

Biomarker Analysis and the Implications for the Treatment of Non-Small Cell Lung Cancer

FACULTY INTERVIEWS

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Lung Cancer™

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Biomarker Analysis and the Implications for the Treatment of Non-Small Cell Lung Cancer

A Continuing Medical Education Audio Activity

OVERVIEW OF ACTIVITY

Recent developments have led to an explosion in lung cancer genetic and biologic knowledge, but the integration of anti-PD-1/PD-L1 checkpoint inhibitors into treatment and the evolution of targeted therapy have complicated decision-making for clinicians caring for patients with metastatic non-small cell lung cancer (NSCLC).

To assist medical oncologists as they think through the complex management of NSCLC, this program features the perspectives of a lung cancer clinical oncology investigator and a pathologist on the results of a patterns of care survey of 25 thoracic oncology experts documenting the current state of biomarker analysis and the related implications for treatment. Upon completion of this CME activity, medical oncologists should be able to formulate an up-to-date and more complete approach to the care of patients with lung cancer.

LEARNING OBJECTIVES

- Analyze the effects of tumor histology, genetic alterations and PD-L1 tumor proportion score on the practice patterns of clinical investigators in the management of NSCLC.
- Recognize the utility and limitations of multiplex and next-generation sequencing platforms, and determine their clinical application for patients with NSCLC.
- Review available research data on the effectiveness of approved EGFR tyrosine kinase inhibitors (TKIs) in patients with various EGFR mutations, and use this information to guide first-line treatment decision-making.
- Describe mechanisms of tumor resistance to EGFR TKIs, and understand the therapeutic options for patients whose disease progresses on first-line EGFR therapy.
- Describe available and emerging data on the efficacy of anti-PD-1/PD-L1 antibodies in NSCLC, and consider this information when counseling patients regarding treatment options.
- Assess new oncogenic pathways mediating the growth of unique NSCLC tumor subsets, and recall emerging data with experimental agents exploiting these targets.

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FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Riely** — Consulting Agreement: Genentech BioOncology; Contracted Research: Ariad Pharmaceuticals Inc, Astellas Pharma Global Development Inc, Novartis, Pfizer Inc. **Dr Ladanyi** — Contracted Research: AstraZeneca Pharmaceuticals LP, Loxo Oncology.

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Interview with Gregory J Riely, MD, PhD

Tracks 1-22

Track 1	Classification of metastatic non-small cell lung cancer (NSCLC) based on biomarker analysis	Track 11	Mechanisms of acquired resistance to osimertinib
Track 2	Optimal testing platforms for patients with metastatic NSCLC	Track 12	Response to EGFR TKIs in patients with CNS metastases
Track 3	Molecular profiling to detect targetable alterations in patients with newly diagnosed metastatic nonsquamous NSCLC	Track 13	Plasma versus tissue genotyping for detection of T790M mutations
Track 4	Choice of first-line therapy for patients with metastatic squamous NSCLC and no targetable mutations	Track 14	Response to osimertinib in patients with T790M-negative metastatic NSCLC
Track 5	Ongoing investigation of immune checkpoint inhibitors with chemotherapy as first-line treatment for metastatic squamous NSCLC with no targetable mutation	Track 15	Therapeutic options for patients with T790M-negative metastatic NSCLC
Track 6	Duration and level of response to immune checkpoint inhibitors based on PD-L1 tumor proportion score (TPS)	Track 16	Choosing between targeted therapy and immunotherapy for patients with metastatic nonsquamous NSCLC and actionable mutations
Track 7	Use of immune checkpoint inhibitors in combination with chemotherapy as front-line therapy for metastatic nonsquamous NSCLC without a targetable mutation	Track 17	Management of lung cancer in patients with ALK and ROS1 genomic alterations
Track 8	Selection of EGFR tyrosine kinase inhibitors (TKIs) as first-line therapy for EGFR-mutated NSCLC	Track 18	Selection of up-front therapy for BRAF mutation-positive metastatic NSCLC
Track 9	Types of EGFR mutations and activity of EGFR TKIs	Track 19	MET exon 14 alterations and implications for treatment
Track 10	Efficacy and tolerability of the EGFR TKI osimertinib as first-line therapy	Track 20	Sequencing therapy for patients with RET rearrangements
		Track 21	Efficacy of HER2-targeted therapy for patients with metastatic NSCLC and HER2 alterations
		Track 22	Analysis of PD-L1 expression and variation over time

Interview with Marc Ladanyi, MD

Tracks 1-13

Track 1	Molecular pathology of lung cancer	Track 5	Assays to detect genomic alterations in patients with lung cancer
Track 2	Genomic testing for patients with newly diagnosed metastatic NSCLC	Track 6	Biology of MET exon 14 alterations in NSCLC
Track 3	Actionable alterations in patients with adenocarcinoma of the lung	Track 7	Incidence of RET fusions in patients with lung adenocarcinoma; response to targeted therapy
Track 4	Targeting KRAS mutation-positive NSCLC		

Interview with Dr Ladanyi (continued)

- | | | | |
|----------|--|----------|--|
| Track 8 | Activity of NTRK inhibitors in patients with NTRK fusions | Track 11 | T790M mutation testing for patients who develop resistance to EGFR TKIs |
| Track 9 | MSK-IMPACT™: Next-generation sequencing assay to detect genomic alterations and inform therapeutic decision-making | Track 12 | Acquired EGFR C797S mutation as a mechanism of resistance to osimertinib |
| Track 10 | Mechanisms of resistance to EGFR TKIs | Track 13 | Detection of ALK fusions in NSCLC |

Video Program

View the corresponding video interviews with (from left) Drs Riely and Ladanyi by Dr Love at www.ResearchToPractice.com/BiomarkersLung17/Video



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Biomarker Analysis and the Implications for the Treatment of Non-Small Cell Lung Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

- A recent survey of 25 clinical investigators regarding the sequencing of systemic therapy for metastatic NSCLC revealed that for patients with squamous histology and a PD-L1 TPS greater than 50%, the preferred first-line treatment option was _____.
 - Carboplatin/*nab* paclitaxel
 - Carboplatin/pemetrexed/bevacizumab
 - Pembrolizumab
- Primary results of the global Phase III ALEX study evaluating alectinib versus crizotinib for treatment-naïve, advanced ALK-positive NSCLC demonstrated a significant improvement in favor of alectinib with respect to _____.
 - Progression-free survival
 - Overall survival
 - Incidence of CNS progression
 - All of the above
 - Both a and c
- Recent studies presented at ASCO 2017 demonstrated that T-DM1 elicited a higher response rate for patients with HER2-mutant lung cancer than for those with HER2-overexpressed disease.
 - True
 - False
- Mechanisms of acquired resistance to EGFR TKIs include _____.
 - Development of the T790M mutation
 - MET amplification
 - HER2 amplification
 - All of the above
- The incidence of RET fusion in patients with lung adenocarcinomas is approximately _____.
 - 1% to 2%
 - 5%
 - 10%
- Which of the following statements is true regarding MET exon 14 alterations?
 - They may result from a splice variant that increases MET signaling
 - They respond well to crizotinib
 - They do not occur concomitantly with MET amplification
 - All of the above
 - Both a and b
- In the survey of 25 clinical investigators analyzing the sequencing of systemic therapy for metastatic NSCLC, for patients with BRAF V600E mutation-positive NSCLC a majority of the investigators chose _____ as the preferred option in the first-line setting, irrespective of TPS.
 - Anti-PD-1/PD-L1 antibodies
 - Chemotherapy
 - Dabrafenib/trametinib
- Patients with EGFR mutation-positive NSCLC are _____ to respond to immunotherapy than are patients who do not have targetable mutations.
 - More likely
 - Less likely
- Recent data suggest that _____ is a mutation that confers resistance to alectinib in patients with ALK-rearranged NSCLC.
 - G1202R
 - T790M
 - C797S
- The third-generation EGFR TKI osimertinib _____.
 - Selectively targets both the T790M mutation and wild-type EGFR
 - Is effective for patients with brain metastases
 - Both a and b

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Biomarker Analysis and the Implications for the Treatment of Non-Small Cell 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					
ALEX: Results of the Phase III study comparing alectinib to crizotinib for treatment-naïve, advanced ALK-positive NSCLC	4	3	2	1	4	3	2	1
Therapeutic implications of the recent FDA approval of pembrolizumab with carboplatin/pemetrexed as front-line treatment for metastatic nonsquamous NSCLC regardless of TPS	4	3	2	1	4	3	2	1
Emerging data on the treatment of lung cancer with other oncogenic drivers beyond EGFR, ALK and ROS1 (eg, BRAF, MET exon 14, HER2)	4	3	2	1	4	3	2	1
Preference among clinical investigators for the use of immune checkpoint inhibitors as up-front therapy for patients with squamous cell lung carcinoma and a TPS greater than 50%	4	3	2	1	4	3	2	1
Efficacy of osimertinib for T790M mutation-positive advanced NSCLC after disease progression on an EGFR TKI	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:

- Analyze the effects of tumor histology, genetic alterations and PD-L1 tumor proportion score on the practice patterns of clinical investigators in the management of NSCLC. 4 3 2 1 N/M N/A
- Recognize the utility and limitations of multiplex and next-generation sequencing platforms, and determine their clinical application for patients with NSCLC. 4 3 2 1 N/M N/A
- Review available research data on the effectiveness of approved EGFR tyrosine kinase inhibitors (TKIs) in patients with various EGFR mutations, and use this information to guide first-line treatment decision-making. 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:

- Describe mechanisms of tumor resistance to EGFR TKIs, and understand the therapeutic options for patients whose disease progresses on first-line EGFR therapy. 4 3 2 1 N/M N/A
- Describe available and emerging data on the efficacy of anti-PD-1/PD-L1 antibodies in NSCLC, and consider this information when counseling patients regarding treatment options. 4 3 2 1 N/M N/A
- Assess new oncogenic pathways mediating the growth of unique NSCLC tumor subsets, and recall emerging data with experimental agents exploiting these targets. . . . 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			
Gregory J Riely, MD, PhD	4	3	2	1	4	3	2	1
Marc Ladanyi, 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™

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