

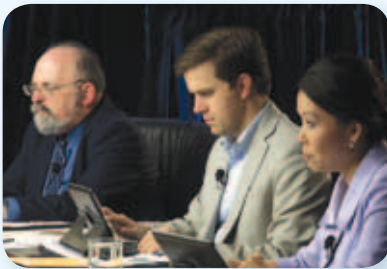
New Biological Insights and Recent Therapeutic Advances in the Management of Lung Cancer

Proceedings from a Clinical Investigator Think Tank



FACULTY

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MODERATOR

Neil Love, MD

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2 Audio CDs



From the publishers of:

Lung Cancer[™]
U P D A T E



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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This activity is supported by educational grants from Astellas Scientific and Medical Affairs Inc, AstraZeneca Pharmaceuticals LP, Biondesix Inc, Clovis Oncology, Foundation Medicine, Genentech BioOncology, Lilly, Merck and Novartis Pharmaceuticals Corporation.

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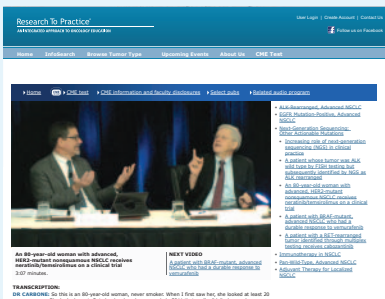
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Video Highlights from this Clinical Investigator Think Tank



The screenshot shows a webpage for a "Clinical Investigator Think Tank" event. At the top, it says "Research To Practice" and "MEDICAL EDUCATION AND RESEARCH PRACTICE". Below that, there are navigation tabs: "Home", "Subscribers", "Browse Think Tank", "Upcoming Events", "About Us", and "CME Task". The main content area features a video player with a thumbnail showing two men in suits talking. To the right of the video player is a list of video highlights with titles and durations. Below the video player, there is a "RESEARCH TO PRACTICE" logo and a short bio: "An 80-year-old woman with advanced, HER2-negative metastatic breast cancer receives her first dose of a clinical trial drug." The bio also mentions "3:27 minutes".

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
- Track 17 Case discussion:** A 62-year-old man and never smoker with EGFR-mutant, advanced NSCLC receives AZD9291 on study after disease progression on erlotinib
- 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

TRACKS 23-45

- 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
- Track 32** **Case discussion:** An 81-year-old woman with a remote smoking history with pan-wild-type metastatic adenocarcinoma of the lung receives carboplatin/pemetrexed
- 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
- Track 35** Factors affecting the decision to administer 4 versus 6 cycles of a platinum-based doublet for metastatic NSCLC
- 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 T2ANOMO, 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

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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 rocicetinib 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:

.....

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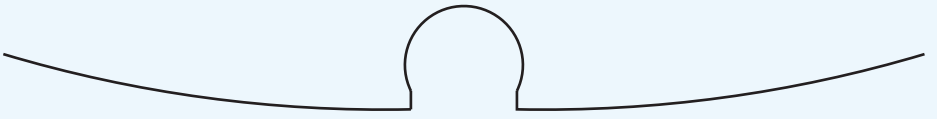
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I certify my actual time spent to complete this educational activity to be _____ hour(s).

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THINK TANK

ISSUE 1 2015

CD **1**

Roundtable Discussion
Tracks 1-22

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THINK TANK

ISSUE 1 2015

CD **2**

Roundtable Discussion
Tracks 1-23