Rounds with the Investigators

National Research Leaders Provide Their Perspectives on the Management of Actual Patients with Lung Cancer

A Case-Based Roundtable Discussion

Co-Chair

Thomas J Lynch Jr, MD

Moderator and Chair

Neil Love, MD

Faculty

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Contents

2 Audio CDs

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Rounds with the Investigators: National Research Leaders Provide Their Perspectives on the Management of Actual Patients with Lung Cancer

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Lung cancer is increasingly recognized as a heterogeneous group of neoplasms. Not long ago it was clinically sufficient to differentiate between small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC). Now individualized treatment decisions are increasingly driven by genetic biomarkers in addition to histologic subtype and patient-specific characteristics. In order to offer optimal patient care — including the option of clinical trial participation — practicing medical oncologists must be well informed of this increased understanding of the phenotypically unique subsets of lung cancer to enable customized treatment planning. To provide clinicians with therapeutic strategies for addressing the disparate needs of patients with lung cancer, the *Rounds with the Investigators* audio series employs an innovative, case-based approach that unites the perspectives of leading lung cancer investigators and community oncologists as they explore the intricacies of clinical decision-making. 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

- Employ case-based learning to effectively implement evidence-based diagnostic and therapeutic approaches for patients with lung cancer.
- Effectively utilize tumor histology in making evidence-based lung cancer treatment decisions.
- Identify distinct subtypes of adenocarcinoma of the lung — including those with EGFR mutations, EML4-ALK gene fusions and other recently identified driver mutations — and the investigational and approved treatment options for patients with these biomarkers.
- Individualize adjuvant chemotherapy for patients with early-stage NSCLC, with consideration of the efficacy and unique side-effect and tolerability profiles of guideline-endorsed regimens.
- Evaluate the potential benefits of low-dose CT screening for appropriately selected individuals at high risk for the development of lung cancer.
- Identify patients with metastatic NSCLC who may experience incremental benefit from maintenance biologic therapy and/or chemotherapy.
- Recall the scientific rationale for ongoing investigation of novel agents or therapeutic approaches in lung cancer, and counsel appropriately selected patients about study participation.

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TRACKS 1-21

ROUNDTABLE DISCUSSION WITH COREY J LANGER, MD AND GREGORY J RIELY, MD, PHD

Track 1 **Case discussion:** A 67-year-old woman and former smoker with Stage IIA adenocarcinoma of the lung with positive peribronchial lymph nodes (LNs) and no mediastinal LNs sampled

Track 2 Adjuvant chemotherapy options for patients with localized non-small cell lung cancer (NSCLC)

Track 3 TREAT: A randomized Phase II trial evaluating the use of adjuvant cisplatin/pemetrexed versus cisplatin/vinorelbine in early-stage NSCLC

Track 4 Critical appraisal of adjuvant regimens in early-stage NSCLC

Track 5 Dosing and schedule of cisplatin/vinorelbine for patients with NSCLC

Track 6 Clinical trials of adjuvant EGFR TKIs for patients with EGFR mutations

Track 7 Available clinical trial data and ongoing studies evaluating adjuvant chemotherapy with and without EGFR inhibitors

Track 8 Role of postoperative radiation therapy in NSCLC

Track 9 **Case discussion:** A 54-year-old current smoker with a 2.7-cm moderately differentiated adenocarcinoma, 2 of 12 positive hilar nodes and 2 positive level 10 lymph nodes receives cisplatin/pemetrexed/bevacizumab followed by maintenance bevacizumab on the ECOG-E1505 trial

Track 10 Perspectives on the duration of bevacizumab in lung cancer and other solid tumors

Track 11 **Case discussion:** A 53-year-old nonsmoker with EGFR mutation-positive adenocarcinoma of the lung with bronchioloalveolar carcinoma (BAC) features and brain metastasis experiences disease progression on erlotinib

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Track 13 Rapidity of response to EGFR TKIs versus chemotherapy among patients with highly symptomatic EGFR-mutant advanced NSCLC

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Track 15 Coping with the stresses of medical oncology practice

Track 16 Investigations of immune-based therapy in NSCLC

Track 17 MARQUEE: A Phase III trial of erlotinib in combination with tivantinib (ARQ 197) versus erlotinib in combination with placebo for patients with previously treated, locally advanced or metastatic NSCLC

Track 18 **Case discussion:** A 41-year-old Chinese woman and nonsmoker with EGFR-negative, ALK-positive squamous cell NSCLC with brain metastasis

Track 19 Considerations for EGFR and ALK testing for patients with squamous cell histology

Track 20 Use of crizotinib for patients with EML4-ALK-positive NSCLC and brain metastasis

Track 21 Perspectives on the use and side-effect profile of crizotinib for ALK-positive NSCLC

TRACKS 1-29

ROUNDTABLE DISCUSSION WITH THOMAS J LYNCH JR, MD AND JYOTI D PATEL, MD

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Track 2 Mutual exclusivity of K-ras, EGFR, ROS1 and ALK mutations in NSCLC

Track 3 ROS1 translocation and potential responsiveness to crizotinib

Track 4 My Cancer Genome — Identification of EGFR mutations in NSCLC

Track 5 Procuring tissue for biomarker analysis to inform clinical decision-making

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Track 7 Use of bevacizumab for older patients with advanced NSCLC

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Track 9 Perspective on the PARAMOUNT study results with maintenance pemetrexed after cisplatin/pemetrexed for advanced nonsquamous NSCLC

Track 10 Duration of maintenance therapy in advanced NSCLC

Track 11 Second opinion: Mutation testing for patients with advanced NSCLC

Track 12 Considerations for the use of an EGFR TKI with versus without stereotactic or whole brain radiation therapy for patients with brain metastasis from NSCLC

Track 13 Erlotinib dosing — standard versus pulse — and rapidity of response with erlotinib versus chemotherapy for patients with symptomatic EGFR-mutant metastatic NSCLC

Track 14 Activity and side effects of the irreversible EGFR TKI afatinib in combination with cetuximab in patients with NSCLC and acquired resistance to EGFR TKIs

Track 15 Continuation of EGFR TKI therapy for initially responsive patients who experience disease progression while receiving erlotinib

Track 16 Bone-targeted therapy for patients with NSCLC and bone metastases

Track 17 Choice of chemotherapy partner to combine with radiation therapy in Stage IIIB/IV NSCLC

Track 18 Results from the National Lung Screening Trial: Reduced lung cancer mortality with low-dose CT screening

Track 19 **Case discussion:** A 63-year-old woman with hypertension, diabetes and a TTF-1-positive recurrent adenocarcinoma of the lung

Track 20 Choice of chemotherapy for patients with NSCLC and diabetes

Track 21 Potential role of *nab* paclitaxel in squamous cell NSCLC

Track 22 Identification of driver mutations in squamous cell NSCLC

Track 23 Use of steroid premedication in the administration of taxanes

Track 24 **Case discussion:** A 67-year-old man and former heavy smoker with extensive-stage small cell lung cancer (SCLC) experiences a complete response to cisplatin/etoposide followed by prophylactic cranial irradiation but experiences post-treatment progressive deconditioning

Track 25 Diagnosis and treatment of SCLC-associated neurologic paraneoplastic syndromes

Track 26 Pathophysiology of paraneoplastic syndromes in SCLC

Track 27 Immune-based therapy in NSCLC

Track 28 Second opinion: Consideration of erlotinib maintenance therapy for responding patients with EGFR wild-type NSCLC

Track 29 Increasing number of targets for biomarker assessment in NSCLC

SELECT PUBLICATIONS

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Ou SH. **Crizotinib: A novel and first-in-class multitargeted tyrosine kinase inhibitor for the treatment of anaplastic lymphoma kinase rearranged non-small cell lung cancer and beyond.** *Drug Des Devel Ther* 2011;5:471-85.

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Wang Y et al. **Erlotinib in the treatment of advanced non-small cell lung cancer: An update for clinicians.** *Ther Adv Med Oncol* 2012;4(1):19-29.

Zhu J et al. **Carboplatin and paclitaxel with vs without bevacizumab in older patients with advanced non-small cell lung cancer.** *JAMA* 2012;307(15):1593-601.

POST-TEST

Rounds with the Investigators: National Research Leaders Provide Their Perspectives on the Management of Actual Patients with Lung Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The results of the Phase II TREAT trial demonstrated that the combination of cisplatin and vinorelbine was better tolerated than cisplatin and pemetrexed for patients with early-stage NSCLC.**
   a. True
   b. False

2. **The TASTE trial is comparing adjuvant cisplatin/pemetrexed to customized adjuvant treatment based on EGFR and ERCC1 status for patients with nonsquamous NSCLC.**
   a. True
   b. False

3. **The PARAMOUNT trial demonstrated a statistically significant benefit in _____ for patients with advanced nonsquamous NSCLC who received maintenance pemetrexed compared to placebo.**
   a. Overall survival
   b. Progression-free survival
   c. Neither of the above
   d. Both a and b

4. **The National Lung Screening Trial reported a 20% relative reduction in mortality from lung cancer with low-dose CT screening.**
   a. True
   b. False

5. **In a study of afatinib with cetuximab for patients with NSCLC and disease progression on erlotinib or gefitinib, investigators reported confirmed responses in _____.**
   a. T790M mutation-positive disease
   b. T790M mutation-negative disease
   c. Both of the above
   d. None of the above

6. **The PointBreak study is comparing the ECOG-E4599 regimen (paclitaxel/carboplatin/bevacizumab followed by maintenance bevacizumab) to which of the following?**
   a. Paclitaxel/carboplatin/bevacizumab → maintenance paclitaxel/bevacizumab
   b. Pemetrexed/carboplatin/bevacizumab → maintenance bevacizumab
   c. Pemetrexed/carboplatin/bevacizumab → maintenance pemetrexed/bevacizumab

7. **The administration of *nab* paclitaxel does not require steroid premedication.**
   a. True
   b. False

8. **The Phase III MARQUEE trial is evaluating erlotinib with tivantinib for patients with _____ locally advanced or metastatic NSCLC.**
   a. Previously treated
   b. Previously untreated

9. **Patients with NSCLC and ROS1 rearrangements are highly unlikely to respond to crizotinib.**
   a. True
   b. False

10. **Results published by Zhu and colleagues in *The Journal of the American Medical Association* indicated that the addition of bevacizumab to carboplatin/paclitaxel was not associated with more favorable survival rates among older patients with advanced NSCLC.**
    a. True
    b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Rounds with the Investigators: National Research Leaders Provide Their Perspectives on the Management of Actual Patients with 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
ROS1 rearrangements and evidence of response to crizotinib in NSCLC	4 3 2 1	4 3 2 1
Activity of afatinib/cetuximab in patients with NSCLC and acquired resistance to erlotinib or gefitinib	4 3 2 1	4 3 2 1
TREAT: A randomized Phase II trial of the refinement of early-stage NSCLC adjuvant chemotherapy with cisplatin/pemetrexed versus cisplatin/vinorelbine	4 3 2 1	4 3 2 1
Diagnosis, pathophysiology and treatment of SCLC-associated paraneoplastic syndromes	4 3 2 1	4 3 2 1
PointBreak: A Phase III study of pemetrexed/carboplatin/bevacizumab followed by maintenance pemetrexed/bevacizumab versus the ECOG-E4599 regimen for Stage IIIB/IV nonsquamous NSCLC	4 3 2 1	4 3 2 1

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:

- Employ case-based learning to effectively implement evidence-based diagnostic and therapeutic approaches for patients with lung cancer. . . . . 4 3 2 1 N/M N/A
- Effectively utilize tumor histology in making evidence-based lung cancer treatment decisions. . . . . 4 3 2 1 N/M N/A
- Identify distinct subtypes of adenocarcinoma of the lung — including those with EGFR mutations, EML4-ALK gene fusions and other recently identified driver mutations — and the investigational and approved treatment options for patients with these biomarkers. . . . . 4 3 2 1 N/M N/A
- Individualize adjuvant chemotherapy for patients with early-stage NSCLC, with consideration of the efficacy and unique side-effect and tolerability profiles of guideline-endorsed regimens. . . . 4 3 2 1 N/M N/A
- Evaluate the potential benefits of low-dose CT screening for appropriately selected individuals at high risk for the development of lung cancer. . . . . 4 3 2 1 N/M N/A
- Identify patients with metastatic NSCLC who may experience incremental benefit from maintenance biologic therapy and/or chemotherapy. . . . . 4 3 2 1 N/M N/A
- Recall the scientific rationale for ongoing investigation of novel agents or therapeutic approaches in lung cancer, and counsel appropriately selected patients about study participation. . . . . 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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:.....

Additional comments about this activity:

.....

.....

As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

☐ Yes, I am willing to participate in a follow-up survey.

☐ No, I am not willing to participate in a follow-up survey.

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
Corey J Langer, MD	4 3 2 1	4 3 2 1
Thomas J Lynch Jr, MD	4 3 2 1	4 3 2 1
Jyoti D Patel, MD	4 3 2 1	4 3 2 1
Gregory J Riely, MD, PhD	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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Lung Cancer™ UPDATE

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