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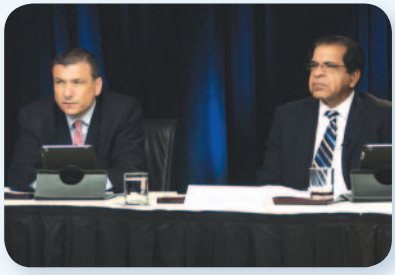
# Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Non-Small Cell Lung Cancer

*Proceedings from a Clinical Investigator Think Tank*



**FACULTY**

Chandra P Belani, MD
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John V Heymach, MD, PhD
Gregory J Riely, MD, PhD
Mark A Socinski, MD
David R Spigel, MD

**MODERATOR**

Neil Love, MD

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# *Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Non-Small Cell Lung Cancer*

## A Continuing Medical Education Audio Program

### OVERVIEW OF ACTIVITY

Lung cancer is increasingly being recognized as a heterogeneous group of tumors. Not long ago, it was clinically sufficient to make a differentiation between small cell lung cancer and non-small cell lung cancer (NSCLC). Today, individualized treatment decisions are increasingly driven by genetic biomarkers in addition to histological subtype and patient-specific characteristics. Determining which treatment approach is most appropriate in a given case requires careful consideration of patient and disease characteristics as well as available health system resources. To facilitate appropriate decision-making for the various presentations of NSCLC, oncology clinicians must be kept abreast of key research developments related to this rapidly evolving field. This CME program uses a roundtable discussion with leading lung cancer clinical investigators to assist practicing clinicians in this regard and ensure they are delivering state-of-the-art care.

### LEARNING OBJECTIVES

- Describe emerging data on the efficacy and safety of tumor immunotherapy directed at the PD-1/PD-L1 pathway in lung cancer, and consider this information when counseling patients regarding clinical trial participation.
- Assess new oncogenic pathways mediating the growth of unique NSCLC tumor subsets, and recall emerging data with experimental agents exploiting these targets.
- Apply the results of existing and emerging clinical research to the multimodality treatment of Stage III NSCLC.
- Develop an evidence-based approach to the selection of induction and maintenance biologic therapy and/or chemotherapy for patients with advanced NSCLC.
- Identify distinct subtypes of adenocarcinoma of the lung — including those with EGFR mutations, EML4-ALK gene fusions, MET amplification and other recently identified driver mutations — and the approved and investigational treatment options for patients with these mutations.

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***This activity is supported by educational grants from Astellas, Biodesix Inc, Genentech BioOncology, Lilly and Novartis Pharmaceuticals Corporation.***

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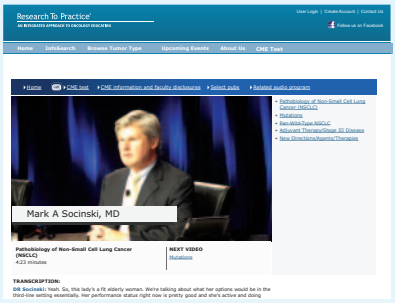
## Video Highlights of the Clinical Investigator Think Tank




**Visit www.ResearchToPractice.com/LCUTT114/Video to access a number of short video segments and corresponding transcripts from the Think Tank featuring the faculty discussing and debating some of the key clinical management and research issues in the field of non-small cell lung cancer.**

# TRACKS 1-25

**Track 1** **Case discussion:** A 57-year-old Asian patient and never smoker with liver metastases and biopsy-proven non-small cell lung cancer (NSCLC) without sufficient tissue for definitive histology and mutation profiling

**Track 2** Appraisal of first-line treatment options for patients with EGFR exon 19 deletion-positive adenocarcinoma of the lung

**Track 3** Use of afatinib versus erlotinib as first-line therapy for patients with EGFR mutation-positive disease

**Track 4** Viewpoints on continuation of erlotinib after disease progression in patients with advanced, EGFR-mutant NSCLC

**Track 5** Approach to maintenance therapy for patients with advanced, EGFR-mutant NSCLC

**Track 6** First-in-human evaluation of CO-1686, an irreversible, highly selective tyrosine kinase inhibitor (TKI) of EGFR-activating and T790M mutations

**Track 7** Erlotinib Beyond Progression study: Results of a Phase II trial comparing chemotherapy in combination with erlotinib to chemotherapy alone in EGFR TKI-responsive NSCLC that subsequently progresses

**Track 8** Genomic landscape of EGFR mutations in NSCLC

**Track 9** Response to erlotinib and prognosis for patients with de novo EGFR T790M mutations

**Track 10** Activity of afatinib in patients with uncommon EGFR mutations on the LUX-Lung 2, 3 and 6 trials

**Track 11** **Case discussion:** A 55-year-old nonsmoker who previously underwent treatment for EGFR wild-type, Stage III adenocarcinoma of the lung is found to harbor an ALK translocation and experiences a near-complete response with crizotinib followed by progression and then response to LDK378

**Track 12** Activity of the second-generation investigational ALK inhibitor LDK378

**Track 13** Therapeutic strategies to overcome crizotinib resistance

**Track 14** Clinical activity of the ALK inhibitor LDK378 in crizotinib-naïve and crizotinib-resistant advanced, ALK mutation-positive NSCLC

**Track 15** Use of dose attenuations of LDK378 for patients with AST/ALT elevations

**Track 16** Activity of the second-generation ALK inhibitor alectinib (CH5424802) for patients with ALK inhibitor-naïve, ALK-rearranged advanced NSCLC

**Track 17** Incorporation of second-generation ALK inhibitors into the treatment algorithm for ALK-rearranged, advanced NSCLC

**Track 18** Activity and increased specificity of second-generation ALK inhibitors

**Track 19** Clinical, pathologic and biologic features associated with BRAF mutations and interim results of the Phase II BRF113928 study of dabrafenib in BRAF V600E mutation-positive NSCLC

**Track 20** Ongoing Phase II trial of dasatinib for patients with NSCLC or other advanced solid tumors harboring DDR2 mutation or inactivating BRAF mutation

**Track 21** Early data with BRAF inhibitors for BRAF-mutant, advanced NSCLC

**Track 22** Results from the Phase III PointBreak trial of pemetrexed, carboplatin and bevacizumab followed by maintenance pemetrexed/bevacizumab versus the ECOG-E4599 regimen for Stage IIIB/IV nonsquamous NSCLC

**Track 23** First-line and maintenance therapy for patients with pan-wild-type adenocarcinoma who are eligible to receive bevacizumab

**Track 24** ECOG-E5508: A Phase III study of maintenance bevacizumab, pemetrexed or the combination in advanced nonsquamous NSCLC

**Track 25** Results of a Phase III trial of pemetrexed in combination with carboplatin → maintenance pemetrexed versus the ECOG-E4599 regimen for advanced nonsquamous NSCLC

## TRACKS 26-47

**Track 26** **Case discussion:** An 82-year-old former heavy smoker who previously underwent treatment for advanced squamous cell lung carcinoma receives the anti-PD-1 receptor antibody nivolumab on a clinical trial

**Track 27** Role of next-generation sequencing in patients with squamous cell carcinoma

**Track 28** Response to the anti-PD-1 monoclonal antibody nivolumab on a clinical trial

**Track 29** Clinical activity, safety and biomarkers of the anti-PD-L1 antibody MPDL3280A in patients with locally advanced or metastatic NSCLC

**Track 30** Tolerability of and "pseudoprogression" with immune checkpoint inhibitors in NSCLC

**Track 31** Clinical response to anti-PD-1 and anti-PD-L1 checkpoint inhibitors

**Track 32** Ongoing trials of checkpoint inhibitors in previously treated metastatic squamous and nonsquamous NSCLC

**Track 33** Forecast for the future development of immune-based therapies in lung cancer

**Track 34** **Case discussion:** An 81-year-old patient who previously underwent treatment for bladder cancer presents with Stage II, KRAS-mutant adenocarcinoma of the lung

**Track 35** Critical appraisals of adjuvant chemotherapy options for younger versus older patients

**Track 36** Response and side effects of adjuvant cisplatin/vinorelbine in elderly patients

**Track 37** **Case discussion:** A 49-year-old never smoker presents with cough and shortness of breath and is diagnosed with Stage III adenocarcinoma of the lung and an EGFR L858R mutation

**Track 38** RTOG-1306: A Phase II trial of individualized combined modality therapy for Stage III NSCLC

**Track 39** Perspectives on clinical trials of neoadjuvant erlotinib in EGFR mutation-positive, Stage III NSCLC

**Track 40** Results of the Phase II OAM4558g trial of onartuzumab (MetMAb) in combination with erlotinib for advanced NSCLC

**Track 41** MetLung (OAM4971g): A Phase III trial of onartuzumab in combination with erlotinib versus placebo with erlotinib for patients with previously treated NSCLC

**Track 42** INSPIRE and SQUIRE: Results of Phase III trials of cisplatin/pemetrexed with or without the human IgG1 anti-EGFR antibody necitumumab as first-line therapy for Stage IV nonsquamous and squamous NSCLC, respectively

**Track 43** **Case discussion:** A 64-year-old former smoker with recurrent squamous cell NSCLC 3 months after treatment with carboplatin/paclitaxel receives docetaxel nanoparticles on a clinical trial

**Track 44** Role of nanoparticle albumin-bound (*nab*) paclitaxel in the treatment of advanced squamous cell carcinoma of the lung

**Track 45** Perspectives on the use of the VeriStrat® assay

**Track 46** Results of PROSE: A Phase III trial of proteomic-stratified (VeriStrat) second-line erlotinib versus chemotherapy for patients with inoperable NSCLC

**Track 47** Viewpoints on tolerability and quality of life with erlotinib versus chemotherapy for NSCLC

## SELECT PUBLICATIONS


**A randomized, multicenter, open-label phase 3 study of gemcitabine-cisplatin chemotherapy plus necitumumab (IMC-11F8) versus gemcitabine-cisplatin chemotherapy alone in the first-line treatment of patients with stage IV squamous non-small cell lung cancer (NSCLC). NCT00981058**

Cardarella S et al. **Clinical, pathologic, and biologic features associated with BRAF mutations in non-small cell lung cancer.** *Clin Cancer Res* 2013;19(16):4532-40.

Edelman MJ et al. **The prevalence of MET expression by immunohistochemistry in the MetLung (OAM4971g) trial: A randomized, placebo-controlled, phase III study with erlotinib + onartuzumab (MetMAb) vs erlotinib + placebo in patients with previously treated non-small cell lung cancer.** *Proc WCLC* 2013;**Abstract MO12.07**.

Gregorc V et al. **Randomized proteomic stratified phase III study of second line erlotinib versus chemotherapy in patients with inoperable non-small cell lung cancer (PROSE): Secondary endpoint analysis.** *Proc WCLC* 2013;**Abstract O01.07**.

Halmos B et al. **Erlotinib beyond progression study: Randomized phase II study comparing chemotherapy plus erlotinib with chemotherapy alone in EGFR tyrosine kinase inhibitor (TKI)-responsive, non-small cell lung cancer (NSCLC) that subsequently progresses.** *Proc ASCO* 2013;**Abstract 8114**.

Lazzari C et al. **Randomized proteomic stratified phase III study of second-line erlotinib versus chemotherapy in patients with inoperable non-small cell lung cancer (PROSE).** *Proc ASCO* 2013;**Abstract LBA8005**.

Patel JD et al. **PointBreak: A randomized phase III study of pemetrexed plus carboplatin and bevacizumab followed by maintenance pemetrexed and bevacizumab versus paclitaxel plus carboplatin and bevacizumab followed by maintenance bevacizumab in patients with stage IIIB or IV nonsquamous non-small-cell lung cancer.** *J Clin Oncol* 2013;31(34):4349-57.

Paz-Ares L et al. **Randomized phase-3 trial (INSPIRE) of necitumumab plus cisplatin-pemetrexed versus cisplatin-pemetrexed alone as first-line therapy in stage IV non-squamous NSCLC.** *Proc WCLC* 2013;**Abstract O03.02**.

Peters S et al. **Dramatic response induced by vemurafenib in a BRAF V600E-mutated lung adenocarcinoma.** *J Clin Oncol* 2013;31(20):e341-4.

**Phase II trial of dasatinib in subjects with advanced cancers harboring DDR2 mutation or inactivating B-RAF mutation. NCT01514864**

Planchard D et al. **Interim results of phase II study BRF113928 of dabrafenib in BRAF V600E mutation-positive non-small cell lung cancer patients.** *Proc ASCO* 2013;**Abstract 8009**.

**Randomized phase II study of individualized combined modality therapy for stage III non-small cell lung cancer (NSCLC). NCT01822496**

Seto T et al. **CH5424802 (RO5424802) for patients with *ALK*-rearranged advanced non-small-cell lung cancer (AF-001JP study): A single-arm, open-label, phase 1-2 study.** *Lancet Oncol* 2013;14:590-8.

Soria JC et al. **First-in-human evaluation of CO-1686, an irreversible, highly selective tyrosine kinase inhibitor of mutations of EGFR (activating and T790M).** *Proc WCLC* 2013;**Abstract O03.06**.

Spigel DR et al. **Clinical activity, safety, and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic non-small cell lung cancer.** *Proc ASCO* 2013;**Abstract 8008**.

Spigel DR et al. **Randomized phase II trial of onartuzumab in combination with erlotinib in patients with advanced non-small-cell lung cancer.** *J Clin Oncol* 2013;31(32):4105-14.

**Study of BMS-936558 (nivolumab) compared to docetaxel in previously treated advanced or metastatic squamous cell non-small cell lung cancer (NSCLC) (CheckMate 017). NCT01642004**

**Study of BMS-936558 (nivolumab) compared to docetaxel in previously treated metastatic non-squamous NSCLC (CheckMate 057). NCT01673867**

Zinner R et al. **Randomized, open-label, phase III study of pemetrexed plus carboplatin followed by maintenance pemetrexed versus paclitaxel/carboplatin/bevacizumab followed by maintenance bevacizumab in patients with advanced nonsquamous non-small cell lung cancer.** *Proc ASCO* 2013;**Abstract LBA8003**.

POST-TEST

*Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Non-Small Cell Lung Cancer*

**QUESTIONS (PLEASE CIRCLE ANSWER):**

1. **A Phase I trial of the novel anti-PD-L1 antibody MPDL3280A for patients with locally advanced or metastatic NSCLC demonstrated that even patients with heavily refractory disease (more than 2 lines of prior systemic therapy) experienced a response rate of approximately 20% to the anti-PD-L1 antibody.**
   a. True
   b. False

2. **Ongoing clinical trials are evaluating the anti-PD-1 antibody nivolumab versus docetaxel for patients with previously treated metastatic _____ NSCLC.**
   a. Nonsquamous
   b. Squamous
   c. Both a and b

3. **A Phase I trial of the novel ALK inhibitor LDK378 in advanced, ALK-positive NSCLC demonstrated that patients with _____ disease experienced an approximate 60% response rate to the ALK inhibitor.**
   a. Crizotinib-resistant
   b. Crizotinib-naïve
   c. Both a and b
   d. Neither a nor b

4. **A Phase I-II trial of the second-generation ALK inhibitor alectinib for patients with ALK inhibitor-naïve, ALK-rearranged advanced NSCLC reported an approximate 93% objective response rate to the ALK inhibitor.**
   a. True
   b. False

5. **The Phase III PointBreak trial evaluating carboplatin/paclitaxel/bevacizumab followed by bevacizumab maintenance therapy versus carboplatin/pemetrexed/bevacizumab followed by pemetrexed/bevacizumab maintenance therapy demonstrated a statistically significant difference in overall survival between the 2 arms.**
   a. True
   b. False

6. **The Phase III ECOG-E5508 trial is evaluating maintenance therapy with bevacizumab or _____ alone or in combination after induction therapy with carboplatin, paclitaxel and bevacizumab for patients with advanced nonsquamous NSCLC.**
   a. Erlotinib
   b. Pemetrexed
   c. Afatinib

7. **In the Phase II OAM4558g trial of erlotinib with or without onartuzumab as second- or third-line therapy for patients with advanced NSCLC, the combination of onartuzumab with erlotinib significantly improved _____ compared to erlotinib alone in the subpopulation of patients with high MET expression.**
   a. Progression-free survival
   b. Overall survival
   c. Both a and b
   d. Neither a nor b

8. **The Phase III MetLung study is investigating _____ with erlotinib versus placebo with erlotinib for patients with advanced MET-positive NSCLC.**
   a. Tivantinib
   b. Onartuzumab
   c. Gefitinib

9. **The results of the Phase III PROSE trial for patients with inoperable NSCLC demonstrated that patients with disease classified as VeriStrat poor had a better overall survival with chemotherapy than with erlotinib in the second-line setting.**
   a. True
   b. False

10. **The Phase III SQUIRE trial is investigating cisplatin/gemcitabine with or without _____ as first-line therapy for Stage IV squamous NSCLC.**
    a. Onartuzumab
    b. *Nab* paclitaxel
    c. Necitumumab

## EDUCATIONAL ASSESSMENT AND CREDIT FORM

### *Current Controversies, Recent Developments and Emerging Strategies in the Practical Management 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 |
|---|---|---|
| Clinical benefits, tolerability and planned and ongoing clinical trials of anti-PD-1 and anti-PD-L1 antibodies in advanced NSCLC | 4 3 2 1 | 4 3 2 1 |
| INSPIRE: Results of a Phase III trial of cisplatin/pemetrexed with or without necitumumab as first-line therapy for Stage IV nonsquamous NSCLC | 4 3 2 1 | 4 3 2 1 |
| Phase III trial results and ongoing studies (ECOG-E5508) evaluating maintenance therapeutic approaches for advanced nonsquamous NSCLC | 4 3 2 1 | 4 3 2 1 |
| Early data with dabrafenib for BRAF-mutant, advanced NSCLC | 4 3 2 1 | 4 3 2 1 |
| Results of PROSE: A Phase III trial of proteomic-stratified (VeriStrat) second-line erlotinib versus chemotherapy for patients with inoperable 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:**

- Describe emerging data on the efficacy and safety of tumor immunotherapy directed at the PD-1/PD-L1 pathway in lung cancer, and consider this information when counseling patients regarding clinical trial participation. . . . . 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
- Apply the results of existing and emerging clinical research to the multimodality treatment of Stage III NSCLC.. . . . . 4 3 2 1 N/M N/A
- Develop an evidence-based approach to the selection of induction and maintenance biologic therapy and/or chemotherapy for patients with advanced NSCLC. . . . . 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, MET amplification and other recently identified driver mutations — and the approved and investigational treatment options for patients with these mutations. . . . . 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 |
|---|---|---|
| Chandra P Belani, MD | 4 3 2 1 | 4 3 2 1 |
| Ramaswamy Govindan, MD | 4 3 2 1 | 4 3 2 1 |
| John V Heymach, MD, PhD | 4 3 2 1 | 4 3 2 1 |
| Gregory J Riely, MD, PhD | 4 3 2 1 | 4 3 2 1 |
| Mark A Socinski, MD | 4 3 2 1 | 4 3 2 1 |
| David R Spigel, MD | 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:**

.....

.....

### REQUEST FOR CREDIT — Please print clearly

Name: ..... Specialty: .....

Professional Designation:

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**I certify my actual time spent to complete this educational activity to be _____ hour(s).**

Signature: ..... Date: .....

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