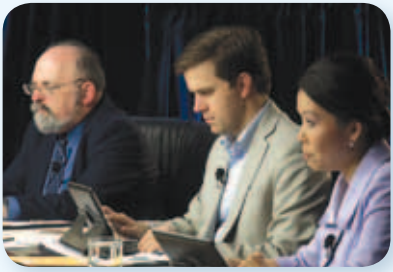
ISSUE 1 • 2015

New Biological Insights and Recent Therapeutic Advances in the Management of Lung Cancer

Proceedings from a Clinical Investigator Think Tank



FACULTY

David P Carbone, MD, PhD
Mark G Kris, MD
Corey J Langer, MD
Geoffrey R Oxnard, MD
David R Spigel, MD
Anne S Tsao, MD

MODERATOR

Neil Love, MD

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New Biological Insights and Recent Therapeutic Advances in the Management of Lung Cancer

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Lung cancer is increasingly being recognized as a heterogeneous group of tumors. Not long ago, it was clinically sufficient to make a differentiation between small cell lung cancer and non-small cell lung cancer (NSCLC). Individualized treatment decisions are increasingly driven by genetic biomarkers in addition to histological subtype and patient-specific characteristics. Determining which treatment approach is most appropriate in a given case requires careful consideration of patient characteristics, biomarkers and available health system resources. Oncology clinicians must possess a clear understanding of the benefits and risks of each of the various available options and how best to integrate emerging data and agents into the treatment algorithm. This CME program uses a roundtable discussion with leading clinical investigators to provide biological insights into the recent therapeutic advances in the management of lung cancer. By reviewing the available clinical trial data and relevant case scenarios, this initiative will help illustrate gaps in medical knowledge and illuminate treatment ambiguities pertinent to this disease.

LEARNING OBJECTIVES

- Develop an evidence-based strategy for the treatment of localized NSCLC, exploring options for adjuvant systemic therapy.
- Devise an evidence-based approach to the selection of induction and maintenance biologic therapy and/or chemotherapy for patients with advanced pan-wild-type NSCLC.
- Employ an understanding of personalized medicine to individualize the use of available EGFR inhibitors in the treatment of NSCLC before and after disease progression on an EGFR tyrosine kinase inhibitor (TKI).
- Communicate the efficacy and safety of crizotinib, ceritinib and emerging ALK inhibitors to appropriate patients with NSCLC, considering the predictive utility of ALK and ROS1 mutation testing.
- Evaluate the emerging data from clinical trials of the third-generation EGFR TKIs rociletinib and AZD9291 in EGFR mutation-positive NSCLC.
- Describe emerging data on the efficacy and safety of tumor immunotherapy directed at the PD-1/PD-L1 pathway in lung cancer, and consider this information when counseling patients regarding current treatment options and clinical trial participation.
- Recognize the results of recently completed Phase III trials examining the efficacy and safety of the novel monoclonal antibodies necitumumab and ramucirumab for patients with advanced NSCLC.

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FACULTY

David P Carbone, MD, PhD
Barbara J Bonner Chair in Lung Cancer Research
President-Elect, International Association for the Study of Lung Cancer
Professor of Medicine
Director, James Thoracic Oncology Center
James Cancer Center
The Ohio State University Medical Center
Columbus, Ohio

Geoffrey R Oxnard, MD
Assistant Professor of Medicine
Dana-Farber Cancer Institute
Harvard Medical School
Boston, Massachusetts

Mark G Kris, MD
William and Joy Ruane Chair in Thoracic Oncology
Attending Physician
Thoracic Oncology Service
Memorial Sloan Kettering Cancer Center
New York, New York

David R Spigel, MD
Program Director, Lung Cancer Research
Sarah Cannon Research Institute
Nashville, Tennessee

Corey J Langer, MD
Director of Thoracic Oncology
Abramson Cancer Center
Professor of Medicine
Perelman School of Medicine
University of Pennsylvania
Vice Chair, Radiation Therapy Oncology Group
Philadelphia, Pennsylvania

Anne S Tsao, MD
Associate Professor
Director, Mesothelioma Program
Director, Thoracic Chemo-Radiation Program
The University of Texas MD Anderson Cancer Center
Department of Thoracic/Head and Neck Medical Oncology
Houston, Texas

MODERATOR

Neil Love, MD
Research To Practice
Miami, Florida

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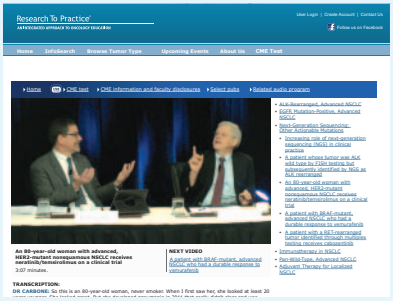

Visit www.ResearchToPractice.com/LCUTT115/Video to access a number of short video segments and corresponding transcripts from the Think Tank featuring the faculty discussing and debating some of the key clinical management and research issues in the field of non-small cell lung cancer.

TRACKS 1-22

Track 1 **Case discussion:** A 35-year-old woman and never smoker in respiratory failure from adenocarcinoma of the lung who requires rapid initiation of treatment

Track 2 Clinical experience with and activity of second-generation ALK inhibitors in patients with crizotinib-resistant disease

Track 3 Activity and tolerability of the ALK inhibitor ceritinib

Track 4 **Case discussion:** A woman with ALK-rearranged, advanced non-small cell lung cancer (NSCLC) receives full-dose ceritinib for 2 years

Track 5 Safety and activity of alectinib in patients with crizotinib-resistant ALK-rearranged NSCLC

Track 6 Potency and tolerability of investigational ALK inhibitors compared to crizotinib

Track 7 Efficacy of pemetrexed in ALK-rearranged NSCLC

Track 8 Targeted agents versus whole brain radiation therapy for patients with asymptomatic EGFR- or ALK-mutant CNS metastases

Track 9 Erlotinib and bevacizumab as first-line therapy for patients with advanced nonsquamous NSCLC harboring EGFR mutations

Track 10 **Case discussion:** A 68-year-old woman and never smoker with EGFR exon 19-deleted adenocarcinoma of the lung experiences a near complete response to erlotinib/bevacizumab followed by disease progression

Track 11 Response to rociletinib (CO-1686) after disease progression on erlotinib/bevacizumab

Track 12 IMPRESS: Results of a Phase III trial of gefitinib/chemotherapy versus chemotherapy in EGFR-mutant NSCLC after disease progression on first-line gefitinib

Track 13 Role of afatinib for patients with disease progression on erlotinib

Track 14 Activity and tolerability of rociletinib in EGFR-mutant, advanced NSCLC with the T790M resistance mutation

Track 15 Sequencing of EGFR tyrosine kinase inhibitors (TKIs)

Track 16 Clinical experience with rociletinib-associated hyperglycemia

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Track 18 Activity and tolerability of AZD9291 in EGFR inhibitor-resistant, advanced NSCLC with the T790M mutation

Track 19 Comparison of AZD9291 and rociletinib

Track 20 Role of next-generation sequencing (NGS) in clinical practice

Track 21 A patient whose tumor was ALK wild type by FISH testing but subsequently identified by NGS as ALK rearranged

Track 22 **Case discussion:** An 80-year-old woman and never smoker with well-differentiated, HER2-mutant adenocarcinoma of the lung receives neratinib/temsirolimus on a clinical trial

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Track 23 Spectrum of HER2 mutations in NSCLC

Track 24 **Case discussion:** A 77-year-old woman with BRAF-mutant, advanced NSCLC experiences a durable response to vemurafenib

Track 25 **Case discussion:** A 78-year-old woman with a RET-rearranged tumor identified through multiplex testing receives cabozantinib

Track 26 **Case discussion:** A 54-year-old man and smoker with pan-wild-type metastatic adenocarcinoma of the lung receives nivolumab for 2 years as second-line therapy

Track 27 **Case discussion:** A 76-year-old man and former remote smoker with heavily treated metastatic squamous cell NSCLC experiences a greater than 15-month response to pembrolizumab

Track 28 Immune checkpoint inhibitor-associated toxicities

Track 29 Variability in assays for PD-L1 expression

Track 30 PD-L1 expression and response to anti-PD-1/anti-PD-L1 antibodies

Track 31 Pseudoprogression with anti-PD-1/anti-PD-L1 antibodies

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Track 33 Organ function and performance status testing as means of identifying elderly patients who can tolerate chemotherapy

Track 34 Isolating the role of bevacizumab in elderly patients with previously untreated nonsquamous NSCLC: Secondary analyses of the ECOG-E4599 and PointBreak trials

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Track 36 Algorithm for maintenance treatment after a first-line platinum-based regimen

Track 37 Benefits of second-line ramucirumab/docetaxel observed in the Phase III REVEL study for patients with Stage IV NSCLC after disease progression on platinum-based therapy

Track 38 Perspective on the Phase III SQUIRE study of necitumumab combined with cisplatin/gemcitabine in advanced squamous cell NSCLC

Track 39 **Case discussion:** An 82-year-old man with advanced NSCLC has a VeriStrat® assay performed and experiences a durable benefit from erlotinib

Track 40 Predictive value of the VeriStrat assay for patients with NSCLC treated with second-line erlotinib or chemotherapy

Track 41 **Case discussion:** A 61-year-old man and 40 pack-year smoker undergoes lobectomy for a T2AN0M0, EGFR-mutant adenocarcinoma of the lung

Track 42 Clinical implications of the Phase III RADIANT study of adjuvant erlotinib with or without chemotherapy

Track 43 RADIANT subset analysis: Benefits of adjuvant erlotinib in patients with EGFR-mutant NSCLC

Track 44 SELECT: Results of a multicenter Phase II trial of adjuvant erlotinib for resected early-stage, EGFR-mutant NSCLC

Track 45 Potential role of EGFR TKIs as adjuvant therapy for patients with sensitizing EGFR mutations

SELECT PUBLICATIONS

Balmanoukian AS et al. **Safety and clinical activity of MK-3475 as initial therapy in patients with advanced non-small cell lung cancer: Novel therapies/experimental therapies.** Chicago Multidisciplinary Symposium in Thoracic Oncology 2014;**Abstract 2**.

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Garon EB et al. **Ramucirumab plus docetaxel versus placebo plus docetaxel for second-line treatment of stage IV non-small-cell lung cancer after disease progression on platinum-based therapy (REVEL): A multicentre, double-blind, randomised phase 3 trial.** *Lancet* 2014;384(9944):665-73.

Gregorc V et al. **Predictive value of a proteomic signature in patients with non-small-cell lung cancer treated with second-line erlotinib or chemotherapy (PROSE): A biomarker-stratified, randomised phase 3 trial.** *Lancet Oncol* 2014;15(7):713-21.

Herbst RS et al. **Predictive correlates of response to the anti-PD-L1 antibody MPDL3280A in cancer patients.** *Nature* 2014;515(7528):563-7.

Janjigian YY et al. **Dual inhibition of EGFR with afatinib and cetuximab in kinase inhibitor-resistant EGFR-mutant lung cancer with and without T790M mutations.** *Cancer Discov* 2014;4(9):1036-45.

Jänne PA et al. **Clinical activity of the mutant-selective EGFR inhibitor AZD9291 in patients with EGFR inhibitor-resistant non-small cell lung cancer.** *Proc ASCO* 2014;**Abstract 8009**.

Kelly K et al. **A randomized, double-blind Phase 3 trial of adjuvant erlotinib vs placebo following complete tumor resection with or without adjuvant chemotherapy in patients with Stage IB-IIIA EGFR positive (IHC/FISH) non-small cell lung cancer: RADIANT results.** *Proc ASCO* 2014;**Abstract 7501**.

Kim DW et al. **Ceritinib in advanced anaplastic lymphoma kinase rearranged non-small cell lung cancer: Results of the ASCEND-1 trial.** *Proc ASCO* 2014;**Abstract 8003**.

Langer CJ et al. **Isolating the role of bevacizumab in elderly patients with previously untreated nonsquamous non-small cell lung cancer: Secondary analyses of the ECOG 4599 and PointBreak trials.** *Am J Clin Oncol* 2015;[Epub ahead of print].

Leighl NB et al. **Molecular testing for selection of patients with lung cancer for epidermal growth factor receptor and anaplastic lymphoma kinase tyrosine kinase inhibitors: American Society of Clinical Oncology endorsement of the College of American Pathologists/International Association for the Study of Lung Cancer/Association for Molecular Pathology guideline.** *J Clin Oncol* 2014;32(32):3673-9.

Mok TS et al. **Gefitinib/chemotherapy vs chemotherapy in epidermal growth factor receptor mutation-positive non-small-cell lung cancer after progression on first-line gefitinib: The phase III, randomized IMPRESS study.** *Proc ESMO* 2014;**Abstract LBA2_PR**.

Rizvi NA et al. **Clinical trials of MPDL3280A (anti-PDL1) in patients with non-small cell lung cancer.** *Proc ASCO* 2014;**Abstract TPS8123**.

Sequist LV et al. **First-in-human evaluation of CO-1686, an irreversible, highly selective tyrosine kinase inhibitor of mutations of EGFR (activating and T790M).** *Proc ASCO* 2014;**Abstract 8010**.

Seto T et al. **Erlotinib alone or with bevacizumab as first-line therapy in patients with advanced non-squamous non-small-cell lung cancer harbouring EGFR mutations (JO25567): An open-label, randomised, multicentre, phase 2 study.** *Lancet Oncol* 2014;15(11):1236-44.

Shepherd FA et al. **Adjuvant erlotinib versus placebo in non-small cell lung cancer patients with tumors carrying EGFR-sensitizing mutations from the RADIANT trial.** *Proc ASCO* 2014;**Abstract 7513**.

Thatcher N et al. **A randomized, multicenter, open-label, phase III study of gemcitabine-cisplatin (GC) chemotherapy plus necitumumab (IMC-11 F8/LY3012211) versus GC alone in the first-line treatment of patients with stage IV squamous non-small cell lung cancer.** *Proc ASCO* 2014;**Abstract 8008**.

POST-TEST

New Biological Insights and Recent Therapeutic Advances in the Management of Lung Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Which of the following patient populations treated with ceritinib experienced high overall response rates on the Phase I ASCEND-1 trial for patients with locally advanced or metastatic ALK-positive NSCLC?**
   a. Those with ALK inhibitor-naïve disease
   b. Those who previously received an ALK inhibitor
   c. Those with previously treated brain metastases
   d. Both a and c
   e. All of the above

2. **Results of a Phase I/II study of the novel ALK inhibitor alectinib for patients with crizotinib-resistant or crizotinib-intolerant locally advanced or metastatic NSCLC demonstrated _____.**
   a. A response rate of more than 50% in the overall patient population
   b. Responses in patients with CNS metastases
   c. Both a and b
   d. Neither a nor b

3. **Adverse events associated with the novel ALK inhibitor ceritinib when used at the dose of 750 mg once daily include _____.**
   a. Diarrhea
   b. Nausea
   c. Elevated transaminases
   d. All of the above

4. **A Phase II trial of erlotinib with or without bevacizumab as first-line therapy for patients with advanced nonsquamous NSCLC harboring EGFR mutations demonstrated a statistically significant improvement in progression-free survival with the addition of bevacizumab.**
   a. True
   b. False

5. **The Phase III IMPRESS trial evaluating gefitinib/chemotherapy versus placebo/chemotherapy for patients with EGFR mutation-positive NSCLC after disease progression on first-line gefitinib concluded that continuation of gefitinib in addition to cisplatin/pemetrexed was of _____ clinical benefit for patients with acquired resistance to gefitinib.**
   a. No
   b. Substantial
   c. Marginal

6. **The Phase I portion of the Phase I/II AURA trial of AZD9291, a selective EGFR TKI, for patients with advanced NSCLC after disease progression on prior therapy with an EGFR TKI demonstrated a(n) _____ overall response rate for patients with EGFR T790M mutation-positive NSCLC compared to those with EGFR T790M mutation-negative disease.**
   a. Higher
   b. Lower
   c. Equivalent

7. **Results from the Phase III SQUIRE trial demonstrated a statistically significant improvement in _____ with the addition of necitumumab to gemcitabine/cisplatin as first-line treatment for Stage IV squamous NSCLC.**
   a. Overall response rate
   b. Median overall survival
   c. Both a and b

8. **The Phase III OAK study is evaluating docetaxel versus MPDL3280A, an _____, for patients with locally advanced or metastatic NSCLC after disease progression on platinum-based therapy.**
   a. Anti-PD-1 antibody
   b. Anti-PD-L1 antibody

EDUCATIONAL ASSESSMENT AND CREDIT FORM

New Biological Insights and Recent Therapeutic Advances in the Management of Lung Cancer

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Clinical utility of NGS in the identification of actionable genomic alterations in the management of lung adenocarcinoma	4 3 2 1	4 3 2 1
Selection of treatment for patients with EGFR-activating mutations; correlation between EGFR mutation type and response	4 3 2 1	4 3 2 1
Efficacy and safety of the third-generation EGFR inhibitors AZD9291 and rociletinib in EGFR mutation-positive NSCLC	4 3 2 1	4 3 2 1
Emerging research, ongoing evaluation and clinical role of anti-PD-1/PD-L1 antibodies in NSCLC	4 3 2 1	4 3 2 1
Activity and safety of ceritinib and investigational ALK inhibitors such as alectinib in patients with crizotinib-resistant ALK-rearranged NSCLC	4 3 2 1	4 3 2 1
Results of the Phase III SQUIRE trial of necitumumab with or without chemotherapy as first-line therapy in Stage IV squamous NSCLC	4 3 2 1	4 3 2 1
REVEL: A Phase III trial of ramucirumab with or without docetaxel as second-line therapy for patients with Stage IV NSCLC after disease progression on platinum-based therapy	4 3 2 1	4 3 2 1

Practice Setting:

☐ Academic center/medical school ☐ Community cancer center/hospital ☐ Group practice

☐ Solo practice ☐ Government (eg, VA) ☐ Other (please specify).....

Approximately how many new patients with lung cancer do you see per year? ..... patients

Was the activity evidence based, fair, balanced and free from commercial bias?

☐ Yes ☐ No If no, please explain:.....

Please identify how you will change your practice as a result of completing this activity (select all that apply).

☐ This activity validated my current practice
☐ Create/revise protocols, policies and/or procedures
☐ Change the management and/or treatment of my patients
☐ Other (please explain):.....

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

The content of this activity matched my current (or potential) scope of practice.

☐ Yes ☐ No If no, please explain:.....

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Develop an evidence-based strategy for the treatment of localized NSCLC, exploring options for adjuvant systemic therapy..... 4 3 2 1 N/M N/A
- Devise an evidence-based approach to the selection of induction and maintenance biologic therapy and/or chemotherapy for patients with advanced pan-wild-type NSCLC..... 4 3 2 1 N/M N/A
- Employ an understanding of personalized medicine to individualize the use of available EGFR inhibitors in the treatment of NSCLC before and after disease progression on an EGFR tyrosine kinase inhibitor (TKI)..... 4 3 2 1 N/M N/A
- Communicate the efficacy and safety of crizotinib, ceritinib and emerging ALK inhibitors to appropriate patients with NSCLC, considering the predictive utility of ALK and ROS1 mutation testing..... 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result of this activity, I will be able to:

- Evaluate the emerging data from clinical trials of the third-generation EGFR TKIs rociletinib and AZD9291 in EGFR mutation-positive NSCLC. . . . . 4 3 2 1 N/M N/A
- Describe emerging data on the efficacy and safety of tumor immunotherapy directed at the PD-1/PD-L1 pathway in lung cancer, and consider this information when counseling patients regarding current treatment options and clinical trial participation. . . . . 4 3 2 1 N/M N/A
- Recognize the results of recently completed Phase III trials examining the efficacy and safety of the novel monoclonal antibodies necitumumab and ramucirumab for patients with advanced NSCLC. . . . . 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

.....

Would you recommend this activity to a colleague?

☐ Yes ☐ No If no, please explain: .....

PART 2 — Please tell us about the faculty and moderator for this educational activity

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

Faculty	Knowledge of subject matter	Effectiveness as an educator
David P Carbone, MD, PhD	4 3 2 1	4 3 2 1
Mark G Kris, MD	4 3 2 1	4 3 2 1
Corey J Langer, MD	4 3 2 1	4 3 2 1
Geoffrey R Oxnard, MD	4 3 2 1	4 3 2 1
David R Spigel, MD	4 3 2 1	4 3 2 1
Anne S Tsao, MD	4 3 2 1	4 3 2 1
Moderator	**Knowledge of subject matter**	**Effectiveness as an educator**
Neil Love, MD	4 3 2 1	4 3 2 1

Please recommend additional faculty for future activities:

.....

Other comments about the faculty and moderator for this activity:

.....

REQUEST FOR CREDIT — Please print clearly

Name: ..... Specialty: .....

Professional Designation:

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I certify my actual time spent to complete this educational activity to be _____ hour(s).

Signature: ..... Date: .....

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