

# Lung Cancer™

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U P D A T E

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

**FACULTY INTERVIEWS**

Tony SK Mok, MD

George R Blumenschein Jr, MD

**EDITOR**

Neil Love, MD



# Lung Cancer™

U P D A T E

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## Lung Cancer Update — A Continuing Medical Education Audio Series

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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

- Describe existing and emerging data on the efficacy and safety of tumor immunotherapy, including approaches directed at the PD-1 and PD-L1 pathways, and of antibody-drug conjugates in lung cancer and mesothelioma, and consider this information when counseling patients regarding protocol and clinical treatment options.
- 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.
- Recognize the recent FDA approvals of ramucirumab and necitumumab for patients with metastatic NSCLC, and discern how these agents can be safely administered to appropriate patients with squamous and nonsquamous disease.
- Compare and contrast the variable CNS permeability of approved ALK inhibitors, and use this information to guide selection of appropriate treatment for patients with ALK-positive NSCLC and brain metastases.
- 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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## CME INFORMATION

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## Interview with Tony SK Mok, MD

### Tracks 1-19

- |                |   |                 |  |
|----------------|---|-----------------|--|
| <b>Track 1</b> | Primary results of the Phase III J-ALEX study: Alectinib versus crizotinib for ALK inhibitor-naïve, ALK-positive non-small cell lung cancer (NSCLC)   | <b>Track 10</b> | Response to osimertinib following disease progression on gefitinib   |
| <b>Track 2</b> | LUX-Lung 7: Results of a Phase IIb study of gefitinib versus afatinib as first-line therapy for EGFR mutation-positive NSCLC  | <b>Track 11</b> | Tolerability of osimertinib and its feasibility as adjuvant therapy for EGFR mutation-positive NSCLC   |
| <b>Track 3</b> | <b>Case discussion:</b> A 68-year-old man and former smoker with Stage IIIA pan-wild-type NSCLC   | <b>Track 12</b> | IMPRESS: Results of a Phase III trial of gefitinib and chemotherapy versus placebo and chemotherapy for patients with EGFR mutation-positive NSCLC and disease progression on first-line gefitinib |
| <b>Track 4</b> | Neoadjuvant chemotherapy for locally advanced NSCLC   | <b>Track 13</b> | Treatment of T790M mutation-negative disease after progression on an EGFR tyrosine kinase inhibitor (TKI)  |
| <b>Track 5</b> | Perspective on the results of the Phase III PROCLAIM trial of pemetrexed/cisplatin or etoposide/cisplatin with thoracic radiation therapy followed by consolidation chemotherapy for locally advanced nonsquamous NSCLC | <b>Track 14</b> | Afatinib/cetuximab in patients with T790M mutation-negative NSCLC  |
| <b>Track 6</b> | Immune checkpoint inhibitors as second-line therapy in NSCLC  | <b>Track 15</b> | MET amplification and exon 14 splice site mutation define unique molecular subgroups of NSCLC  |
| <b>Track 7</b> | <b>Case discussion:</b> A 56-year-old woman and never smoker with EGFR exon 19 mutation-positive, metastatic adenocarcinoma of the lung   | <b>Track 16</b> | Use of next-generation sequencing for patients with EGFR mutation-negative, ALK-negative nonsquamous NSCLC   |
| <b>Track 8</b> | Clinical trials of osimertinib as first-line therapy for EGFR mutation-positive metastatic NSCLC  | <b>Track 17</b> | Treatment options after disease progression on osimertinib   |
| <b>Track 9</b> | EGFR T790M mutation testing in tissue, serum, urine or cytology fluid   | <b>Track 18</b> | Response to immune checkpoint inhibitors in patients with EGFR or ALK mutations  |
|                |   | <b>Track 19</b> | Targeting KRAS mutation-positive NSCLC   |

## Interview with George R Blumenschein Jr, MD

### Tracks 1-22

- |                |   |                |  |
|----------------|---|----------------|--|
| <b>Track 1</b> | <b>Case discussion:</b> A 55-year-old man with recurrent epithelioid mesothelioma                             | <b>Track 5</b> | Activity of the antibody-drug conjugate rovalpituzumab tesirine in small cell lung cancer  |
| <b>Track 2</b> | Results of the Phase III MAPS study of chemotherapy and bevacizumab for malignant pleural mesothelioma        | <b>Track 6</b> | ECOG-E1505: A Phase III trial of adjuvant chemotherapy with or without bevacizumab for early-stage NSCLC — A subset analysis of outcomes by chemotherapy |
| <b>Track 3</b> | Activity and tolerability of the anti-mesothelin antibody-drug conjugate anatumab ravtansine for mesothelioma | <b>Track 7</b> | <b>Case discussion:</b> A 70-year-old man with metastatic squamous cell NSCLC receives second-line nivolumab   |
| <b>Track 4</b> | JAVELIN trial: Efficacy and safety of the anti-PD-L1 antibody avelumab in unresectable advanced mesothelioma  |                |  |

## Interview with Dr Blumenschein (continued)

- Track 8** Clinical experience with the recently FDA-approved anti-EGFR antibody necitumumab in combination with cisplatin/gemcitabine as first-line therapy for metastatic squamous cell NSCLC
- Track 9** Therapeutic options for patients with metastatic squamous cell NSCLC after disease progression on an immune checkpoint inhibitor
- Track 10** Rationale for the ongoing Phase II/III Lung Master Protocol (SWOG-S1400) evaluating biomarker-targeted second-line therapy for recurrent Stage IV squamous cell lung cancer
- Track 11** Multiplex testing in squamous cell NSCLC
- Track 12** Algorithm for mutation testing in metastatic nonsquamous NSCLC
- Track 13** Use of immune checkpoint inhibitors alone or in combination regimens for patients with targetable mutations
- Track 14** T790M mutation testing and treatment of metastatic nonsquamous NSCLC after disease progression
- Track 15** Treatment of T790M mutation-negative metastatic NSCLC
- Track 16** Tolerability of osimertinib and management of treatment-related neutropenia
- Track 17** **Case discussion:** A 70-year-old man with EGFR mutation-positive metastatic NSCLC experiences disease progression on an EGFR TKI and is determined to have T790M-positive disease
- Track 18** Antitumor activity and ongoing investigation of the third-generation EGFR TKIs olmutinib (BI 1482694) and ASP8273 for advanced EGFR mutation-positive NSCLC
- Track 19** **Case discussion:** A 53-year-old woman with recurrent KRAS mutation-positive adenocarcinoma of the lung and brain metastases receives an immune checkpoint inhibitor
- Track 20** Viewpoint on the use of immune checkpoint inhibitor therapy for patients with preexisting autoimmune disease
- Track 21** **Case discussion:** A 45-year-old man with ALK-positive NSCLC and brain metastases
- Track 22** J-ALEX study: Alectinib versus crizotinib for ALK inhibitor-naïve, ALK-positive NSCLC

## Related Video Program

Visit [www.ResearchToPractice.com/LCU316/Video](http://www.ResearchToPractice.com/LCU316/Video) to view video highlights of the interviews with (from left) Drs Mok and Blumenschein by Dr Love and earn additional *AMA PRA Category 1 Credit™*.



### Topics covered include:

- ▶ Targeted therapy for patients with tumor mutations or alterations
- ▶ Checkpoint inhibitors in the treatment of lung cancer
- ▶ Chemobiologic therapy for patients with pan-wild-type NSCLC
- ▶ Management of advanced mesothelioma

## SELECT PUBLICATIONS

- Blumenschein GR et al. **Phase I study of anti-mesothelin antibody drug conjugate anetumab ravtansine (AR).** *Proc ASCO* 2016;**Abstract 2509.**
- Goss G et al. **Osimertinib for pretreated EGFR Thr790Met-positive advanced non-small-cell lung cancer (AURA2): A multicentre, open-label, single-arm, phase 2 study.** *Lancet Oncol* 2016;17(12):1643-52.
- Hassan R et al. **A pivotal randomized phase II study of anetumab ravtansine or vinorelbine in patients with advanced or metastatic pleural mesothelioma after progression on platinum/pemetrexed-based chemotherapy (NCT02610140).** *Proc ASCO* 2016;**Abstract TPS8576.**
- Hassan R et al. **Avelumab (MSB0010718C; anti-PD-L1) in patients with advanced unresectable mesothelioma from the JAVELIN solid tumor phase 1b trial: Safety, clinical activity, and PD-L1 expression.** *Proc ASCO* 2016;**Abstract 8503.**
- Jänne PA et al. **AZD9291 in EGFR inhibitor-resistant non-small-cell lung cancer.** *N Engl J Med* 2015;372(18):1689-99.
- Jia Y et al. **Overcoming EGFR(T790M) and EGFR(C797S) resistance with mutant-selective allosteric inhibitors.** *Nature* 2016;534(7605):129-32.
- Mok TS et al; AURA3 Investigators. **Osimertinib or platinum-pemetrexed in EGFR T790M-positive lung cancer.** *N Engl J Med* 2016;[Epub ahead of print].
- Nokihara H et al. **Alectinib (ALC) versus crizotinib (CRZ) in ALK-inhibitor naive ALK-positive non-small cell lung cancer (ALK+ NSCLC): Primary results from the J-ALEX study.** *Proc ASCO* 2016;**Abstract 9008.**
- Oxnard GR et al. **Association between plasma genotyping and outcomes of treatment with osimertinib (AZD9291) in advanced non-small-cell lung cancer.** *J Clin Oncol* 2016;34(28):3375-82.
- Park K et al. **Afatinib versus gefitinib as first-line treatment of patients with EGFR mutation-positive non-small-cell lung cancer (LUX-Lung 7): A phase 2B, open-label, randomised controlled trial.** *Lancet Oncol* 2016;17(5):577-89.
- Park K et al. **BI 1482694 (HM61713), an EGFR mutant-specific inhibitor, in T790M+ NSCLC: Efficacy and safety at the RP2D.** *Proc ASCO* 2016;**Abstract 9055.**
- Rossi A. **Rovalpituzumab tesirine and DLL3: A new challenge for small-cell lung cancer.** *Lancet Oncol* 2017;18(1):3-5.
- Rudin CM et al. **Rovalpituzumab tesirine, a DLL3-targeted antibody-drug conjugate, in recurrent small-cell lung cancer: A first-in-human, first-in-class, open-label, phase 1 study.** *Lancet Oncol* 2017;18(1):42-51.
- Rudin CM et al. **Safety and efficacy of single-agent rovalpituzumab tesirine (SC16LD6.5), a delta-like protein 3 (DLL3)-targeted antibody-drug conjugate (ADC) in recurrent or refractory small cell lung cancer (SCLC).** *Proc ASCO* 2016;**Abstract LBA8505.**
- Senan S et al. **PROCLAIM: Randomized phase III trial of pemetrexed-cisplatin or etoposide-cisplatin plus thoracic radiation therapy followed by consolidation chemotherapy in locally advanced nonsquamous non-small-cell lung cancer.** *J Clin Oncol* 2016;34(9):953-62.
- SOLAR: An open-label, randomized phase 3 efficacy study of ASP8273 vs erlotinib or gefitinib in first-line treatment of patients with stage IIIB/IV non-small cell lung cancer tumors with EGFR activating mutations.** **NCT02588261**
- Soria JC et al. **Gefitinib plus chemotherapy versus placebo plus chemotherapy in EGFR-mutation-positive non-small-cell lung cancer after progression on first-line gefitinib (IMPRESS): A phase 3 randomised trial.** *Lancet Oncol* 2015;16(8):990-8.
- Tan DS et al. **Cancer genomics: Diversity and disparity across ethnicity and geography.** *J Clin Oncol* 2016;34(1):91-101.
- Tong JH et al. **MET amplification and exon 14 splice site mutation define unique molecular subgroups of non-small cell lung carcinoma with poor prognosis.** *Clin Cancer Res* 2016;22(12):3048-56.
- Wakelee HA et al. **E1505: Adjuvant chemotherapy +/- bevacizumab for early stage NSCLC — Outcomes based on chemotherapy subsets.** *Proc ASCO* 2016;**Abstract 8507.**
- Yu HA et al. **Antitumor activity of ASP8273 300 mg in subjects with EGFR mutation-positive non-small cell lung cancer: Interim results from an ongoing phase 1 study.** *Proc ASCO* 2016;**Abstract 9050.**
- Zalcman G et al. **Bevacizumab 15 mg/kg plus cisplatin-pemetrexed (CP) triplet versus CP doublet in malignant pleural mesothelioma (MPM): Results of the IFCT-GFPC-0701 MAPS randomized phase 3 trial.** *Proc ASCO* 2015;**Abstract 7500.**

QUESTIONS (PLEASE CIRCLE ANSWER):

1. Primary results of the Phase III J-ALEX study evaluating alectinib versus crizotinib for patients with ALK inhibitor-naïve NSCLC demonstrated improvement in \_\_\_\_\_ with alectinib.
  - a. Progression-free survival
  - b. Objective response rate
  - c. Incidence of nausea/diarrhea
  - d. All of the above
  - e. Both a and c
  
2. The Phase IIb LUX-Lung 7 trial \_\_\_\_\_ a progression-free survival advantage with afatinib compared to gefitinib as first-line therapy for EGFR mutation-positive advanced NSCLC.
  - a. Demonstrated
  - b. Did not demonstrate
  
3. The Phase III MAPS study evaluating cisplatin and pemetrexed with or without bevacizumab for patients with newly diagnosed malignant pleural mesothelioma reported a statistically significant improvement in median overall survival with the addition of bevacizumab.
  - a. True
  - b. False
  
4. Which of the following mechanisms of action describes anetumab ravtansine?
  - a. ALK inhibitor
  - b. Antibody-drug conjugate
  - c. EGFR TKI
  - d. Anti-PD-L1 antibody
  
5. Which of the following appears to be the dose-limiting toxicity of anetumab ravtansine?
  - a. Alopecia
  - b. Corneal epithelialization
  - c. Both a and b
  
6. The novel agent avelumab, which has demonstrated activity in patients with unresectable advanced mesothelioma, is an \_\_\_\_\_.
  - a. Antibody-drug conjugate
  - b. ALK inhibitor
  - c. Anti-PD-L1 monoclonal antibody
  
7. Data from a first-in-human trial of the DLL3-targeted antibody-drug conjugate rovalpituzumab tesirine demonstrated robust responses with this agent in patients with \_\_\_\_\_.
  - a. Advanced mesothelioma
  - b. Pan wild-type advanced NSCLC
  - c. Recurrent or refractory small cell lung cancer
  
8. The anti-EGFR antibody necitumumab was recently approved by the FDA for use in combination with chemotherapy as first-line therapy for metastatic \_\_\_\_\_ NSCLC.
  - a. Squamous cell
  - b. Nonsquamous cell
  - c. Both a and b
  
9. 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
  
10. Osimertinib is FDA approved for the treatment of patients with EGFR T790M mutation-positive NSCLC after disease progression on or after treatment with other EGFR-blocking therapy.
  - a. True
  - b. False



**EDUCATIONAL ASSESSMENT AND CREDIT FORM**

*Lung Cancer Update — Issue 3, 2016*

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
	<b>BEFORE</b>		<b>AFTER</b>	
Primary results of the Phase III J-ALEX study: Alectinib versus crizotinib in ALK inhibitor-naïve, ALK-positive NSCLC	4	3	2	1
Efficacy and tolerability of the recently FDA-approved EGFR TKI osimertinib	4	3	2	1
Antitumor activity and ongoing investigation of the third-generation EGFR TKIs olmutinib (BI 1482694) and ASP8273 for advanced EGFR mutation-positive NSCLC	4	3	2	1
Activity and tolerability of the antimesothelin antibody-drug conjugate anetumab ravtansine for mesothelioma	4	3	2	1
LUX-Lung 7: Results of a Phase IIb study of gefitinib versus afatinib as first-line therapy for EGFR mutation-positive NSCLC	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:**

- Describe existing and emerging data on the efficacy and safety of tumor immunotherapy, including approaches directed at the PD-1 and PD-L1 pathways, and of antibody-drug conjugates in lung cancer and mesothelioma, and consider this information when counseling patients regarding protocol and clinical treatment options..... 4 3 2 1 N/M N/A
- 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
- Recognize the recent FDA approvals of ramucirumab and necitumumab for patients with metastatic NSCLC, and discern how these agents can be safely administered to appropriate patients with squamous and nonsquamous disease. .... 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:**

- Compare and contrast the variable CNS permeability of approved ALK inhibitors, and use this information to guide selection of appropriate treatment for patients with ALK-positive NSCLC and brain metastases. .... 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			
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George R Blumenschein Jr, 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™

U P D A T E

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