

Proceedings from the 14th Annual **Winter Lung Cancer Conference**

CME Information

TARGET AUDIENCE

This educational activity has been designed to meet the educational needs of medical oncologists, hematology-oncology fellows and other allied cancer professionals involved in the treatment of lung cancer.

OVERVIEW OF ACTIVITY

Lung cancer is a devastating disease with broad-reaching impact on public health as it accounts for 14% of all new cancer cases in the United States and the most cancer-related deaths among both men and women. In the year 2017, it is estimated that more than 222,500 individuals will be diagnosed and more than 155,870 will die from the disease. Today, however, this field is seeing renewed optimism as recent research advances have led to an explosion in lung cancer genetic and biologic knowledge among scientists and clinicians working in this area of cancer medicine. Over the past several years major clinical trials in advanced lung cancer have witnessed a host of promising successes, many of which are already being operationalized in clinical practice. Even so, these achievements will doubtlessly continue to be dissected and will further challenge the collective understanding of the biology and optimal management of this disease. Several consensus- and evidence-based treatment guidelines are currently available and aim to assist clinicians with making lung cancer treatment decisions in the face of this dynamic clinical environment, but despite the existence of these tools, many areas of controversy persist within academic and community settings.

This CME activity will use the perspectives of a multidisciplinary panel of clinical investigators on key challenges and controversies in the treatment of lung cancer to address the existing management uncertainties of clinician learners and help keep them up to date in a continuously evolving therapeutic environment.

LEARNING OBJECTIVES

- Develop an evidence-based strategy for the treatment of localized non-small cell lung cancer (NSCLC), exploring the role of (neo)adjuvant systemic therapy.
- Apply the results of emerging clinical research to optimize the multimodality management of Stage III NSCLC.
- Employ an understanding of personalized medicine to individualize the use of available EGFR inhibitors in the treatment of NSCLC.
- Describe mechanisms of tumor resistance to EGFR tyrosine kinase inhibitors, and identify investigational therapeutic opportunities to circumvent this process.
- Communicate the efficacy and safety of crizotinib, ceritinib, alectinib, brigatinib and emerging ALK inhibitors to appropriate patients with NSCLC, considering the predictive utility of ALK and ROS1 mutation testing.
- Devise an evidence-based approach to the selection of induction and maintenance systemic therapy for patients with NSCLC without a targetable mutation.
- Consider biologic and patient-related factors in the selection of second- and later-line therapy for patients with progressive NSCLC without a targetable mutation.
- Describe available and 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 protocol and nonresearch options.
- Assess new oncogenic pathways mediating the growth of unique NSCLC tumor subsets, and recall emerging data with experimental agents exploiting these targets.
- Formulate management strategies for small cell lung cancer, considering the contributory roles of local and systemic therapy.
- Consider the use of multimodality therapy for appropriate patients with mesothelioma who may potentially be cured with this approach, and devise optimal management strategies for advanced disease.
- Recall the design of ongoing clinical trials evaluating novel investigational agents in lung cancer, and counsel appropriately selected patients about availability and participation.

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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:

Paul A Bunn Jr, MD

Distinguished Professor and James Dudley Chair in Cancer Research
University of Colorado Cancer Center
Aurora, Colorado

Advisory Committee: Genentech BioOncology, Lilly; **Consulting Agreements:** AstraZeneca Pharmaceuticals LP, Celgene Corporation, EMD Serono Inc, Genentech BioOncology, Lilly, Merck, Novartis, Pfizer Inc.

Roy H Decker, MD, PhD

Associate Professor of Therapeutic Radiology
Clinical Research Program Leader, Therapeutic Radiology
Director, Residency Training Program
Director, Thoracic/Stereotactic Body Radiotherapy Program
Vice Chair for Clinical Research
Yale Comprehensive Cancer Center
Yale School of Medicine
New Haven, Connecticut

Contracted Research: Merck.

Roy S Herbst, MD, PhD

Ensign Professor of Medicine (Oncology)
Professor of Pharmacology
Chief of Medical Oncology
Director, Thoracic Oncology Research Program
Associate Director for Translational Research
Yale Comprehensive Cancer Center
Yale School of Medicine
New Haven, Connecticut

Consulting Agreements: AstraZeneca Pharmaceuticals LP, Genentech BioOncology, Kolltan Pharmaceuticals Inc, Lilly, Merck, Pfizer Inc; **Contracted Research:** Genentech BioOncology, Merck.

Karen Kelly, MD

Professor of Medicine
Associate Director for Clinical Research
Jennifer Rene Harmon Tegley and Elizabeth Erica Harmon
Endowed Chair in Cancer Clinical Research
UC Davis Comprehensive Cancer Center
Sacramento, California

Advisory Committee: Ariad Pharmaceuticals Inc, AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, G1 Therapeutics, Genentech BioOncology, Lilly; **Contracted Research:** AbbVie Inc, Celgene Corporation, EMD Serono Inc, Five Prime Therapeutics Inc, Genentech BioOncology, Gilead Sciences Inc; **Data Monitoring Committee:** AstraZeneca Pharmaceuticals LP, Genentech BioOncology; **Other Remunerated Activities:** UpToDate Inc.

Mark G Kris, MD

William and Joy Ruane Chair in Thoracic Oncology
Attending Physician, Thoracic Oncology Service
Memorial Sloan Kettering Cancer Center
New York, New York

No relevant conflicts of interest to disclose.

Corey J Langer, MD

Director of Thoracic Oncology
Abramson Cancer Center
Professor of Medicine
Perelman School of Medicine
University of Pennsylvania
Vice Chair, Radiation Therapy Oncology Group
Philadelphia, Pennsylvania

Advisory Committee: Abbott Laboratories, AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, EMD Serono Inc, Genentech BioOncology, GlaxoSmithKline, ImClone Systems, a wholly owned subsidiary of Eli Lilly and Company, Lilly, Merck, Novartis, Pfizer Inc; **Consulting Agreements:** AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Genentech BioOncology, GlaxoSmithKline, ImClone Systems, a wholly owned subsidiary of Eli Lilly and Company, Lilly, Merck, Novartis, Pfizer Inc; **Contracted Research:** Advantagene Inc, Celgene Corporation, GlaxoSmithKline, Merck, Inovio Pharmaceuticals Inc; **Data and Safety Monitoring Board:** Abbott Laboratories, Amgen Inc, Lilly, Peregrine Pharmaceuticals Inc, Synta Pharmaceuticals Corp.

Rogier C Lilenbaum, MD (Co-Chair and Moderator)

Professor of Medicine
Yale School of Medicine
Chief Medical Officer
Smilow Cancer Hospital
Yale Cancer Center
New Haven, Connecticut

Advisory Committee: AstraZeneca Pharmaceuticals LP, Celgene Corporation, Genentech BioOncology; **Consulting Agreement:** Roche Laboratories Inc; **Contracted Research:** Celgene Corporation.

Barbara L McAneny, MD

Member, Board of Trustees
American Medical Association
CEO of New Mexico Oncology Hematology Consultants Ltd
Albuquerque, New Mexico

No relevant conflicts of interest to disclose.

Joel W Neal, MD, PhD

Assistant Professor of Medicine
Division of Oncology
Stanford Cancer Institute
Stanford University
Palo Alto, California

Consulting Agreements: Ariad Pharmaceuticals Inc, ARMO BioSciences, Boehringer Ingelheim Pharmaceuticals Inc, CARET/Physician Resource Management, Clovis Oncology, Nektar; **Contracted Research:** Ariad Pharmaceuticals Inc, ArQule Inc, Boehringer Ingelheim Pharmaceuticals Inc,

Exelixis Inc, Genentech BioOncology, Merck, Nektar, Novartis, Roche Laboratories Inc.

Geoffrey R Oxnard, MD

Lowe Center for Thoracic Oncology
Dana-Farber Cancer Institute
Assistant Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Advisory Committee: Ariad Pharmaceuticals Inc, AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals Inc, Genentech BioOncology, Inivata, Takeda Oncology; **Consulting Agreements:** AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals Inc.

Nathan A Pennell, MD, PhD

Associate Professor, Hematology and Medical Oncology
Cleveland Clinic Lerner College of Medicine
of Case Western Reserve University
Director, Cleveland Clinic Lung Cancer
Medical Oncology Program
Cleveland, Ohio

Advisory Committee: AstraZeneca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals Inc; **Contracted Research:** AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Celgene Corporation, Genentech BioOncology, Merck, Pfizer Inc.

Naiyer Rizvi, MD

Professor of Medicine
Director of Thoracic Oncology and
Phase I Immunotherapeutics
Price Chair in Clinical Translational Research
Columbia University Medical Center
New York, New York

Advisory Committee and Consulting Agreements: AstraZeneca Pharmaceuticals LP, Merck, Novartis, Roche Laboratories Inc; **Ownership Interest:** Gritstone Oncology.

Alice Shaw, MD, PhD

Associate Professor of Medicine
Harvard Medical School
Center for Thoracic Cancers
Massachusetts General Hospital
Boston, Massachusetts

Advisory Committee: EMD Serono Inc, Genentech BioOncology, Novartis, Pfizer Inc, Roche Laboratories Inc; **Consulting Agreements:** Blueprint Medicines, Daiichi Sankyo Inc, EMD Serono Inc, Ignyta Inc, Novartis, Pfizer Inc, Roche Laboratories Inc, Taiho Oncology Inc.

Mark A Socinski, MD (Co-Chair and Moderator)

Executive Medical Director
Member, Thoracic Oncology Program
Florida Hospital Cancer Institute
Orlando, Florida

Advisory Committee: Bristol-Myers Squibb Company, Takeda Oncology; **Contracted Research:** AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Celgene Corporation, Genentech BioOncology, GlaxoSmithKline, Lilly, Pfizer Inc; **Speakers Bureau:** Bristol-Myers Squibb Company, Celgene Corporation, Genentech BioOncology.

Thomas E Stinchcombe, MD

Co-Director, Multidisciplinary Thoracic Oncology Program
Duke University School of Medicine
Durham, North Carolina

Consulting Agreements: Boehringer Ingelheim Pharmaceuticals Inc, Celgene Corporation, Lilly; **Contracted Research:** Bristol-Myers Squibb Company, EMD Serono Inc, Genentech BioOncology.

Eric Vallières, MD

Surgical Director, Lung Cancer Program
Medical Director, Division of Thoracic Surgery
Swedish Cancer Institute
Seattle, Washington

Consulting Agreements: Genentech BioOncology, GlaxoSmithKline, Spiration Inc.

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A monitor set to 1280 x 1024 pixels or more
Internet Explorer 7 or later, Firefox 3.0 or later, Chrome, Safari 3.0 or later
Adobe Flash Player 10.2 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

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Select Publications

History, Major Findings and Lessons Learned from the Lung Cancer Mutation Consortium

Paul A Bunn Jr, MD

- Aisner D et al. **Effect of expanded genomic testing in lung adenocarcinoma (LUCA) on survival benefit: The Lung Cancer Mutation Consortium II (LCMC II) experience.** *Proc ASCO* 2016;Abstract 11510.
- Awad MM. **Impaired c-Met receptor degradation mediated by MET exon 14 mutations in non-small-cell lung cancer.** *J Clin Oncol* 2016;34(8):879-81.
- Bayliss R et al. **Molecular mechanisms that underpin EML4-ALK driven cancers and their response to targeted drugs.** *Cell Mol Life Sci* 2015;73(6):1209-24.
- Camidge DR et al. **Safety and efficacy of brigatinib (AP26113) in advanced malignancies, including ALK+ non-small cell lung cancer (NSCLC).** *Proc ASCO* 2015;Abstract 8062.
- Ceccon M et al. **Treatment efficacy and resistance mechanisms using the second-generation ALK inhibitor AP26113 in human NPM-ALK-positive anaplastic large cell lymphoma.** *Mol Cancer Res* 2015;13(4):775-83.
- Friboulet L et al. **The ALK inhibitor ceritinib overcomes crizotinib resistance in non-small cell lung cancer.** *Cancer Discov* 2014;4(6):662-73.
- Goldman JW et al. **Pretreatment and serial plasma assessments of EGFR mutations in NSCLC patients treated with rociletinib (CO-1686).** *Proc AACR* 2015;Abstract 927.
- Katayama R et al. **Two novel ALK mutations mediate acquired resistance to the next-generation ALK inhibitor alectinib.** *Clin Cancer Res* 2014;20(22):5686-96.
- Katayama R et al. **Mechanisms of acquired crizotinib resistance in ALK-rearranged lung cancers.** *Sci Transl Med* 2012;4(120):120ra17.
- Kim D-W et al. **Ceritinib in advanced anaplastic lymphoma kinase (ALK)-rearranged (ALK+) non-small cell lung cancer (NSCLC): Results of the ASCEND-1 trial.** *Proc ASCO* 2016;Abstract 8003.
- Kodityal S et al. **A novel acquired ALK F1245C mutation confers resistance to crizotinib in ALK-positive NSCLC but is sensitive to ceritinib.** *Lung Cancer* 2016;92:19-21.
- Kris MG et al. **Using multiplexed assays of oncogenic drivers in lung cancers to select targeted drugs.** *JAMA* 2014;311(19):1998-2006.
- Maemondo M et al. **Gefitinib or chemotherapy for non-small-cell lung cancer with mutated EGFR.** *N Engl J Med* 2010;362(25):2380-8.
- Mitsudomi T et al. **Gefitinib versus cisplatin plus docetaxel in patients with non-small-cell lung cancer harbouring mutations of the epidermal growth factor receptor (WJTOG3405): An open label, randomised phase 3 trial.** *Lancet Oncol* 2010;11(2):121-8.
- Mok TS et al. **Gefitinib or carboplatin-paclitaxel in pulmonary adenocarcinoma.** *N Engl J Med* 2009;361(10):947-57.
- Ou S-H et al. **Efficacy and safety of the ALK inhibitor alectinib in ALK+ non-small-cell lung cancer (NSCLC) patients who have failed prior crizotinib: An open-label, single-arm, global phase 2 study (NP28673).** *Proc ASCO* 2015;Abstract 8008.
- 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.
- Rosell R et al. **Erlotinib versus chemotherapy (CT) in advanced non-small cell lung cancer (NSCLC) patients (p) with epidermal growth factor receptor (EGFR) mutations: Interim results of the European Erlotinib Versus Chemotherapy (EURTAC) phase III randomized trial.** *Proc ASCO* 2011;Abstract 7503.
- Sequist LV et al. **Efficacy of rociletinib (CO-1686) in plasma-genotyped T790M-positive non-small cell lung cancer (NSCLC) patients (pts).** *Proc ASCO* 2015;Abstract 8001.
- Shaw AT et al. **Resensitization to crizotinib by the lorlatinib ALK resistance mutation L1198F.** *N Engl J Med* 2016;374(1):54-61.
- Shaw AT et al. **Clinical activity and safety of PF-06463922 from a dose escalation study in patients with advanced ALK+ or ROS1+ NSCLC.** *Proc ASCO* 2015;Abstract 8018.
- Shaw AT et al. **Crizotinib in ROS1-rearranged non-small-cell lung cancer.** *N Engl J Med* 2014;371(21):1963-71.
- Toyokawa G et al. **Identification of a novel ALK G1123S mutation in a patient with ALK-rearranged non-small-cell lung cancer exhibiting resistance to ceritinib.** *J Thorac Onc* 2015;10(7):e55-7.

Weickhardt A et al. **Continuation of EGFR/ALK inhibition after local therapy of oligoprogressive disease in EGFR mutant (Mt) and ALK+ non-small cell lung cancer (NSCLC).** *Proc ASCO* 2012;Abstract 7526.

Wu B et al. **Pharmacokinetics (PK) of blinatumomab and its clinical implications.** *Proc ASCO* 2013;Abstract 3048.

Yang JC-H et al. **LUX-Lung 3: A randomized, open-label, phase III study of afatinib versus pemetrexed and cisplatin as first-line treatment for patients with advanced adenocarcinoma of the lung harboring EGFR-activating mutations.** *Proc ASCO* 2012;Abstract LBA7500.

Yu HA et al. **Local therapy as a treatment strategy in EGFR-mutant advanced lung cancers that have developed acquired resistance to EGFR tyrosine kinase inhibitors.** *Proc ASCO* 2012;Abstract 7527.

Zou HY et al. **PF-06463922, an ALK/ROS1 inhibitor, overcomes resistance to first and second generation ALK inhibitors in preclinical models.** *Cancer Cell* 2015;28(1):70-81.

Session 1: Current and Future Application of Immunotherapy in Non-Small Cell Lung Cancer (NSCLC)

Roy S Herbst, MD, PhD

Facciabene A et al. **T-regulatory cells: Key players in tumor immune escape and angiogenesis.** *Cancer Res* 2012;72(9):2162-71.

Herbst RS et al. **Interim safety and clinical activity in patients with advanced NSCLC from a multi-cohort phase 1 study of ramucirumab (R) plus pembrolizumab (P).** *Proc ESMO* 2016;Abstract LBA38.

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Reck M et al. **KEYNOTE-024: Pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) as first-line therapy for advanced NSCLC with a PD-L1 tumor proportion score (TPS) $\geq 50\%$.** *Proc ESMO* 2016;Abstract LBA8_PR.

Reck M et al. **Pembrolizumab versus chemotherapy for PD-L1-positive non-small-cell lung cancer.** *N Engl J Med* 2016;375(19):1823-33.

Socinski M 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.

Voron T et al. **Control of the immune response by pro-angiogenic factors.** *Front Oncol* 2014;4:70.

Joel W Neal, MD, PhD

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. **Nivolumab versus docetaxel in advanced squamous-cell non-small-cell lung cancer.** *N Engl J Med* 2015;373(2):123-35.

Garon EB et al. **Pembrolizumab for the treatment of non-small-cell lung cancer.** *N Engl J Med* 2015;372(21):2018-28.

Gettinger SN et al. **First-line monotherapy with nivolumab (NIVO; anti-programmed death-1 [PD-1]) in advanced non-small cell lung cancer (NSCLC): Safety, efficacy and correlation of outcomes with PD-1 ligand (PD-L1) expression.** *Proc ASCO* 2015;Abstract 8025.

Gettinger SN et al. **Overall survival and long-term safety of nivolumab (anti-programmed death 1 antibody, BMS-936558, ONO-4538) in patients with previously treated advanced non-small-cell lung cancer.** *J Clin Oncol* 2015;33(18):2004-12.

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Hirsch FR et al. **PD-L1 immunohistochemistry assays for lung cancer: Results from phase 1 of the blueprint PD-L1 IHC assay comparison project.** *J Thorac Oncol* 2017;12(2):208-22.

Horn L et al. **Clinical activity, safety and predictive biomarkers of the engineered antibody MPDL3280A (anti-PDL1) in non-small cell lung cancer (NSCLC): Update from a phase Ia study.** *Proc ASCO* 2015;Abstract 8029.

Rebelatto MC et al. **Development of a PD-L1 companion diagnostic assay for treatment with MEDI4736 in NSCLC and SCCHN patients.** *Proc ASCO* 2015;Abstract 8033.

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.

Rizvi NA et al. **Cancer immunology. Mutational landscape determines sensitivity to PD-1 blockade in non-small cell lung cancer.** *Science* 2015;348(6230):124-8.

Naiyer Rizvi, MD

- 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.
- 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* 2016;18(1):31-41.
- Hui R et al. **Long-term OS for patients with advanced NSCLC enrolled in the KEYNOTE-001 study of pembrolizumab (pembro).** *Proc ASCO* 2016;Abstract 9026.
- Inoue Y et al. **Prognostic impact of CD73 and A2A adenosine receptor expression in non-small-cell lung cancer.** *Oncotarget* 2017;8(5):8738-51.
- Lee CK et al. **Checkpoint inhibitors in metastatic EGFR-mutated non-small cell lung cancer — A meta-analysis.** *J Thorac Oncol* 2017;12(2):403-7.
- Rizvi NA et al. **Safety and response with nivolumab (anti-PD-1; BMS-936558, ONO-4538) plus erlotinib in patients (pts) with epidermal growth factor receptor mutant (EGFR MT) advanced NSCLC.** *Proc ASCO* 2014;Abstract 8022.
- Vogelstein B et al. **Cancer genome landscapes.** *Science* 2013;339(6127):1546-58.

Nathan A Pennell, MD, PhD

- Antonia S et al. **Safety and antitumour activity of durvalumab plus tremelimumab in non-small cell lung cancer: A multicentre, phase 1b study.** *Lancet Oncol* 2016;17(3):299-308.
- Gettinger S et al. **First-line nivolumab monotherapy and nivolumab plus ipilimumab in patients with advanced NSCLC: Long-term outcomes from CheckMate 012.** *Proc WCLC* 2016;Abstract OA03.01.
- Gubens MA et al. **Phase I/II study of pembrolizumab (pembro) plus ipilimumab (ipi) as second-line therapy for NSCLC: KEYNOTE-021 cohorts D and H.** *Proc ASCO* 2016;Abstract 9027.
- Langer C et al. **Randomized, phase 2 study of carboplatin and pemetrexed with or without pembrolizumab as first-line therapy for advanced NSCLC: KEYNOTE-021 cohort G.** *Proc ESMO* 2016;Abstract LBA46_PR.
- Larkin J et al. **Combined nivolumab and ipilimumab or monotherapy in untreated melanoma.** *N Engl J Med* 2015;373(1):23-34.

Session 2: EGFR Mutation-Positive NSCLC

Paul A Bunn Jr, MD

- Aisner D et al. **Effect of expanded genomic testing in lung adenocarcinoma (LUCA) on survival benefit: The Lung Cancer Mutation Consortium II (LCMC II) experience.** *Proc ASCO* 2016;Abstract 11510.
- Drilon A et al. **Broad, hybrid capture-based next-generation sequencing identifies actionable genomic alterations in lung adenocarcinomas otherwise negative for such alterations by other genomic testing approaches.** *Clin Cancer Res* 2015;21(16):3631-9.
- Herbst RS et al. **TRIBUTE: A phase III trial of erlotinib hydrochloride (OSI-774) combined with carboplatin and paclitaxel chemotherapy in advanced non-small-cell lung cancer.** *J Clin Oncol* 2005;23(25):5892-9.
- Lippitz B et al. **Stereotactic radiosurgery in the treatment of brain metastases: The current evidence.** *Cancer Treat Rev* 2014;40(1):48-59.
- Lynch TJ et al. **Activating mutations in the epidermal growth factor receptor underlying responsiveness of non-small-cell lung cancer to gefitinib.** *N Engl J Med* 2004;350(21):2129-39.
- Paez JG et al. **EGFR mutations in lung cancer: Correlation with clinical response to gefitinib therapy.** *Science* 2004;304(5676):1497-500.
- Pao W et al. **EGF receptor gene mutations are common in lung cancers from “never smokers” and are associated with sensitivity of tumors to gefitinib and erlotinib.** *Proc Natl Acad Sci USA* 2004;101(36):13306-11.
- Schrock AB et al. **Comprehensive genomic profiling identifies frequent drug-sensitive EGFR exon 19 deletions in NSCLC not identified by prior molecular testing.** *Clin Cancer Res* 2016;22(13):3281-5.
- Weickhardt AJ et al. **Continuation of EGFR/ALK inhibition after local therapy of oligoprogressive disease in EGFR mutant (Mt) and ALK+ non-small cell lung cancer (NSCLC).** *Proc ASCO* 2012;Abstract 7526.
- Yamamoto M et al. **Stereotactic radiosurgery for patients with multiple brain metastases (JLGK0901): A multi-institutional prospective observational study.** *Lancet Oncol* 2014;15(4):387-95.

Yu HA et al. **Local therapy with continued EGFR tyrosine kinase inhibitor therapy as a treatment strategy in EGFR-mutant advanced lung cancers that have developed acquired resistance to EGFR tyrosine kinase inhibitors.** *J Thorac Oncol* 2013;8(3):346-51.

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Alice Shaw, MD, PhD

Jänne PA et al. **AZD9291 in EGFR inhibitor-resistant non-small-cell lung cancer.** *N Engl J Med* 2015;372(18):1689-99.

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Mok TS et al. **Gefitinib or carboplatin-paclitaxel in pulmonary adenocarcinoma.** *N Engl J Med* 2009;361(10):947-57.

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