

TODAY'S HIGHLIGHTS

Plenary Session: Immunology in Lung Cancer Update 2017

8:15-9:45
 Plenary Hall (Exhibit Hall D)

Mini Symposium: Being Mortal: Learning from ZEN

11:00-12:30 • Room 316

Mini Symposium: The Cost of Lung Cancer

11:00-12:30 • Room 502

Educational Session: Recent Advances in Diagnostics and Interventional Bronchoscopy

11:00-12:30 • Room 503

Mini Symposium: Engaging Patients in Research: Best Practices

14:30-16:15 • Room 311 + 312

Educational Session: Recent Progress in the Management of Small Cell Lung Cancer

14:30-16:15 • Room 501

Educational Session: Radiation Treatment Update

14:30-16:15
 F201 + F202 (Annex Hall)

Closing Plenary: Where We Are Now, and Where We Will Be in 10 Years

16:30-17:45 • Main Hall

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Top Three Abstracts Discussed at Presidential Symposium

By *Cynthia L. Kryder, MS*

The Presidential Symposium on Tuesday morning recognized the authors of three exceptional abstracts submitted to WCLC 2017.

Patient-reported Outcomes from the PACIFIC Trial

According to previously reported efficacy and safety results of the PACIFIC trial, patients receiving durvalumab had a significant improvement in progression-free survival (16.8 months vs. 5.6 months) (see Figure 1 on page 2), and a lower incidence of new lesions, including new brain metastases, compared with patients receiving placebo after definitive chemoradiation therapy for locally advanced NSCLC. Additionally, durvalumab was well tolerated with a manageable safety profile. In Tuesday's session, Rina Hui, MBBS, FRACP, PhD, Crown Princess Mary Cancer



Rina Hui, MBBS, FRACP, PhD

Centre, Westmead, Australia, presented additional data on patient-reported outcomes, a secondary endpoint of the PACIFIC trial, a randomized, placebo-controlled, double-blind, phase III study in locally advanced, unresectable NSCLC.

see **Presidential Symposium**, page 2

Community Engagement Program Designed to Reduce Lung Cancer Disparities

By *Lori L. Alexander, MTPW, ELS, MWC®*

Disparities in lung cancer exist among racial/ethnic minorities and the medically underserved. A study to be presented on Wednesday addresses this issue with the use of a specialized educational program to improve cancer health literacy and outcomes in disparate populations.

The authors evaluated the effect of cancer-Community Awareness Access Research & Education (c-CARE), a program designed to increase community awareness of lung cancer risk factors and screening criteria.

"Minority and medically underserved populations are less likely than others to adopt new cancer screenings,"



Lovoria B. Williams, PhD, APRN-BC, FAANP

explains Lovoria B. Williams, PhD, APRN-BC, FAANP, Georgia Cancer Center, Augusta University, Augusta, USA, who will present the findings.

see **Community Engagement**, page 9

Presidential Symposium

Continued from page 1

Dr. Hui and colleagues randomly assigned 713 patients who had previously received two or more cycles of platinum-based concurrent chemotherapy with definitive dose radiation without disease progression to durvalumab (476 patients) or placebo (237 patients) for up to 12 months. Key symptoms, physical function, and global health status/quality of life were assessed using the EORTC QLQ-C30 v3 questionnaire and its lung cancer module, QLQ-LC13. Changes from baseline were analyzed using a mixed model for repeated measures.

Dr. Hui reported that compliance for questionnaire completion was above 80% in both groups and there were no between-group differences at baseline for key symptoms,

physical function, or global health status/quality of life. She stated that treatment with durvalumab after concurrent chemoradiation therapy did not worsen symptoms, function, or global health status/quality of life for patients with locally advanced, unresectable NSCLC (Figure 2). Similarly, she noted that the change from baseline for key symptoms was minimal with both durvalumab and placebo.

“Combined with the efficacy and safety findings from PACIFIC, these data further support the use of durvalumab in this disease setting,” concluded Dr. Hui.

Discussant Michael Boyer, MBBS, PhD, Sydney Cancer Centre, Sydney, Australia, commented that measuring patient-reported outcomes is a vital component of clinical trials such as PACIFIC to ensure that a survival improvement is not outweighed by a

negative impact on quality of life.

Mature Survival Results: Spanish Lung Cancer Group Trial

Bartomeu Massuti, MD, Alicante University Hospital, Alicante, Spain, presented the mature survival results of SCAT, a randomized phase III multicenter trial that examined whether it might be possible to customize adjuvant chemotherapy based on *BRCA1* expression in patients with resected node-positive NSCLC. Dr. Massuti explained that *BRCA1* and *BRCA2* are important DNA repair factors primarily involved in the repair of double-strand DNA breaks. *BRCA1* deficiency has been found to enhance resistance to cisplatin, whereas loss of *BRCA1* function is associated with sensitivity to DNA-damaging chemotherapy. SCAT investigators hypothesized that a signifi-



Bartomeu Massuti, MD

cant proportion of patients with high *BRCA1* expression would be cisplatin-resistant and would benefit from single-agent docetaxel.

A total of 500 patients were randomly assigned to the control (108 patients) or experimental arm (392 patients). Patients in the control arm received docetaxel plus cisplatin. In the experimental arm, 110 patients with low *BRCA1* expression levels received cisplatin and gemcitabine, 127 patients with intermediate levels received cisplatin and docetaxel, and 110 patients with high levels received docetaxel alone (see Figure 3 on page 3). Overall survival was the primary endpoint.

Dr. Massuti reported that customization of adjuvant chemotherapy according to *BRCA1* levels did not yield significant differences in overall survival for the overall population in node-positive resected NSCLC (see Figure 4 on page 3). In the subgroup with low *BRCA1* levels, experimental treatment with cisplatin/gemcitabine proved superior to the control group (74 months vs. 40.1 months). In addition, survival for the subgroup with high *BRCA1* expression levels receiving treatment without platinum was similar to that for the control group. Dr. Massuti noted that higher *BRCA1* expression levels were associated with male sex, squamous histology, and current or former smoking status.

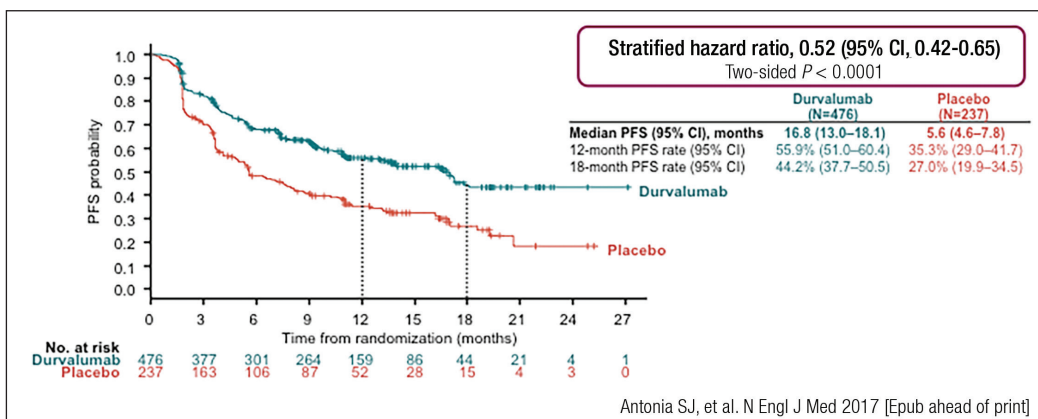


Figure 1. The primary endpoint in PACIFIC was progression-free survival (by blinded independent central review).

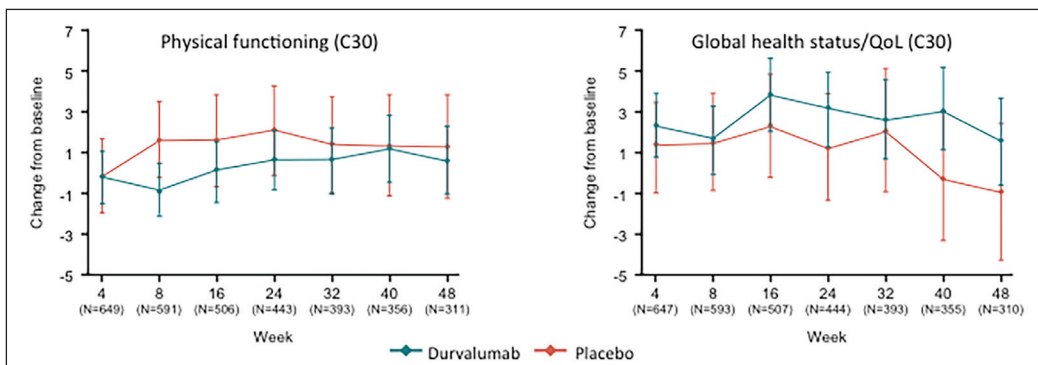


Figure 2. Changes from baseline in function and global health status between groups in PACIFIC. QOL = quality of life.

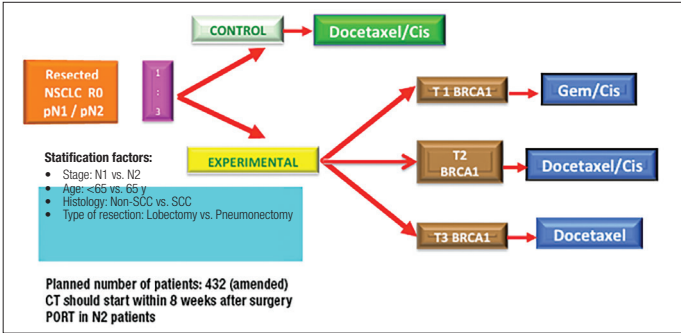


Figure 3. Trial design for SCAT, a phase III trial of customized adjuvant chemotherapy based on *BRCA1* expression level.

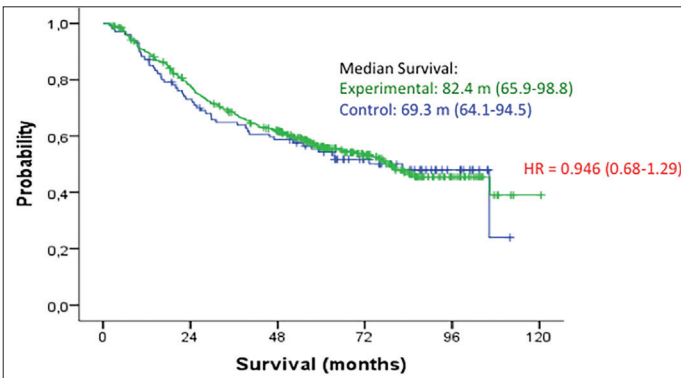


Figure 4. Overall survival in SCAT (cut-off July 31, 2017).

Discussant Joan Schiller, MD, University of Texas-Southwestern Medical Center, Dallas, USA, remarked that relatively few DNA repair-driven clinical trials have examined the role of *BRCA1* in lung cancer, as Dr. Massuti and colleagues have done. She noted that although SCAT was negative for its primary endpoint of survival in the experimental arm compared with the control arm, it does provide evidence that patients with high *BRCA1* expression levels have a worse prognosis and that *BRCA1* status may serve well as a stratification factor in future trials. In addition, *BRCA1* expression might be even more important in determining the role of a taxane than a platin.

IASLC Lung Cancer Staging Project: Analysis of Resection Margin Status and Proposals for R Status Descriptors

The residual tumor (R) classification, which describes tumor status after

surgery, reflects the effectiveness of treatment, has prognostic impact, and may affect further treatment. John Edwards, MD, University of Sheffield, Sheffield, UK, reported on the efforts of the IASLC R Domain Subcommittee to analyze existing and potential R status criteria, including the 2005 proposed IASLC definition for “uncertain” resection margin status using data collected for the IASLC Lung Cancer Staging Project. Dr. Edwards reported

the results based on 14,712 patients undergoing surgery for NCSLC for whom full R status and survival data were available.

Dr. Edwards and colleagues reviewed data and re-assigned cases to the uncertain category [R(un)] if any of the following parameters were present: examination of fewer than three N1 or N2 nodes; less than lobe-specific systematic lymph node dissection; extracapsular invasion of N2 nodes; positive highest lymph node station; carcinoma in situ at bronchial resection margin; and positive pleural lavage cytology. Revised categories of R0, R(un), R1, and R2 were designated and tested for survival impact.

Dr. Edwards reported that 56% of cases became R(un) after recoding. The majority of cases were R(un) due to intraoperative staging that proved less rigorous than systematic lymph node dissection. He noted that in pN2 cases with the highest station positive, median survival was 14 months less compared with highest station-negative cases. In node-positive cases, median survival was 20 months less for those with R(un) status compared with R0 (Figure 5).

Dr. Edwards stated that these results show that the

IASLC Proposed Definition for Complete Resection has relevance, according to the 8th Edition Database. High-quality surgical staging, he indicated, gives the most accurate assignment of stage group and the most favorable survival data, stage by stage. Likewise, optimal staging data enable the most appropriate decision-making for routine adjuvant therapy.



John Edwards, MD

“In designing and analyzing clinical trials of adjuvant therapies, undertaking a thorough evaluation and characterization of R status is critical,” concluded Dr. Edwards. “Further detailed data collection will be necessary to see the full impact of R status subcategories in a clinical setting, and we urge institutions to participate in the IASLC Lung Cancer Staging Project. Our confirmation of the IASLC’s proposed criteria is an im-

see **Presidential Symposium**, page 5

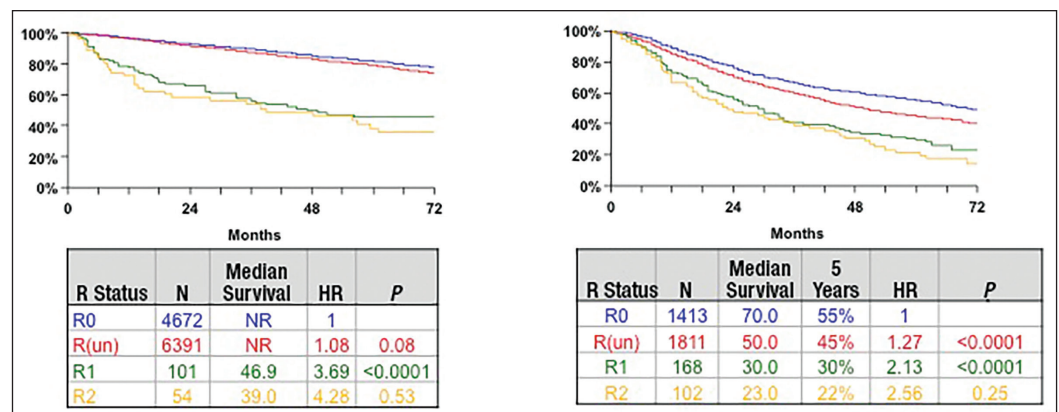


Figure 5. Survival according to R status in N0 (left) and N-positive (right) cases in the IASLC Lung Cancer Staging Project.



Giving Ceritinib with Meals Can Mitigate GI Side Effects

By Mary Nishikawa

A lower dose of ceritinib taken with a low-fat meal has comparable pharmacokinetics and efficacy and a more favorable gastrointestinal (GI) safety profile than a higher dose taken while fasting.

Ceritinib, a second-generation ALK inhibitor, is approved for patients with *ALK*-positive NSCLC who are treatment-naïve, have disease progression during treatment with crizotinib, or are intolerant to crizotinib. The ASCEND-4 study demonstrated that ceritinib at a dose of 750 mg, taken while fasting, was associated with a significantly improved progression-free survival compared with platinum-based chemotherapy (16.6 months vs, 8.1 months; $P < 0.00001$). However, the drug has been associated with high rates of GI adverse events.

Byoung Chul Cho, MD, PhD, Yonsei Cancer Center, South Korea, reported late-breaking efficacy and safety results from the phase I open-label, multicenter ASCEND-8 study, which evaluated lower dosages of ceritinib and administration with food to reduce GI toxicity while maintaining efficacy. Patients were eligible if they had stage IIIB or IV *ALK*-positive metastatic NSCLC and were treatment-

naïve or previously treated with either chemotherapy and crizotinib or crizotinib alone.

From April 2015 to July 2017, 267 patients were randomly assigned to one of three arms: ceritinib at a dose of either 450 mg or 600 mg, taken with food, or ceritinib 750 mg taken while fasting. Baseline characteristics were well balanced among the treatment arms, with minor differences in gender. The key metastatic site of cancer was the brain for about 30% of patients in each arm.

An interim efficacy analysis was conducted for a homogenous group of treatment-naïve patients. Dr. Cho reported the updated safety results on all 265 treated patients and preliminary efficacy for 121 treatment-naïve patients. The median duration of follow-up (from randomization to data cut-off) was 14.3 months for all randomized patients and 9.7 months for the treatment-naïve patients.

The objective response rate and the disease control rate were similar for the three treatment arms, although a large proportion of patients in all arms were censored (ongoing without event or death) due to the immaturity of the data, said Dr. Cho. The estimated 15-month progression-free survival rate was higher for the 450 mg



Byoung Chul Cho, MD, PhD

arm (66.4%) than for the 600 mg arm (58.0%), or the 750 mg arm (41.0%).

The rates of drug exposure and relative dose intensity were highest in the 450 mg arm; the median relative dose intensity was 100% for the 450 mg arm compared with 85.8% for the 600 mg arm and 90.2% for the 750 mg arm.

The rates of dose reductions and dose interruptions were lowest for the 450 mg arm; 18% of patients in that arm had one or more dose reductions compared with 58% (600 mg arm) and 51% (750 mg arm). With regard to dose interruptions, 42% of patients in the 450 mg arm had one or more dose interruptions compared with 64% (600 mg arm) and 61% (750 mg arm).

Overall, the adverse event profile was similar among the three treatment arms ex-

cept for a lower proportion of GI toxicities in the 450 mg arm (Table). Of note, none of the patients in the 450 mg arm had grade 3 or 4 nausea or vomiting, and only one patient had grade 3 or 4 diarrhea. In the 450 mg arm, no drug discontinuation or dose adjustments were due to GI adverse events and approximately 7% of dose interruptions were related to GI adverse events.

“These data suggest that ceritinib at dose of 450 mg with food could be a potential new treatment regimen for managing GI adverse events with efficacy similar to the 750 mg fasting dose for treatment-naïve patients with *ALK*-rearranged advanced NSCLC,” said Dr. Cho. “This finding has profound clinical implications. We have found a solution to reduce these adverse events without compromising efficacy.” ●

Table. Gastrointestinal Adverse Events with Ceritinib*

	Ceritinib, 450 mg (with meal) (N = 89)			Ceritinib, 600 mg (with meal) (N = 86)			Ceritinib, 750 mg (fasting) (N = 90)		
	Grade 1	Grade 2	Grade 3/4	Grade 1	Grade 2	Grade 3/4	Grade 1	Grade 2	Grade 3/4
Diarrhea (%)	41 (46.1)	8 (9.0)	1 (1.1)	38 (44.2)	13 (15.1)	2 (2.3)	43 (47.8)	18 (20.0)	7 (7.8)
Nausea (%)	30 (33.7)	10 (11.2)	0	30 (34.9)	13 (15.1)	5 (5.8)	28 (31.1)	12 (13.3)	5 (5.6)
Vomiting (%)	27 (30.3)	4 (4.5)	0	35 (40.7)	10 (11.6)	1 (1.2)	37 (41.1)	9 (10.0)	4 (4.4)

*Results in the safety-analysis set.

Presidential Symposium

Continued from page 3

portant step in promoting high-quality intraoperative staging and detailed pathologic assessment.”

Discussant Kemp Kernstine, MD, PhD, University of Texas-Southwestern Medical Center, Dallas, USA, noted that these data confirm that R(un) is problematic, as half of the cases had an uncertain complete resection and in this group survival was poor, although better than R1 and R2. He remarked that in the database of 94,708 patients, only 15.5% of patients had sufficient information for analysis. In the future, it would be important to determine what components or combinations of components in the IASLC database are problematic.

James Cox Lectureship Award

James D. Cox, MD, University of Texas MD Anderson Cancer Center, Houston, USA, concluded the symposium with his thoughts on his eponymous lectureship award, to be awarded beginning in 2018. He individually thanked his mentors and collaborators and underscored the importance of interdisciplinary management of lung cancer.

Francoise Mornex, MD, PhD, University Claude Bernard, Lyon, France, an outgoing IASLC Board member, commented on the creation of the Lectureship Award in Dr. Cox’s name.

“This IASLC Lectureship Award in Radiation Oncology is naturally given to Jim Cox as great recognition for his professional life dedicated to oncology, radiother-



James D. Cox, MD

apy, and combined modalities. His prestigious CV reflects his unique capacities for teaching, research, and dedicated patient care. He is also recognized worldwide for his outstanding accomplishments in tutoring young investigators and for his work in the effects of accidental radiation exposure.

This Lectureship Award highlights a man promoting the strategic role of radiation oncology in the management of lung cancer. He is highly respected, admired, and appreciated for his open-mindedness, empathy, and generosity, as well as his luminous smile and unique deep voice.” ●

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TAKE ACTION

Against Lung Cancer!



Plenary Session Focuses on Advances in Immuno-oncology

By Cynthia L. Kryder, MS

Today's Plenary Session will focus on immunology and immunotherapies for lung cancer. Professor Tasuku Honjo, Graduate School of Medicine Kyoto University, Kyoto, Japan, will kick off the session with the keynote lecture on immunology, "Serendipities of Acquired Immunity." Other speakers include Naiyer Rizvi, MD, Columbia University Medical Center, New York, USA, who will discuss biomarkers in immune-oncology therapy; Ming Sound Tsao, MD, Princess Marg-

aret Cancer Centre, Toronto, Canada, who will present the results of Blueprint 2, a PD-L1 immunohistochemistry comparability study;

Blueprint 2: PD-L1 Immunohistochemistry Comparability Study in Real-Life, Clinical Samples

PD-L1 immunohistochemistry assays have been developed as companion diagnostics for specific anti-PD-1/PD-L1 immunotherapies. The Blueprint phase 1 feasibility study demonstrated that three PD-L1 assays (28-8, 22C3, and SP263) showed comparable analytic performance for assessment of PD-L1 expression on tumor cells. Dr. Tsao will present the results of the subsequent Blueprint phase 2A trial,

which was designed to validate the assay comparability results obtained in Blueprint 1 using real-world clinical lung cancer samples and five clinically used PD-L1 assays (28-8, 22C3, SP142, SP263, and 73-10). Blueprint 2 also assessed the comparability and heterogeneity of PD-L1 assay results in surgical tumor resection, core-needle, and fine-needle aspiration samples prepared from the same tumor, and examined the concordance of PD-L1 scoring by pathologists from around the world using standard light microscopy versus digital images accessed by a web-based system.

Current Status and Future of Immunotherapy in Lung Cancer

Dr. Reck will conclude the session with a discussion of the current status of immunotherapy in lung cancer with a glimpse into what the future might hold with regard to the development

of new immunotherapies. Dr. Reck notes that immunotherapy in lung cancer began with inhibition of one immune checkpoint. In multiple randomized trials, multiple anti PD-1/anti PD-L1 antibodies have shown significant improvement in overall survival compared with chemotherapy, as well as an improved safety profile.

An understanding of resistance mechanisms and the creation of strategies to overcome resistance will be of paramount importance for the development of future novel immunotherapeutic agents either as monotherapy or in combination with checkpoint inhibitors, notes Dr. Reck. ●

Plenary Session: Immunology in Lung Cancer Update 2017

8:15-9:45 | Plenary Hall (Exhibit Hall D)

ret Cancer Centre, Toronto, Canada, who will present the results of Blueprint 2, a PD-L1 immunohistochemistry comparability study;

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Stop by the Social Media Corner located on Level 3F of the Conference Center to send tweets and post images from WCLC 2017. A special backdrop is available in the area for taking pictures to post online. You can also stay up-to-date with the WCLC conversation by reviewing screens with live feeds from IASLC's social media accounts, including Twitter, Facebook, and Instagram. Remember to use #WCLC2017 as the hashtag for your posts. ●



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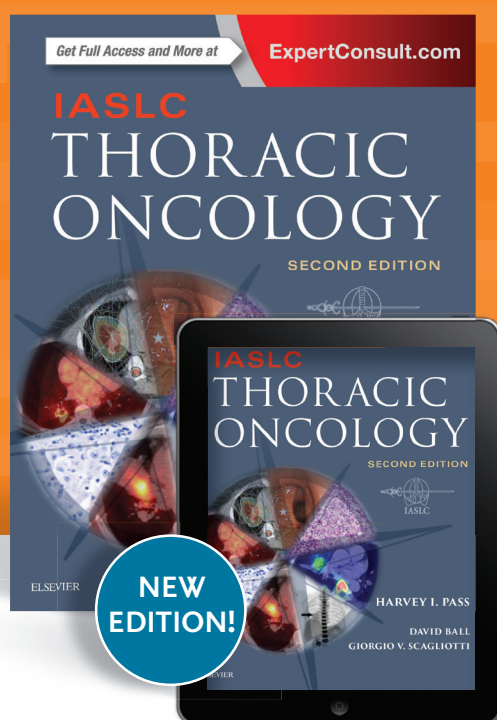
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Molecular Testing in Lung Cancer Moves Forward

By Cynthia L. Kryder, MS

Experts in molecular testing discussed various issues on this topic on Tuesday afternoon. Neil Lindeman, MD, Brigham and Women's Hospital, Boston, USA, led off the session with an overview of the update to the College of American Pathologists (CAP), International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP) 2013 molecular testing guideline in lung cancer. Dr. Lindeman indicated that updating guidelines at least every 5 years is a recommended practice. He identified several factors that influenced the current update, including the emergence of new biomarkers and

targeted therapies; advances in testing technology, such as next-generation sequencing (NGS) and blood-based liquid biopsy; and reconsideration of squamous cancers and SCLCs.

Dr. Lindeman reviewed the draft recommendations (Table 1), noting that the 2013 guidelines, which advised testing for *EGFR* and *ALK*, remain largely unchanged. He explained that *ROS1* testing is now also recommended and should be performed on all advanced-stage adenocarcinomas, irrespective of clinical characteristics. Molecular testing for *BRAF*, *RET*, *ERBB2 (HER2)*, *MET*, and *KRAS* is not currently indicated as a routine stand-alone test outside the context of a clinical trial;

however, it is appropriate to include these as part of larger testing panels performed either initially or when routine *EGFR*, *ALK*, and *ROS1* testing proves negative.

Ignacio Wistuba, MD, University of Texas MD Anderson Cancer Center, Houston, USA, discussed the advantages and challenges of NGS platforms (Table 2). He stressed that these panels provide information in multiple targetable gene abnormalities, and give data on mutation, copy number variations, indels, and translocations. He pointed out that NGS can be performed in routine small formalin-fixed paraffin-embedded tissue samples and liquid biopsy samples. Turnaround time generally is acceptable for clinical management. Clinically, NGS may allow patients to have more options to receive off-label treatment and enter in genomic-based clinical trials, concluded Dr. Wistuba.

Caroline Dive, PhD, Cancer Research UK Manchester Institute, Manchester, UK, discussed the growing application of blood-based liquid biopsy in lung cancer. "It is now clearly obvious that blood is an easily obtained repeatable clinical sample," said Dr. Dive, "whereas serial tumor biopsy is often challenging, more expensive, and not always without risk." She predicts that in 2 years blood tests will stratify most patients with cancer for sequential personalized therapies, will detect relapse early, and will identify drug-resistance mechanisms. Dr. Dive noted that blood tests for early cancer detection, which she considers the Holy Grail, will take a little longer.

Molecular testing using cytology specimens was the



Neil Lindeman, MD

focus of the presentation by Lukas Bubendorf, MD, University Hospital Basel, Basel, Switzerland. Dr. Bubendorf discussed specimen management for biomarker testing, as well as methods for biomarker analyses, including immunohistochemistry, fluorescence in situ hybridization, and mutation analysis. Dr. Bubendorf concluded that cytology is equivalent to histology for molecular testing; however, given the variation in cytologic preparations, such as fixatives and cell block techniques, more standardization is needed with regard to preanalytics and protocols.

Philip Mack, PhD, University of California Davis, Sacramento, USA, was the final speaker in this session. He discussed the optimal collection, processing, and analysis of clinical samples for molecular testing. "Great science and great clinical correlations are contingent on the collection of adequate clinical samples," stated Dr. Mack. He noted that tumor tissue biopsy remains the gold standard; however, if tissue samples are inadequate, blood, urine, and saliva may be suitable substitutes. ●

Table 1. Overview of New Draft Recommendations for Molecular Testing Since 2013

New Biomarkers Added
<ul style="list-style-type: none"> • <i>ROS1</i> for all patients • Add <i>BRAF</i>, <i>ERBB2</i>, <i>MET</i>, <i>RET</i> if obtaining a large panel • PD1/PDL1 are important, but will be included in a different guideline
Testing Technologies
<ul style="list-style-type: none"> • IHC is acceptable for <i>ALK</i> and screening for <i>ROS1</i>, not <i>EGFR</i> • <i>EGFR</i> T790M methods for resistance need high sensitivity Other resistance mutations require further study • Equality for all cytology specimens Smears are acceptable, sensitivity is reduced to 20% tumor content • Cell-free DNA is appropriate when biopsy is difficult to obtain If cell-free DNA is negative, biopsy is needed • NGS panels are preferred over multiple single assays; turnaround time of 2 weeks is recommended

IHC = immunohistochemistry

Table 2. Advantages and Challenges of Targeted Next-Generation Sequencing Panels

Advantages	Challenges
High throughput	Selection of test platform
Better sensitivity	Evaluation of multigene panels
Efficient use of limited tissue	Establishment of assay characteristics
Consolidation of platforms	Validation on different sample types
Wider range of mutation detection	Results interpretation and reporting
	Legal and ethical issues

Courtesy of Raja Luthra, PhD, MD Anderson Cancer Center



Community Engagement

Continued from page 1

Lung cancer is the leading cause of cancer-related deaths among both black men and women. The study was conducted in the state of Georgia, USA, where the incidence of lung cancer and lung cancer-related mortality is high in 25 of the state's

clinics that serve the medically underserved, and a community recreation center. Most (92%) of the 481 participants were black, 73% were women, and 16% were tobacco users. Participants were asked to complete surveys before and after the educational intervention to assess changes in their knowledge and beliefs about cancer and attitudes regarding clinical trial participation.

“We found that a community engagement intervention is effective in increasing knowledge and changing attitudes

about cancer screening, clinical trial participation, and prevention behaviors,” says Dr. Williams. “Increasing

screening and tobacco cessation among minority populations may improve lung cancer health disparities.”

Dr. Williams will describe the c-CARE program and discuss the differences in the before and after survey results with regard to knowledge of lung cancer screening, harmfulness of

e-cigarettes, effects of nicotine, and cancer risk factors; perceived susceptibility, threat, and severity related to lung cancer; perceived benefits and barriers related to lung cancer screening and smoking cessation; and self-efficacy, or confidence in one's ability to achieve intended results. ●

Reducing Lung Cancer Mortality in Disparate Populations through cancer-Community Awareness Access Research and Education (c-Care)

Oral Session 11

11:00-12:30 | Room 313 + 314

159 counties.

Thirteen community sites were enrolled: nine black churches, three community



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Wednesday Sessions Focus on Liquid Biopsy

Tissue biopsy has been the gold standard in cancer diagnosis and molecular diagnosis of NSCLC for several years. However, its use is sometimes hindered by several factors, including the location, and tumor heterogeneity can also affect testing results. Over the past few years, the feasibility of liquid biopsy has been explored, and studies are ongoing to determine its value and the concordance of testing results between tissue and liquid biopsy. In parallel, the availability of liquid biopsy assays has increased. Plasma testing is now a standard approach

for EGFR mutation testing with approved tests, and broader applications are becoming available.

Several studies focused on liquid biopsy will be presented on Wednesday (see box), including the four abstracts highlighted here. In addition, a Pro/Con Session features a debate on the issue.

The increasing popularity of liquid biopsy and the wider availability of testing methods led the IASLC to develop a consensus statement (see page 11). ●

Alternative Liquid Biopsy Samples

By Lori L. Alexander, MTPW,
ELS, MWC®

While several studies have been exploring the utility of molecular testing on plasma, other studies have focused on the value of EGFR mutation testing in other body fluids, such as urine and sputum from patients with NSCLC. Zhen Wu, Chinese PLA General Hospital, Chinese PLA Medical School, Beijing, China, will report results of a study designed to evaluate the diagnostic and prognostic efficacy of liquid biopsy using different specimens and detection methods and

to compare the results of liquid and tissue biopsy.

The prospective study includes 50 patients with either newly diagnosed NSCLC (35 patients) or acquired drug resistance after treatment with a first-generation EGFR tyrosine kinase inhibitor (15 patients). Tumor tissue, plasma, urine, and sputum samples were collected from all patients before treatment. Tumor tissue was collected after every instance of disease progression, and body fluid samples were collected every 2 to 3 months or until disease progression or death.

The researchers conducted capture-based next-

generation sequencing on all samples with a cell-free DNA (cfDNA) panel covering significant exons and introns from 400 human genes, including EGFR, KRAS, ALK, ROS1, c-MET, and other important genes in the tumor-related signaling pathways, such as PI3K-AKT-mTOR, JAK-STAT, Notch, and Wnt.

Dr. Wu will report on the concentration and length of cfDNA in the three different body fluids, compare the sensitivities of EGFR mutation testing in the various types of samples, and discuss the correlation of testing results with clinical response data. ●

Oral Sessions

Liquid Biopsy for Genomic Alterations

11:00-12:30
F201 + F202 (Annex Hall)

Emerging Genomic Targets

11:00-12:30
F203 + F204 (Annex Hall)

Pro/Con Session

Which Do You Prefer: Liquid Biopsy or Tissue Biopsy for Molecular Diagnosis?

11:00-12:30
Room 303 + 304

Utility of Liquid Biopsies as Adjunctive Screening Tools for MET Exon 14 Alterations

By Cynthia L. Kryder, MS

MET exon 14 alterations are present in up to 4% of NSCLCs—a frequency comparable to that of ALK-rearranged lung cancers. More importantly, these alterations are clinically actionable drivers. Consequently, it is important for clinicians to screen for MET exon 14 alterations, as they are one of the molecular mechanisms triggering MET-positive NSCLC. Alexander Drilon, MD, Memorial Sloan Kettering Cancer Center, New York, USA, will present late-breaking results of PROFILE 1101, an open-label, multicenter, phase I trial examining the utility of liquid biopsies as adjunctive screening tools for MET exon 14 alterations.

Dr. Drilon will present plasma profiling results for 18 patients with MET exon 14-altered advanced NSCLC that

was confirmed by local tumor molecular profiling who were treated with crizotinib, a small-molecule ALK, ROS1, and c-MET tyrosine kinase inhibitor approved for the treatment of patients with ALK-positive or ROS1-positive metastatic NSCLC. Although these drivers can be detected by sequencing tumor samples with use of a comprehensive molecular profiling assay such as DNA-based next-generation sequencing, the utility of plasma genomic profiling (liquid biopsies) has not previously been explored, Dr. Drilon notes.

“The takeaway message here is that liquid biopsies should be considered as adjunctive screening tests for MET exon 14 alterations to complement tumor testing in patients with NSCLC,” said Dr. Drilon. “Our results echo data previously established in other driver-positive subsets of cancers, including EGFR-mutant lung cancers.” ●



Comparison of Three Plasma Assays in AURA 3

By Lori L. Alexander, MTPW,
ELS, MWC®

EGF tyrosine kinase inhibitors (TKIs) are recommended as first-line therapy for *EGFR*-mutant NSCLC based on high response rates and longer progression-free survival compared with platinum-doublet chemotherapy. Unfortunately, acquired resistance to *EGFR* TKIs eventually develops in most patients. *EGFR* T790M mutation is the most common resistance mechanism, accounting for 50% to 60% of patients with *EGFR* TKI resistance.

Osimertinib is an oral irreversible third-generation *EGFR* TKI selective for both *EGFR* TKI-sensitizing and *EGFR* T790M-resistance mutations with activity in the central nervous system. AURA 3, a randomized open-label, international phase III trial, demonstrated significant improvement in response rate and progression-free

survival with osimertinib compared with platinum-pemetrexed in patients with T790M-positive resistance mutations and is recommended for patients with T790M-positive advanced NSCLC. Therefore, to understand the underlying resistance mechanism and to guide optimal treatment, repeated biopsy is essential and considered the gold standard at the time of progression. However, the invasive nature of repeated biopsies makes it difficult to obtain samples from patients, especially those with poor performance status or in whom the tumor is inaccessible for any reason. Tumor heterogeneity is another limitation, and a single snapshot study cannot represent the dynamic changes of genetic abnormalities due to the evolving nature of tumor progression.

As minimally invasive methods, the circulating cell free DNA (cfDNA) in plasma and circulating tumor cells (CTCs) have been

used as surrogates for tumor tissues in detecting genetic alterations. Myung-Ju Ahn, MD, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea, and colleagues evaluated patients' baseline samples from AURA 3, and tested plasma ctDNA samples for *EGFR* mutation (T790M, exon 19 deletion, L858R) using three distinct testing platforms: allele-specific polymerase chain reaction, next-generation sequencing, and droplet digital PCR.

"The results of our study suggest that reliable plasma-based biomarker testing is essential for identifying patients eligible for targeted treatment for *EGFR* mutation-positive NSCLC and to reduce the need for an invasive tissue biopsy," says Dr. Ahn, who will report the results of the study. "These results will give physicians confidence in the use of appropriate, validated blood-based testing." ●

Molecular Profiling Using Cell-free DNA

By Cynthia L. Kryder, MS

Molecular characterization of tumors can guide the choice of therapy for patients with NSCLC. However, tumor samples are complicated by spatial heterogeneity and sometimes may not be of sufficient quality and quantity for analysis. Next-generation sequencing using plasma cell-free DNA (cfDNA) input may capture temporal and spatial heterogeneity, and enable genomic profiling in patients without adequate available tumor tissue. Nevertheless, although tar-

geted gene panels allow for robust detection of known oncogenic drivers, they may not be comprehensive enough to screen for novel biomarkers or mechanisms or acquired resistance. Whole-exome sequencing offers an alternative, but may be technically challenging in the setting of limited tumor-derived DNA content in plasma cfDNA.

Molecular geneticist Dana Tsui, Memorial Sloan Kettering Cancer Center, New York, USA, will discuss the feasibility of using cfDNA to identify actionable alterations to inform treat-

ment decisions in patients without sufficient tissue for molecular characterization. She will report on findings from 20 patients with NSCLC receiving a variety of treatments whose cfDNA samples were analyzed using low-pass shallow whole-genome sequencing and MSK-IMPACT, a hybridization capture-based assay that targets more than 400 cancer-related genes. The aim of this study was to develop a workflow to guide the selection of samples for targeted and whole-exome sequencing for noninvasive molecular profiling. ●

IASLC Develops Liquid Biopsy Consensus Statement

As a leader in the field of lung cancer research, the IASLC's most important aim is to educate professionals working in the field of thoracic oncology and help them understand the latest developments in a timely manner. A new resource is the IASLC consensus statement on liquid biopsy, which is expected to be published in the *Journal of Thoracic Oncology* by the end of 2017. The consensus statement was developed by a multidisciplinary expert panel of thoracic oncology experts



Christian Rolfo, MD, PhD to help clinicians understand liquid biopsy, select the right patients for assessment, and analyze the results with the most appropriate strategies for the best treatment of their patients. The writing group for the statement has been led by Christian Rolfo, MD, PhD, Antwerp University Hospital, Belgium, a member of the IASLC Education Committee. Here, Dr. Rolfo discusses the role of liquid biopsy and the need for the consensus statement.

Q: Why this consensus statement?

A: During the last few years, several druggable molecules see **Liquid Biopsies**, page 12



Liquid Biopsies

Continued from page 11

ular alterations have been identified in NSCLC, which has led to robust therapeutic successes with targeted therapies. Tissue is crucial for the determination of these biomarkers, but unfortunately tissue is not always easy to obtain from all patients. In addition, the need to monitor the response to treatment and to identify molecular mechanisms of resistance has become increasingly important. Therefore, the role of liquid biopsy has grown progressively more valuable. However, several questions still need to be answered: 1) What are the requirements for the proper execution of liquid biopsy? 2) What are the

standards and the platforms for the execution of molecular analysis from liquid biopsy? 3) What is the proper way to report molecular results for liquid biopsy? and 4) What is the clinical value of molecular results in the different settings of treatment of patients with NSCLC?

Q: What is the current utility of liquid biopsy?

A: For patients with advanced NSCLC, circulating tumor DNA (ctDNA) is the liquid biopsy analysis used most often in clinical practice, mainly for the detection of *EGFR* sensitizing alterations and for the identification of one of the most frequent *EGFR* inhibitor resistance mechanisms, T790M mutation. The *EGFR* inhibitor osimertinib was re-

cently approved for patients with this acquired resistance mutation detectable in either tissue or in ctDNA. Currently, the introduction of new technologies, such as next-generation sequencing, is making it possible to access a wide range of information on several druggable targets, including fusions and amplifications, in ctDNA.

Q: What is the future of liquid biopsy?

A: The future of liquid biopsy is very exciting. The possibility of using a noninvasive method to understand and to identify mechanisms of resistance to new drugs, both targeted and immunotherapeutic alike, as well as to identify new biomarkers, will be extremely beneficial for patients. This

may be especially true for immunotherapy, as this field is evolving so rapidly. In addition to ctDNA, circulating tumor cell (CTC) and exosomes are also yielding promising results. At WCLC 2017, we are witnessing important advances in the field.

Q: Does liquid biopsy replace tumor biopsy?

A: No. As of today, tissue is still the standard for initial molecular diagnosis. However, a positive concordance exists between circulating DNA and tissue with regard to common alterations, which means that, in some clinical settings, in which tissue is limited and/or insufficient for molecular testing, physicians may use ctDNA assay as a substitute to identify mutations. ●

What Does the Future Hold?

Where we are now and where we will be in 10 years is the topic of the Closing Plenary Session on Wednesday afternoon. Three key opinion leaders will share their unique perspectives on what the future holds for thoracic oncology.

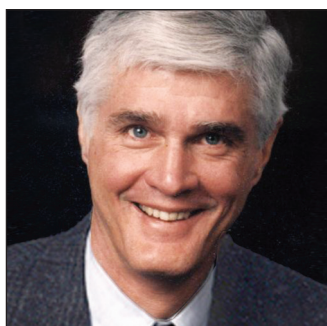
Paul A. Bunn, Jr., MD, University of Colorado, Denver, USA, will provide the North American perspective. Dr. Bunn has served as president of

ASCO, IASLC, and the Association of American Cancer Institutes, was chair of the FDA Oncology Drug Advisory Committee, and is a former Executive Director of the IASLC.

Nagahiro Saijo, MD, PhD, will offer the Asian perspective. Dr. Saijo is the Chief Executive Officer of the Japan Society of Medical Oncology, a past president of the IASLC, and a former chair of the Japanese Clinical Oncology Group.

He received the 2015 European Society for Medical Oncology (ESMO) Lifetime Achievement Award.

The European perspective will be delivered by Giorgio Scagliotti, MD, PhD, Chief of the Medical Oncology Division, S. Luigi Hospital, Turin, Italy, and Head of the Department of Oncology at the University of Turin. Dr. Scagliotti is the 2017-2019 President of the IASLC. ●



Paul A. Bunn, Jr., MD



Nagahiro Saijo, MD, PhD



Giorgio Scagliotti, MD, PhD

Erratum. The comments attributed to Carolyn Dresler, MD, MPA, in yesterday's article on the Plenary Session are purely her own observations and perspectives and do not represent those of the US Food & Drug Administration.

See You in Toronto

By *Natasha Leighl, MD, MMSc, FRCPC; Andrea Bezjak, MD, MSc, FRCPC; and Gail Darling, MD, FRCSC, WCLC 2018 Co-Presidents*

On behalf of the IASLC and the Organizing Committee, we are delighted to invite you to the 19th IASLC WCLC in Toronto, Canada, September 23 to 26, 2018.

WCLC 2018 will feature the latest scientific innovations and the current state of the art in prevention, diagnosis, treatment, and support of thoracic cancers. If you are passionate about taking action against lung cancer, this meeting is for you!

We look forward to welcoming the global lung cancer

community to Toronto next year, including advocates, scientists, nurses, and medical specialists involved in diagnosis, treatment, support, and prevention. Important advances in tobacco control, nursing care, and survivorship will be incorporated throughout the conference. Dedicated tracks for patient advocates, nurses and allied health care professionals, and young investigators are already in preparation, in addition to highlighting the most recent progress in lung cancer research and clinical care.

September is a wonderful time to visit Toronto. Set on the shores of Lake Ontario, one of Canada's Great Lakes, Toronto has direct flights to and from almost every major



city worldwide. Once you arrive, please enjoy our Canadian hospitality—you'll get to see every nationality and taste every cuisine here as part of Toronto's multicultural mosaic, where everyone is welcome. Stunning views of Niagara Falls, Canadian wine country, and the beautiful fall colors of our forests and provincial parks are just

an hour or two away. With so many world-class hotels within walking distance of Toronto's Metro Convention Centre, you'll be able to enjoy the arts, shopping, and nightlife of downtown Toronto, all while you take action against lung cancer.

We look forward to welcoming you to Toronto. See you soon! ●

Journal of Thoracic Oncology

Official Journal of the International Association for the Study of Lung Cancer

Editor-in-Chief:
Alex A. Adjei, MD, PhD, FACP, Mayo Clinic, Rochester, MN, USA

The *Journal of Thoracic Oncology (JTO)*, the official journal of the International Association for the Study of Lung Cancer, is the primary educational and informational publication for topics relevant to detection, prevention, diagnosis, and treatment of thoracic malignancies. *JTO* emphasizes a multidisciplinary approach, and includes original research (clinical trials and translational or basic research), reviews, and opinion pieces. The audience consists of epidemiologists, medical oncologists, radiation oncologists, thoracic surgeons, pulmonary specialists, radiologists, pathologists, and research scientists with a special interest in thoracic oncology.



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To subscribe visit jto.org



Ado-trastuzumab Emtansine for the Treatment of *HER2*-mutant Lung Cancers

Human epidermal growth factor receptor 2 (*HER2*, *ERBB2*) mutation and amplification each occurs in 2% of lung cancers, resulting in receptor dimerization and oncogenic signaling with in vitro sensitivity to trastuzumab. Ado-trastuzumab emtansine is a *HER2*-targeted antibody drug conjugate linking trastuzumab with the anti-microtubule agent emtansine. This morning,

Bob T Li, MD, PhD, Memorial Sloan Kettering Cancer Center, New York, USA, will present the results of research demonstrating that ado-trastuzumab was active and well tolerated in patients with advanced *HER2*-mutant or amplified lung cancers.

Dr. Li will report the overall response rates, progression-free survival, and

New Paradigms in Clinical Trials

Oral Session 14

11:00-12:30 | Room 311 + 312

toxicities for 18 patients in the first *HER2*-mutant cohort. He notes that while cohort expansion is ongoing, this study met its primary endpoint in patients with *HER2*-activating mutations. ●



IASLC Research Awards Encourage Innovative Research

Eleven young researchers have received awards through the IASLC Fellowship Award Program, which is designed to recognize scientific excellence and encourage innovative research in lung cancer prevention and translational medicine worldwide. This year's awards comprise Fellowship Awards, Young Investigator Awards, the IASLC/Lung Cancer Foundation of America Fellowship Award, the IASLC/Boehringer Ingelheim Chinese Research Fellowship Award, the Bonnie J. Addario Lung Cancer Foundation/IASLC Award, and the IASLC/Prevent Cancer Foundation/Richard C. Devereaux Fellowship Award.

Applications for Fellowship and Young Investigator Awards are accepted each January. The applications are evaluated by the IASLC Career Development and Fellowship Committee for their merit, innovation, and potential impact on the management of lung cancer. ●

2017-2018 IASLC Fellowship Award

Atiqur Rahman, PhD, *University of Newcastle, Australia*

Project: Cell-free microRNA: A Potential Biomarker for the Early Detection of Lung Cancer

Masaoki Ito, PhD, *The Health Sciences Research Institute of the Germans Trias I Pujol Foundation, Barcelona, Spain*

Project: Exploring the Potential Oncogenic Role of the p21-Activated Kinase 1 (PAK1): A Novel Approach for Personalized Therapy in Non-small Cell Lung Cancer

Hou-Fu Guo, PhD, *The University of Texas MD Anderson Cancer Center, Houston, USA*

Project: Structural Insights into a Pro-metastatic Collagen Lysyl Hydroxylase

2017-2018 Young Investigator Award

Paolo Ceppi, PhD, *Interdisciplinary Center for Clinical Research (IZKF), University of Erlangen-Nuremberg, Erlangen, Germany*

Project: The Role of Thymidylate Synthetase in Epithelial-to-Mesenchymal Transition in Non-small Cell Lung Cancer

William Lockwood, PhD, *British Columbia Cancer Agency, University of British Columbia, Vancouver, Canada*
Project: Therapeutic Strategies and Mechanisms of Resistance in Lung Adenocarcinomas Driven by MET Splice-Site Mutations

Pedro Medina Vica, PhD, *University of Granada, Granada, Spain*
Project: New Therapies for Lung Cancer Based on Gene-Editing Technologies

2017-2018 IASLC/Lung Cancer Foundation of America Fellowship Award

Carla Martins, PhD, *University of Cambridge, Cambridge, UK*
Project: Exploiting the Metabolic Heterogeneity of Mutant Kras Lung Tumours to Optimize Therapy

Kellie Smith, PhD, *Johns Hopkins University, Baltimore, USA*

Project: Neoantigen Targeting in Patients with Early Stage NSCLC Receiving Neoadjuvant Nivolumab

2017-2018 IASLC/Boehringer Ingelheim Chinese Research Fellowship Award

Deshui Jia, PhD, *Fred Hutchinson Cancer Research Center, Seattle, USA*
Project: Using Mouse Models to Study Roles for CREBBP as a Small Cell Lung Cancer Tumor Suppressor

Shengxiang Ren, PhD, *Shanghai Pulmonary Hospital, Shanghai, China*
Project: Early Diagnosis in Lung Cancer

2017-2019 Bonnie J. Addario Lung Cancer Foundation/IASLC Award

Evgeny Izumchenko, PhD, *Johns Hopkins University, Baltimore, USA*
Project: Comprehensive Analysis of the Genetic Landscape during Progression of Non-small Cell Lung Adenocarcinoma

2016-2017 IASLC/Prevent Cancer Foundation/Richard C. Devereaux Fellowship Award

Valsamo Anagnostou, MD, PhD, *Johns Hopkins University, Baltimore, USA*
Project: Comprehensive Genomic Analysis for Early Detection of Recurrence and Therapeutic Intervention in Stage I/II Non-small Cell Lung Cancer

New IASLC Reference Provides Valuable Resource to Thoracic Clinicians

As witnessed by the findings presented throughout WCLC 2017 sessions, new discoveries, novel trials, and changes in the standard of care are occurring at an extraordinary rate. This pace of research over the past few years calls for reliable and up-to-date sources of information, filtered by experts in the field, for all health care professionals in thoracic oncology. In 2014, IASLC took the first step in addressing this need with the development and publication of the *IASLC Multidisciplinary Approach to Thoracic Oncology*. Earlier this year, IASLC published the second edition of this comprehensive resource, *IASLC Thoracic Oncology*, with Harvey I. Pass,

MD, again serving as Executive Editor, and David Ball, MB BS, MD, FRANZCR, and Giorgio V. Scagliotti, MD, PhD, serving as Editors.

“We never imagined the explosion of information that would occur over a 2-year period that would need to be presented to the reader,” says Dr. Pass. As examples, he notes the expansion in genomic phenotyping of lung cancer necessitating the discovery and validation of third-generation targeted agents; modifications and external validation of the staging system for lung cancer; enhancements in the histologic classification of the disease that have helped to define high-risk patients with early-stage cancer; the

refinements in radiation techniques that allow for greater implementation in oligometastatic and early-stage disease; and, most dramatically, new immunotherapeutic strategies that now dominate many of the novel trials for metastatic disease as well as for neoadjuvant and adjuvant therapy.

The second edition of the reference textbook includes updated material for more than 50% of the book. The textbook is meant to provide both practitioners and fellows with an updated reference source that will be useful in dealing with lung cancer.

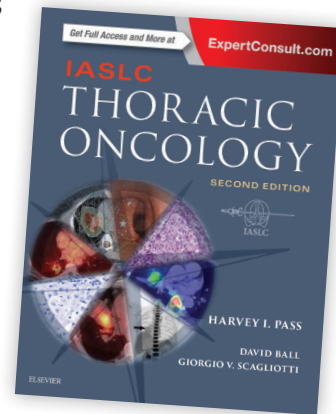
“It is also meant to further unify the international community through recog-

nition that wars are won by forming allies; and in the battle against lung and other thoracic cancers, the IASLC

stands for such an alliance,” says Dr. Pass. He adds, “The editors’ most profound wish is that the knowledge highlighted in the book and all of its associated future ventures will

help to move the survival curves upward and toward the right.”

IASLC Thoracic Oncology is available in print and digital format. A 50% discount is available with referral of WCLC. WCLC delegates can order this essential textbook at the IASLC Booth (Booth #2404) or online at elsevierhealth.com/IASLC or www.IASLC.org. ●



Upcoming Lung Cancer-Related Meetings

Mayo Clinic Cancer Center: Thoracic Oncology Update State-of-the-Art Evaluation and Management of Thoracic Cancers 2017
November 10-11, 2017
Phoenix, USA

European Society for Medical Oncology (ESMO) Asia
November 17-19, 2017
Singapore

ESMO Immuno Oncology Congress
December 7-10, 2017
Geneva, Switzerland

Fifth AACR-IASLC International Joint Conference on Lung Cancer Translational Science: From the Bench to the Clinic
January 8-11, 2018
San Diego, USA

ESMO Summit Africa – Oncology Updates: From Evidence to Practice
February 14-16, 2018
Cape Town, South Africa

IASLC 18th Annual Targeted Therapies of the Treatment of Lung Cancer
February 21-24, 2018
Santa Monica, USA

International Congress on Targeted Anticancer Therapies
March 5-7, 2018
Paris, France

European Lung Cancer Congress
April 11-14, 2018
Geneva, Switzerland

American Association for Cancer Research
April 14-18, 2018
Chicago, USA





Question of the Day

What is the most important thing you learned at the conference?



"I'm interested in gene detection of plasma, in other words, liquid biopsy. I have seen some advantages, not only for *EGFR*, but also for many new genes. It's not only about DNA sequencing but RNA and some exosomes are sequenced too. I think this is a very interesting area in cancer research now."

Jia Zhong, MD, Department of Thoracic Medical Oncology, Peking University Cancer Hospital, China



"Physicians are struggling with the management of adverse events from immune checkpoint inhibitors, and there are no established rules to manage those adverse events. At medical affairs, we would like to support them, give them as much valuable information as soon as possible. That's the most important thing I learned from this year's conference."

Mamoru Nozawa, MSD, Dept of Medical Affairs, Japan



"I am a cell biologist, so I liked the molecular cancer sessions, however, since I know about that, I have enjoyed sessions on new clinical trials, how clinical trials are directed from phase I to III, especially the so-called basket trials on genetic alterations and the genetic profiles of tumors."

Monserrat Sánchez-Céspedes, Principal Investigator, Institut D'Investigacio Biomedica de Bellvitge, Hospital Duran, Barcelona, Spain



"There are many cases of brain metastasis in lung cancer, about 40% of patients eventually get that. Targeted therapy has traditionally not worked that well to penetrate the blood-brain barrier. Now I am learning that there are second- and third-generation drugs that do penetrate to treat CNS metastasis."

Reiko Nishiguchi, MS, MBA, Precision Medicine Liaison, Japan



"The most important thing I learned so far was what was discussed in the session QOL Evaluation in Practice from the Viewpoint of Physicians and Nurses."

Eunjung Ryu, RN, PhD, Department of Nursing, Professor, Chung-Ang University, Seoul, Korea, Oncology Nursing Practice

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September 23-26, 2018 Toronto, Canada

Upcoming IASLC meetings, including the IASLC 19th World Conference on Lung Cancer in Toronto, Canada September 23-26, 2018



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