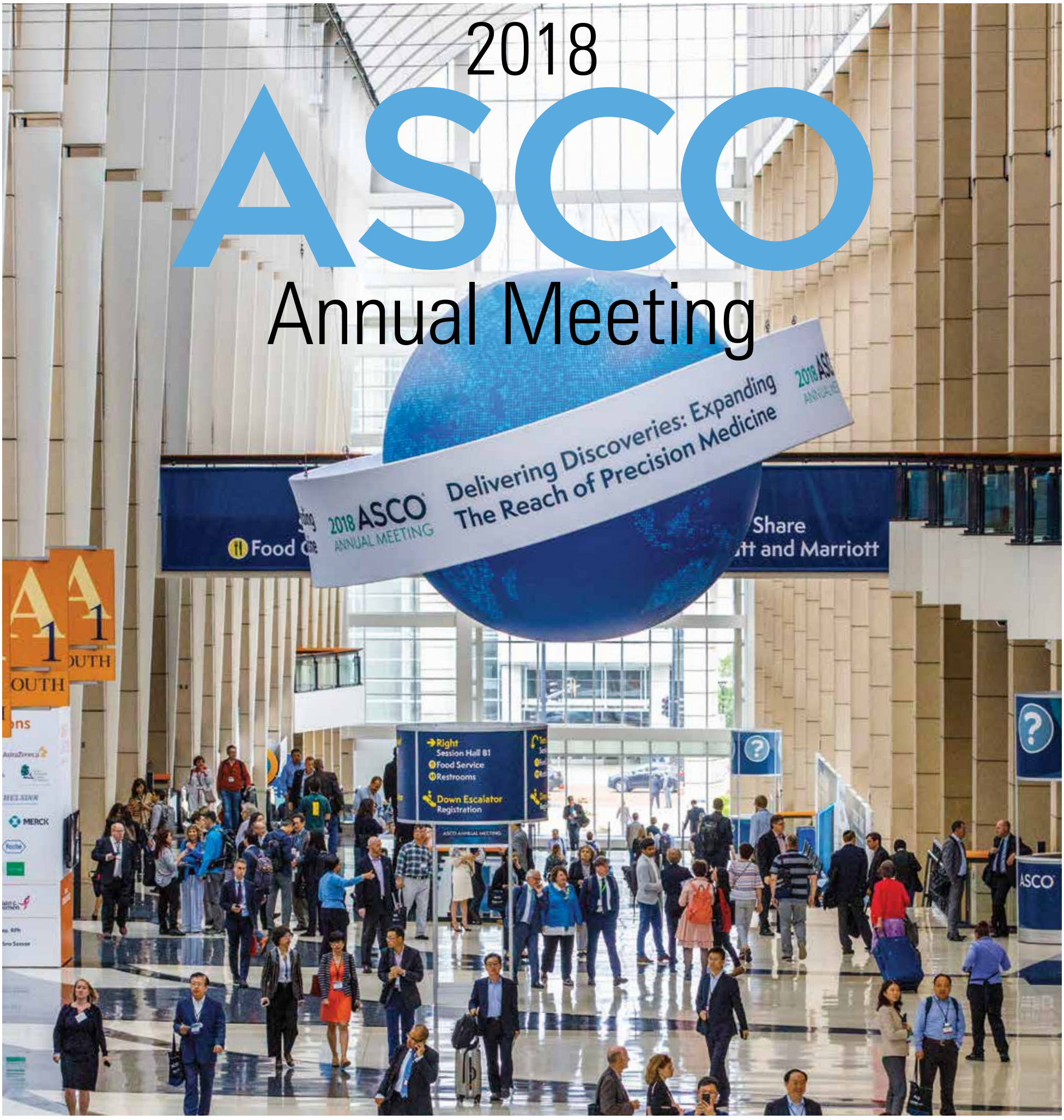
ASCO Daily News®

Evening Edition

SATURDAY • JUNE 2, 2018

2018 ASCO Annual Meeting



INSIDE THIS ISSUE

Public Service Award	3
Beat the Burnout	3
Reduce Obesity Risk for Cancer	4
Excellence in Teaching Award	9
International Women Who Conquer Cancer Award	10
Breast Cancer Research Foundation	10
What's Happening Tonight	11
American Cancer Society Award	11
Sunday Preview: Science and Education Sessions	16
Programs for Oncology Administrators	17
Cocktail Bar Recommendations	17
ASCO University® Resources	20
Save the Date: 2018 ASCO Oncology Practice Conference	22
Why I Attend: Dr. Michael G. Martin	22

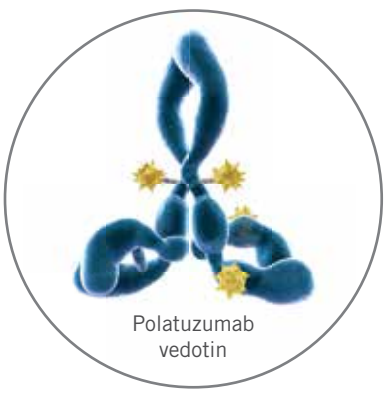
Polatuzumab vedotin (RG7596): An investigational anti-CD79b antibody-drug conjugate (ADC)[1]

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.

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BIOONCOLOGY®

Dr. Gideon Blumenthal Receives Public Service Award for Leadership in Clinical Trial Development

Gideon Michael Blumenthal, MD, a medical oncologist, has been named the recipient of ASCO's 2018 Public Service Award. Dr. Blumenthal serves as acting deputy director of the Office of Hematology and Oncology Products (OHOP) and the associate director of Precision Therapeutics at OHOP, both of which are offices within the U.S. Food and Drug Administration (FDA).

Dr. Blumenthal is being recognized for his leadership role in developing policy and science on how best to design the growing number of clinical trials for targeted and immunologic therapies. He also is involved in efforts to expedite the development of highly effective and less-toxic therapies to treat patients with cancer.

"We're re-envisioning our approach to clinical trials. The old paradigm for clinical trials was that every company studied each drug in a single disease type, often without the aid of biomarkers," Dr. Blumenthal said. "It was a very sequential, linear process. We are now moving into using master protocols, where multiple companies are studying multiple drugs, with a focus on biomarkers, not necessarily the site of origin of the tumor."

Part of the FDA's new approach is reflected in its breakthrough therapy designation, which began in 2012.[1] This designation brings promising drugs to market at an accelerated pace. In this context, however, it is equally important to ensure that patients are enrolled on clinical trials in the safest way possible and are not exposed to unreasonable risk. To ensure that both these factors have been considered, the FDA has demonstrated flexibility in the endpoints it evaluates for approval.[2]

"Although overall survival is still considered the gold standard for clinical trials, other endpoints may also be beneficial for patients," Dr. Blumenthal said. "These include a significant delay in tumor progression, an extension of progression-free survival, or a reduction in tumor size for a prolonged period. In the era of molecularly targeted therapies, it may not be practical to conduct a trial to look for survival gains. In some circumstances, the degree of durable tumor shrinkage is so large that a large study to look for survival is not necessary."

These changes have already had a significant impact. The FDA is now working more closely with sponsors to tailor each clinical trial to the specific needs of the patient population and the disease under study. For breakthrough therapies, patients with few treatment options are now benefiting from state-of-the-art protocols.[2]

Dr. Gideon Blumenthal lectures during the 2016 Markers in Cancer Diagnostic Development Tutorial. With the 2018 Public Service Award, Dr. Blumenthal is being recognized for his leadership role in drug development and clinical trial design.

An Active Participant in the Oncology Community

As a fellow in medical oncology and hematology at the National Cancer Institute, part of the National Institutes of Health (NIH), Dr. Blumenthal's goal was to pursue academic medicine. After meeting Richard Pazdur, MD, acting director of OHOP, Dr. Blumenthal changed his mind.

"I realized that at the FDA, I would be able to impact drug development from a unique vantage point that I wouldn't necessarily have as an academic investigator," Dr. Blumenthal said.

Originally a primary reviewer at the FDA, Dr. Blumenthal became a clinical team leader for lung cancer and head and neck cancer, managing a team of oncologists overseeing the development and approval of new agents during an unprecedented time

See Public Service Award, Page 4

Beat the Burnout: Emphasizing and Promoting Wellness Through Resiliency

Burnout among oncologists is a pressing issue that directly affects physicians' ability to provide the highest quality of patient care. It is estimated that approximately 44% to 80% of oncologists worldwide experience symptoms associated with burnout.[1] That number is 44.7% among U.S. oncologists, according to an ASCO-sponsored study of burnout and career satisfaction.[1,2]

Although burnout is not formally recognized as a disorder, it is characterized by three core symptoms: physical and emotional exhaustion, cynicism and depersonalization, and low sense of professional accomplishment.[1] Burnout is chronic and can arise subtly, with the initial symptoms slowly developing over the course of 1 year.[1]

Certain personal characteristics are risk factors for burnout, including younger age, being a woman, relationship status, and high student loan debt.[1] Professional characteristics associated with burnout include hours worked per week, seeing a larger number of patients per week, and method of compensation.[2] Residents and medical students have high rates of burnout and disproportionate rates of depression and suicide. Every year, approximately 400 physicians are lost to suicide in the United States.[1]

Resilience is a positive physiological adaptation to stress and puts emphasis on the human capacity to cope with, overcome, and become strengthened by personal and professional distress. Empowering physicians at the individual and organizational level with tailored resilience strategies is crucial to ensuring clinician wellness. Resilience interventions may include burnout education, work-life balance, adjustment of one's relationship to work, mindful practice, and acceptance of the clinical work environment.[1]

ASCO Intervenes to Improve Physician Wellness

ASCO has a continued interest in working toward improving physician well-being and is now in the second year of piloting a resilience intervention, the Resiliency Skills Training Program, to address burnout in medical oncology/hematology fellowship programs. The goal of the program is to improve physician wellness in oncology through a proactive, burnout-prevention approach. The Resiliency Skills Training Program targets current trainees to help create a culture change surrounding wellness, burnout, and resilience in oncology.

In order to create a culture change in the field of oncology, this program targets first-year trainees and will take place in more than 30 institutions over 16 weeks. It requires a partnership

Dr. Anna Maria Storniolo

between the program director, who builds the training into the fellows' schedules, and a social worker/psychologist, who leads the Resiliency Skills Training Program at each institution.

Anna Maria Storniolo, MD, of Indiana University Melvin and Bren Simon Cancer Center, has been in practice for more than 30 years and has learned that setting priorities is one of the hardest things a physician will ever have to

See Beat the Burnout, Page 9

ASCO Aims to Reduce Obesity Risk for Cancer

Obesity is a major public health issue in the United States, and the rates have risen dramatically since 1990.[1] In many states, 36.5% of adults and 17.0% of children and adolescents are obese.[2] Obesity contributes to major noncommunicable diseases including cardiovascular disease, diabetes, and cancer, both in terms of risk and mortality. As many as 84,000 cancer diagnoses each year are attributed to obesity, and overweight and obesity are implicated in 15% to 20% of total cancer-related mortality.[3]

Obesity is also associated with a worse prognosis after a cancer diagnosis and may negatively affect the delivery of systemic therapy, contribute to the morbidity of cancer treatment, and raise the risk of second malignancies and comorbidities.[3]

ASCO has been raising awareness of the connections between obesity and cancer risk and outcomes since 2013 when the Energy Balance Work Group was developed to evaluate the evidence and generate recommendations for the role ASCO should take in these areas. Despite the strong connections between obesity and both cancer risk and cancer outcomes, most Americans are unaware that obesity will increase their risk of developing or dying from cancer.

"When we started this effort, the goals were to make the oncology community more aware of the connection between obesity, inactivity, and cancer risk, and find ways to help providers talk to patients about this," Jennifer A. Ligibel, MD, of the Dana-Farber Cancer Institute, said. "The research shows that when people are diagnosed with cancer, they are more open to changing their lifestyle and losing weight, which makes this a teachable moment."

Dr. Jennifer Ligibel

Dr. Clifford Hudis

"There was growing evidence from basic and translational science that obesity was a contributing factor to various cancers," ASCO Chief Executive Officer Clifford A. Hudis, MD, FACP, FASCO, said.

This motivated ASCO's Board of Directors in 2013 to "elevate the issue of obesity strategically and put ASCO resources to work in addressing it," Dr. Hudis said. The board's strategic obesity initiative focused on raising public awareness, research, policy, and advocacy.

In October 2017, as a result of the continued need for ASCO's involvement in obesity awareness and prevention, the temporary Energy Balance Work Group became the Obesity and Energy Balance Subcommittee, a permanent branch of the Cancer Prevention Committee. Dr. Ligibel, who chairs the subcommittee, told the *ASCO Daily News* that the subcommittee met in December 2017 to "consider where ASCO should focus its efforts in this area, and how ASCO's unique role representing oncology professionals could have the biggest influence in reducing the impact of obesity on cancer risk and outcomes."

The Obesity and Energy Balance Subcommittee developed plans for a number of new initiatives over the next few years, including:

- A survey of ASCO members to determine whether they are discussing physical activity and weight management with patients during and after cancer treatment, and to identify tools and resources that could help support oncology providers in these discussions;
- Development of guidelines that would incorporate physical activity, weight management, and dietary intake at different points during the cancer trajectory; and
- Development of initiatives to educate oncology professionals at all career stages about the relationship between obesity and cancer, as well as strategies to help patients lose weight and make other lifestyle changes during and after treatment.

ASCO's Previous Obesity Efforts

ASCO's new initiatives to combat obesity build upon an already robust effort by the Society. For example, in recognition that a broad-based collaboration needed to tackle this public health crisis, ASCO hosted the Summit on Addressing Obesity Through Multidisciplinary Collaboration in 2016. "We brought different professional organizations together that have been working in this area to look at where we can synergize and harmonize our efforts. We realized that by coordinating our efforts, we could avoid duplication, reach a broader audience, and have more of an impact than working on our own," Dr. Ligibel said.

> "There was growing evidence from basic and translational science that obesity was a contributing factor to various cancers."
> –DR. CLIFFORD HUDIS

The subcommittee's efforts were in addition to the resources and events developed by the original Energy Balance Work Group in 2014, including:

- ASCO's "Position Statement on Obesity and Cancer," published in the *Journal of Clinical Oncology (JCO)*. The statement outlines ASCO's interest in obesity and cancer, its priorities, and its initiatives to increase awareness of the links between obesity and cancer.[3]
- The Obesity Toolkit, designed to educate oncologists and patients about the role weight management and healthy lifestyle behaviors play in cancer. The toolkit was updated in 2015 and has been translated into Spanish and French. For more information, visit asco.org/obesity.

See Reduce Obesity Risk, Page 18

Public Service Award

Continued from page 3

of approvals of targeted therapies and immunotherapies.

Dr. Blumenthal's role also extends beyond the FDA and includes engaging with other key stakeholders. For example, he has collaborated with the American Association for Cancer Research as a co-chair of two public workshops discussing liquid biopsies in oncology drug and device development. Additionally, he was involved in the creation of the Blood Profiling Atlas in Cancer Consortium as part of the Cancer Moonshot. This project is striving to accelerate the development and validation of liquid biopsy assays by creating a collaborative infrastructure for information-sharing among stakeholders in industry, academia, and regulatory agencies.[3]

> "I realized that at the FDA, I would be able to impact drug development from a unique vantage point that I wouldn't necessarily have as an academic investigator."
> –DR. GIDEON BLUMENTHAL

Dr. Blumenthal has also been active in the design and development of master protocols for lung cancer. Working with many partners, including the Friends of Cancer Research, NIH, and the Foundation for the NIH, he has been involved in the development of the Lung-MAP clinical trial, a unique public-private partnership that uses multidrug targeted screening to match patients with studies of investigational new treatments.

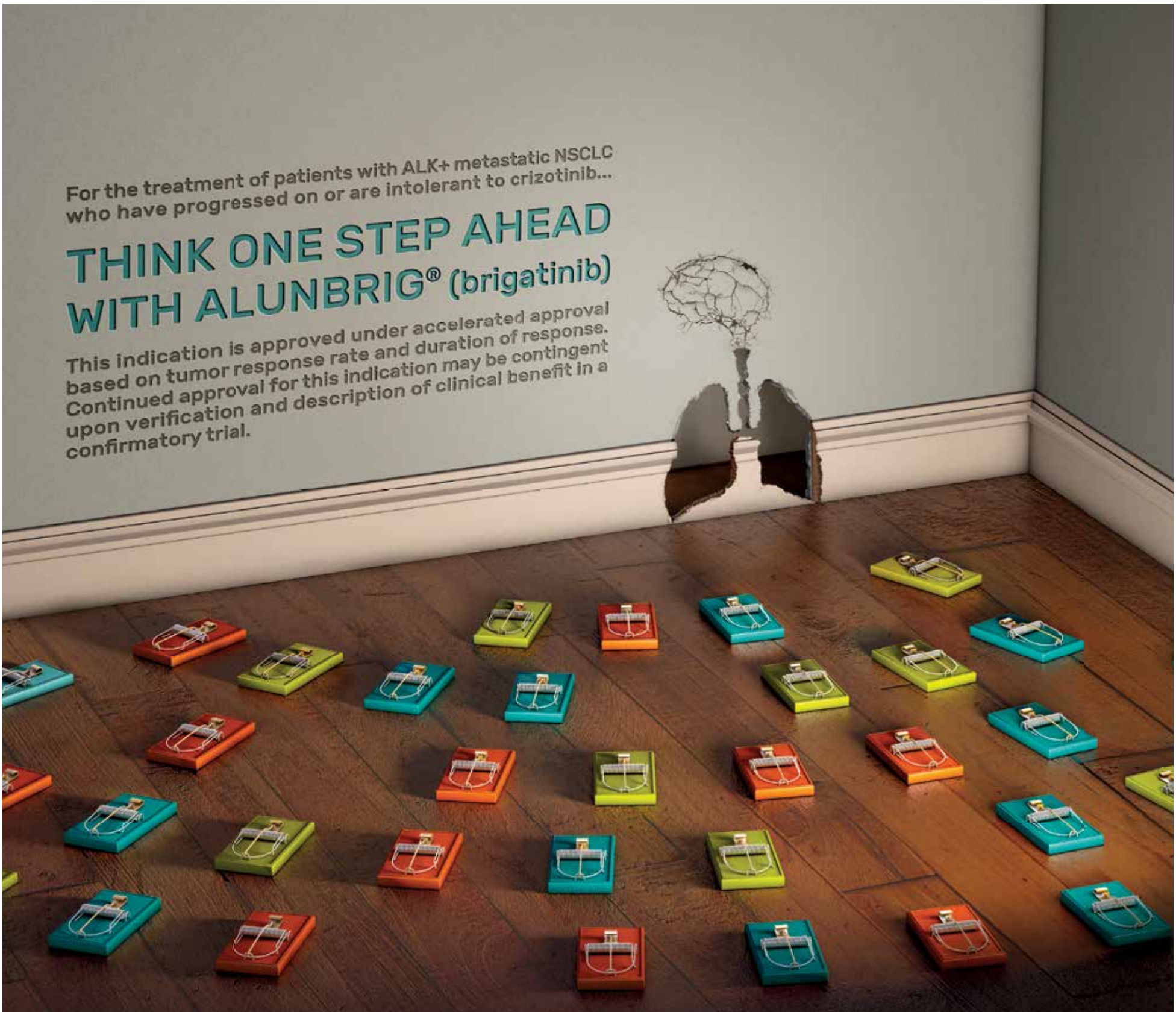
At the FDA, Dr. Blumenthal has taken a leading role in creating a roadmap for lung cancer drug development. As part of this project, he has partnered with the International Association for the Study of Lung Cancer and has co-chaired a meeting on neoadjuvant endpoints in lung cancer clinical trials. In addition, he has worked extensively with the LUNGevity Foundation on a broad range of issues to improve the clinical trial process, including expanding eligibility criteria, decreasing unnecessary safety reporting, and looking at real-world evidence in oncology clinical trials. His group has published several meta-analyses investigating earlier, intermediate endpoints for lung cancer clinical trials.

"This is an exciting time to be in the drug development field," Dr. Blumenthal said. "We are well positioned to help move targeted therapies forward and to see what a meaningful impact they have on patients." ●

–Marilyn Fenichel

References:

1. U.S. Food & Drug Administration. Breakthrough Therapy. www.fda.gov/ForPatients/Approvals/Fast/ucm405397.htm. Updated January 4, 2018. Accessed February 14, 2018.
2. Blumenthal GM, et al. *The Oncologist*. 2017;22:762-7.
3. Fawcett N. University of Michigan Health. How a Database and Collaboration Might Move the Needle on Liquid Biopsies. labblog.uofmhealth.org/industry-dx/how-a-database-and-collaboration-might-move-needle-on-liquid-biopsies. Published October 19, 2016. Accessed February 13, 2018.



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.

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

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

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

Long-Time Educator Dr. Gregory P. Kalemkerian to Receive Excellence in Teaching Award

During his 25-year academic career as a medical oncologist and scientist, Gregory P. Kalemkerian, MD, has mentored and taught countless trainees. Now, ASCO will honor Dr. Kalemkerian's work with its Excellence in Teaching Award, which recognizes individuals who have inspired and shaped trainees' practice of cancer medicine.

Dr. Kalemkerian serves as associate director of the Hematology/Oncology Fellowship Program and associate division chief for Faculty Development and Education at the University of Michigan. He has been honored with several awards including Teacher of the Year, Outstanding Clinician, and election to the university's League of Clinical Excellence.

"Receiving an award for teaching is very humbling. There are many excellent teachers at many institutions, including the University of Michigan. To be recognized for making a difference in [the oncology] field is a wonderful honor," Dr. Kalemkerian said.

Dr. Gregory P. Kalemkerian

Engaging Trainees

Dr. Kalemkerian's teaching style is a mix of passion, interactive learning, and making science clinically relevant. "The more enthusiasm you demonstrate for your subject matter, the more your students will get out of your presentation," he said. Teaching topics include lung cancer, drug development, and cancer biology.

Dr. Kalemkerian uses collaborative, patient-based teaching sessions to engage trainees. He presents real-world situations and guides trainees to develop rational care plans based on available evidence. He has extended this approach to his recent lectures for an online thoracic oncology course[1] and to the *Handbook of Lung Cancer and Other Thoracic Malignancies*,[2] which he coauthored and edited.

Dr. Kalemkerian also makes his lectures clinically relevant. For example, when he teaches cancer biology, he connects the topic to patient care. "Trainees are more likely to pay attention to and recall a discussion on the pathophysiology of cancer if I tie in the latest clinical interventions," he said.

Trends in Medical Education

A recent trend in medical education is patient-based, multidisciplinary learning. Dr. Kalemkerian has led seminars for medical students with faculty from radiology, oncology, pathology, and pharmacology focused on reviewing a patient's care over several years.

"After the faculty dissect the patient's medical history, my patient talks about their experience with advanced lung cancer—their feelings and struggles over the course of the disease. Many students have told me that this seminar reminded them of why they entered medicine," Dr. Kalemkerian said.

Trainees are also learning how to educate patients with cancer. "I spend a lot of time talking with patients about their situation, explaining their cancer, treatment options, and goals of care. I try to instill in our fellows the need to ensure that people fully understand their situation by keeping communication simple and always giving patients a personalized recommendation for further care."

The Broader Impact of Mentoring

When Dr. Kalemkerian was a junior faculty member at Wayne State University/Karmanos Cancer Institute, several residents interested in oncology worked with him in his lab and on clinical research projects. A number of them have gone on to become leaders in lung cancer research. "I realized early on that by inspiring and mentoring trainees, I could have a broader impact on the field than what I could achieve alone. We were learning together, so I tried to treat them as colleagues and give them full credit for their work."

Now, as a senior researcher, Dr. Kalemkerian understands the need to give trainees ownership of their research projects while still providing guidance and oversight. "They are the ones doing the legwork for their projects: talking with industry liaisons, meeting with regulatory staff, and writing the protocols and papers," he said.

In his role with the fellowship program at the University of Michigan, Dr. Kalemkerian encourages fellows to find and follow their passion in oncology, whether it's in research or patient care. "Our job is to ensure that they obtain the necessary skills to achieve their career goals," he said.

Helping Trainees Succeed

Dr. Kalemkerian has also directed the lung cancer program at the University of Michigan for many years. "One of the things I am proudest of in my career is that all four of my immediate colleagues are my former fellows, and we are training our current fellows as a group to give them a broader experience," he said.

Seeing his former trainees succeed and advance in their careers is very satisfying, Dr. Kalemkerian said. "Three of them are now full professors, including two who have endowed professorships. Although I can't take full credit for their success, I did help them get started on their career paths and, hopefully, instilled some degree of passion and rigor for the work they're doing now." ●

–Christine Lehmann, MA

References:

1. Thoracic Oncology: The Lung Cancer Problem. The University of Michigan. coursera.org/learn/thoracic-oncology/lecture/GeI48/the-lung-cancer-problem. Accessed January 16, 2018.
2. Kalemkerian G, et al. *Handbook of Lung Cancer and Other Thoracic Malignancies*. New York, NY: Springer Publishing Company; 2016.

Beat the Burnout

Continued from page 3

do—but it's vital. "Put that [priority] list in your brain and in your heart and live by it—it's all about what's important to you," Dr. Storniolo said. "You're the only person responsible for you, and you're the only person that can make you happy."

ASCO's Resiliency Skills Training Program consists of eight modules, and each session addresses a specific resilience skill: (1) identifying and utilizing strengths, (2) activating the resilience zone, (3) recognizing cognitive distortions, (4) mindfulness, (5) self-compassion, (6) setting healthy boundaries, (7) finding meaning in everyday work, and (8) building self-care and resilience.

ASCO Connection also has a page devoted to physician wellness and professional burnout (connection.asco.org/physician-wellness). It features a collection of ASCO resources and includes links to practical advice for maintaining wellness, personal stories and videos from members about burnout, and suggestions for further reading. In addition, *ASCO Connection* welcomes guest blog posts from members on all topics related to wellness and burnout. Email ascoconnection@asco.org to learn how to contribute. ●

–Lindsay Pickell, MFA

References:

1. Hlubocky FJ, et al. *Am Soc Clin Oncol Educ Book*. 2017;37:771-81.
2. Shanafelt TD, et al. *J Clin Oncol*. 2014;32:678-86.

WHAT IS YOUR FAVORITE THING TO DO DURING A NIGHT OUT IN CHICAGO?

"Go out to dinner. There are so many amazing restaurants in Chicago."

–Swati Kulkarni, MD, FACS

"Catch up on a live show, and grab a slice of deep-dish pizza."

– Murtuza Rampurwala, MD, MPH

"One of my favorite activities in the summer is to have dinner and drinks al fresco. There are many rooftop terraces in the city with beautiful views of the city skyline or the lake. It is an enjoyable way to spend an evening with friends."

–Rita Nanda, MD

Long-Time Mentor Dr. Rejin Kebudi to Receive International Women Who Conquer Cancer Award

Rejin Kebudi, MD, a professor of pediatrics and a pediatric hematologist-oncologist with Istanbul University, Turkey, is the 2018 recipient of the International Women Who Conquer Cancer Mentorship Award. ASCO's Conquer Cancer Foundation gives the award to women oncologists who are both leaders and mentors in their field over a sustained period of time.

When Dr. Kebudi was in high school and in medical school in Turkey, she was already receiving awards from the Scientific and Technological Research Council of Turkey for her research.

"I knew at a young age that I would pursue an academic career in medicine. I chose pediatric oncology when I realized I could help save children's lives. It's very rewarding to see children I have treated live to become adults and have families, but, it's also emotionally hard when some children don't survive cancer and you have to communicate that to families, which is why empathy is so important," Dr. Kebudi said.

She loves her work and is proud that the Cerrahpasa Medical Faculty and the Istanbul University Oncology Institute, where she conducts research mainly

See Conquer Cancer Award, Page 18

Dr. Rejin Kebudi (middle) pictured with her fellow and residents.

Breast Cancer Research Foundation and Conquer Cancer Form Research Collaboration

Even the most talented of athletes cannot win major championships on their own. Victory is the result of teamwork, training, perseverance, and occasionally a stroke of luck. The same holds true when it comes to tackling breast cancer. Since 2001, the Breast Cancer Research Foundation (BCRF) has been teaming up with ASCO's Conquer Cancer Foundation to advance cutting-edge breast cancer research.

Myra Biblowit (left) and Evelyn Lauder

BCRF has provided support to early-career physician-scientists through the Young Investigator Award and other Conquer Cancer programs.

BCRF was founded in 1993 by the late Evelyn H. Lauder and her husband, Leonard Lauder, along with Larry Norton, MD, the medical director of the Evelyn H. Lauder Breast Center at Memorial Sloan Kettering Cancer Center, who continues to serve as BCRF's scientific director. It was formed with Mrs. Lauder's unyielding view that research was the only way to end breast cancer, and that empowering the best minds in the field would fuel the innovations to move the needle forward. Those principles still define BCRF.

When BCRF was founded, the research and treatment landscape looked vastly different than it does today. Thanks to the tireless efforts of BCRF and others, breast cancer mortality rates in the United States are down 39% from 1989-2015,[1] and as of January 1, 2016, there were more than 3.5 million women and men alive with a history of breast cancer.[2] This is largely a result of advances in early detection, adjuvant treatment, and targeted drugs. Treatment for breast cancer is no longer a one-size-fits-all approach. Therapy is guided by tumor biology, and although not always curative, it has made formerly deadly diseases, such as *HER2*-positive breast cancer, more treatable. In 2017, women diagnosed with early-stage localized breast cancer had a 99% chance of 5-year survival.[3]

BCRF has a unique model that focuses on funding people, not projects. The focus is on investigators who have demonstrated success in the field, allowing them the freedom to be nimble and creative in their approach to science. Yet BCRF also recognizes how critical it is for young investigators to have their own support to fund their paths to independence. "Today's young investigators are tomorrow's innovators, and our partnership with Conquer Cancer allows us to foster this intellectual pool," Myra J. Biblowit, BCRF's president and chief executive officer, said.

The longstanding collaboration between BCRF and Conquer Cancer has provided a mechanism by which BCRF can provide support to talented and rigorously vetted early-career physician-scientists through the Young Investigator Award (YIA) and other Conquer Cancer programs. Past recipients have gone on to receive other BCRF grants, including Vered Stearns, MD, and Lajos Pusztai, MD, D.Phil, who serve on the BCRF Scientific Advisory Board, and many others who continue working to improve patients' lives.

In 2018, BCRF is supporting an Advanced Clinical Research Award, a Conquer Cancer Foundation of ASCO Career Development Award, and five YIAs, including the Evelyn H. Lauder Endowed Young Investigator Award. The latter was established in 2012 in memory of Mrs. Lauder and supports one YIA each year in perpetuity. Since 2001, BCRF has invested more than $10 million in support of 69 breast cancer research grants through Conquer Cancer.

"Conquer Cancer is extremely appreciative of the generous and ongoing support for many years from BCRF to fund cutting-edge breast cancer research. We deeply value this partnership, which provides critical support for early-career scientists working to unravel the mysteries of breast cancer and help even more patients and families," Nancy R. Daly, MS, MPH, the executive vice president and chief philanthropic officer of Conquer Cancer, said.

BCRF-funded investigators have been involved in every major breakthrough in breast cancer prevention, diagnosis, treatment, and survivorship over the last 2 decades. Notable highlights include identification of genetic risk and screening, improved diagnostics and surgery, drug discovery and novel therapies, advances in the science behind lifestyle and risk reduction, and improving quality of life for survivors of breast cancer.

BCRF recognizes that although incredible strides have been made over the last 25 years, much critical work remains to be done. In spite of great progress, breast cancer incidence rates have remained stable, making prevention an important priority, and as of 2016, metastasis continues to take the lives of more than 40,000 women and men each year.[4]

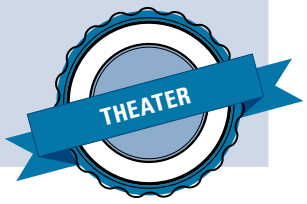
Through the committed funds of the Evelyn H. Lauder Founder's Fund Initiative in metastatic breast cancer, BCRF investigators are identifying new targets and teasing out the molecular underpinnings of metastatic breast cancer that can someday lead to better treatments and prevention interventions.

See Breast Cancer Research Foundation, Page 15

Forever Plaid
Theatre at the Center

Tonight, 7:30 PM
chicago-theater.com

Go back to the 60s and sing along with The Plaids quartet. Originally debuting off-Broadway, *Forever Plaid* follows the story of the imaginary singing group as they make their way through the music business. Harmonize with hits such as "Moments to Remember," "Chain Gang," and "Love is a Many-Splendored Thing."



WHAT'S HAPPENING TONIGHT

Bolingbrook Fest
The Promenade

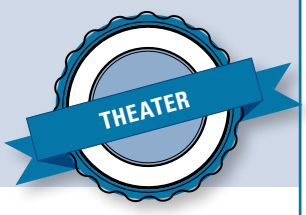
Tonight, Until 10:00 PM
chicagoevents.com/events/taste-of-bolingbrook

Welcome the start of summer as 25 local restaurants show off their signature dishes. From sushi and Mongolian delights to barbecue and Italian favorites, every palate is sure to be satisfied. Top off the night with an exotic ice-cream treat and dance the night away to live music.

Laugh Out Loud Theater Chicago
3851 N. Lincoln Avenue

Tonight, shows start at 6:00 PM
laughoutloudtheater.com

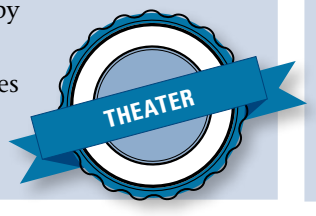
See a variety of improv shows almost every night of the week in the North Center neighborhood. Featuring family-friendly shows, drinking games for adults, storytelling, and more, there's something for everyone at Laugh Out Loud Theater Chicago.



South Pacific
Drury Lane Theater Oakbrook Terrace

Tonight, 8:30 PM
chicago-theater.com

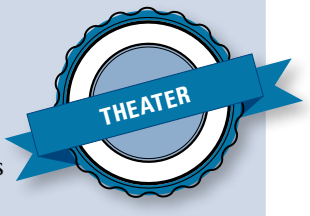
This Pulitzer-winning classic takes you through Rodgers and Hammerstein's story of romance in the face of adversity. Set in World War II in the Pacific Islands and written to confront racial bigotry witnessed in America, *South Pacific* revolves around two love stories complicated by personal and social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



Macbeth
Chicago Shakespeare Theater

Tonight, 8:00 PM
chicago-theater.com

This famed Scottish play gets a new spin from directors Aaron Poser and Teller (as in the magician duo Penn and Teller). Watch tyranny, madness, and murder collide on stage as the all-consuming effect of power destroys the Macbeth family.



Taste of Mexico
26th & California (Little Village)

Tonight, 10:00 PM
chicagoevents.com/events/taste-of-mexico

Held in the Little Village neighborhood, Taste of Mexico is a culinary extravaganza featuring 20 neighborhood and other local restaurants selling authentic Mexican street foods including tacos, flautas, enchiladas, tortas, gorditas, and more. It also includes a music and entertainment stage, as well as arts and crafts.

Dr. Karen H. Lu Receives the American Cancer Society Award

Karen H. Lu, MD, of The University of Texas MD Anderson Cancer Center, has been named the 2018 American Cancer Society Award recipient in recognition of her career-long contributions to prevention and early detection of gynecologic cancers.

Dr. Lu is an international leader in translational research in gynecologic oncology and currently serves as one of the principal investigators of the National Cancer Institute (NCI) Specialized Program of Research Excellence (SPORE) for endometrial cancer. Her clinical research is focused on understanding the early molecular changes in endometrial and ovarian cancers and ways to detect them to facilitate early diagnosis and improve patient outcomes.

Early Beginnings and Motivation

In an interview with the *ASCO Daily News*, Dr. Lu commented on her early beginnings in gynecologic oncology and the motivation behind her work caring for women with ovarian and endometrial cancer.

"When I was a fellow in gynecologic oncology in 1996, *BRCA-1* and *BRCA-2* were discovered as the causes of hereditary ovarian cancer, and I was really fascinated by that discovery," she said. "I believed that it would have a huge impact on identifying women who hadn't developed the disease but were at a very, very high risk for it."

Dr. Lu noted that this discovery helped shape her future research interests in gynecologic oncology. Encouraged by her mentors, Michael G. Muto, MD, and Judy E. Garber, MD, MPH, of the Dana-Farber Cancer Institute, she continued to focus her research efforts on gynecologic cancer prevention and early detection.

"Two questions I always think about when I see patients in my practice are: Could we have prevented this cancer? And, how would the outcome be

See American Cancer Society Award, Page 14

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

American Cancer Society Award

Continued from page 11

different if we were able to detect the cancer at an earlier stage? Searching for these answers allows me to devote much of my time to research cancer prevention and early detection," she said.

Preventing Endometrial Cancer in High-Risk Women

Dr. Lu's team at MD Anderson has conducted research characterizing endometrial cancer risk and management strategies for women with Lynch syndrome who are at a very high risk of developing endometrial cancer due to a defect in one of four genes: *MLH1, MSH2, MSH6,* or *PMS2*.[1-3]

"We completed a very difficult study in which we demonstrated that oral contraceptives might be effective in decreasing endometrial cancer risk in these high-risk women," she said. "Based on the molecular marker analyses of uterine tissue, we were able to demonstrate a chemoprotective effect of oral contraceptives in this group."

Dr. Lu's work in endometrial cancer chemoprevention in women with Lynch syndrome led to an interest in understanding the role of obesity in endometrial cancer. Among all cancers, endometrial cancer has the strongest link to obesity, with increasing numbers of young, obese women presenting with endometrial cancer diagnoses.[4]

"It has been fascinating to look at endometrial cancer risk in two parallel but distinct high-risk populations. As a part of the NCI-SPORE grant at MD Anderson, we are developing a strategy that will allow us to deliver drugs through an intrauterine device for conservative management in an attempt to reverse endometrial cancer," she said.

Exploring New Approaches to Genetic Testing

Dr. Lu is currently working on developing innovative ways to eliminate existing barriers and deliver genetic testing to women at high risk of developing gynecologic cancers. One of her projects, the MAGENTA study, funded by the advocacy partners Stand Up To Cancer, Ovarian Cancer Research Fund Alliance, and the National Ovarian Cancer Coalition Dream Team,

See American Cancer Society Award, Page 22

Breast Cancer Research Foundation

Continued from page 10

In addition to the Founder's Fund and BCRF's flagship investigator program, the organization will continue to grow initiatives including the Drug Research Collaborative—a unique partnership that allows BCRF investigators to test new or pipeline drugs to provide more treatment options for patients with metastatic breast cancer. As long as there is breast cancer, BCRF will continue to seek solutions to the persistent challenges in breast cancer, including drug resistance, late recurrences, inherited risk, prevention, and quality of life.

To learn more about BCRF, visit BCRF.org. To learn more about Conquer Cancer, visit CONQUER.org. ●

References:

1. DeSantis C, et al. *CA Cancer J Clin*. 2017;67:439-48.
2. American Cancer Society. Breast Cancer Fact & Figures, 2017-2018. cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2017-2018.pdf. Published 2017. Accessed March 9, 2018.
3. ASCO Cancer.Net. Breast Cancer: Statistics. cancer.net/cancer-types/breast-cancer/statistics. Published April 2017. Accessed March 9, 2018.
4. Green L. *Oncology Nursing News*. The Elephant in the Pink Room: Living With Metastatic Breast Cancer. oncnursingnews.com/publications/oncology-nurse/2016/october-2016/the-elephant-in-the-pink-room-living-with-metastatic-breast-cancer. Published October 14, 2016. Accessed March 9, 2018.

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

ASCO Daily News: Evening Edition

Vol. 3, No. 1 | June 2018

ASCO Daily News: Evening Edition is published by the American Society of Clinical Oncology.

Sunday Preview: Science and Education Sessions

The Plenary is the must-see session of the ASCO Annual Meeting, featuring the four abstracts deemed to have the greatest impact on oncology research and practice. Below, read more about the Plenary and other featured sessions taking place tomorrow. For full session details, including faculty and presentation titles, refer to the ASCO iPlanner mobile app or the Annual Meeting Program.

7:30 AM-9:15 AM

Highlights of the Day Session I

Hall D1

Looking for a high-level recap of the key findings presented in today's Oral Abstract Sessions? Arrive at the convention center early and attend tomorrow's Highlights of the Day session, where expert discussants will summarize the top abstracts from Saturday's sessions and place findings into clinical context.

Tracks discussed include:

- Central Nervous Sytem Tumors
- Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeuitcs
- Developmental Therapeutics—Imunotherapy
- Health Services Research, Clinical Informatics, and Quality of Care
- Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant
- Hematologic Malignancies—Plasma Cell Dyscrasia

8:00 AM-9:30 AM

Overcoming Unique Obstacles to Implementing Precision Medicine Trials in the Community Setting

S100bc

Precision medicine shows great promise for effective treatment options for patients, but many community-based sites do not have access to or are reluctant to participate in these trials. Furthermore, they experience unique barriers to participating in precision medicine trials compared to their academic counterparts. This session will provide necessary information about best practices, resources, and tools to encourage community-based sites to participate in these trials and ensure that their patients gain access to these important treatment options.

8:00 AM-11:00 AM

Oral Abstract Sessions

- Breast Cancer—Metastatic (Hall D2)
- Cancer Prevention, Hereditary Genetics, and Epidemiology (S404)
- Genitourinary (Nonprostate) Cancer (Arie Crown Theater)
- Head and Neck Cancer (E451)
- Patient and Survivor Care (S102)
- Pediatric Oncology II (S504)

8:00 AM-11:30 AM

Poster Sessions

Hall A

- Gastrointestinal (Colorectal) Cancer
- Gastrointestinal (Noncolorectal) Cancer
- Lung Cancer—Non–Small Cell Local-Regional/Small Cell/Other Thoracic Cancers
- Lung Cancer—Non–Small Cell Metastatic

9:45 AM-11:00 AM

ASCO/European CanCer Organisation (ECCO) Joint Session: Access and Innovation With Multiplex Genomic Testing

S100a

Speakers in this joint session, chaired by leadership from ASCO and ECCO, will examine the use of multiplex testing in the United States and Europe. Discussion topics include reimbursement and payment in the United States and the European patient perspective.

9:45 AM-11:15 AM

Clinical Science Symposia

- Compelling Combinations: Raising the Bar With Immunotherapy (Hall D1)
- Engaging the Immune System in Ovarian Cancer (S406)

9:45 AM-12:45 PM

Oral Abstract Session

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

11:30 AM-12:45 PM

Poster Discussion Sessions

- Gastrointestinal (Colorectal) Cancer (Hall D2)
- Lung Cancer—Non–Small Cell Metastatic (Arie Crown Theater)

11:30 AM-1:00 PM

Clinical Science Symposium

- Innovative Approaches to Oncology Education (S103)

11:30 AM-1:00 PM

Collecting and Using Real-World Evidence: Supplementing and Perhaps Replacing Clinical Trials

S100a

This session will examine how real-world data are being used in the patient care setting. Discussion topics include how the registry community and the Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute is enhancing the real-world evidence ecosystem as well as the U.S. Food and Drug Administration's (FDA) evolving efforts to use real-world evidence to inform effectiveness in the pre- and post-approval settings. This session includes presentation of the Public Service Award to Gideon Blumenthal, MD, of the FDA's Oncology Center for Excellence.

1:00 PM-4:00 PM

Plenary Session Including the Science of Oncology Award and Lecture

Hall B1 (Simulcast: Hall D1)

Four clinically significant abstracts have been selected for Plenary presentation and discussion. The Plenary Session also includes the Science of Oncology Lecture by award recipient Douglas Lowy, MD, of the National Cancer Institute, who will discuss prevention of HPV-associated cancers through vaccination.

Plenary Abstract Presentations

LBA1

TAILORx: Phase III trial of chemoendocrine therapy versus endocrine therapy alone in hormone receptor-positive, HER2-negative, node-negative breast cancer and an intermediate prognosis 21-gene recurrence score.
First Author: Joseph A. Sparano, MD

LBA2

Maintenance low-dose chemotherapy in patients with high-risk (HR) rhabdomyosarcoma (RMS): A report from the European Paediatric Soft Tissue Sarcoma Study Group (EpSSG).
First Author: Gianni Bisogno, MD, PhD

LBA3

CARMENA: Cytoreductive nephrectomy followed by sunitinib versus sunitinib alone in metastatic renal cell carcinoma: Results of a phase III noninferiority trial.
First Author: Arnaud Mejean, MD, PhD

LBA4

Pembrolizumab (pembro) versus platinum-based chemotherapy (chemo) as first-line therapy for advanced/metastatic NSCLC with a PD-L1 tumor proportion score (TPS) ≥ 1%: Open-label, phase 3 KEYNOTE-042 study.
First Author: Gilberto Lopes, MBA, MD

Post-Plenary Discussion Sessions

- 4:00 PM-4:30 PM: Post-Plenary Discussion Session I: Breast Cancer—Local/Regional/Adjuvant (S100a)
- 4:30 PM-5:00 PM: Post-Plenary Discussion Session II: Rhabdomyosarcoma (S100bc)
- 5:00 PM-5:30 PM: Post-Plenary Discussion Session III: Kidney Cancer (S100a)
- 5:30 PM-6:00 PM: Post-Plenary Discussion Session IV: Lung Cancer (S100bc)

4:45 PM-6:00 PM

Precision Medicine for a Single Patient: What Does It Really Mean and How Do We Do It?

S406

Precision medicine offers great promise for targeted cancer care, but it also presents a number of challenges and complexities. This session will look at the role of big data and informatics to inform patient selection and guide the application of precision medicine, and will also examine research challenges such as trial size, off-label usage, and single-patient requests for investigational new drugs. ●

ASCO's Programs for Oncology Administrators: Helping Practices Deliver High-Value Care

Oncology administrators play a vital role in the cancer care landscape. They ensure clinical processes remain efficient, financial systems remain effective, and practices remain capable of providing the best care possible to patients with cancer as the health care landscape continuously evolves.

Given the essential role administrators play, it is critical that they have the resources, services, and information they need to stay on top of changes and improve upon on current processes. ASCO is dedicated to providing these tools to oncology administrators and practices, enabling them to enhance business operations and help providers deliver high-quality, high-value cancer care to their patients.

Membership

ASCO's Practice Administrator membership category is available to individuals who monitor and supervise the business operations of an oncology medical practice, cancer center, or facility and who devote a majority of their professional activity to financial, facility, reimbursement, and human resource management. Membership includes access to premier oncology periodicals, including free online access to the *Journal of Oncology Practice*, as well as access to practice improvement tools, discounts on career and educational development resources such as ASCO University®, and opportunities to participate in ASCO activities geared toward improving oncology practices and meeting administrators' needs.

Practice Central

All of ASCO's services for administrators are conveniently accessible on the new ASCO Practice Central website, practice.asco.org.

ASCO Practice Central

The site is a one-stop shop for practice support services, billing and coding, and practice management and quality improvement programs. Among other resources, administrators will find the following:

Practice Engagement Program

Adapting to sweeping changes in physician reimbursement can be difficult—especially when it involves implementing entirely new systems. ASCO's Practice Engagement Program helps administrators get started. The program is a concierge service for oncology practices, through which ASCO provides a single point of contact to help administrators identify and connect with ASCO's host of tools and programs. ASCO's Practice Engagement Team identifies practices' specific needs and assists them in resolving challenges through the most appropriate resources. Practice Engagement Team members are available through phone calls, email, or on-site visits, and will help practices with any questions they may have—from improving Merit-based Incentive Payment System (MIPS) scores to transitioning from volume-based to value-based care and demonstrating a commitment to quality.

Practice Consulting Services and Support

ASCO Practice Consulting Services and Support are personalized and comprehensive. Practices receive personal support from a team of nationally recognized experts in oncology practice management. ASCO consultants offer a readiness assessment to prepare practices to transition into a value-based care model; a practice operational assessment through which administrators may review their process, staffing, and financial efficiency; and a host of analytical services, practice transformation support services, and implementation support for triage pathways to help administrators offer their patients the right care at the right time in the right place.

Dr. Peter Yu

"ASCO Practice Consulting Services and Support provide a trusted, independent consulting service to look across our practice sites for unwarranted variation and gaps in best practices," Peter Paul Yu, MD, FASCO, FACP, 2014-2015 ASCO past president and physician-in-chief of Hartford HealthCare Cancer Institute, said. "Having a trusted organization such as ASCO provide an objective comparison to the experiences of oncology practices across the country is a strong catalyst for opening positive discussions on uncomfortable topics."

Practice Benchmarking

Using benchmarks to compare practice processes, care model, and productivity relative to other comparable practices can help administrators identify goals and areas for improvement. ASCO's benchmarking services, including the ASCO Practice Census, the Survey of Oncology Practice Operations, and PracticeNET can help administrators do just that.

See Programs for Oncology Administrators, Page 18

Saturday Night Cocktail Bar Recommendations

Looking for recommendations for cocktail bars close to McCormick Place? Look no further than the *ASCO Daily News: Evening Edition*. We encourage you to call or visit individual restaurant websites for more information. Miles listed represent the distance from McCormick Place, and most suggestions are within walking distance from public transportation or the Convention Center itself. ●

Arc Bar
mccormickplace.regency.hyatt.com/en/hotel/dining/arcbar.html
2233 S Martin Luther King Drive (0.2 miles)
Grab a seat right next door from McCormick Place in the Hyatt Regency for craft beers and cocktails.

CH Distillery
chdistillery.com
564 W Randolph Street (4.1 miles; 0.2 miles from Clinton Metra Station)
A combination of industrial chic and new-age creations, CH Distillery features innovative cocktails from their on-site stills and upscale bar food with a twist.

M Lounge
mloungechicago.com
1520 S Wabash Avenue (1.0 miles; 0.2 miles from the Michigan & 16th Street Bus Stop)
Featuring an array of fine spirits (as well as nonalcoholic beverages), the M Lounge is especially known for its martinis.

RM Champagne Salon
rmchampagnesalon.com
116 N Green Street (3.8 miles; 0.2 miles from Morgan Metra Station)
Champagne flows as Executive Chef Jared Van Camp creates classic pairings such as steak frites, assorted cheeses, and a delicious raw bar.

Rocky's Sports Restaurant
rockyschicago.com
234 W 31st Street (2.5 miles; 0.4 miles from Sox-35th Metra Station)
With a relaxed atmosphere and craft drinks, Rocky's combines the beloved sports teams of Chicago with a wide variety of cuisine to satisfy every palate.

Sakura Karaoke Bar
sakurakaraokebar.com
234 W Cermak Road (2.2 miles; 0.1 miles from Cermak-Chinatown Metra Station)
One of the best-known places in Chicagoland, Sakura provides the stage for you to test your singing skills while you sip on house-crafted martinis and munch on both Western and Japanese fare.

Weather Mark Tavern
weathermarktavern.com
1503 Michigan Avenue (1.5 miles; 0.1 miles from Michigan & 16th Street Bus Stop)
This nautical-themed tavern mixes up signature cocktails and delicious food to create the perfect hangout for a Saturday evening.

Conquer Cancer Award

Continued from page 10

on solid tumors, have achieved a 74% 5-year survival rate for children with cancer.[1]

Meanwhile, the national childhood cancer survival rates in Turkey have increased to 65% through the research, collaboration, and leadership of Dr. Kebudi and her colleagues in local and national oncology organizations.[2]

For example, as a board member and former president of the Turkish Pediatric Oncology Group, Dr. Kebudi and her colleagues helped create an ongoing campaign with the Ministry of Health in 2006 to educate local primary care physicians and nurses to recognize the signs of pediatric cancer so children could be diagnosed and treated earlier.

Dr. Kebudi also cofounded the Istanbul Pediatric Febrile Neutropenia Working Group in 1998, which increased awareness of pediatricians and oncologists throughout Turkey about the importance of supportive care in children being treated with intensive chemotherapy. "If a child is running a fever from chemotherapy-induced neutropenia, it's critical that the child be hospitalized immediately and started on antibiotics. Without this care, the child could die," Dr. Kebudi said.

She continues to raise awareness of supportive care as past co-chair of the International Society of Pediatric Oncology (SIOP)-Pediatric Oncology in Developing Countries Supportive Care and Nutrition Working Group and as the current co-chair of the SIOP-Supportive Care Working Group.

She is also working with colleagues from the Middle East Cancer Consortium to improve pediatric palliative care services in the region and was involved in developing a course on pain management.

A Long-Time Mentor

Dr. Kebudi has been mentoring fellows, residents, and medical students since 1993 when she earned her associate professor degree from Istanbul University. She involves her mentees in the research she conducts by writing papers together and collaborating on presentations given at international oncology meetings such as the ASCO Annual Meeting in Chicago.

"The research and treatment advances presented every year [during the ASCO Annual Meeting] are invaluable for participants, especially those coming from developing countries," Dr. Kebudi said.

Dr. Kebudi also engages mentees in clinical pediatric oncology work at the Istanbul University Oncology Institute. For example, weekly pediatric tumor boards have been held there for almost 40 years. "We invite residents and fellows from all pediatric oncology centers in Istanbul to participate," she said. "Our tumor boards are multidisciplinary teams with many specialties represented including pediatric oncologists, radiation oncologists, surgeons, radiologists, and pathologists. All cases are discussed, and the relevant literature is reviewed; it's very educational."

According to Dr. Kebudi, the majority of pediatric oncologists in Turkey are women, leading to more female mentees in hematology-oncology. "I tell my female mentees that you can combine an academic medical career with raising a family if you are self-confident, well organized, and hardworking," Dr. Kebudi, who is married with two grown sons, said.

Witnessing her mentees succeed and become leaders in pediatric hematology-oncology is very rewarding, Dr. Kebudi said. "Most of the pediatric oncologists I have trained hold good positions in academia. One mentee heads a department of pediatrics at another major university in Istanbul, and several others head the hematology-oncology divisions at their academic centers in Istanbul and in other cities."

In fact, Fatma Betul Cakir, MD, a hematology-oncology fellow who trained under Dr. Kebudi, won ASCO's International Development and Education Award in Palliative Care in 2014.

"I was fortunate to have had very distinguished national and international mentors," Dr. Kebudi said. "It's important to pass on our knowledge and experience to young mentees so they become good academicians who go on to mentor the next generation." ●

–Christine Lehmann, MA

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Reduce Obesity Risk

Continued from page 4

- ASCO's Research Summit on Advancing Obesity Clinical Trials in Cancer Survivors, held in 2014 to identify the unmet needs and opportunities for research regarding obesity, weight loss, and cancer. "Most of the research studies up to this point have been observational. We looked at what types of additional data will be needed to establish weight loss and physical activity as a standard part of cancer care," Dr. Ligibel said. The recommendations from the summit were published in *JCO* in November 2015.[4]

"ASCO has recognized that obesity is an area of increasing research. Having high-quality research will enable us to determine what policies we should advocate for on behalf of our patients with cancer and enable oncology providers to give patients evidence-based information to make the necessary lifestyle changes to reduce obesity," Dr. Ligibel said. ●

–Christine Lehmann, MA

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Programs for Oncology Administrators

Continued from page 17

When practices submit their core business, operational, and administrative data through the secure PracticeNET system, they receive comprehensive analyses that indicate how that practice compares to others, how the practice is trending over time, and the relative efficacy of their current business operations and resource allocation. PracticeNET participants also engage and discuss analytics and practice operations with experts and the community through a moderated listserv and community sharing platform.

Billing, coding, and reporting

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program, which is transforming the way physicians are reimbursed for services provided under Medicare Part B. To help practices prepare for these challenges, ASCO provides up-to-date materials and access to ASCO's Quality Oncology Practice Initiative (QOPI®) Reporting Registry for MIPS reporting. ASCO also offers a hotline service for administrators to ask questions related to coding, billing, and reimbursement and submit any Medicare coverage challenges they might be facing.

Staff recruiting and development

To ensure high-quality care, practices must employ and train high-quality care providers. To assist in this process, ASCO offers materials on physician recruiting strategies, preventing physician burnout, and practice-based training, including access to human resource tools and Oncology 101 training for staff new to oncology. Access to ASCO's Oncology Career Center also offers practices the opportunity to post jobs and monitor applications, search ASCO's database for quality candidates, and filter applications with screening questions. Advanced Practitioner Certificate Programs and a selection of career-based learning opportunities are also available.

Events

ASCO hosts a number of events, workshops, and meetings directed toward practices and oncology administrators. One such event is the yearly ASCO Oncology Practice Conference. Through a comprehensive, up-to-date calendar located on the Practice Central website, administrators can browse and filter ASCO events and deadlines.

Oncology Practice Insider

ASCO's Oncology Practice Insider (OPI) is a comprehensive news source covering the latest oncology practice news, information, and educational tools to assist administrators with successfully managing oncology practices and delivering high-quality patient care. OPI is a source for updates on the U.S. Food and Drug Administration, cancer-related health policy, Medicare news, billing and coding best practices, and ASCO

ASCO PracticeNET

programs and services. Administrators may either sign up for the biweekly OPI email newsletter or visit the OPI page on the Practice Central website, which publishes practice-related news on a continual basis. Readers may search for past news stories and filter content based on category and date. ●

–Caroline Hopkins

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How to Improve Your Practice Using ASCO University® Resources

The *ASCO Daily News* spoke with ASCO members about their experience using ASCO University® resources in their practices. In the following article, the members discuss their top four products and why they would recommend them to other oncologists and clinical researchers.

Personalized Learning Dashboard

Participants can use the Personalized Learning Dashboard to take a quick self-assessment of their preferred learning methods and current knowledge, and then a personalized learning plan will guide them through continued learning. The Personalized Learning Dashboard offers videos, text-based articles, audio podcasts, and eLearning courses.

Travis Osterman, DO, of Vanderbilt University School of Medicine, credits the Personalized Learning Dashboard with helping him gauge areas of weakness in his knowledge base along with offering recommendations on how to address them.


Dr. Travis Osterman

"The Personalized Learning Dashboard will fill a need that has been voiced frequently by trainees; we need a way to evaluate their knowledge," Dr. Osterman said. "Before the Personalized Learning Dashboard, this would typically occur only once a year during ASCO in-service exams."

But now, in what Dr. Osterman calls a "breakthrough moment for ASCO University," the Personalized Learning Dashboard "balances the wide breadth of material with different learning methods to allow trainees to use information that best suits them at any time," he said.

Courses

ASCO University offers courses in various tumor types as well as additional oncology topics, including patient and survivor care, professional development, and ethics.

Dr. Osterman said that he uses the Molecular Oncology Tumor Boards, a series of bimonthly discussion-based courses on using and interpreting tumor molecular profiling tests and studies, "to get up-to-date information, as the field changes so frequently. It's a great opportunity to see what expert opinions are in the field."

Like Dr. Osterman, Filipa Lynce, MD, of the Georgetown Lombardi Comprehensive Cancer Center, said she likes to use the Molecular Oncology Tumor Boards as they are released to keep her engaged with the most up-to-date oncology material. She also uses ASCO University courses that are specific to her specialization and research interests.


Dr. Filipa Lynce

"As an oncologist, I have completed different courses that are of particular relevance for my areas of interest, such as the Immuno-Oncology Program or the Cancer Genetics Program," Dr. Lynce said.

Catherine "Katie" Lai, MD, MPH, of the Georgetown Lombardi Comprehensive Cancer Center, said that regardless of the course a learner selects, ASCO University offers participants the opportunity to explore different topics in oncology and gain new perspectives on familiar ones.

"These courses are especially good for learners who came from smaller institutions who may not encounter all tumor types to ensure the gap is filled where knowledge is deficient," Dr. Lai said. "Alternatively, those at large institutions may gain a perspective that was not considered previously."


Dr. Catherine Lai

MOC

ASCO University offers a number of different activities to help learners address knowledge gaps. These include *ASCO-SEP*® 6th Edition, a traditional textbook that includes a general review of topics and questions, as well as the ASCO MOC app courses, which prompt users with weekly questions and answer rationales.

Dr. Lai and Dr. Lynce both said *ASCO-SEP* and the ASCO MOC app courses are useful for those early in their careers as well as those who have been in practice for some time.

"For example, 10 years from now, if I'm only seeing patients with leukemia, the MOC app will allow me to stay informed about the latest treatments in the other tumor types," Dr. Lai said. "Oncology is becoming more subspecialized, but I still want to know the most recent advances in other cancers."

Dr. Lynce said she also uses ASCO University's MOC resources to keep her general oncology knowledge fresh, and it helps when preparing talks for residents and fellows.

Since 2015, ASCO's MOC app-based courses have offered a convenient way to earn ABIM MOC points. The ASCO MOC app allows easy access to self-assessment questions designed for a mobile device. The courses offer an engaging technique to help oncologists retain information with a pulsed-education approach. The app sends notifications every other day with a selection of course questions ready to complete. This technique assists with knowledge retention while easily fitting into an oncologist's busy schedule. Multiple-choice questions include a wide variety of general oncology topics; the app provides not only these questions, but also patient case information, educational links, and answer rationales.

The courses are available through the subscription to ASCO University Essentials; otherwise, ASCO members receive a 20% discount, and course bundles are available for added savings. The 2018 bundle offers three new courses and is currently available for $108 for ASCO members and $135 for nonmembers. Each course now provides learners with 40 multiple-choice questions for a total of 120 questions in each bundle. After successfully completing the questions, eligible ABIM diplomates may claim five MOC points per course. In addition, for the 2018 courses, *5 AMA PRA Category 1 Credits™* are available upon successful completion.

Why use the app?

Those who have already used the app to earn MOC points speak to its helpful technique and convenience.

"This simple, bite-sized ASCO MOC app for my smartphone has helped satisfy my remaining MOC point requirements," Dean H. Gesme, MD, FASCO, FACP, president of Minnesota Oncology, said. "It allowed me to download low-cost clinical teaching modules with multiple-choice questions each day, with immediate feedback on my answers. I was able to accomplish this by simply spending 5 to 10 minutes a day on the app. What a better way to learn while maintaining a busy oncology practice."


Dr. Dean Gesme

Vikki A. Canfield, MD, of Mercy Oncology, who has completed several modules using the MOC app, commented on its utility. "[The MOC app] is easy and fun to use. I like that I can do a few questions a day. I highly recommend this forum for obtaining MOC points and ongoing learning," she said.


Dr. Vikki A. Canfield

The app is helpful for any oncology professional who is working to satisfy MOC requirements or simply to stay current in oncology. Download it from Google Play, the Apple App Store, or the ASCO University Bookstore (shop.asco.org).

Meeting Library

The Meeting Library is an archive of scientific and education session content from ASCO and ASCO-cosponsored symposia and meetings. The library contains presentation slides, videos, and links to abstracts and related content for most sessions.

Dr. Lynce said she uses the Meeting Library to review general oncology topics, whereas Dr. Lai said that she relies on its content to teach oncology fellows about the most recent studies, as well as clinical trial design.

"If you miss a session or want to see it again, you can go back to it in the Meeting Library and re-watch the presentation again or pull up the slides," Dr. Lai said. "It's helpful when I teach fellows, and I want to show them a graph from a presentation."

For more information about ASCO University's products and resources, visit university.asco.org. ●

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American Cancer Society Award

Continued from page 14

aims to evaluate whether a modern approach to genetic counseling and genetic testing can be as effective as the standard approach.

The MAGENTA study offers genetics testing and genetic counseling services to women at high risk of developing ovarian cancer based on their family history. Interested participants can express their interest and sign consent forms online, after which those selected for the study are sent a saliva sample collection kit.

"The testing [of the saliva sample] is done for *BRCA1* and *BRCA2* gene mutations and several other genetic markers that increase the risk for developing ovarian cancer. When testing is complete, the results can be accessed online, along with educational materials," Dr. Lu said. "There is no need to go to a hospital or a clinic."

During her lecture on June 4, Dr. Lu will provide an overview of prevention strategies for ovarian and endometrial cancer in high risk women. She will also reflect on how caring for patients with cancer has driven her interest in cancer prevention and early detection. ●

–Jasenka Piljac Žegarac, PhD

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Save the Date: 2018 ASCO Oncology Practice Conference

The 2018 ASCO Oncology Practice Conference will take place September 27, 2018, in Phoenix. This 1-day conference brings together top leaders in the field to discuss regulatory, administrative, and legal challenges faced by oncology practices. Topics covered during the meeting include MACRA, lessons in sustaining a practice, and alternate payment models. Sessions are educational in nature and zero in on the processes of adapting new models of care and delivery, as well as establishing productive processes and business operations.

"Oncology practices face many challenges in the current dynamic environment," conference Planning Committee Chair Robin Zon, MD, FACP, FASCO, said. "The goal of the conference is to address these issues by sharing best practices and strategies to preserve the delivery of high-quality, cost-effective care."

Registration for the 2018 ASCO Oncology Practice Conference is now open. For more information, visit opc.asco.org. ●

ASCO ONCOLOGY PRACTICE CONFERENCE
The Business of Cancer Care

WHY I ATTEND: DR. MICHAEL G. MARTIN

Michael G. Martin, MD, a medical oncologist of West Cancer Center, has attended the ASCO Annual Meeting for more than 10 years. In the following interview, Dr. Martin discusses why he continues to attend the Annual Meeting and shares his perspective about why it's a critical event for medical oncologists.

Q: Why have you continued to attend the Annual Meeting?
Dr. Martin: Since I was a medicine resident, the ASCO Annual Meeting has been an integral part of my career development. I couldn't be an informed, up-to-date medical oncologist without attending. It's the only way to fully engage in the presentations, question-and-answer sections, and Education Sessions, and to hear how people struggle with very important questions and issues.

Q: Why is it important for medical oncologists to attend?
Dr. Martin: Medicine is constantly changing. We need to be able to serve our patients and offer cutting-edge care. ASCO provides a variety of opportunities to engage with emerging therapies. It is important not only to attend Plenary and Oral Abstract Sessions, but to walk through the Poster Sessions, talk to fellows standing in front of their posters, and learn the valuable current trends in research. First-line therapies are often defined in medical oncology by the Plenary and Oral Abstract Sessions, but new, potential options of what to do if the first-line treatment fails are presented during the Poster Sessions. ASCO provides a dynamic way to digest that amount of data.

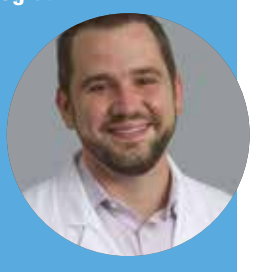
Q: Apart from the actual science, what are some of the benefits of attending?
Dr. Martin: Chicago is an amazing city that has much to offer each evening when the Meeting closes. But more important is the chance to sit down and chat with others in your field, strike up a conversation about what was just presented, and what information to take home to the clinic.

Q: What has changed about the ASCO Annual Meeting over the years you've attended?
Dr. Martin: Over my decade-plus of attending the Annual Meeting, it feels bigger and more kinetic—and hence more intimidating. But it also has become so vital to truly understanding the data and how to treat patients in the clinic. We are no longer watching presentations of randomized phase III trials of a thousand patients with advanced lung cancer that fail or add only a month to overall survival. We are seeing the evolution of oncology and movement toward potentially curing the incurable. It is an amazing time to be a medical oncologist.

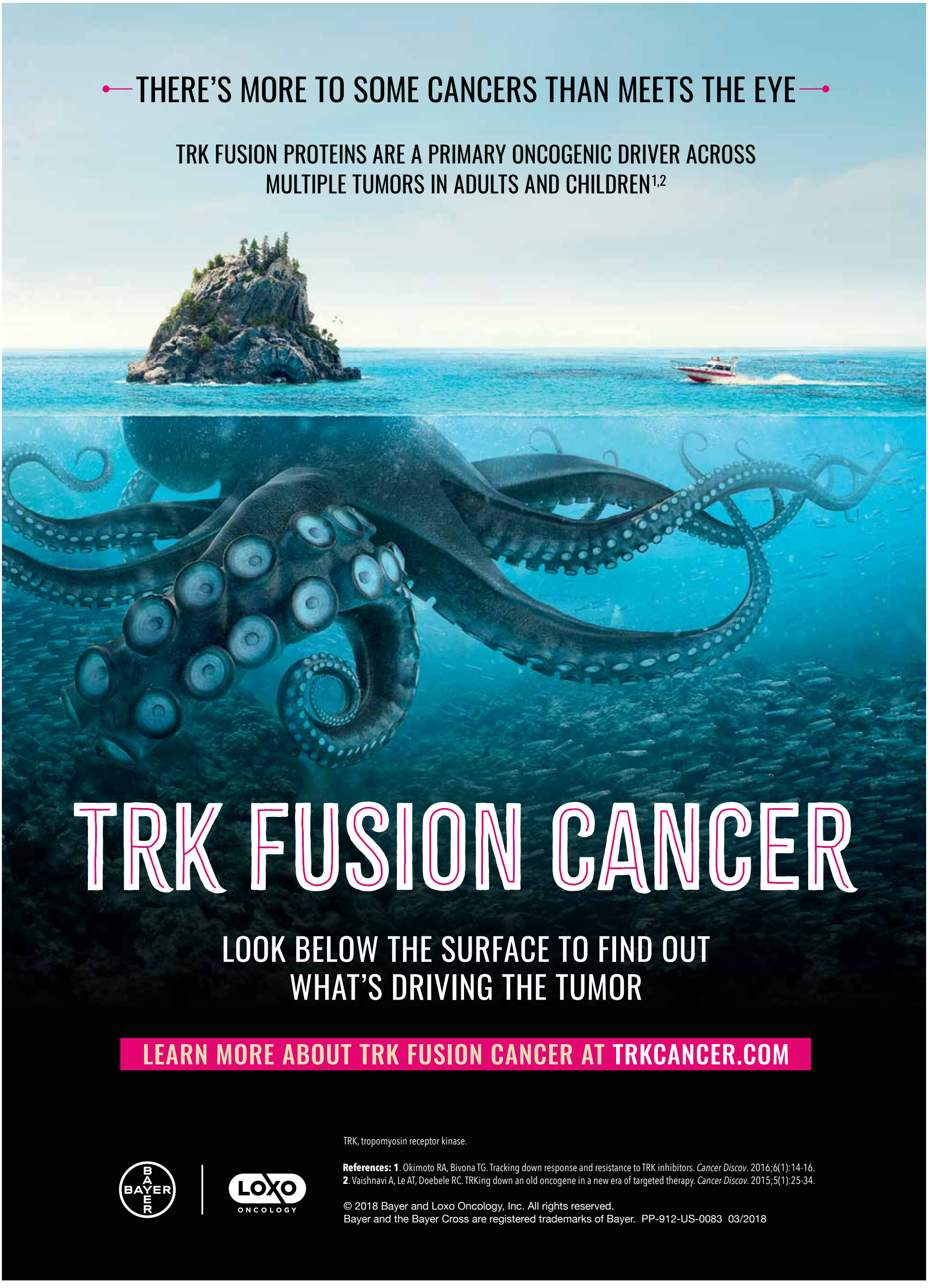
Walking through the Poster Sessions and talking to researchers about their posters are key ways to learn current research trends.

Q: What do you think the Annual Meeting will be focused on in 10 years?
Dr. Martin: I think the emphasis on immunotherapy will continue. In addition to highlighting new therapies, however, there are two important issues emerging that need to be addressed in oncology: access to care and cost control issues. Although many of the recent advances have been amazing, they are extremely expensive. As a community, we need to figure out how to deploy these advances to practice socially responsible medicine, and to save every life that we can—that is the oath we all took. How do we make these therapies accessible to everyone?

Q: Why do you think it's important to attend the Meeting in person as opposed to following the research virtually?
Dr. Martin: The dedicated time it takes to be there removes other distractions and allows you to focus on learning and how you can best serve your next patient. There is nothing like being present and watching it all unfold, running between the sessions, jotting down notes, and growing as an oncologist. ●



Michael G. Martin, MD, is a medical oncologist at West Cancer Center.



TRK, tropomyosin receptor kinase.

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