ASTRO), has 25 CMS-approved quality measures from which the practices can choose. The QOPI Reporting Registry also allows practices to submit a high volume of patient data electronically to CMS and earn points for their CMS Merit-based Incentive Payment System (MIPS) score, Dr. Grubbs said.


Dr. Stephen S. Grubbs

ASCO's QOPI Steering Group is reviewing the estimated 190 QOPI measures that practices use as benchmarking tools to ensure that they are still relevant, perform well, and can be abstracted electronically. "We expect to complete our current review this spring and then we will schedule regular reviews of all measures," John Hamm, MD, of Norton Healthcare and chair of the QOPI Steering Group, said.


Dr. Robert D. Siegel


Dr. John Hamm

### Benefits of QOPI Certification

Since the program began in 2010, more than 300 oncology practices have achieved QOPI Certification, which is a 3-year process. These practices have scored well on key QOPI quality measures and have demonstrated compliance with the QOPI Certification standards, a subset of the ASCO/Oncology Nursing Society (ONS) chemotherapy safety standards.

"Our practice was QOPI Certified in 2015 and recertified in 2018, which enables us to participate in a process of ongoing organizational improvement without having to identify or create standards of our own," Robert D. Siegel, MD, FACP, of St. Francis Cancer Center and chair of the QOPI Certification Steering Group, said. "[QOPI] is a teambuilding exercise that optimizes quality and professionalism and creates a safer environment for our staff and our patients."

In January, ASCO updated the 26 standards addressing how chemotherapy is administered in the QOPI Certification Program. "ASCO maintains the value of the certification process because it allows the standards to evolve with changing practices. The revised standards have a more logical grouping of prior requirements and provide more guidance for the management of oral chemotherapy," Dr. Siegel said.

### International Certification

"About one-third of ASCO members practice oncology outside the United States," Dr. Hamm, who also serves on ASCO's International Quality Task Force, said. "ASCO is meeting the needs of these members by offering its expertise and quality programs internationally," which it has done since 2013.

In January, Clínica AMO, an outpatient cancer clinic network based in Brazil, became the second oncology practice in the country and the sixth international practice to receive QOPI Certification since 2013.

"To meet QOPI requirements, our team had to implement new key steps in the process of patient care," Carlos Sampaio, MD, president of Clínica AMO, said. "As we are deeply committed to quality values and have developed a patient-centered culture, these changes were well accepted and supported by team members."

For example, a pain score was missing from the clinic's electronic health record. "When we added that piece of information, we began systematically recording patients' pain scores at every clinical visit. This has led to better pain management," Dr. Sampaio said.

Last September, three oncology hospital practices in Spain achieved QOPI Certification through a collaboration between ASCO and the Foundation for Excellence and Quality in Oncology (ECO), an organization formed by Spanish oncologists to globally analyze the specialty and improve the quality of care, according to Vincente Guillem, MD, PhD, president of ECO. ECO has offered all Spanish hospitals the chance to meet the QOPI/ASCO measures criteria since 2015 and QOPI Certification since 2017.


Dr. Carlos Sampaio


Dr. Vincente Guillem

"It was a historical moment because it was the first time that a Spanish hospital received ASCO's accreditation and only the third time any practice outside the United States had achieved this recognition," Dr. Guillem said. He is also head of the oncology department at Instituto Valenciano de Oncología, one of the three practices receiving the certification.

"As a result of their intensive work, these certified practices have demonstrated their commitment to quality to their staff and patients, the medical community, and to society," Dr. Guillem said.

ECO is currently working with ASCO to license the first Quality of Care Symposium for Europe in 2019. "We are very excited about this opportunity and are developing a dynamic symposium with experts, panel discussions, and abstract presentations similar to the ASCO Quality Care Symposium in the United States," Dr. Guillem said.

### Practice Improvement Through Quality Training

ASCO's Quality Training Program (QTP) is a 6-month, data-driven course in quality improvement for oncology providers who need to measure performance, investigate quality and safety issues, and implement change. This year, the QTP was offered for the first time in Miami in addition to ASCO Headquarters in Alexandria, Virginia, and more regional locations are planned in the future. Institutions can host regional sessions and/or a 1-day workshop, which is a condensed version of the 6-month course.

Valorie Harvey, MBA, of Parkland Health and Hospital Systems, and her multidisciplinary team participated in the QTP last year at ASCO Headquarters. "We planned to apply for QOPI Certification but knew that there would be a lot of heavy lifting to get to where we wanted to be. We also are participating in the CMS Oncology Care Model pilot program, which requires a practice redesign, and we thought the QTP would provide a framework to accomplish all of this."

Ms. Harvey has used the QTP framework to implement small- and large-scale projects. "We learned to use objective and quantifiable data that can be tailored to different audiences for engagement and buy-in. Once you know the process, you can use it repeatedly. We have already completed three projects, with a fourth in progress," she said. For example, Ms. Harvey and her team worked closely with their information technology team to extract data from electronic

*See Innovation Programs, Page 10*

ASCO
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

**ASCO Daily News: Evening Edition**

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## Innovation Programs

*Continued from page 9*

ASCO QOPI® Certification Program

health records to identify a subset of patients who became sick after chemotherapy and ended up in the emergency room. They created a same-day acute care clinic to direct patients to the clinic for symptom management.

"Our goal was to improve the time to care as well as the patient experience while avoiding an unnecessary and costly emergency room visit," Ms. Harvey said.

Ms. Harvey enjoyed the training so much that she became a QTP coach after an invitation from ASCO. "My job is to be a resource, provide insight from my experience, and provide support to the assigned teams so they stay on track and have a successful experience," she said.

### ASCO Launches New Quality Resource

On March 6, 2018, ASCO launched Practice Central, an online resource with information and tools to help practices provide efficient, high-quality patient care. For more information about QOPI, QOPI Certification, the QOPI Reporting Registry, and the QTP, visit Practice Central at practice.asco.org. ●

**–Christine Lehmann, MA**

## Save the Date: 2018 ASCO Quality Care Symposium


The ASCO Quality Care Symposium brings together top leaders in the field of oncology to share strategies and methods for improving the measurement and implementation of quality and safety in cancer care. The dynamic 2-day Symposium features invited experts, panel discussions, and abstract presentations that promote innovation and collaboration in cancer-focused quality measurement and improvement and health services research.

The agenda for this year's Quality Care Symposium will include a mixture of educational and scientific presentations, including Oral Abstract Sessions. Presentations in past years have covered topics ranging from cost, value, and policy, to big data, benchmarking, and transitioning to new care models. The Symposium also serves as an opportunity for attendees to network and collaborate with attendees across the cancer care continuum.

"We are planning some exciting sessions on quality measurement and improvement and person-centered care from different perspectives from years past," Symposium Planning Committee Chair Monika Krzyzanowska, MD, MPH, FRCPC, said. "The Symposium is an excellent opportunity for those interested in health care quality, whether they are new to the field or have been working in it for some time."

**Dr. Monika Krzyzanowska**

The 2018 ASCO Quality Care Symposium will take place September 28 and 29 in Phoenix, and registration is now open. The abstract submission deadline is June 12, 2018, at 11:59 PM EDT. For more information, visit quality.asco.org. ●

ASCO Quality Care Symposium

# Dr. John Mendelsohn to Receive ASCO's Distinguished Achievement Award

John Mendelsohn, MD, is internationally renowned for his contributions to basic science and clinical trials that helped explicate the role of EGFRs on cancer cell proliferation. These efforts have led to significant improvements in mortality, morbidity, and quality of life for countless patients.

In recognition of this and other numerous career accomplishments, Dr. Mendelsohn is being honored with ASCO's Distinguished Achievement Award, which recognizes an individual who has provided leadership or mentorship benefitting ASCO members and their patients.

From 1976 to 1985, Dr. Mendelsohn served as a founding director of a National Cancer Institute–designated cancer center at the University of California, San Diego. He then spent the next 11 years at Memorial Sloan Kettering Cancer Center, where he was chair of the Department of Medicine and led the Program in Molecular Pharmacology and Therapeutics. From 1996 to 2011, Dr. Mendelsohn served as president of The University of Texas MD Anderson Cancer Center. He continues to serve as co-director of MD Anderson's Sheikh Khalifa Bin Zayed Al Nahyan Institute for Personalized Cancer Therapy.

**Dr. John Mendelsohn**

In the following interview, Dr. Mendelsohn reflects on his career and how he sees the future of oncology research.

**Q: You've had an incredibly long, distinguished career. What are your keys to success?**

**Dr. Mendelsohn:** A big part of it was having the right people around me. While I was with MD Anderson, we were very fortunate. The funding sources and commitment from the researchers—it came together at the right time. It was not a one-person shop that I should get credit for. Our entire research group involved roughly 30 cancer programs.

It was also a good time because the amount of energy and resources put into expanding cancer research had doubled in less than a decade. We had the opportunities to expand, and we had the resources and commitment to make that happen. In that way, the timing was very fortunate.

**Q: What do you hope you are remembered for when the field looks back at your work?**

**Dr. Mendelsohn:** On one hand, you'd like to help improve patient care so that people who used to die from the disease are cured or are living longer. In 1963, when I first began, only one out of every three patients diagnosed with

*See Distinguished Achievement Award, Page 20*

# Shaping Real Careers With Virtual Mentorship

Of the many activities ASCO conducts to improve global cancer care, one of the most recent additions is the Virtual Mentors program. This program pairs a mentee oncologist from a low- or middle-income country (LMIC) with a mentor from a high-income country and facilitates clinical and/or research collaborations between the pair, possibly for a long-term future.

When the pilot mentor program launched in 2015, I was extremely excited about it. This program represented a wonderful opportunity to learn from world-class experts on a one-on-one basis without actually having to spend a dollar or travel a mile. What more could one ask for? I was delighted when I was selected for the pilot program, becoming one of the very first mentees in the ASCO Virtual Mentors program.

I was paired with Mahesh Y. Iddawela, MBBS, FRACP, MRCP, a mentor based in Australia, and we discussed various career paths including both clinical and research activities. I was receiving my training in Japan, so clinical knowledge as such was not an issue, but implementing that knowledge in the setting of a low-income country, Nepal, was a big challenge. Dr. Iddawela, who is originally from Sri Lanka, understood this well, so it was easy to discuss these issues.

Another challenge for me was academic research and publication. I had come from a medical schooling culture in Nepal, where conducting research and publishing in medical journals were essentially nonexistent, to Japan, where patience is considered the utmost virtue. Thus, despite having interests and ideas on cancer policy and global oncology, I was not active in academics. Not having an English-speaking mentor around didn't help either. Being accepted into the ASCO Virtual Mentors program changed my career completely. Once I started having conversations with Dr. Iddawela about various ideas that I had, I started to become more proactive and we began working on a few papers. Three such papers have been published in major oncology journals. I learned a career-defining lesson from this experience: I didn't have to think locally; I could think globally and chase any dream I had.

Indeed, oncologists from LMICs usually don't have the means or

**Dr. Bishal Gyawali**

confidence to dream beyond our borders. Through the Virtual Mentors program, I gained the confidence to speak out about my ideas and ambitions and seek out the means to make them come true. I understood the importance of online platforms to make connections and build collaborations. The program taught me that no dream was too big to chase. That inspiration was the most important takeaway from the virtual mentor experience.

Using that experience and confidence, I now have many virtual mentors. Thus, the ASCO program didn't just give me one mentor—it taught me the skills and gave me the means to connect with all the mentors that I need. Today, I have collaborations with mentors and colleagues from a number of institutions and countries, including the United States, Canada, the United Kingdom, Italy, Australia, Japan, and Nepal. These collaborations have led to me authoring and co-authoring more than 40 journal articles—all within the past 3 years.

These papers are not the only marker of success. Participating in the ASCO Virtual Mentors program informed me more about ASCO's international activities. As a result, I also applied to and was selected for the *Journal of Global Oncology* Editorial Fellowship this year.

I hope to use the skills, knowledge, and experience I have gained through the program to improve cancer care in my own country and also around the world. Using my firsthand experience with cancer care in low-, middle-, and high-income countries, I collaborate with colleagues from Nepal, India, and parts of South America to discuss challenges and help with cancer cases and research activities. Using online tools, I have now participated in tumor boards for many hospitals in LMICs and shared my experience. My belief is that all of us can be virtual mentors and mentees in our own ways. When I try to imagine my career path without the Virtual Mentors opportunity, I realize that there are many oncologists in the world who need this opportunity. Although I am still a trainee myself, I try to reach out to other colleagues and help them with whatever I can.

I encourage every oncologist from an LMIC to participate in ASCO's Virtual Mentors program, as it is a unique and life-defining experience. I also strongly encourage experienced oncologists from high-income countries to volunteer as mentors. In my case, I had to wait for a long time before ASCO found a mentor for me, and that was a little saddening. Prospective mentors should look at the Virtual Mentors program as an important opportunity to learn more about global oncology firsthand by discussing cases and careers with their mentees. Working in a high-resource setting, it is easy to forget how difficult it is to practice oncology in a resource-constrained setting without the help of modern investigations, drugs, or referral facilities. This can be a great learning opportunity for the mentee to embrace the progress from high-income countries and a humbling experience for the mentor to comprehend the gulf between the two parts of the world. Thus, it is more of a two-way experience rather than a one-way pedagogy.

When oncologists from high-income countries and LMICs work together, we have the best chance of addressing the common needs of patients with cancer across the globe.

The Virtual Mentors program is supported in part by the Conquer Cancer Foundation of ASCO. ●

**–Bishal Gyawali, MD**

Reprinted and adapted with permission from the 2017 September issue of *ASCO Connection*.

## Virtual Mentors Program: An Inside Look

As part of his involvement with ASCO's Virtual Mentors program, Bishal Gyawali, MD, became a mentor himself. He was paired with Sabrine Haddad, MD, a surgical oncologist with a special interest in breast cancer. Dr. Haddad is currently with Salah Azaiez Institute in Tunisia.

**Dr. Sabrine Haddad**

Although Dr. Haddad is new to the program, she is already convinced of its benefits. "This opportunity is life-changing in my career as a surgical oncologist," Dr. Haddad said. "Here in Tunisia, our medical studies are in French. Studying medical English to access scientific studies was very challenging, and I am still working on improving it. Dr. Gyawali was very kind and encouraged me to apply so that I could improve my writing skills."

As Dr. Haddad continues her education in her fellowship as an early-career surgical oncologist, working with Dr. Gyawali in the Virtual Mentors program gives her ample opportunity to use her medical English so she can be better prepared when she practices medicine in the United States—her ultimate goal. "I aim to find good opportunities to work as a trainee in oncology in the United States, especially in breast cancer," Dr. Haddad said.

Participating first as a mentee himself and now as a mentor, Dr. Gyawali has a unique perspective on the Virtual Mentors program and knows firsthand what Dr. Haddad is experiencing. "I know the difficulties mentees face, the expectations they have from their mentors, and the challenges in mentor-mentee communication," Dr. Gyawali said.

Additionally, both Dr. Gyawali and Dr. Haddad come from low- to middle-income countries, connecting them both personally and professionally. "I can understand the challenges she faces in her daily professional life, and I try to support her," Dr. Gyawali said. "Because I am now working in the United States, supporting her as a mentor helps me stay focused and always remember that there is a lot to be done for the global oncology community.

"Dr. Haddad is very proactive and energetic, is clear about her goals, and is pursuing bigger dreams despite the resource-limited settings she has been working in. Working with her inspires me in my own work and fills me with a sense of responsibility to give back to the global oncology community in whatever way I can, including mentorship like this," Dr. Gyawali continued.

For more information about the Virtual Mentors program, visit asco.org. ●

**–Renee Simpson**

# MOMENTS MATTER

## HALAVEN® is the first and only single agent to show a significant overall survival benefit in patients with third-line metastatic breast cancer[1-4]

HALAVEN improved median overall survival in metastatic breast cancer vs Treatment of Physician's Choice (TPC) updated OS analysis: (13.2 months vs 10.6 months) when following 2 prior chemotherapies for metastatic breast cancer.[4]

From the Phase III, randomized, open-label, multicenter, multinational Eisai Metastatic Breast Cancer Study Assessing Physician's Choice versus E7389 (Eribulin) (EMBRACE) trial of HALAVEN versus TPC in patients with mBC (N=762). Primary endpoint was OS.[1,4]

**Results of the updated analysis, conducted when 77% of events (deaths) had been observed, were consistent with the primary analysis**, which was conducted when ~50% of events (deaths) had been observed. HALAVEN demonstrated a median OS of 13.1 months (95% CI: 11.8, 14.3, 274 deaths) vs 10.6 months with the TPC arm (95% CI: 9.3, 12.5, 148 deaths), hazard ratio (HR)=0.81 (95% CI: 0.66, 0.99) (*P*=0.041).[1,4]

OS=overall survival; CI=confidence interval.

### Indication

**Metastatic Breast Cancer**

HALAVEN (eribulin mesylate) Injection is indicated for the treatment of patients with metastatic breast cancer (mBC) who have previously received at least 2 chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.

### Selected Safety Information

**Warnings and Precautions**

**Neutropenia:** Severe neutropenia (ANC <500/mm$^3$) lasting >1 week occurred in 12% of patients with mBC. Febrile neutropenia occurred in 5% of patients with mBC and 2 patients (0.4%) died from complications. Patients with mBC with elevated liver enzymes >3 × ULN and bilirubin >1.5 × ULN experienced a higher incidence of Grade 4 neutropenia and febrile neutropenia than patients with normal levels. Monitor complete blood cell counts prior to each dose, and increase the frequency of monitoring in patients who develop Grade 3 or 4 cytopenias. Delay administration and reduce subsequent doses in patients who experience febrile neutropenia or Grade 4 neutropenia lasting >7 days.

**Peripheral Neuropathy:** Grade 3 peripheral neuropathy occurred in 8% of patients with mBC (Grade 4=0.4%) and 22% developed a new or worsening neuropathy that had not recovered within a median follow-up duration of 269 days (range 25-662 days). Neuropathy lasting >1 year occurred in 5% of patients with mBC. Patients should be monitored for signs of peripheral motor and sensory neuropathy. Withhold HALAVEN in patients who experience Grade 3 or 4 peripheral neuropathy until resolution to Grade 2 or less.

**Embryo-Fetal Toxicity:** HALAVEN can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with HALAVEN and for at least 2 weeks following the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with HALAVEN and for 3.5 months following the final dose.

**QT Prolongation:** Monitor for prolonged QT intervals in patients with congestive heart failure, bradyarrhythmias, drugs known to prolong the QT interval, and electrolyte abnormalities. Correct hypokalemia or hypomagnesemia prior to initiating HALAVEN and monitor these electrolytes periodically during therapy. Avoid in patients with congenital long QT syndrome.

**Please see Selected Safety Information continued on the following page and adjacent brief summary of HALAVEN full Prescribing Information.**

# HALAVEN® offers a meaningful survival benefit and an established safety profile[4]

Visit us at booth **7025**

## HALAVEN is for patients with mBC

HALAVEN may be appropriate for your patients **who are ready for chemotherapy in third-line mBC** and who have received 2 prior chemotherapies for mBC. Their previous treatment should have included an anthracycline and a taxane in the adjuvant or metastatic setting.[4]

### Patients in the HALAVEN arm of the EMBRACE trial:

DEMONSTRATED

**13.2 months** (95% CI: 12.1, 14.4) Deaths=386

**MEDIAN OS** VS 10.6 MONTHS WITH THE TPC ARM* (95% CI: 9.2, 12.0) DEATHS=203[4]

**81.3%**

HAD **VISCERAL DISEASE**[5]

### A growing body of real-world experience

**Over 50,000 patients**

HAVE BEEN **PRESCRIBED HALAVEN** IN THE UNITED STATES[5†]

Number of patients at risk at measured timepoints were as follows[4]:

- **HALAVEN arm:** n=508 (month 0), 406 (month 6), 274 (month 12), 142 (month 18), 54 (month 24), 11 (month 30), and 0 (month 36)
- **TPC arm:** n=254 (month 0), 178 (month 6), 106 (month 12), 61 (month 18), 26 (month 24), 5 (month 30), and 0 (month 36)

NCCN®=National Comprehensive Cancer Network®.
*Therapies in the TPC arm consisted of 97% chemotherapy (26% vinorelbine, 18% gemcitabine, 18% capecitabine, 16% taxanes [including paclitaxel, docetaxel, nab-paclitaxel, and ixabepilone], 9% anthracyclines, and 10% other chemotherapy) and 3% hormone therapy.[1,4]
†Patient treatment based on estimate of average patient usage provided by IntrinsiQ® intelliVIEW™. Total number of vials from November 2010 to December 2017.

**ERIBULIN (HALAVEN) IS LISTED AS A PREFERRED SINGLE AGENT FOR mBC IN THE NCCN CLINICAL PRACTICE GUIDELINES IN ONCOLOGY (NCCN GUIDELINES®)[6]**

## Selected Safety Information

### Adverse Reactions

In patients with mBC receiving HALAVEN, the most common adverse reactions (≥25%) were neutropenia (82%), anemia (58%), asthenia/fatigue (54%), alopecia (45%), peripheral neuropathy (35%), nausea (35%), and constipation (25%). Febrile neutropenia (4%) and neutropenia (2%) were the most common serious adverse reactions. The most common adverse reaction resulting in discontinuation was peripheral neuropathy (5%).

### Use in Specific Populations

**Lactation:** Because of the potential for serious adverse reactions in breastfed infants from eribulin mesylate, advise women not to breastfeed during treatment with HALAVEN and for 2 weeks after the final dose.

**Hepatic and Renal Impairment:** A reduction in starting dose is recommended for patients with mild or moderate hepatic impairment and/or moderate or severe renal impairment.

**References: 1.** Cortes J, O'Shaughnessy J, Loesch D, et al; EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389) investigators. Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomised study. *Lancet*. 2011;377(9769):914-923. **2.** Saad ED, Katz A, Buyse M. Overall survival and post-progression survival in advanced breast cancer: a review of recent randomized clinical trials. *J Clin Oncol*. 2010;28(11):1958-1962. **3.** Sparano JA, Vrdoljak E, Rixe O, et al. Randomized phase III trial of ixabepilone plus capecitabine versus capecitabine in patients with metastatic breast cancer previously treated with an anthracycline and a taxane. *J Clin Oncol*. 2010;28(20):3256-3263. **4.** HALAVEN [package insert]. Woodcliff Lake, NJ: Eisai Inc; 2016. **5.** Data on file, Eisai Inc. **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.3.2017. © National Comprehensive Cancer Network, Inc. 2017. All rights reserved. Accessed January 31, 2018. To view the most recent and complete version of the guideline, go online to NCCN.org.

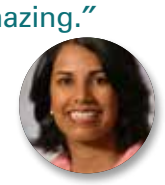


Halaven® (eribulin mesylate) Injection | 0.5 mg per mL

## WHAT IS YOUR FAVORITE PLACE TO GET A DRINK?

"The new City Winery Chicago on the Riverwalk. The people watching there is amazing."

**–Swati Kulkarni, MD, FACS**



"Allium at the Four Seasons because of the ambience and, for me in particular, exceptional nonalcoholic drink options as well."

**–Murtuza Rampurwala, MD, MPH**

"There are so many wonderful bars to choose from. The Aviary has some of the most creative cocktails I've ever had. It's worth a visit if you can get a reservation!"

**–Rita Nanda, MD**

# Texas Society of Clinical Oncology Makes Investment in Young Investigators

The Texas Society of Clinical Oncology (TxSCO) is one of the newest Young Investigator Award (YIA) supporters for ASCO's Conquer Cancer Foundation. An ASCO state affiliate, TxSCO currently has more than 600 members who represent a diverse array of oncology health providers in Texas.

"We are a collective to serve as a guiding force for cancer specialists and overall cancer care in Texas," Debra Patt, MD, MPH, MBA, secretary of TxSCO's Board of Directors, said.

TxSCO was founded in 1988 as the Texas Society of Medical Oncology but changed its name in 2011 to be more reflective and inclusive of the entire cancer care team. The organization espouses expanding the scope of practice toward a collaborative oncology model that incorporates advanced practice providers such as physician assistants and nurse practitioners. TxSCO's mission is to advocate for patients with cancer in the state of Texas and promote standards of excellence for high-quality cancer care. The organization presents a Leadership Day in the spring for members of the multidisciplinary care team and a larger Annual Conference in the fall organized by the Oncology State Society Network at the Association of Community Cancer Centers. For the fall Annual Conference, TxSCO promotes quality oncology research, including research by fellows who are awarded scholarships to attend.

**Dr. Debra Patt**

Advocacy is a key component of TxSCO's mission. The group advocates for cancer care at the state level while informing its membership of ASCO policy updates on the national scene. The salient issues that TxSCO has recently worked on include responding to the opioid crisis while ensuring that patients with cancer are appropriately palliated and introducing legislation to make unused pharmaceuticals available for cancer care.

The 2018 Conquer Cancer/Texas Society of Clinical Oncology YIA comports with TxSCO's goal to develop oncology leaders in the state. "It's a high-yield investment for young physicians to begin a career in research and have protected time to clarify research goals that will launch them on a career path," Dr. Patt, who received a YIA in 2006 for her work at The University of Texas MD Anderson Cancer Center, said. "We look at supporting the YIA as an investment in our future cancer leaders in the state of Texas. The YIA that I received planted the seed for my cancer research career, which is focused on health services research and informatics, and I'm grateful to ASCO for that opportunity."

Dr. Patt is a firm believer in investing in the careers of emerging physician-scientists. Several years after receiving her YIA, she graduated from the ASCO Leadership Development Program's Class of 2014 and went on to participate in several ASCO committees, including serving as past-chair and current nominating committee member of the Clinical Practice Committee and editor-in-chief of *JCO Clinical Cancer Informatics*. In addition to her leadership volunteer work with TxSCO, she serves as vice president of Texas Oncology, where she directs policy initiatives and serves on the Texas Medical Association.

"We would encourage other state societies to follow this lead," Dr. Patt said. "Supporting the YIA is a tangible way they can contribute to cancer research in their state and help develop young cancer leaders." ●

# Monday Preview: Science and Education Sessions

Tomorrow is day 4 of the Annual Meeting, and it might just be your busiest day yet—Monday offers more than 80 sessions to choose from. Below, we provide an overview of the scientific program as well as a selection of Education Sessions of interest across the oncology community.

For full session details, including faculty and presentation titles, refer to the ASCO iPlanner app or the Annual Meeting Program.

**7:30 AM–9:15 AM**

### Highlights of the Day Session II

**Hall D1**

Miss an Oral Abstract Session today? There's still a chance to learn about the top abstracts in tomorrow morning's session. Start your day with a recap of yesterday's top science in the following categories:

- Breast Cancer—Metastatic
- Genitourinary (Nonprostate) Cancer
- Head and Neck Cancer
- Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
- Patient and Survivor Care
- Pediatric Oncology

**8:00 AM–9:15 AM**

### Hepatocellular Carcinoma: A Global Perspective

**S406**

This session will review the worldwide variations in epidemiology and therapeutic approaches for patients with hepatocellular carcinoma. Presenters will also evaluate the role of viral hepatitis in the development and prevention of the disease.

**8:00 AM–9:30 AM**

### Clinical Science Symposium

- Tumor Testing in Precision Oncology: From Heredity to Counseling to Implementation (S102)

**8:00 AM–11:00 AM**

### Oral Abstract Sessions

- Breast Cancer—Local/Regional/Adjuvant (Hall D2)
- Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers (Hall B1)
- Melanoma/Skin Cancers (Arie Crown Theater)
- Sarcoma (S100a)

**8:00 AM–11:30 AM**

### Poster Sessions

**Hall A**

- Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeutics
- Developmental Therapeutics—Immunotherapy
- Education Research
- Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant
- Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
- Hematologic Malignancies—Plasma Cell Dyscrasia

**9:45 AM–11:00 AM**

### Cancer Care for Displaced Populations: Conflict and Natural Disasters

**S504**

This session will explore the potential circumstances that patients with cancer who are displaced by war or natural disasters may experience and will look at strategies to address the unique challenges facing these patients.

**9:45 AM–11:15 AM**

### Clinical Science Symposia

- The Arrival of Biosimilars (Hall D1)
- Innovative Immune and Genomic Biomarkers for Solid Tumors (E451)

**9:45 AM–11:15 AM**

### ASCO/American Association for Cancer Research (AACR) Joint Session: GENIE and CancerLinQ—Two Models for Real-World Data Curation and Integration

**S406**

This special joint session, chaired by ASCO and AACR leadership, will examine the challenges of oncology data curation and real-world application. Presenters will draw on their experiences working with ASCO's CancerLinQ® health information technology platform, aimed at enhancing and improving the understanding and treatment of cancer, and AACR's Project GENIE, an international data-sharing project that aggregates and links clinical-grade cancer genomic data with clinical outcomes.

**11:30 AM–12:45 PM**

### Poster Discussion Sessions

- Developmental Therapeutics—Immunotherapy (Hall B1)
- Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant (E450)

**11:30 AM–12:45 PM**

### Cardio-Oncology: Novel Cardiac Toxicities in the Era of Precision Medicine

**S100bc**

This session will describe current evidence of cardiotoxicity in anticancer agents, discuss the associated cardiotoxicity of newer therapies, and outline the potential use of imaging and cardiac biomarkers.

### Molecular Oncology Tumor Board: Synchronous Primary Lung Cancers

**E451**

Anthony John Iafrate, MD, and experts in medical oncology, surgery, and pathology will review current clinical understanding of synchronous primary lung cancers.

**1:15 PM–2:30 PM**

### Poster Discussion Session

- Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia (E450)

**1:15 PM–2:30 PM**

### Advances in Fertility Preservation for Young Women With Cancer

**E451**

Session speakers will discuss the potential benefits of fertility preservation for younger patients with breast cancer, but will also address safety considerations and potential challenges. New developments in reproductive endocrinology techniques will also be addressed.

### How Much Time Do I Have, Doc? Communicating Prognosis in the Era of Exceptional Responders

**S100bc**

Amid increasing discussions about value in cancer care, attention is needed to improve patients' understanding of prognosis and to facilitate more informed, shared decision-making and goal-concordant care among those with advanced, incurable disease. Speakers in this session will discuss the prognostic challenges posed by precision medicine and will offer communication techniques to assess and facilitate understanding of prognosis in patients with advanced cancer.

### The Emergence of Cancer Biosimilars in the United States: A Clinician's Guide

**S406**

This session will look at examples of preclinical and clinical development of biosimilars in oncology and review the U.S. regulatory process in place to guide the review of biosimilar applications. Discussion topics will include the importance of building a post-market evidence base in the use of biosimilars in treating patients with cancer.

**1:15 PM–2:45 PM**

### Clinical Science Symposium

- Personalizing Care for Older Adults With Cancer: From Decision-Making to Care Delivery (S404)

**1:15 PM–4:45 PM**

### Poster Sessions

**Hall A**

- Gynecologic Cancer
- Melanoma/Skin Cancers
- Patient and Survivor Care
- Tumor Biology

**3:00 PM–4:15 PM**

### Poster Discussion Sessions

- Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeutics (S406)
- Hematologic Malignancies—Plasma Cell Dyscrasia (E450)

**3:00 PM–4:15 PM**

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

**S102**

This session will begin with a presentation on physician burnout in Europe, and will then transition to a discussion of the challenges and opportunities in implementing a burnout prevention program among fellows, followed by a look at institutional programs for burnout prevention.

**3:00 PM–4:30 PM**

### Clinical Science Symposium

- Breast Cancer Immunotherapy: Can We Crack the Code? (Hall D2)

**3:00 PM–6:00 PM**

### Oral Abstract Sessions

- Gastrointestinal (Noncolorectal) Cancer (Arie Crown Theater)
- Genitourinary (Prostate) Cancer (Hall D1)
- Lung Cancer—Non-Small Cell Metastatic (Hall B1)

**4:30 PM–6:00 PM**

### Clinical Science Symposium

- Targeted Therapy in Leukemia (E450)

**4:45 PM–6:00 PM**

### Poster Discussion Sessions

- Gynecologic Cancer (S100bc)
- Melanoma/Skin Cancers (E451)
- Patient and Survivor Care (S404)
- Tumor Biology (S406) ●

# Monday's Special Award Lectures

**9:45 AM–11:00 AM**

### ASCO/American Cancer Society Award and Lecture

**S102**

Karen Lu, MD, of The University of Texas MD Anderson Cancer Center, is this year's recipient of the ASCO/American Cancer Society Award for her work treating women with ovarian and endometrial cancers, as well as her leadership in the cancer genetics field. Dr. Lu's lecture will address evolving strategies in hereditary cancer genetic testing and risk reduction.

**1:15 PM–2:30 PM**

### Pediatric Oncology Award and Lecture and Presentation of the Partners in Progress Award

**S504**

ASCO recognizes Gregory Reaman, MD, FASCO, of the U.S. Food and Drug Administration, with the 2018 Pediatric Oncology Award for his extensive work in the biology and treatment of childhood acute leukemia and new drug development for pediatric cancers. Dr. Reaman's lecture will address the facilitation of precision oncology for children with cancer, and specifically recent legislative changes that have the potential to change the landscape in pediatric cancer drug development.

Also in this session, Danielle Leach, MPA, of St. Baldrick's Foundation, will receive the Partners in Progress Award.

**3:00 PM–4:15 PM**

### B. J. Kennedy Award and Lecture for Scientific Excellence in Geriatric Oncology

**S404**

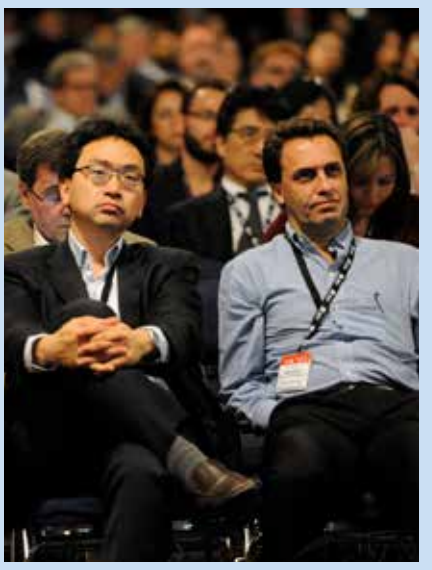
Supriya Gupta Mohile, MD, MS, of the University of Rochester Medical Center, is the recipient of the 2018 B. J. Kennedy Award. Dr. Mohile's research interests include the evaluation of patterns of care, health outcomes, and quality of life related to treatment for systemic cancer in older patients. In her lecture, Dr. Mohile will discuss honoring the preferences of older patients with cancer through improved communication.

**4:45 PM–6:00 PM**

### Gianni Bonadonna Breast Cancer Award and Lecture

**Hall D2**

ASCO presents the 2018 Gianni Bonadonna Breast Cancer Award to Gabriel N. Hortobagyi, MD, of The University of Texas MD Anderson Cancer Center, for his outstanding work in breast cancer treatment as well as for his work in clinical trial design and implementation. Dr. Hortobagyi's lecture will address the significance of academic mentoring. ●



# Twisted Pink Joins Forces With ASCO's Conquer Cancer Foundation to Support Metastatic Breast Cancer Research

As one of the few organizations exclusively focused on funding research for metastatic breast cancer, Twisted Pink has a unique story to tell. Based in Louisville, Kentucky, the organization was founded in 2014 by breast cancer survivor Caroline Johnson. Although Ms. Johnson fully recovered from her disease, she was startled to learn the statistics involving potential recurrence and the chance of developing stage IV disease, even years after recovery.

"During my treatment, I learned that too many people who get breast cancer progress to a metastatic or stage IV disease," Ms. Johnson said. "I was surprised to find out that less than 10% of research funding was directed to metastatic research. I knew something had to be done to change this statistic."

The name Twisted Pink signifies shifting focus from awareness to working toward a cure. "Our logo represents that we are planting a seed to change the way we approach breast cancer awareness," Ms. Johnson said. She recognized early on that other organizations offer quality educational programs to patients and caregivers, so she did not want to duplicate efforts. "We are strictly an organization that focuses 100% on funding metastatic breast cancer research," she said.

**Caroline Johnson**

As she was launching the organization, Ms. Johnson sought out breast cancer survivors, caregivers, a former researcher, and others touched by the disease to join the board. The organization's main fundraiser, the Masquerade Ball, was first held in 2015 and raised more than $100,000. Two years later, the event more than doubled its proceeds. In the 3 years since Twisted Pink was founded, the organization has raised enough funding to award grants to investigators totaling $440,000. The 2019 Masquerade Ball will be held on February 16 at The Seelbach Hilton in Louisville.

Twisted Pink has become one of the newest Young Investigator Award supporters for ASCO's Conquer Cancer Foundation. "Researchers have many different paths to choose from when deciding a research focus," Ms. Johnson said. "Twisted Pink wants to inspire a young investigator to dedicate his or her career to metastatic breast cancer research so that we can decrease the number of lives lost." Conquer Cancer's rigorous peer-reviewed grants process was a strong factor in Twisted Pink's decision to direct its research funding through the Young Investigator Award program.

Although its funding is restricted to research projects, Twisted Pink believes that awareness of stage IV breast cancer needs to increase. "According to the Metastatic Breast Cancer Alliance, 61% of people know very little about metastatic disease," she said. "You can't really do something when you know so little about it." Toward that end, Twisted Pink seeks to partner with similar, like-minded organizations and is an active member of the Metastatic Breast Cancer Alliance.

"Conquer Cancer is honored to work with Twisted Pink in encouraging further research in metastatic breast cancer, which has been significantly underfunded," Nancy R. Daly, MS, MPH, Conquer Cancer's executive vice president and chief philanthropic officer, said.

For more information, visit twistedpink.org. ●

# Exit Plan: Travel and Transportation Tips

As you prepare to leave ASCO, travel smart by taking advantage of insider tips on getting to the airport and the best places to grab a bite once you're there.

## Make the Most of McCormick Place

***Check your bag***

If you plan on heading to the airport directly from McCormick Place, you can check your bags at one of four locations:

- South Building, Level 1, Room S104 (Near Gate 2)
- South Building, Level 1, Main Entrance (Near Gate 4)
- North Building, Level 1, Lobby (Near Gate 26)
- East Building, Level 2, Room E257

Bag check locations are open from 7:00 AM to 7:00 PM on June 4, and 7:00 AM to 2:00 PM on June 5.

***Charge your phone***

If you forgot to charge your phone at the hotel—or if your battery has drained during the day—you can find power strips located on round tables throughout McCormick Place.

No time to sit and charge? Consider renting a portable battery charger for $5, available at three different locations:

- East Building, Level 3, by the Information Desk
- North Building, Level 2, by the Shoe Shine
- South Building, Level 1, at the escalators going up to Level 2.5

ASCO also offers lockable charging stations, available for rent throughout the building. Stop by any Information Desk for locations.

***Print your boarding pass***

To expedite the check-in process at the airport, print your boarding pass at McCormick Place. Internet stations with printers can be found at the following location:

- North Building, Level 2.5

## Transportation to the Airport

The distance between McCormick Place and O'Hare International Airport is just over 20 miles, but travel times vary considerably depending on traffic and weather conditions. And with more than 30,000 ASCO attendees heading home over the next few days, it's best to leave yourself plenty of extra travel time.

Expect the most traffic congestion on the evening of June 4 and the morning of June 5—a trip to O'Hare during those times can take up to 90 minutes.

***Taxi, bus, or train?***

Taxis to the airport can cost upwards of $60. If you don't mind sharing a taxi—and splitting the cab fare—strike up a conversation with others in the cab line. Chances are good that they, too, are heading to the airport.

Van or shuttle service from McCormick Place can be a more affordable alternative to taxis. GO Airport Express offers a shared-ride service (direct, with no stops) to both airports. Tickets range from $20 to $40 (price depends on time, airport, and total passengers), and 10% of each ticket will be donated to support Conquer Cancer, the ASCO Foundation. Tickets can be purchased at the Airport Express booth next to Gate 3. Airport Express can also book private vehicles, including limos and SUVs. Prices start at $99 and vary based on the number of passengers.

The "L" train also provides service to both O'Hare and Midway. Cermak-McCormick Place station is less than a quarter mile from the McCormick Place West Building. To get to O'Hare, board a northbound Green Line train at Cermak and switch to the Blue Line at Clark/Lake. Expect the trip to take at least 80 minutes. Travel to Midway from Cermak is a bit faster—approximately 25 minutes once you reach the station. Board a northbound Green Line train and then switch to the Orange Line at Roosevelt.

## At the Airport: Guide to O'Hare

One of the busiest airports in the world, O'Hare has top-notch services and amenities—including more than 100 dining options—to accommodate the millions of passengers traveling through its gates each month.

***Best spots to grab and go***

A perennial top pick, Tortas Frontera (terminals 1, 3, and 5) features Mexican fast casual dining from celebrity chef Rick Bayless. Highlights include a fresh guacamole bar and hand-shaken margaritas.

Other great options include The Goddess and Grocer (terminal 5), a gourmet Chicago deli/bakery chain that offers salads, flatbreads, sandwiches, and pastries (including vegan options), and B-Smooth (terminal 3), a locally owned purveyor of fresh smoothies and made-to-order salads.

If you missed your chance to try Chicago-style hot dogs, we recommend stopping by Gold Coast Dogs in terminal 3 or Galileo in terminal 1. Not sure what to expect from Chicago style? Think an all-beef frank on a poppy-seed bun with an array of toppings, including mustard, tomato, pickle, relish, onion, and celery salt.

***Best restaurants to stay a while***

At Wicker Park Seafood and Sushi (terminal 2), a 104-seat restaurant, professional sushi chefs make each sushi roll to order.

If farmhouse fare is more your style, try Publican Tavern (terminal 3), a spinoff of the celebrated Fulton Market restaurant The Publican. This airport outpost offers sandwiches and salads, as well as a selection of craft beer and wine.

***Best gift shops***

Looking for last-minute souvenirs? Try Garrett Popcorn Shops (terminals 1 and 3) where you can pick up a bag of The Chicago Mix, a combination of their famous handmade CaramelCrisp and CheeseCorn varieties. Nuts on Clark (terminals 1, 2, and 3), another Chicago favorite, offers gourmet nut and popcorn confections. Want more chocolate but less popcorn? Try Vosges Haut-Chocolat (terminals 1 and 3), a local chocolate boutique known for their truffles and chocolate bars.

If you'd rather not travel with food, check out The Field Museum Store (terminals 1 and 3) for a selection of gifts from Chicago's famous natural history museum, or I Love Chicago (terminal 5), a boutique gift shop featuring a variety of handmade products from local Chicago artisans.

***Best spots to forget you're at an airport***

Practice your down dog in the Yoga Room, located on the Mezzanine Level of the Terminal 3 Rotunda. Then check out the nearby O'Hare Urban Garden, an aeroponic garden featuring 26 towers and more than 1,100 planting spots. Among the produce grown on-site: Swiss chard, cilantro, and bibb lettuce.

Fit in some pampering before your flight at the Terminal Getaway Spa (terminals 1 and 3) or XpresSpa (terminal 5), which offer manicures, pedicures, and a variety of other treatments.

## At the Airport: Dining at Midway

Last year, Midway underwent a complete renovation to its concessions areas, adding more than two dozen new dining options. Below are our top picks for finding a satisfying bite at Midway.

***Best spot to grab and go***

Tabo Sushi offers two locations, in Concourse B and in the Triangle Food Court. Both offer options for quick bites, including California rolls and salmon nigiri.

***Best restaurants to stay a while***

The Go-Go White Sox Grill is the airport's tribute to Chicago's South Side baseball team. Located in the Triangle Food Court, it offers sandwiches, flatbreads, and salads. Other options include Reilly's Daughter, a recently expanded Irish pub, and the HVAC Pub. ●

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# WHAT'S HAPPENING TONIGHT

## South Pacific
Drury Lane Theatre
Oakbrook Terrace

**Tonight, 6:00 PM**
**chicago-theater.com**

This Pulitzer-winning classic takes you through Rodgers and Hammerstein's story of romance in the face of adversity. Set in World War II in the Pacific Islands and written to confront racial bigotry witnessed in America, *South Pacific* revolves around two love stories complicated by personal and social pressures of the times.

THEATER

## Do Division Street Fest
2000 W. Division Street

**Tonight, Until 10:00 PM**
**do-divisionstreetfest.com/fest**

Taking place on Division Street between Damen and Leavitt in West Town Chicago, Do Division Street Fest features two live music stages, local vendors and food, and of course plenty of cold beer, wine, and spirits. Plus, see the latest fashion trends and listen to live DJs at the nearby Do Fashion.

FOOD FESTIVAL

## David Byrne
Auditorium Theatre

**Tonight, 7:30 PM**
**chicago-theater.com**

Former Talking Heads frontman David Byrne hits the stage once again. Hear both old and new favorites as he promotes his newest record, *American Utopia*.

MUSIC

## Chicago Alternative Comics Expo (CAKE)
Center on Halsted

**Tonight, Until 10:00 PM**
**cakechicago.com**

CAKE is a curated tradeshow highlighting both established and emerging artists in the comic world. Explore comics for sale, workshops, exhibits, panel discussions, and more at this weekend-long celebration.

COMICS EXPO

## Wendella's Signature Lake and River Tour
East Dock at 400 North Michigan Avenue

**Tonight, Tours beginning at 6:00 PM**
**wendellaboats.com**

Experience unbelievable views of Chicago's historic skyline from Lake Michigan on this 90-minute boat tour. Learn about more than 200 years of cultural and political history of the city as you float down calm, cool waters.

ARCHITECTURAL TOUR

## Chicago's Original Architecture Tour®
East Dock at 400 North Michigan Avenue

**Tonight, Tours begin at 5:00 PM**
**wendellaboats.com**

This 75-minute, captivating boat tour takes you down all three branches of the Chicago River to explore the city's legendary architecture. Your professionally trained architecture guide will take you through more than 130 years of history and innovation.

ARCHITECTURAL TOUR

### Distinguished Achievement Award

*Continued from page 10*

cancer lived 5 years. Today, two out of three patients live 5 years or longer.

What is tremendously important to me is what happens to individual people—people who had tumors and were dying but now, with treatment, can live a normal existence again. So many people are living 5 years or longer instead of the majority dying, and that's remarkable progress accumulated from the work of hundreds of scientists.

**Q: Can you offer any advice for early-career scientists hoping to achieve similar success?**
**Dr. Mendelsohn:** Part of it is that I was working during a period of time when the number of patients enrolled at MD Anderson more than doubled in 5 years. But if you had come into the field a decade earlier or later, those challenges would have been far greater. So, part of it is just blending resources, opportunities, and shared commitment to improving the quality and outcome of cancer treatment.

I also think it's important to try new things. The safe thing is to repeat what has already been done but in more detail. Often times, though, the most important changes occur when you go in a brand new direction. That means taking chances. But you have to accept the fact that it can create new challenges and opportunities.

**Q: Looking ahead, what do you think the field of oncology research needs to do to continue making progress and improving patient outcomes?**
**Dr. Mendelsohn:** Research is much more complicated than it was 15 years ago. Now, it takes a few weeks instead of days to make decisions, because the decisions are more complicated and involve so many more approaches. The challenge now is to improve research but not to overdo it, meaning our excess time is spent developing instead of actually moving the research forward and making progress with patients.

It's time for leadership in the field to help researchers balance moving forward quickly and efficiently, on one hand, with collecting more and more data on the other. We need to make actual decisions. That's hard; it's a challenge. But that's science. And I hope I can continue to be a part of it and help us succeed. ●

**–Emily Kuhl, PhD**

# IT TAKES BOLD ACTION TO REDUCE CANCER IN KENTUCKY

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## WHY I ATTEND: ANA M. MOLINA, MD

Ana M. Molina, MD, specializes in genitourinary medical oncology at Weill Cornell Medicine and New York-Presbyterian Hospital and is a long-time ASCO Annual Meeting attendee. In the following interview, Dr. Molina shares why she continues to attend the Meeting and her perspective about its future directions.

**Q: Why is it important for medical oncologists to attend Annual Meeting?**
**Dr. Molina:** Whether you are a medical oncologist in private practice or in academic medicine, attending the ASCO Annual Meeting is an excellent way to stay up to date with the latest advances in cancer research and practice-changing patient care. For example, the data from the LATITUDE study, first presented at the Plenary Session at the 2017 Meeting, of abiraterone acetate plus prednisone or placebo in newly diagnosed high-risk metastatic hormone-naive prostate cancer was practice-changing and has led to the use of abiraterone earlier on in the disease course.

**Q: Apart from the science, what are some of the benefits of attending?**
**Dr. Molina:** Attending the Annual Meeting provides the opportunity to meet with people of all disciplines whom you would normally not have a chance to meet. In addition, there are sessions provided by other ASCO committees such as the ASCO Professional Development Committee. Last year, I attended various discussions in the Women's Networking Center that related to important issues that affect women in oncology such as leadership, promotion, and work-life balance.

**Q: What has changed about the ASCO Annual Meeting over the years you've attended?**
**Dr. Molina:** There has been a shift globally toward cancer genomics and precision medicine, cancer immunotherapy, and biomarker discovery. These topics are at the forefront of the way we're trying to develop new therapies and cures and are being addressed in both hematologic and oncologic malignancies.

**Q: Have you made any connections at Annual Meeting that have lasted and/or improved your career?**
**Dr. Molina:** I have certainly made connections that have positively impacted my career in academic medicine. I have maintained friendships and have reconnected with colleagues from training who have gone to other institutions or the pharmaceutical industry. These connections have led to collaborations on clinical trials and research projects. In addition, the transfer of new ideas, wealth of knowledge, and advice gained has been invaluable.

**Q: What do you think the Annual Meeting will be most focused on 10 years from now?**
**Dr. Molina:** I believe it will expand the reach of precision medicine. The Meeting will continue to report cancer discoveries and treatment advances that will benefit millions of patients living with cancer today and in the future. I feel fortunate to work at an institution with a robust program in precision medicine, enabling me to incorporate this into my clinical research and practice. In 10 years, I feel this personalized, narrowly tailored approach to cancer care will impact a much wider group of patients. In addition, over the next decade, I am very optimistic that we will collectively answer the questions of how cancer develops and spreads and how best to treat each individual patient.

**Q: Why do you think it's important to actually attend the meeting in person as opposed to following the research virtually?**
**Dr. Molina:** Although it is possible to follow research virtually through the Annual Meeting Videos & Slides, you do miss out on many of the benefits one gains by attending in person. The Meeting is a great opportunity to meet and network with oncologists and scientists nationally and internationally. These face-to-face interactions are important to establish multidisciplinary collaborations.

**Q: What do you always make sure to pack when traveling to Chicago?**
**Dr. Molina:** I always make sure to pack my running shoes when traveling to Chicago, although, I don't always get to use them. ●

**Ana M. Molina, MD, is a genito-urinary medical oncologist with Weill Cornell Medicine and New York–Presbyterian Hospital.**

# Sunday's Restaurant Recommendations: Healthy Choices

Looking for restaurant recommendations close to McCormick Place? Look no further than our daily dining suggestions in the *ASCO Daily News: Evening Edition*. We encourage you to call or visit individual restaurant websites for more dining information or to make reservations. ●
*Miles represent distance from McCormick Place.*

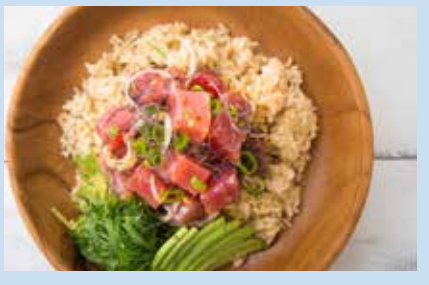
**Aloha Poke Co**
*alohapokeco.com*
125 S Clark Street (2.5 miles; 0.3 miles from Adams/Wabash Metra Station)
Get a taste of Hawaii by creating your own poke bowl with ahi tuna, salmon, or tofu. You can also choose a premade bowl with plenty of greens and tasty vinaigrettes.

**Beatrix**
*beatrixrestaurants.com*
834 W Fulton Market (3.9 miles; 0.2 miles from Morgan Metra Station)
Get all your grandma's favorites—without the expanding waistline. Try the "neatloaf" with turkey, sweet potato, and greens, or one of the many vegan or gluten-free options.

**Doc B's Fresh Kitchen**
*docbsfreshkitchen.com*
55 E Grand Avenue (3.9 miles; Next to Grand Metra Station)
Fresh plates, such as the Cajun-crusted trout with brussels sprouts or the quinoa kitchen salad with house-made vinaigrette, leave you feeling satisfied without the guilt.

**LYFE Kitchen**
*lyfekitchen.com*
413 N Clark Street (3.5 miles; 0.3 miles from Clark/Lake Metra Station)
Calorie-conscious meets crave-able creations at LYFE Kitchen, where sustainability and locally sourced greens come together to bring healthy—and delicious—options to the city of Chicago.

**True Food Kitchen**
*truefoodkitchen.com/chicago*
1 W Erie Street (3.8 miles; 0.6 miles from State/Lake Metra Station)
A "truly" nutritious and seasonal menu at True Food offers vegan, vegetarian, and gluten-free options. The expansive menu features edamame dumplings, a Tuscan kale salad, butternut squash pizza, and grass-fed steak tacos.



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

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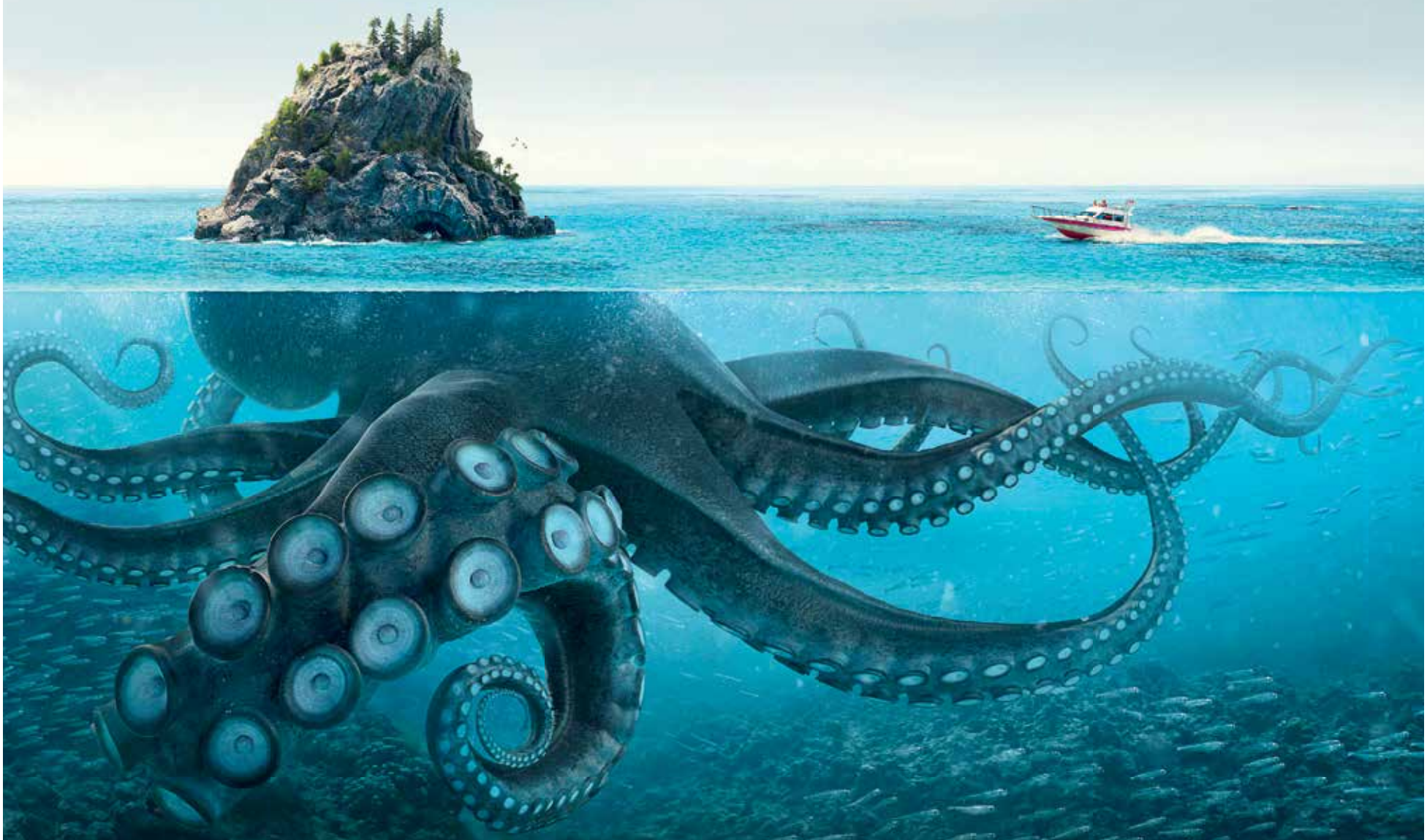

# TRK FUSION CANCER

## 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.

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