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# FOR THORACIC SPECIALISTS

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# **EXAMPLE ASSOCIATION FOR THE STUDY OF LUNG CANCER**

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Fred R. Hirsch, MD, PhD IASLC CEO

# Welcome, IASLC Lung Cancer News!

IASLC is proud to launch the *IASLC Lung Cancer News*. Lung cancer is a major health issue all over the world, with roughly 1.6 million patients diagnosed globally every year, including 225,000 new patients every year just in the US. In light of the progress happening these days in the prevention and treatment of this disease, from screening to novel treatments for advanced disease, including personalized therapy, we see a strong continued on page 2

## From the Editor / Corey J. Langer, MD, FACP

### Greetings.

It is my privilege to introduce the IASLC Lung Cancer News (ILCN). I will be serving as Editor with the able assistance of my Associate Editors, Fabrice Barlesi, MD from Europe and Caicun Zhou, MD from Asia. ILCN is a new tabloid publication that will highlight updates on thoracic malignancy research, including diagnostics, screening, tobacco control, therapeutic interventions, quality of life, symptom management, and survivorship. This tabloid will acknowledge the complex interplay that exists between these investigational realms and between all stakeholders in the research and care of individuals with thoracic cancers, and will feature expert commentary from thoracic oncology leaders, industry, and regulators. The target audience for this publication encompasses researchers, physicians, and other specialists, including allied health professionals, involved in the care of patients with thoracic malignancy.

ILCN is structured to present the most recent and noteworthy lung cancer-related information worldwide; in addition, themed issues will be planned around particular topics or meetings, and we will not shy away from ongoing controversies and debates. We have twin goals of facilitating professional development and improving patient care and



research, and ultimately clinical outcome. Year 1 of the publication will consist of 1 issue each quarter, 16 pages each, and will be distributed in print and electronically to US and international thoracic cancer specialists. During year 2, we plan to transition to an issue every two months, with up to 32 pages each.

Each issue will include, but will not be limited to, the following topics:

- Meeting Highlights and Previews
- Expert Corner
- NCI Corner
- FDA Corner
- Global Research Spotlights
- Recent International Drug Approvals
- Lung Cancer Screening
- Tobacco Control and Smoking Cessation
- Navigating Therapeutic Controversy continued on page 11



## Welcome from David Carbone, MD, PhD, IASLC President

These are exciting times in lung cancer treatment and research, but there is still a lot of room for improvement in propagating these discoveries to all lung cancer patients around the world, and converting responses to cures; in this context, as President of the International Association for the Study of Lung Cancer, I am pleased to welcome you to the first issue of *IASLC Lung Cancer News*.

Important issues for lung cancer experts and health care providers worldwide will be covered in *IASLC Lung Cancer News*, spanning all specialties and ranging from the role of screening and early detection to the latest treatment approaches and management strategies for advanced disease.

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### MEETING PREVIEW HIGHLIGHTS

# IASLC and ESMO Present 6th European Lung Cancer Conference

By Nicola M. Parry, DVM

From April 13-16, 2016, the International Association for the Study of Lung Cancer (IASLC) and the European Society for Medical Oncology (ESMO) will once again join forces to host the 6th European Lung Cancer Conference (ELCC) at Palexpo in Geneva, Switzerland. This meeting is a collaborative effort of key multidisciplinary societies representing thoracic oncology specialists—all working to advance science, provide education, and enhance the practice of lung cancer specialists worldwide. It plays a key role in providing an updated overview of prevention, screening, diagnosis, and treatment of lung cancer, as well as results of basic, clinical, and translational research.

Now held annually, ELCC is an important conference in Europe for all clinicians involved in the diagnostic workup and treatment of lung cancer and other thoracic malignancies. The conference attracts a diverse audience that includes medical oncologists, radiotherapists, thoracic surgeons, respiratory



physicians, interventional radiologists, and pathologists. In this way, the meeting aims to foster productive multidisciplinary interaction among specialists in order to strengthen an integrated approach to diagnosis and treatment of lung and other thoracic cancers.

During the 4-day program, an internationally renowned faculty of thoracic oncology specialists will present updates on a variety of topics that address the scientific and educational needs of continued on page 6

### MEETING HIGHLIGHTS

# 16th Annual Meeting on Targeted Therapies for Lung Cancer

Leading experts in the biology, diagnosis and treatment of lung cancer met for 3 days in February 2016 at the 16th Annual Meeting on Targeted Therapies for Lung Cancer. Held from February 17-20 in Santa Monica, US, this work-in-progress meeting is an annual event sponsored by the IASLC and is designed to bring together translational researchers and lung cancer investigators to assess current areas of research and future directions.

The meeting focused on new ideas and developments in lung cancer research, including the latest advances in immunotherapy, immunotherapeutic combinations, and biomarkers for immunotherapy, as well as targetdelineated therapies, including EGFR and ALK, with a new focus on acquired resistance.

The development of specific molecular treatments in lung cancer has led to a paradigm shift in thoracic oncology research for which meetings such as Targeted Therapies for Lung Cancer provide vital leadership. Conferences such as this annual event serve to catalyze and promote new ideas, and foster active collaboration between multiple academic institutions and industry. The educational design of Targeted Therapies for Lung Cancer is structured to provide an informal yet expert forum on research in progress.

Advances in various areas of research as well as disappointing results in other



Proceedings at the 16th Annual Meeting on Targeted Therapies for Lung Cancer.

areas were the subject of networking events throughout the meeting. "The Santa Monica meetings provide a unique opportunity for thoracic oncology investigators from around the world to informally discuss their latest research and network with colleagues," says Fred R. Hirsch, MD, PhD, IASLC Chief Executive Officer. "Many of the scientific presentations later made at larger meetings around the globe are first discussed at this event."

"Coverage and summaries of scientific meetings around the globe and throughout the world are a core content area of *IASLC Lung Cancer News*," said Dr. Corey J. Langer, Editor. "The Annual Meeting on Targeted Therapies for Lung Cancer is comprehensive; it provides an important platform leading to continued collaboration and scientific discovery so vital for the treatment of patients with lung cancer." •

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### INTERVIEW WITH GIDEON BLUMENTHAL, MD / BY ERIK J. MACLAREN, PHD

In 2015, the US Food and Drug Administration (FDA) approved an unprecedented 7 new drugs or new uses for drugs for patients with lung cancer, an increase driven by the proliferation of targeted therapies in the area of thoracic oncology. The advent of precision medicine in oncology has raised new questions about how to adapt the evaluation and approval process to capitalize on the potential of these new technologies. *IASLC Lung Cancer News* spoke with **Gideon Blumenthal, MD**, from the FDA's Office of Hematology and Oncology Products (OHOP) about



these challenges, including the use of surrogate endpoints in lung cancer trials and the emergence of next-generation sequencing (NGS) in oncology.

**Q:** Last year, you and your colleagues published a meta-analysis of NSCLC trials in the *Journal of Clinical Oncology*<sup>1</sup> that showed a strong association between overall response rate (ORR) and progression-free survival (PFS), but not between either of these surrogate endpoints and overall survival (OS). Are there ways to improve how surrogate endpoints are used in clinical trials?

**A:** That is a great question, and certainly something we ruminate over all the time. While it is true that we did not observe associations on a trial level between ORR and OS or between PFS and OS, there are some caveats to those results. High rates of crossover might wash out the effect on OS, and if the target population is small, it may be hard to power a study to see a survival benefit. Also, patients with oncogene-addicted malignancies such as EGFR or ALK can live a long time after progression, contributing to the difficulties of designing a study to detect a survival gain. Particularly in trials of some immunotherapies, ORR and PFS do not seem to fully capture the clinical benefits of some of these agents. Are there new ways to measure responses to these treatments? That is an area in OHOP that we are definitely investigating. We are also talking to thought leaders in the lung cancer community because we know there are others in the academic community looking at this issue as well.

### **Q:** NGS offers new opportunities to dramatically expand the genetic characterization of both patients and tumors. How do you think these technologies will affect the way new cancer therapies are tested and used in the clinic?

**A:** I have recently co-written an article in *JAMA Oncology* on this issue.<sup>2</sup> I think lung cancer doctors are at the forefront of using NGS both in terms of selecting patients for trials and in using information derived from NGS in the clinic because

there are at least 2 actionable mutations in lung cancer, EGFR and ALK, and in the near future there may be others. Using a single multiplex platform makes a lot of sense in lung cancer patients because tissue is scarce in the metastatic setting and we could potentially spare patients repeated biopsies. From a drug development standpoint, the model of 1 companion diagnostic for a single drug may soon give way to a model using a single platform that has several companion diagnostic indications with several drugs tied to it. That way, drug developers and device manufacturers don't have to reinvent the wheel with every development program. It also makes a lot of sense from a research perspective because you can see many different genomic changes at the same time with a single test. There was a public workshop on February 25, 2016 to discuss some of these NGS-based oncology panels. We hope that there will be many platforms that can be used, but the key issue is standardizing these platforms so that the calls you get on one platform are the same as the calls you get from a different vendor.

# **Q:** Are there any big developments on the horizon in the development of precision medicine for lung cancer treatment such as testing circulating tumor DNA (ctDNA), and if so, how will this be integrated into the approval process?

**A:** I think ctDNA is a very exciting emerging technology because it has a lot of potential clinical applications: early detection, risk stratification of patients after surgical resection, monitoring patients, and even potentially down the road as a surrogate endpoint to discern drug activity. The FDA is in the early planning stages of a workshop on ctDNA in lung cancer this summer.

The other big development has been the emergence of immunotherapies in lung cancer. We approved our first 2 immunotherapies for the treatment of certain types of lung cancer in 2015, and there is a lot of interest in combining various immunotherapies, developing biomarkers to identify patients more likely to respond or not respond to an immunotherapy, and enhancing the immune response.

### References

- Blumenthal GM, Karuri SW, Zhang H, et al. Overall response rate, progression-free survival, and overall survival with targeted and standard therapies in advanced non-small-cell lung cancer: US Food and Drug Administration trial-level and patient-level analyses. *J Clin Oncol.* 2015;33(9):1008-1014.
- 2. Blumenthal GM, Mansfield E, Pazdur R. Next-Generation Sequencing in Oncology in the Era of Precision Medicine. *JAMA Oncol.* 2016;2(1):13-14.