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Lung Cancer™ UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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ABIM CME MOC ACCREDITED

CME Certified

Lung Cancer™ UPDATE

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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

- Evaluate the efficacy and safety data on tumor immunotherapy directed at the PD-1/PD-L1 pathway in lung cancer, and compare and contrast expert perspectives on the incorporation of these agents into the treatment of locally advanced and metastatic disease.
- Develop a genomic testing algorithm to assist in identifying appropriate patients eligible for protocol and clinical targeted treatment options.
- Formulate an evidence-based approach for selection and sequencing of crizotinib, ceritinib, alectinib, brigatanib and emerging ALK inhibitors in the treatment of non-small cell lung cancer (NSCLC), considering the predictive utility of ALK and ROS1 mutation testing.
- 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.
- 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.
- Devise an evidence-based approach to the selection of initial, second-line and later systemic therapy for patients with NSCLC without an identified targetable mutation.

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Interview with Matthew Gubens, MD, MS

Tracks 1-29

Track 1	**Case:** A 79-year-old man and former smoker with KRAS mutation-positive metastatic adenocarcinoma of the lung receives second-line treatment with nivolumab
Track 2	Incidence, monitoring and management of immune checkpoint inhibitor-associated pneumonitis
Track 3	PACIFIC: A Phase III trial of durvalumab after chemoradiation therapy for Stage III non-small cell lung cancer (NSCLC)
Track 4	Treatment options for patients with locally advanced NSCLC and rapid disease progression
Track 5	Pseudoprogression in patients receiving immune checkpoint inhibitors
Track 6	Immune checkpoint inhibitor-associated side effects
Track 7	Use of immune checkpoint inhibitor therapy for patients with preexisting autoimmune disorders
Track 8	**Case:** A 51-year-old woman and previous smoker with metastatic adenocarcinoma of the lung and no actionable mutations responds to pembrolizumab and carboplatin/pemetrexed on the Phase II KEYNOTE-021 trial
Track 9	Approach to first-line therapy for patients with newly diagnosed, mildly symptomatic adenocarcinoma of the lung and a high PD-L1 tumor proportion score (TPS)
Track 10	Therapeutic options for patients with a PD-L1 TPS of 1% to 49%
Track 11	Choosing between pembrolizumab alone or in combination with carboplatin/pemetrexed as first-line therapy for metastatic nonsquamous NSCLC
Track 12	Single-agent pembrolizumab as first-line therapy for patients with advanced NSCLC and a high PD-L1 TPS
Track 13	Immune checkpoint inhibitor-associated cellulitis and conjunctivitis
Track 14	Decision-making about the discontinuation of immune checkpoint inhibitor therapy after a prolonged response
Track 15	MYSTIC trial: Lack of progression-free survival (PFS) benefit with durvalumab/tremelimumab versus platinum-based chemotherapy for previously untreated metastatic NSCLC
Track 16	Nivolumab/ipilimumab as second-line therapy for small cell lung cancer (SCLC)
Track 17	Potential benefit of immune-directed therapies for patients with preexisting paraneoplastic syndromes
Track 18	**Case:** A 77-year-old woman and never smoker with ALK-rearranged metastatic adenocarcinoma of the lung experiences disease progression on third-line alectinib
Track 19	Resolution of choroidal metastases with crizotinib
Track 20	Testing for specific gene mutations to direct up-front targeted therapy for adenocarcinoma of the lung
Track 21	Therapeutic options for patients with ALK-rearranged advanced NSCLC and disease progression on crizotinib
Track 22	Clinical utility of FDA-approved (alectinib, brigatinib, ceritinib) and investigational (lorlatinib) ALK inhibitors in advanced NSCLC
Track 23	**Case:** A 74-year-old man and never smoker with EGFR exon 19 mutation-positive adenocarcinoma of the lung and multifocal brain metastases receives osimertinib
Track 24	First-line erlotinib versus afatinib or gefitinib for EGFR-mutated metastatic NSCLC
Track 25	Identification of T790M EGFR resistance mutations in NSCLC

Interview with Dr Gubens (continued)

Track 26	Utility of osimertinib for patients with advanced NSCLC who acquire the T790M EGFR mutation
Track 27	BLOOM: Activity of osimertinib in patients with leptomeningeal disease from EGFR-mutated advanced NSCLC in a Phase I study
Track 28	Activity of osimertinib in patients with T790M mutation-positive advanced NSCLC and brain metastases
Track 29	Mechanism of action and efficacy of the antibody-drug conjugate rovalpituzumab tesirine (Rova-T) in DLL3-expressing recurrent SCLC

Interview with Suresh S Ramalingam, MD

Tracks 1-34

Track 1	**Case:** An 83-year-old woman and never smoker with EGFR exon 19 mutation-positive advanced adenocarcinoma of the lung acquires a T790M mutation
Track 2	Selection among available EGFR tyrosine kinase inhibitors (TKIs) as first-line therapy for EGFR mutation-positive NSCLC
Track 3	Tolerability of osimertinib compared to erlotinib
Track 4	FLAURA study results: Osimertinib versus erlotinib or gefitinib as first-line therapy for EGFR-mutated advanced NSCLC
Track 5	Antitumor activity and no evidence of acquired EGFR T790M mutation after disease progression with osimertinib as first-line therapy for EGFR-mutated advanced NSCLC on the Phase I/II AURA trial
Track 6	Plasma testing for T790M mutations
Track 7	Design of the Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials (ALCHEMIST) for patients with early-stage disease
Track 8	ADJUVANT (CTONG 1104): Initial results of a Phase III trial evaluating adjuvant gefitinib or vinorelbine/platinum for EGFR mutation-positive Stage II to IIIA NSCLC
Track 9	**Case:** A 63-year-old woman with ALK-rearranged metastatic NSCLC who had to discontinue crizotinib/immune checkpoint inhibitor therapy on a clinical trial subsequently receives alectinib
Track 10	Overview of the activity of available ALK inhibitors
Track 11	Efficacy and tolerability of brigatinib
Track 12	Second-line therapeutic options for patients with ALK-rearranged NSCLC
Track 13	Alectinib versus crizotinib for ALK-rearranged NSCLC
Track 14	**Case:** A 64-year-old woman with concurrent ER/PR-negative, HER2-positive breast cancer and BRAF V600E-mutated adenocarcinoma of the lung
Track 15	Dabrafenib/trametinib for BRAF V600E mutation-positive metastatic NSCLC
Track 16	**Case:** A 63-year-old man with metastatic squamous cell NSCLC and Type 2 diabetes receives carboplatin/*nab* paclitaxel followed by second-line atezolizumab
Track 17	Second-line immunotherapy options for patients with metastatic squamous cell NSCLC
Track 18	Necitumumab or docetaxel/ramucirumab as second-line treatment for advanced squamous cell NSCLC
Track 19	Using metaphors to explain molecular testing to patients with cancer
Track 20	Biology of resistance to TKIs in patients with EGFR mutations
Track 21	ECOG-ACRIN 2511: A Phase I/II study of cisplatin and etoposide with or without the PARP inhibitor veliparib as front-line therapy for extensive-stage SCLC
Track 22	Rova-T in DLL3-positive SCLC
Track 23	Activity of combined anti-PD-1 and anti-CTLA-4 inhibitors in SCLC

Interview with Dr Ramalingam (continued)

Track 24	Toxicity comparison of anti-PD-1 and anti-PD-L1 antibodies
Track 25	Cardiac allograft rejection as a complication of PD-1 checkpoint blockade
Track 26	Safety of immune checkpoint inhibitors for patients who have undergone organ transplants
Track 27	Rationale for combining the anti-CD38 antibody daratumumab with immune checkpoint inhibitors for NSCLC
Track 28	First-line pembrolizumab compared to chemotherapy for patients with PD-L1-positive NSCLC
Track 29	Duration of response to first-line pembrolizumab
Track 30	First-line carboplatin/pemetrexed/ pembrolizumab for advanced nonsquamous NSCLC
Track 31	Choosing between pembrolizumab monotherapy and pembrolizumab with chemotherapy for patients with advanced NSCLC
Track 32	Molecular testing algorithm for patients with nonsquamous NSCLC
Track 33	Biologic background of the activity of immune checkpoint inhibitors in patients with NSCLC and driver mutations
Track 34	Meta-analysis comparing the efficacy of immune checkpoint inhibitors to that of chemotherapy in patients with EGFR wild-type versus mutated NSCLC

Video Program

View the corresponding video interviews with (from left) Drs Gubens and Ramalingam by Dr Love at www.ResearchToPractice.com/LCU217/Video

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Results of the global Phase III ALEX study evaluating alectinib versus crizotinib demonstrated a significant PFS improvement with alectinib for patients with _____ advanced ALK-rearranged NSCLC.**
   a. Treatment-naïve
   b. Previously treated

2. **Pembrolizumab is FDA approved as first-line therapy for metastatic nonsquamous NSCLC in which of the following indications?**
   a. As a single agent for patients whose tumors have a 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

3. **Which of the following categories reflects the mechanism of action of Rova-T?**
   a. ALK inhibitor
   b. Antibody-drug conjugate
   c. Anti-PD-1/PD-L1 antibody
   d. EGFR TKI

4. **Results of the Phase III FLAURA study comparing first-line osimertinib to either erlotinib or gefitinib for patients with advanced EGFR-mutated NSCLC demonstrated a significant improvement in PFS for patients who received osimertinib.**
   a. True
   b. False

5. **Patients with ALK-rearranged NSCLC who undergo treatment with brigatinib and experience treatment-associated pulmonary toxicity generally do so _____.**
   a. In an acute manner typically in the first week of treatment
   b. In a chronic fashion in which it persists over the course of treatment

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

7. **Initial results of the Phase III ADJUVANT (CTONG 1104) 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 an EGFR-activating mutation.**
   a. Disease-free survival
   b. Overall survival
   c. Both a and b

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

9. **Results of a meta-analysis performed by Lee and colleagues to compare the role of immune checkpoint inhibitors to that of docetaxel as second-line therapy for EGFR wild-type versus mutated advanced NSCLC demonstrated a statistically significant overall survival advantage for patients with _____ who received checkpoint inhibitors.**
   a. EGFR-mutated advanced NSCLC
   b. EGFR wild-type advanced NSCLC
   c. Both a and b

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 2

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
FLAURA: Results of a Phase III trial of first-line osimertinib versus erlotinib or gefitinib for patients with EGFR mutation-positive advanced NSCLC	4 3 2 1	4 3 2 1
Choosing among the recently FDA-approved immunotherapy options for patients with metastatic NSCLC	4 3 2 1	4 3 2 1
Safety of durvalumab as sequential treatment after chemoradiation therapy for patients with locally advanced, unresectable NSCLC on the Phase III PACIFIC trial	4 3 2 1	4 3 2 1
Risk-benefit ratio of nivolumab/ipilimumab as second-line therapy for SCLC	4 3 2 1	4 3 2 1
ADJUVANT (CTONG 1104): Initial results of a Phase III trial of adjuvant gefitinib or vinorelbine/platinum for EGFR mutation-positive Stage II to IIIA NSCLC	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:

- Evaluate the efficacy and safety data on tumor immunotherapy directed at the PD-1/PD-L1 pathway in lung cancer, and compare and contrast expert perspectives on the incorporation of these agents into the treatment of locally advanced and metastatic disease. ..... 4 3 2 1 N/M N/A
- Develop a genomic testing algorithm to assist in identifying appropriate patients eligible for protocol and clinical targeted treatment options. ..... 4 3 2 1 N/M N/A
- Formulate an evidence-based approach for selection and sequencing of crizotinib, ceritinib, alectinib, brigatinib and emerging ALK inhibitors in the treatment of non-small cell lung cancer (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:

- 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
- 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
- Devise an evidence-based approach to the selection of initial, second-line and later systemic therapy for patients with NSCLC without an identified targetable mutation. . . . . 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**
Matthew Gubens, MD, MS	4 3 2 1	4 3 2 1
Suresh S Ramalingam, 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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