LCU | VOL 14 | ISSUE 1

Lung Cancer™ UPDATE

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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Lung Cancer™ UPDATE

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Lung Cancer Update
A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Traditional chemotherapy, surgery and radiation therapy have had a modest effect on long-term outcomes for patients with lung cancer. However, the advent of biologic and immunotherapeutic agents has led to recent improvements in disease-free and overall survival in select populations. In order to offer optimal patient care — including the option of clinical trial participation — clinicians must be well informed of these advances. Featuring information on the latest research developments, this program is designed to assist medical and radiation oncologists with the formulation of up-to-date strategies for the care of patients with lung cancer.

LEARNING OBJECTIVES

- Review recent FDA approvals and available research data documenting the safety and efficacy of pembrolizumab alone or in combination with carboplatin/pemetrexed for patients with previously untreated metastatic non-small cell lung cancer (NSCLC), and use this information to appropriately integrate the use of pembrolizumab into this setting.
- Consider age, performance status and other patient- or disease-related factors to guide the selection of first-line therapy for patients with newly diagnosed metastatic squamous and nonsquamous NSCLC without an identifiable driver mutation.
- Educate patients about the side effects associated with recently approved novel agents and immunotherapeutic approaches, and provide preventive strategies to reduce or ameliorate these toxicities.
- Consider published safety and efficacy data with available and emerging therapeutic strategies, and appropriately incorporate targeted therapies into the care of patients with identified tumor driver mutations or alterations.
- Recall the scientific rationale for ongoing investigation of novel agents or therapeutic approaches in NSCLC, and counsel appropriately selected patients about study participation.

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Please note, this program has been specifically designed for the following ABIM specialty: **medical oncology**.

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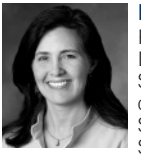

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Interview with D Ross Camidge, MD, PhD

Tracks 1-21

Track 1	**Case discussion:** A 56-year-old woman and never smoker with newly diagnosed adenocarcinoma of the lung, a MET exon 14 skipping mutation and a high PD-L1 tumor proportion score (TPS)
Track 2	Changing landscape of clinically relevant predictive biomarkers in advanced non-small cell lung cancer (NSCLC)
Track 3	Efficacy of larotrectinib (LOXO-101), a selective tropomyosin receptor kinase (TRK) inhibitor, in adult and pediatric TRK fusion cancers
Track 4	Approach to first-line therapy for patients with newly diagnosed adenocarcinoma of the lung, a driver mutation and a high PD-L1 TPS
Track 5	PD-L1 expression level and response to immunotherapy in patients with MET exon 14-altered NSCLC
Track 6	Choosing between pembrolizumab alone or in combination with carboplatin/pemetrexed as first-line therapy for metastatic nonsquamous NSCLC
Track 7	Efficacy and tolerability of crizotinib in MET exon 14-altered NSCLC
Track 8	Results of a Phase II trial of T-DM1 for patients with HER2 mutation-positive NSCLC
Track 9	Investigational strategies for patients with MET-positive NSCLC
Track 10	Treatment after disease progession in patients receiving therapy with an immune checkpoint inhibitor
Track 11	**Case discussion:** A 62-year-old woman and 60 pack-year smoker who presents with de novo metastatic squamous cell carcinoma (SCC) of the lung and a high PD-L1 TPS experiences a near-complete response with single-agent pembrolizumab
Track 12	**Case discussion:** A 76-year-old woman and former smoker with SCC, a solitary brain metastasis and a low PD-L1 TPS initially receives carboplatin/paclitaxel
Track 13	**Case discussion:** A 33-year-old man and never smoker with previously treated adenocarcinoma of the lung is found to harbor an ALK rearrangement
Track 14	Primary results of the Phase III ALEX study: Alectinib versus crizotinib for ALK inhibitor-naïve, ALK-positive metastatic NSCLC
Track 15	Sequencing crizotinib, alectinib, ceritinib and brigatinib
Track 16	Tolerability profiles of FDA-approved ALK inhibitors
Track 17	**Case discussion:** A 62-year-old man and never smoker with metastatic EGFR L858R mutation-positive adenocarcinoma of the lung
Track 18	EGFR exon 19 deletion mutations and the presence of diffuse miliary nodules
Track 19	Alectinib-associated photosensitivity
Track 20	**Case discussion:** An 81-year-old woman and former smoker initially diagnosed with pan-wild-type adenocarcinoma of the lung who received carboplatin/pemetrexed is found to harbor a BRAF V600E mutation
Track 21	Activity and tolerability of the antibody-drug conjugate rovalpituzumab tesirine targeting DLL3-expressing tumors in small cell lung cancer (SCLC)

Interview with Heather Wakelee, MD

Tracks 1-20

Track 1	ADJUVANT: Initial results of a Phase III trial evaluating gefitinib versus vinorelbine/cisplatin as adjuvant therapy for Stage II to IIIA NSCLC with EGFR-activating mutations
Track 2	Efficacy of immune checkpoint inhibitors in mesothelioma and SCLC
Track 3	Activity of HER2-targeted agents in patients with HER2-overexpressing advanced NSCLC

Interview with Dr Wakelee (continued)

Track 4	Sequencing anti-PD-1/PD-L1 antibodies and targeted therapies for patients with NSCLC and driver mutations
Track 5	Pembrolizumab alone or in combination with carboplatin/pemetrexed as first-line therapy for metastatic nonsquamous NSCLC
Track 6	**Case discussion:** A 33-year-old woman and never smoker with newly diagnosed adenocarcinoma of the lung and a high PD-L1 TPS
Track 7	**Case discussion:** A 46-year-old woman receives osimertinib after disease progression on erlotinib for EGFR mutation-positive metastatic NSCLC
Track 8	Plasma and urine genotyping to identify T790M mutations in NSCLC
Track 9	Activity of osimertinib in patients with T790M-positive advanced NSCLC and brain metastases
Track 10	Ongoing investigation of osimertinib in earlier lines of therapy
Track 11	Incidence of cardiac toxicity in patients receiving osimertinib
Track 12	**Case discussion:** A woman in her forties with relapsed/refractory NSCLC is found to harbor a ROS1 translocation
Track 13	Therapeutic options for patients with metastatic NSCLC harboring ROS1 gene rearrangements
Track 14	Clinical experience with immune checkpoint inhibitor-associated pulmonary toxicities
Track 15	ECOG-E1505: A Phase III trial of adjuvant chemotherapy with or without bevacizumab for early-stage NSCLC — A subset analysis of outcomes by chemotherapy
Track 16	Neoadjuvant checkpoint inhibitors for resectable NSCLC
Track 17	Perspective on the activity of rovalpituzumab tesirine in advanced SCLC
Track 18	PACIFIC: A Phase III trial evaluating the anti-PD-L1 antibody durvalumab as monotherapy after chemoradiation therapy for Stage III NSCLC
Track 19	Approach to first-line therapy for patients with metastatic SCC of the lung and low PD-L1 TPS
Track 20	Tolerability of nanoparticle albumin-bound (*nab*) paclitaxel in advanced SCC of the lung

Video Program

View the corresponding video interviews with (from left) Drs Camidge and Wakelee by Dr Love at www.ResearchToPractice.com/LCU117/Video

SELECT PUBLICATIONS

A phase II study of lorlatinib (PF-06463922) in advanced anaplastic lymphoma kinase (ALK) and ROS proto-oncogene 1 (ROS1) rearranged non-small cell lung cancer (NSCLC) with central nervous system (CNS) metastasis in the absence of measurable extracranial lesions. NCT02927340

A phase III, randomised, double-blind, placebo-controlled, multi-centre, international study of MEDI4736 as sequential therapy in patients with locally advanced, unresectable non-small cell lung cancer (stage III) who have not progressed following definitive, platinum-based, concurrent chemoradiation therapy (PACIFIC). NCT02125461

Adjuvant lung cancer enrichment marker identification and sequencing trial (ALCHEMIST). NCT02194738

An open-label, single-arm, phase 2 study evaluating the efficacy, safety and pharmacokinetics of rovalpituzumab tesirine (SC16LD6.5) for third-line and later treatment of subjects with relapsed or refractory delta-like protein 3-expressing small cell lung cancer (TRINITY). NCT02674568

Camidge DR. **Drinking not drowning: How to deal with the deluge of potential predictive biomarker approaches in non-small-cell lung cancer.** *J Oncol Pract* 2017;13(4):229-30.

Forde P et al. **Neoadjuvant anti-PD1, nivolumab, in early resectable non-small-cell lung cancer.** *Proc ESMO* 2016;**Abstract LBA41_PR**.

Gadgeel SM et al. **Clinical activity of osimertinib in EGFR mutation positive non-small cell lung cancer (NSCLC).** *Proc IASLC* 2016;**Abstract P3.02b-115**.

Gandara DR et al. **Atezolizumab treatment beyond disease progression in advanced NSCLC: Results from the randomized Ph III OAK study.** *Proc ASCO* 2017;**Abstract 9001**.

Hann CL et al. **A study of rovalpituzumab tesirine in frontline treatment of patients with DLL3 expressing extensive small cell lung cancer.** *Proc ASCO* 2017;**Abstract TPS2598**.

Hellmann MD et al. **Nivolumab (nivo) ± ipilimumab (ipi) in advanced small-cell lung cancer (SCLC): First report of a randomized expansion cohort from CheckMate 032.** *Proc ASCO* 2017;**Abstract 8503**.

Hyman DM et al. **The efficacy of larotrectinib (LOXO-101), a selective tropomyosin receptor kinase (TRK) inhibitor, in adult and pediatric TRK fusion cancers.** *Proc ASCO* 2017;**Abstract LBA2501**.

Katayama R et al. **Cabozantinib overcomes crizotinib resistance in ROS1 fusion-positive cancer.** *Clin Cancer Res* 2015;21(1):166-74.

Laetsch TW et al. **A pediatric phase I study of larotrectinib, a highly selective inhibitor of the tropomyosin receptor kinase (TRK) family.** *Proc ASCO* 2017;**Abstract 10510**.

Li BT et al. **Ado-trastuzumab emtansine in patients with HER2 mutant lung cancers: Results from a phase II basket trial.** *Proc ASCO* 2017;**Abstract 8510**.

Mok T et al. **CNS response to osimertinib in patients (pts) with T790M-positive advanced NSCLC: Data from a randomized phase III trial (AURA3).** *Proc ASCO* 2017;**Abstract 9005**.

Riess JW et al. **A case series of lengthy progression-free survival with pemetrexed-containing therapy in metastatic non-small-cell lung cancer patients harboring ROS1 gene rearrangements.** *Clin Lung Cancer* 2013;14(5):592-5.

Sabari JK et al. **PD-L1 expression and response to immunotherapy in patients with MET exon 14-altered non-small cell lung cancers (NSCLC).** *Proc ASCO* 2017;**Abstract 8512**.

Scherpereel A et al. **Second- or third-line nivolumab (nivo) versus nivo plus ipilimumab (ipi) in malignant pleural mesothelioma (MPM) patients: Results of the IFCT-1501 MAPS2 randomized phase II trial.** *Proc ASCO* 2017;**Abstract LBA8507**.

Shaw AT et al. **Efficacy and safety of lorlatinib in patients (pts) with ALK+ non-small cell lung cancer (NSCLC) with one or more prior ALK tyrosine kinase inhibitor (TKI): A phase I/II study.** *Proc ASCO* 2017;**Abstract 9006**.

Stinchcombe T et al. **Efficacy, safety, and biomarker results of trastuzumab emtansine (T-DM1) in patients (pts) with previously treated HER2-overexpressing locally advanced or metastatic non-small cell lung cancer (mNSCLC).** *Proc ASCO* 2017;**Abstract 8509**.

Wakelee HA et al. **E1505: Adjuvant chemotherapy +/- bevacizumab for early stage NSCLC — Outcomes based on chemotherapy subsets.** *Proc ASCO* 2016;**Abstract 8507**.

Wu YL et al. **Gefitinib (G) versus vinorelbine + cisplatin (VP) as adjuvant treatment in stage II-IIIA (N1-N2) non-small-cell lung cancer (NSCLC) with EGFR-activating mutation (ADJUVANT): A randomized, Phase III trial (CTONG 1104).** *Proc ASCO* 2017;**Abstract 8500**.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The investigational agent larotrectinib (LOXO-101) demonstrated response rates higher than 70% for adult and pediatric patients with tumors harboring _____.**
   a. MET exon 14 skipping mutations
   b. ALK rearrangements
   c. NTRK rearrangements

2. **Data presented by Sabari and colleagues at ASCO 2017 evaluating the use of immune checkpoint inhibitors for patients with MET exon 14-altered NSCLC found that rates of response to immunotherapy were low overall and lower than those reported with targeted therapy.**
   a. True
   b. False

3. **Pembrolizumab is FDA approved as first-line therapy for metastatic nonsquamous NSCLC in which of the following applications?**
   a. As a single agent for patients whose tumors have high PD-L1 TPS and no EGFR or ALK genomic tumor aberrations
   b. In combination with pemetrexed and carboplatin
   c. Both a and b
   d. Neither a nor b

4. **Crizotinib is FDA approved for patients with _____ metastatic NSCLC.**
   a. ALK-positive
   b. MET exon 14-rearranged
   c. ROS1-positive
   d. All of the above
   e. Both a and b
   f. Both a and c

5. **Which of the following categories reflects the mechanism of action of rovalpituzumab tesirine?**
   a. ALK inhibitor
   b. Antibody-drug conjugate
   c. Anti-PD-1/PD-L1 antibody
   d. EGFR tyrosine kinase inhibitor

6. **Which of the following ALK inhibitors penetrates the central nervous system (CNS) well and thus exhibits significant activity in patients with NSCLC and CNS metastases?**
   a. Alectinib
   b. Crizotinib
   c. Both a and b

7. **Initial results of the Phase III ADJUVANT trial presented at ASCO 2017 demonstrated that adjuvant gefitinib significantly prolonged _____ in comparison to vinorelbine/cisplatin for patients with resected Stage II to IIIA NSCLC with EGFR-activating mutations.**
   a. Disease-free survival
   b. Overall survival
   c. Both a and b
   d. Neither a nor b

8. **Osimertinib is FDA approved for the treatment of EGFR T790M mutation-positive NSCLC after disease progression on or after another EGFR-blocking therapy.**
   a. True
   b. False

9. **Lorlatinib is an investigational agent in the treatment of NSCLC and a potent inhibitor of _____.**
   a. PD-1
   b. EGFR
   c. ALK

10. **Osimertinib _____ marked activity in patients with brain metastases from T790M-positive advanced NSCLC.**
    a. Does not exhibit
    b. Exhibits

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Lung Cancer Update — Volume 14, Issue 1

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
Diagnostic and therapeutic implications of the recent FDA approval of pembrolizumab with carboplatin/pemetrexed as front-line treatment for metastatic nonsquamous NSCLC regardless of PD-L1 TPS	4 3 2 1	4 3 2 1
Identification of and protocol and nonresearch treatment for patients with other oncogenic drivers beyond EGFR, ALK and ROS1 (eg, MET exon 14, HER2)	4 3 2 1	4 3 2 1
Efficacy and tolerability of the recently FDA-approved EGFR tyrosine kinase inhibitor osimertinib in patients with T790M-positive advanced NSCLC and brain metastases	4 3 2 1	4 3 2 1
ADJUVANT: Initial results of a Phase III trial evaluating gefitinib versus vinorelbine/cisplatin as adjuvant therapy for Stage II to IIIA NSCLC with EGFR-activating mutations	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:

- Review recent FDA approvals and available research data documenting the safety and efficacy of pembrolizumab alone or in combination with carboplatin/pemetrexed for patients with previously untreated metastatic non-small cell lung cancer (NSCLC), and use this information to appropriately integrate the use of pembrolizumab into this setting. ..... 4 3 2 1 N/M N/A
- Consider age, performance status and other patient- or disease-related factors to guide the selection of first-line therapy for patients with newly diagnosed metastatic squamous and nonsquamous NSCLC without an identifiable driver mutation. ..... 4 3 2 1 N/M N/A
- Educate patients about the side effects associated with recently approved novel agents and immunotherapeutic approaches, and provide preventive strategies to reduce or ameliorate these toxicities. ..... 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:

- Consider published safety and efficacy data with available and emerging therapeutic strategies, and appropriately incorporate targeted therapies into the care of patients with identified tumor driver mutations or alterations. . . . . 4 3 2 1 N/M N/A
- Recall the scientific rationale for ongoing investigation of novel agents or therapeutic approaches in NSCLC, and counsel appropriately selected patients about study participation. . . . . 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 editor for this educational activity

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

Faculty	**Knowledge of subject matter**	**Effectiveness as an educator**
D Ross Camidge, MD, PhD	4 3 2 1	4 3 2 1
Heather Wakelee, MD	4 3 2 1	4 3 2 1
Editor	**Knowledge of subject matter**	**Effectiveness as an educator**
Neil Love, MD	4 3 2 1	4 3 2 1

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Lung Cancer™ UPDATE

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