

# BEYOND THE GUIDELINES: CLINICAL INVESTIGATORS PROVIDE PERSPECTIVES ON BIOMARKER-GUIDED DECISION-MAKING FOR PATIENTS WITH NON-SMALL CELL LUNG CANCER

## CME Information

### TARGET AUDIENCE

This activity is intended for medical oncologists and other healthcare providers involved in the treatment of lung cancer.

### 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 bridge the gap between research and patient care, this video presentation by Alexander E Drilon uses a review of recent relevant publications and presentations, ongoing clinical trials and clinical investigator treatment preferences to assist medical oncologists and other healthcare providers involved in the treatment of lung cancer with the formulation of up-to-date clinical management strategies.

### LEARNING OBJECTIVES

- Evaluate existing guideline recommendations regarding the indications and optimal testing platform for mutational analysis for patients with metastatic NSCLC, and use this information to implement a comprehensive approach to genomic assessment.
- Use mutation status, clinical characteristics and tumor histology to appropriately prioritize front-line and subsequent treatment approaches for patients with metastatic NSCLC.
- Employ an understanding of personalized medicine to individualize the use of available EGFR inhibitors in the long-term management of EGFR mutation-positive NSCLC, and discern how novel EGFR tyrosine kinase inhibitors can be optimally administered to patients with progressive EGFR mutation-positive disease.
- Communicate the efficacy and safety of approved and other emerging ALK inhibitors to appropriate patients with NSCLC, considering the predictive utility of ALK mutation testing.
- Recall existing and emerging research information demonstrating the efficacy and safety of anti-PD-1/PD-L1 antibodies for patients with squamous and nonsquamous metastatic NSCLC, and use this information to guide treatment planning.

- Recall the design of ongoing clinical trials evaluating novel investigational agents in NSCLC, and counsel appropriately selected patients about availability and participation.

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Adobe Flash Player 27 plug-in or later

Adobe Acrobat Reader

(Optional) Sound card and speakers for audio

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## Select Publications

- Borghaei H et al. **Updated results from KEYNOTE-021 cohort G: A randomized, phase 2 study of pemetrexed and carboplatin (PC) with or without pembrolizumab (pembro) as first-line therapy for advanced nonsquamous NSCLC.** *Proc ESMO* 2017;Abstract LBA49.
- Borghaei H et al. **Nivolumab versus docetaxel in advanced nonsquamous non-small-cell lung cancer.** *N Engl J Med* 2015;373(17):1627-39.
- Brahmer J et al. **Progression after the next line of therapy (PFS2) and updated OS among patients with advanced NSCLC and PD-L1 TPS  $\geq$ 50% enrolled in KEYNOTE-024.** *Proc ASCO* 2017;Abstract 9000.
- Brahmer J et al. **Nivolumab versus docetaxel in advanced squamous-cell non-small-cell lung cancer.** *N Engl J Med* 2015;373(2):123-35.
- Drilon AE et al. **Antitumor activity and safety of crizotinib in patients (pts) with advanced MET exon 14-altered non-small cell lung cancer (NSCLC).** *Proc ASCO* 2016;Abstract 108.
- Drilon A et al. **Cabozantinib in patients with advanced RET-rearranged non-small-cell lung cancer: An open-label, single-centre, phase 2, single-arm trial.** *Lancet Oncol* 2016;17(12):1653-60.
- Gadgeel S et al. **Alectinib vs crizotinib in treatment-naïve ALK+ NSCLC: CNS efficacy results from the ALEX study.** *Proc ESMO* 2017;Abstract 12980\_PR.
- Gainor JF et al. **EGFR mutations and ALK rearrangements are associated with low response rates to PD-1 pathway blockade in non-small cell lung cancer: A retrospective analysis.** *Clin Cancer Res* 2016;22(18):4585-93.
- Gandara D et al. **Atezolizumab treatment beyond disease progression in advanced NSCLC: Results from the randomized ph III OAK study.** *Proc ASCO* 2017;Abstract 9001.
- Garon EB et al. **Pembrolizumab for the treatment of non-small-cell lung cancer.** *N Engl J Med* 2015;372(21):2018-28.
- Govindan R et al. **ALCHEMIST trials: A golden opportunity to transform outcomes in early-stage non-small cell lung cancer.** *Clin Cancer Res* 2015;21(24):5439-44.
- Hall RD et al. **Phase 3 study of platinum-based chemotherapy with or without pembrolizumab for first-line metastatic, nonsquamous non-small cell lung carcinoma (NSCLC): KEYNOTE-189.** *Proc ASCO* 2016;Abstract TPS9104.
- Hellmann MD et al. **Nivolumab plus ipilimumab as first-line treatment for advanced non-small-cell lung cancer (CheckMate 012): Results of an open-label, phase 1, multicohort study.** *Lancet Oncol* 2017;18(1):31-41.
- Hellmann MD et al. **CheckMate 012: Safety and efficacy of first-line (1L) nivolumab (nivo; N) and ipilimumab (ipi; I) in advanced (adv) NSCLC.** *Proc ASCO* 2016;Abstract 3001.
- Herbst RS et al. **Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): A randomised controlled trial.** *Lancet* 2016;387(10027):1540-50.
- Hida T et al. **Alectinib versus crizotinib in patients with ALK-positive non-small-cell lung cancer (J-ALEX): An open-label, randomised phase 3 trial.** *Lancet* 2017;390(10089):29-39.
- Jänne PA et al. **AZD9291 in EGFR inhibitor-resistant non-small-cell lung cancer.** *N Engl J Med* 2015;372(18):1689-99.
- Kris MG et al. **Using multiplexed assays of oncogenic drivers in lung cancers to select targeted drugs.** *JAMA* 2014;311(19):1998-2006.
- Mok TS et al. **CNS response to osimertinib in patients (pts) with T790M-positive advanced NSCLC: Data from a randomized phase III trial (AURA3).** *Proc ASCO* 2017;Abstract 9005.
- Mok TS et al. **Osimertinib or platinum-pemetrexed in EGFR T790M-positive lung cancer.** *N Engl J Med* 2017;376(7):629-40.
- Ou SHI et al. **Alectinib in crizotinib-refractory ALK-rearranged non-small-cell lung cancer: A phase II global study.** *J Clin Oncol* 2016;34(7):661-8.
- 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.
- Oxnard G et al. **Plasma genotyping for predicting benefit from osimertinib in patients (pts) with advanced NSCLC.** *Proc ESMO* 2016;Abstract 1350\_PR.
- 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.

## Select Publications

- Paz-Ares L et al. **PACIFIC: A double-blind, placebo-controlled phase III study of durvalumab after chemoradiation therapy (CRT) in patients with stage III, locally advanced, unresectable NSCLC.** *Proc ESMO 2017*;Abstract LBA1.
- Paz-Ares L et al. **Afatinib (A) vs gefitinib (G) in patients (pts) with EGFR mutation-positive (EGFRm+) non-small-cell lung cancer (NSCLC): Overall survival (OS) data from the phase IIb trial LUX-Lung 7 (LL7).** *Proc ESMO 2016*;Abstract LBA43.
- Planchard D et al. **Phase 2 trial (BRF113928) of dabrafenib (D) plus trametinib (T) in patients (pts) with previously untreated BRAF V600E-mutant metastatic non-small cell lung cancer (NSCLC).** *Proc ESMO 2017*;Abstract LBA51.
- Ramalingam S et al. **Osimertinib as first-line treatment for EGFR mutation-positive advanced NSCLC: Updated efficacy and safety results from two phase I expansion cohorts.** *Proc ELCC 2016*;Abstract LBA1\_PR.
- Rittmeyer A et al. **Atezolizumab versus docetaxel in patients with previously treated non-small-cell lung cancer (OAK): A phase 3, open-label, multicentre randomised controlled trial.** *Lancet 2017*;389(10066):255-65.
- Shaw A et al. **Alectinib versus crizotinib in treatment-naive advanced ALK positive non-small cell lung cancer (NSCLC): Primary results of the global phase III ALEX study.** *Proc ASCO 2017*;Abstract LBA9008.
- Shaw AT et al. **Crizotinib in advanced ROS1-rearranged non-small cell lung cancer (NSCLC): Updated results from PROFILE 1001.** *Proc ESMO 2016*;Abstract 1206PD.
- Socinski MA et al. **CheckMate 026: A phase 3 trial of nivolumab vs investigator's choice (IC) of platinum-based doublet chemotherapy (PT-DC) as first-line therapy for stage iv/recurrent programmed death ligand 1 (PD-L1)-positive NSCLC.** *Proc ESMO 2016*;Abstract LBA7\_PR.
- Soria JC et al. **First-line ceritinib versus platinum-based chemotherapy in advanced ALK-rearranged non-small-cell lung cancer (ASCEND-4): A randomised, open-label, phase 3 study.** *Lancet 2017*;389(10082):917-29.
- Wakelee HA et al. **Epidermal growth factor receptor (EGFR) genotyping of matched urine, plasma and tumor tissue from non-small cell lung cancer (NSCLC) patients (pts) treated with rociletinib.** *Proc ASCO 2016*;Abstract 9001.
- Yang JC et al. **Osimertinib activity in patients (pts) with leptomeningeal (LM) disease from non-small cell lung cancer (NSCLC): Updated results from BLOOM, a phase I study.** *Proc ASCO 2016*;Abstract 9002.