Meet The Professor
Management of Lung Cancer

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Assistant Professor of Medicine
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University of Pennsylvania
Philadelphia, Pennsylvania

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Commercial Support

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Dr Love — Disclosures

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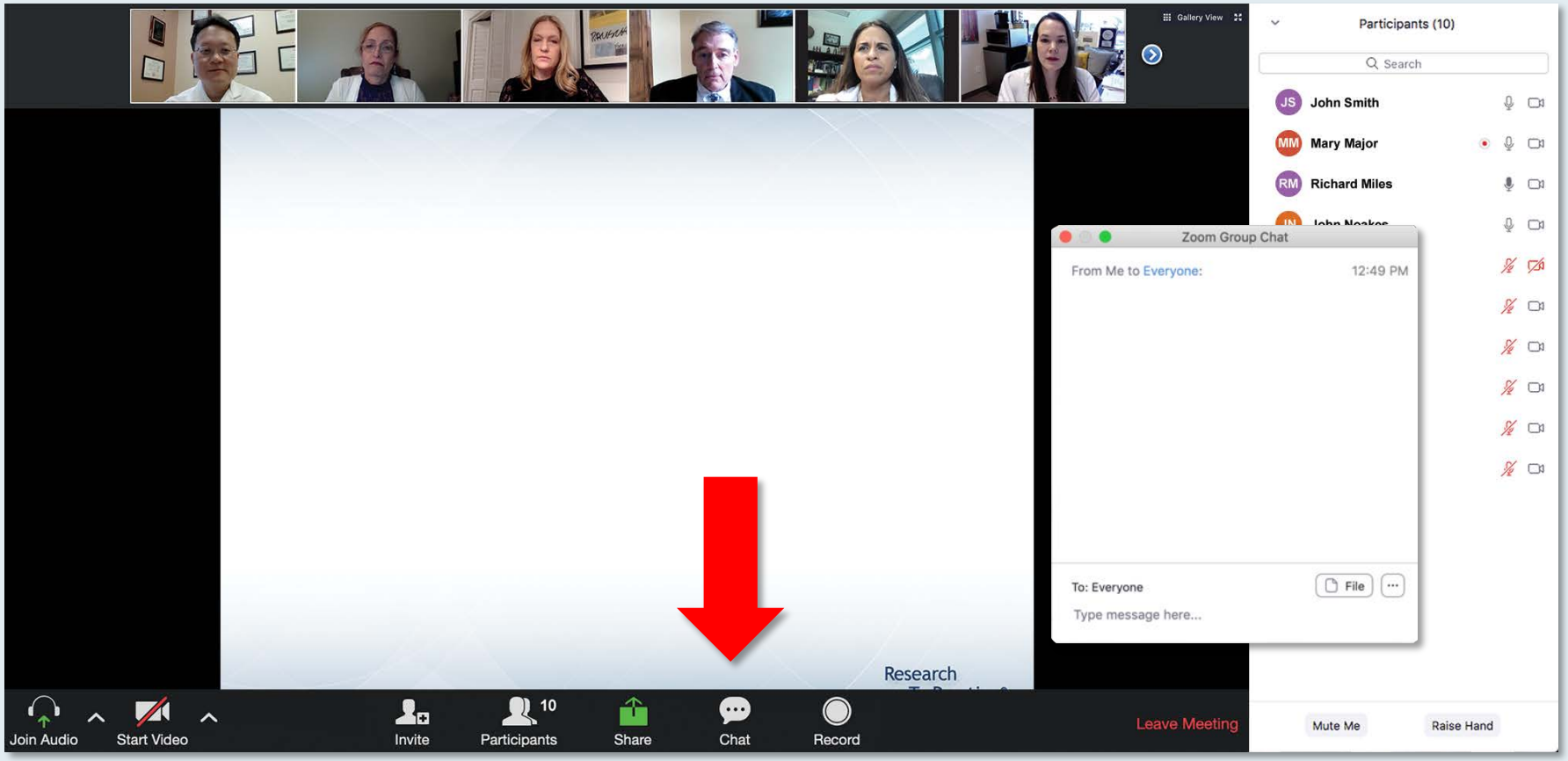
Dr Bauml — Disclosures

Consulting Agreements	AstraZeneca Pharmaceuticals LP, Ayala Pharmaceuticals, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Genentech, a member of the Roche Group, Guardant Health, Inivata, Janssen Biotech Inc, Merck, Novartis, Regeneron Pharmaceuticals Inc, Takeda Oncology
Contracted Research	AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Carevive Systems, Carisma Therapeutics, Clovis Oncology, Janssen Biotech Inc, Merck, Novartis, Takeda Oncology

We Encourage Clinicians in Practice to Submit Questions



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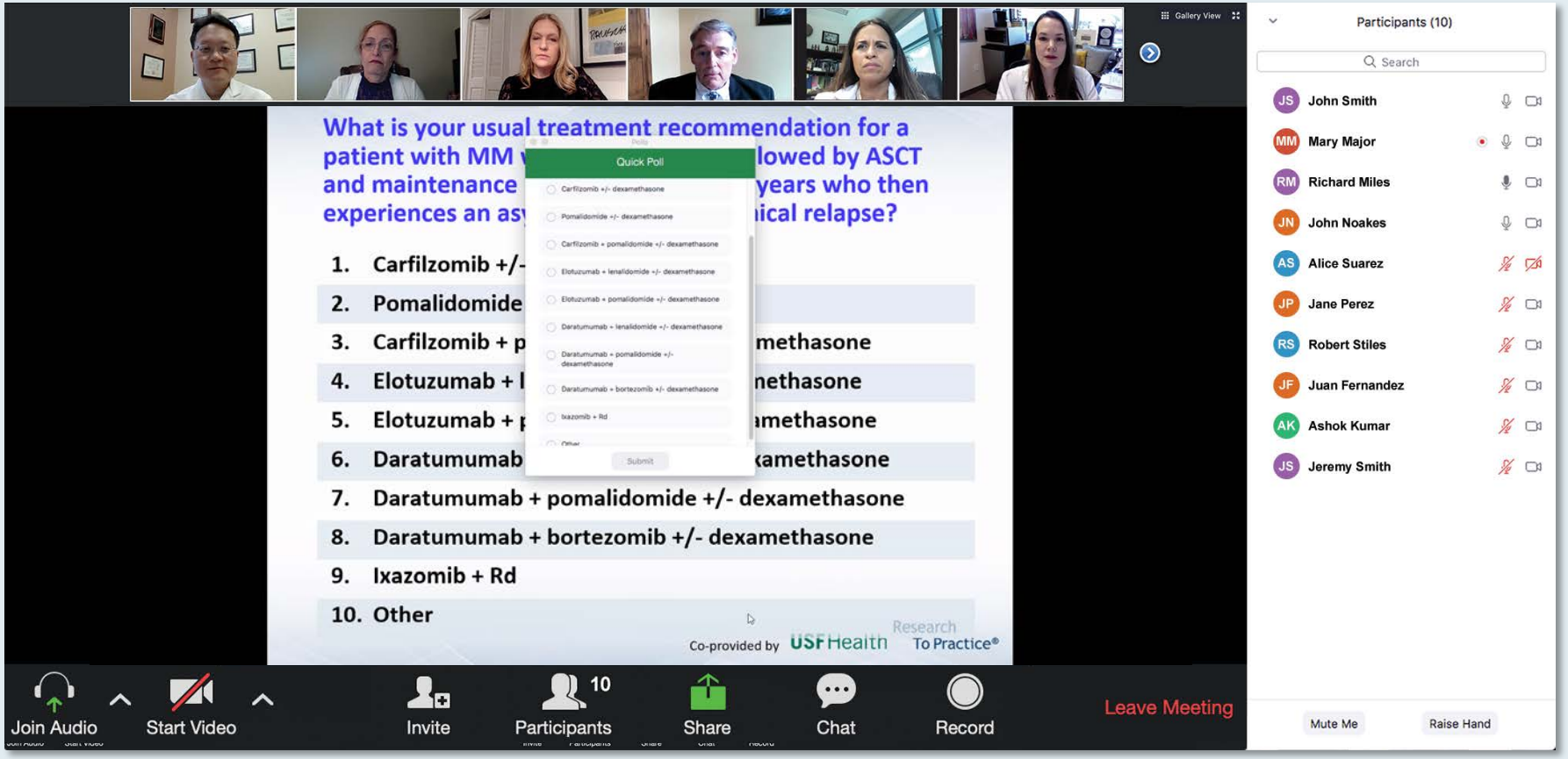

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Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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Year in Review — Clinical Investigators Provide Perspectives on the Most Relevant New Publications, Data Sets and Advances in Oncology:

Breast Cancer

Tuesday, February 9, 2021
5:00 PM – 6:00 PM ET

Faculty

Harold Burstein, MD
Lisa Carey, MD

Moderator

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2021
YEAR IN REVIEW

Recent Advances in Hematologic Oncology: A 4-Part Live Webinar Series Reviewing Key Data and Presentations from the 62nd ASH Annual Meeting

Part 3 — Multiple Myeloma

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Eric Van Cutsem, MD, PhD

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RTP RESEARCH TO PRACTICE


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Fulvestrant
Tamoxifen
Other hormone inhibitor
Palbociclib + fulvestrant
Palbociclib + letrozole
Ribociclib + fulvestrant
Ribociclib + letrozole
Abemaciclib + fulvestrant
Abemaciclib + letrozole
Other

Current Concepts and Recent Advances in Oncology: A Daylong Clinical Summit Hosted in Partnership with North Carolina Oncology Association (NCOA) and South Carolina Oncology Society (SCOS)

Saturday, February 13, 2021
8:30 AM – 4:30 PM ET

Faculty

Courtney D DiNardo, MD, MSCE
Robert Dreicer, MD, MS
Justin F Gainor, MD
Sara Hurvitz, MD
Ian E Krop, MD, PhD
John M Pagel, MD, PhD
Alexander Perl, MD
Daniel P Petrylak, MD
Philip A Philip, MD, PhD, FRCP
Paul G Richardson, MD
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Saturday, February 13, 2021 — 8:30 AM – 4:30 PM

Chronic Lymphocytic Leukemia and Lymphomas:
John Pagel, Mitchell Smith

Multiple Myeloma: Paul Richardson, Peter Voorhees

Genitourinary Cancers: Robert Dreicer, Daniel Petrylak

Lung Cancer: Justin Gainor, Heather Wakelee

Gastrointestinal Cancers: Philip Philip, Eric Van Cutsem

Breast Cancer: Sara Hurvitz, Ian Krop

Acute Myeloid Leukemia and Myelodysplastic Syndromes:
Courtney DiNardo, Alexander Perl

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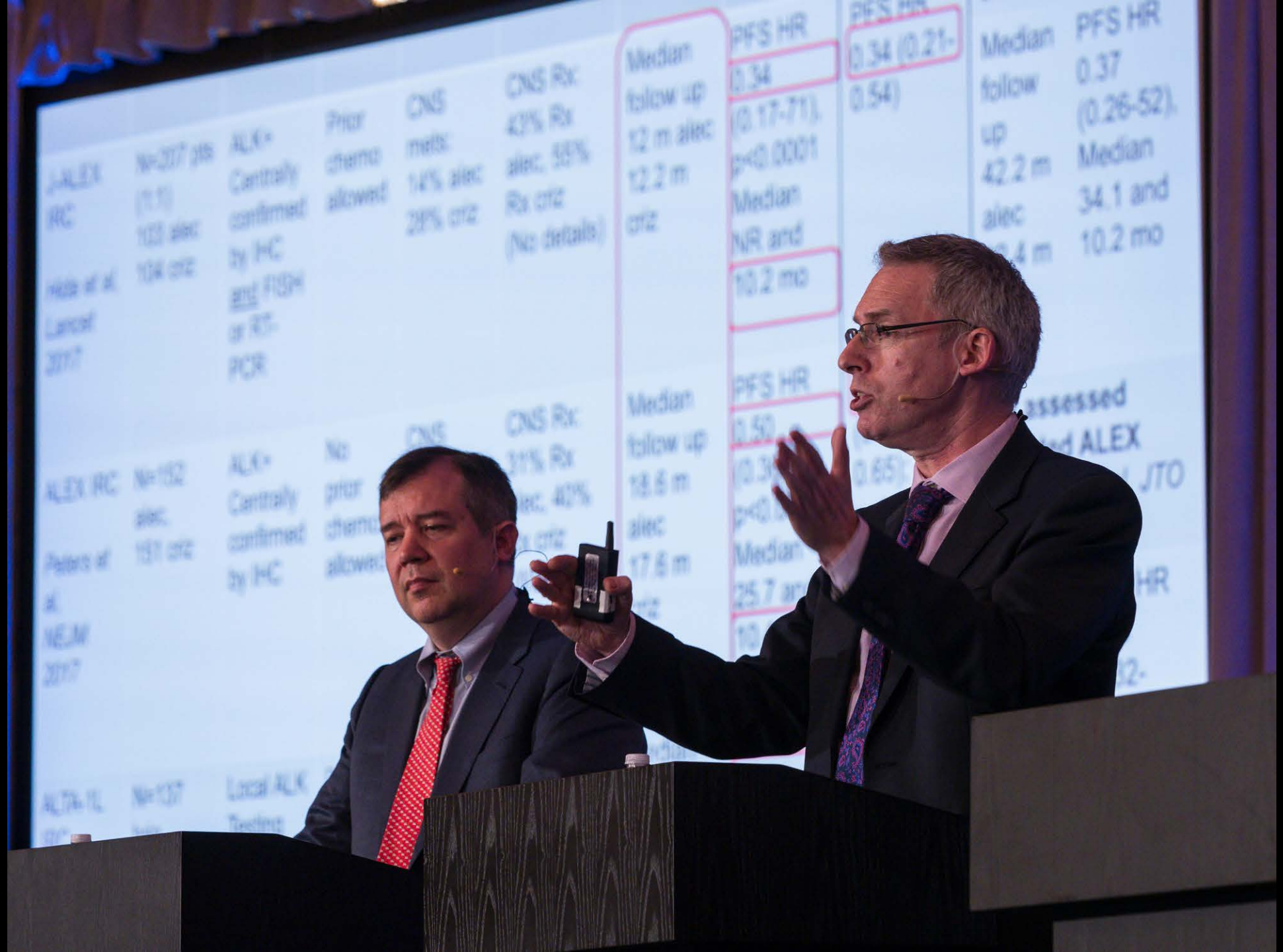
with an NTRK gene fusion?
32%
5%
10%
3%


J-ALEX IRC
Hida et al. Lancet 2017
N=207 pts (1:1) 103 alec 104 crz
ALK+ Centrally confirmed by IHC and FISH or RT-PCR
Prior chemo allowed
CNS mets: 14% alec 29% crz
CNS Rx: 43% Rx alec, 55% Rx crz (No details)
Median follow up 12 m alec 12.2 m crz
PFS HR
0.34 (0.17-71), p<0.0001
Median NR and 10.2 mo
0.34 (0.21-0.54)
Median follow up 42.2 m alec
PFS HR 0.37 (0.26-52). Median 34.1 and 10.2 mo
ALEX IRC
Peters et al. NEJM 2017
N=152 alec, 151 crz
ALK+ Centrally confirmed by IHC
No prior chemo allowed
CNS
CNS Rx: 31% Rx alec, 40% Rx crz
Median follow up 18.6 m alec 17.6 m crz
PFS HR
0.50
Median 25.7 mo
0.65
ssessed
ALEX
JTO
HR
ALTA-1L
N=137
Local ALK Testing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Meet The Professor Program Participating Faculty

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MD Anderson Cancer Center
Houston, Texas

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Director, Thoracic Oncology Research Program
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Medical Center
Nashville, Tennessee

Corey J Langer, MD
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Abramson Cancer Center
Professor of Medicine
Perelman School of Medicine
University of Pennsylvania
Philadelphia, Pennsylvania

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Meet The Professor Program Participating Faculty

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Johns Hopkins Sidney Kimmel Cancer Center
at Sibley Memorial
Washington, DC

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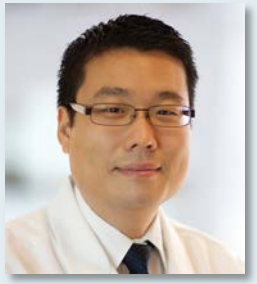
Division of Oncology
Department of Medicine
Stanford Cancer Institute
Stanford University
Palo Alto, California

Professor Tony SK Mok, MD
Chairman, Department of Clinical Oncology
The Chinese University of Hong Kong
Hong Kong, China



Paul K Paik, MD
Associate Attending Physician
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Director, Cleveland Clinic Lung Cancer Medical
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Director, Center for Innovation in Early
Cancer Detection
Massachusetts General Hospital Cancer Center
The Landry Family Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Professor Solange Peters, MD, PhD
Head, Medical Oncology
Chair, Thoracic Malignancies
Oncology Department
Lausanne University Hospital (CHUV)
Lausanne, Switzerland

David R Spigel, MD
Chief Scientific Officer
Program Director
Lung Cancer Research
Sarah Cannon Research Institute
Nashville, Tennessee

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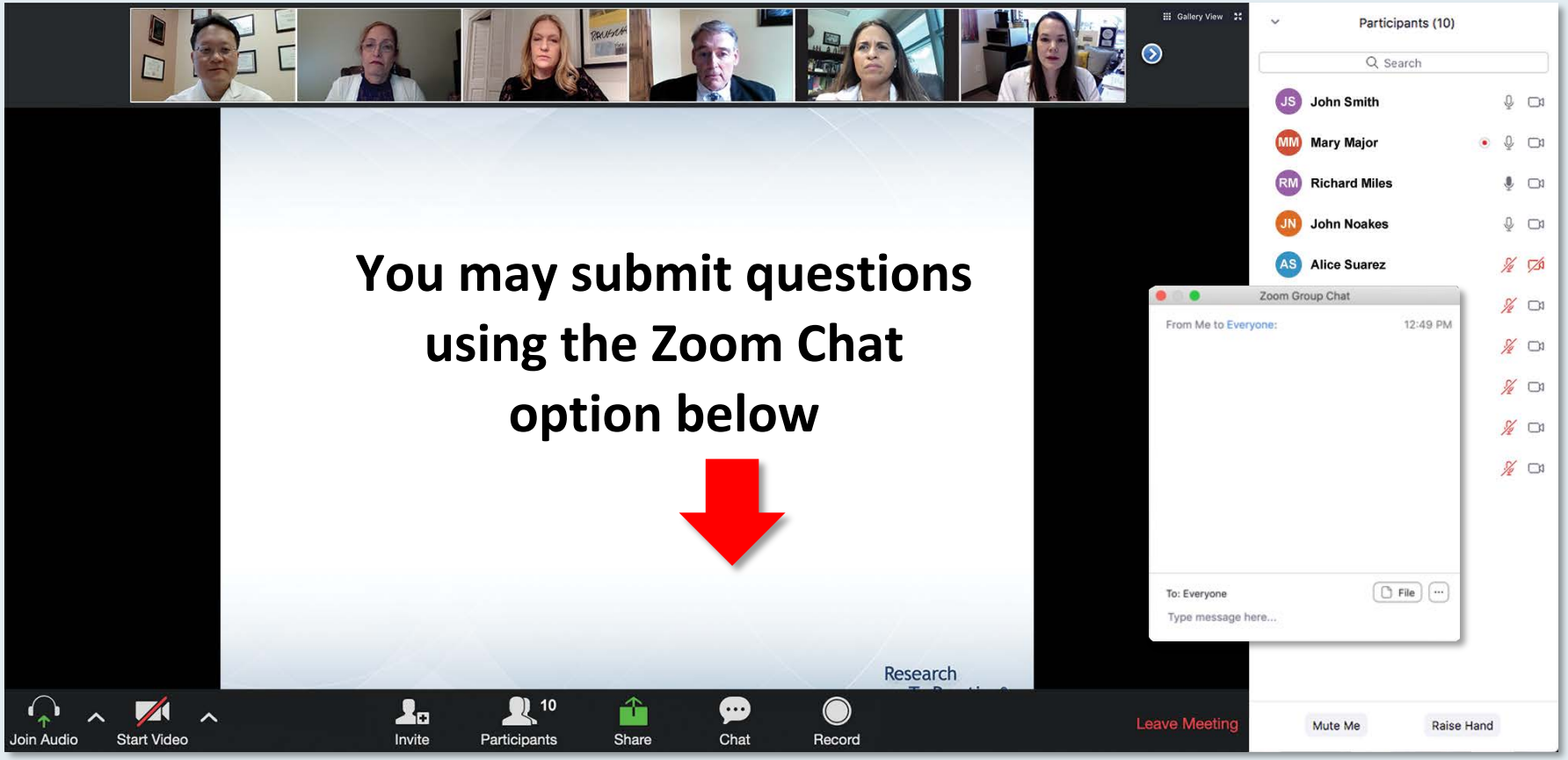

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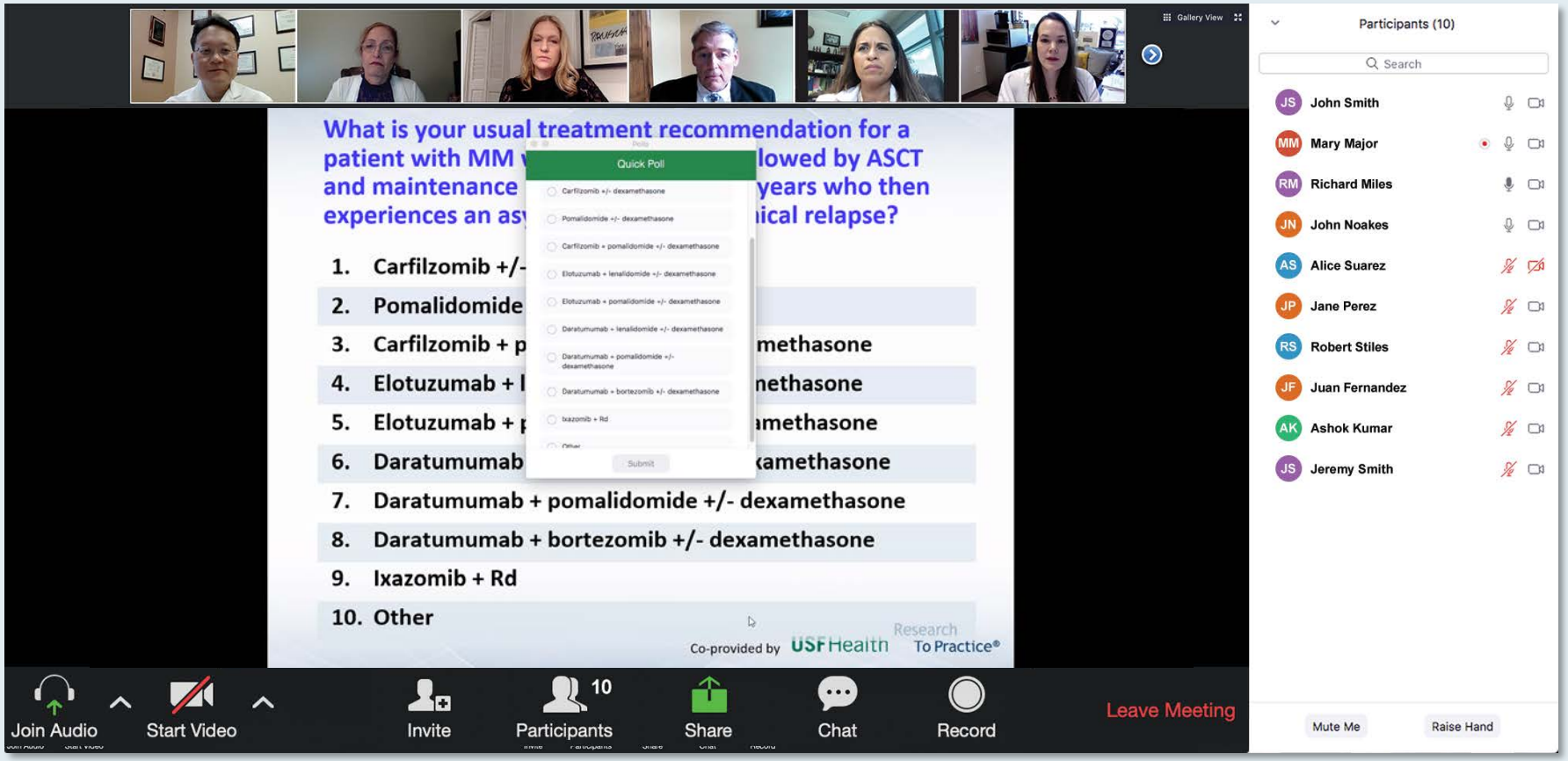

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Spencer Henick Bachow, MD
Hematologist/Oncologist at Lynn Cancer Institute
Affiliate Assistant Professor of Medicine at FAU Schmidt College of Medicine
Boca Raton, Florida

Jarushka Naidoo, MB BCH, MHS
Consultant Medical Oncologist
Beaumont Hospital Dublin
Adjunct Assistant Professor of Oncology
Johns Hopkins University
Dublin, Ireland

Meet The Professor with Dr Bauml

Module 1: Cases from Drs Bachow and Naidoo

- Dr Bachow: A 38-year-old woman with Stage IIIB adenocarcinoma of the lung – ROS1-positive, PD-L1 50%
- Dr Bachow: A 69-year-old woman with metastatic adenocarcinoma of the lung – EGFR L858R mutation
  - Parts 1 and 2
- Dr Naidoo: A 61-year-old woman with advanced squamous NSCLC metastatic to bone and liver – PD-L1 0%
- Dr Bachow: A 69-year-old man with metastatic mucinous adenocarcinoma of the lung – HER2 mutation
- Dr Naidoo: A 76-year-old man with extensive-stage SCLC and heavy smoking history
  - Parts 1, 2 and 3

Module 2: Lung Cancer Journal Club with Dr Bauml

Module 3: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

Module 4: Key Papers and Recent Approvals

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Case Presentation – Dr Bachow: A 38-year-old woman with Stage IIIB adenocarcinoma of the lung – ROS1-positive, PD-L1 50%

Dr Spencer Bachow

- 10/2020: Diagnosed with Stage IIIB adenocarcinoma of the lung
- Light smoking history: 2.5 pack-years
- MRI brain: NED
- ROS1-positive by IHC, indeterminate by NGS. TMB-high, PD-L1: 50%
- Cisplatin/etoposide with concurrent RT

Questions

- In patients with Stage IIIB NSCLC on concurrent chemoradiotherapy that are being considered for consolidation durvalumab, would you hold durvalumab if a mutation was present, especially in light of never smokers? Would you consider consolidation with additional chemotherapy or targeted therapy instead? Would you expect substantial toxicity if durvalumab was given?
- If they were ROS1-positive would you give the ROS1-targeting agent off label to the patient after chemoradiation instead of just doing standard of care durvalumab?

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Case Presentation – Dr Bachow: A 69-year-old woman with metastatic adenocarcinoma of the lung – EGFR L858R mutation – Part 1

Dr Spencer Bachow

- PMH: ITP s/p splenectomy; breast cancer s/p lumpectomy and RT, no adjuvant chemotherapy and currently receiving adjuvant anastrozole; never smoker
- 9/2020: Diagnosed with metastatic adenocarcinoma of the lung, involving the liver and 5 brain lesions
  - No mass effect, neurologic signs or symptoms
- NGS of primary tumor and ctDNA: EGFR L858R mutation
- 10/2020: SRS to brain lesions delayed 14 days due to an asymptomatic COVID-19 infection

Questions

- Can osimertinib be given alone, without radiation therapy, if the patient is neurologically asymptomatic?
- In lung cancer patients who are doing well on checkpoint inhibitor therapy and develop COVID-19 infection, are you stopping therapy? What if they are receiving chemotherapy or targeted therapy?
- What are your thoughts about patients on checkpoint inhibitors receiving the COVID-19 vaccine?

Case Presentation – Dr Bachow: A 69-year-old woman with metastatic adenocarcinoma of the lung – EGFR L858R mutation – Part 2

Dr Spencer Bachow

- PMH: ITP s/p splenectomy; breast cancer s/p lumpectomy and RT, no adjuvant chemotherapy and currently receiving adjuvant anastrozole; never smoker
- 9/2020: Diagnosed with metastatic adenocarcinoma of the lung, involving the liver and 5 brain lesions
  - No mass effect, neurologic signs or symptoms
- NGS of primary tumor and ctDNA: EGFR L858R mutation
- ***10/2020: Initiated osimertinib, with significant shrinkage to primary and liver lesions***
  - ***Grade 1 fatigue but tolerating therapy well***
- ***MRI brain: Pending***

Case Presentation – Dr Naidoo: A 61-year-old woman with newly diagnosed, advanced squamous NSCLC metastatic to bone and liver – PD-L1 0%

Dr Jarushka Naidoo

- Presents with coughing and wheezing (ECOG PS = 1)
- Work up reveals: Advanced squamous NSCLC, with metastases to bone and liver
- PD-L1: 0%

Questions

- What is the most appropriate treatment option?

Treatment Options

1. Chemotherapy and immunotherapy combination
2. Immunotherapy alone
3. Immunotherapy and sensitizing chemotherapy
4. Anti-angiogenic therapy with a PD-L1 antibody

Case Presentation – Dr Bachow: A 69-year-old man with metastatic mucinous adenocarcinoma of the lung – HER2 mutation

Dr Spencer Bachow

- 10/2016: S/p left lower lobectomy and adjuvant cisplatin/gemcitabine x 4 for pT3N0 mucinous adenocarcinoma of the lung
- 11/2017: Recurrent disease, with HER2 V659D mutation identified → Afatinib
- 11/2020: Slow disease progression, with the development of dysphagia
  - Esophageal stent
- Plan: Palliative EBRT and trastuzumab deruxtecan
  - Patient and wife considering palliative care/best supportive care/hospice approach

Questions

- How often do you see pneumonitis and other pulmonary issues with trastuzumab deruxtecan?
- For patients receiving trastuzumab deruxtecan how do you monitor them for pulmonary toxicity? Would you do more frequent CT scans or staging CT scans? Would you do pulmonary function tests?

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Case Presentation – Dr Naidoo: A 76-year-old man with extensive-stage SCLC and heavy smoking history – Part 1

Dr Jarushka Naidoo

- Presents with hemoptysis → 10-cm mediastinal mass and bilateral lung lesions
- Biopsy: Small cell lung carcinoma

Questions

- What is the optimal first-line treatment for this patient?

Treatment Options

1. Carboplatin/etoposide/atezolizumab
2. Carboplatin/etoposide/durvalumab
3. Carboplatin/etoposide
4. Carboplatin/etoposide and thoracic radiotherapy

Case Presentation – Dr Naidoo: A 76-year-old man with extensive-stage SCLC and heavy smoking history – Part 2

Dr Jarushka Naidoo

- Presents with hemoptysis → 10-cm mediastinal mass and bilateral lung lesions
- Biopsy: Small cell lung carcinoma
- ***Carboplatin/etoposide/atezolizumab***
- ***MRI after completion of treatment: No brain metastases***

Questions

- ***What are the optimal treatment options moving forward?***

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Treatment Options

1. Observation alone
2. Prophylactic cranial irradiation
3. A 3-monthly CT scan of the brain
4. A 3-monthly MRI scan of the brain

Case Presentation – Dr Naidoo: A 76-year-old man with extensive-stage SCLC and heavy smoking history – Part 3

Dr Jarushka Naidoo

- Presents with hemoptysis → 10-cm mediastinal mass and bilateral lung lesions
- Biopsy: Small cell lung carcinoma
- Carboplatin/etoposide/atezolizumab
- MRI brain after completion of treatment: No brain metastases
- ***Three months after completion of treatment: Profound weakness, confusion, headaches***
- ***MRI brain: Uptake on the surface of the brain***
- ***CSF studies suspicious for autoimmune process***

Questions

- ***What is the diagnosis and consequent recommended management?***

Treatment Options

1. Paraneoplastic syndrome, which can be treated with observation only
2. Progressive disease treated with whole-brain radiation therapy
3. An immune-related encephalitis treated with high-dose corticosteroids
4. A viral encephalitis treated with antivirals

Meet The Professor with Dr Bauml

Module 1: Cases from Drs Bachow and Naidoo

Module 2: Lung Cancer Journal Club with Dr Bauml

- Clinical implications of plasma-based genotyping for personalized therapy in metastatic NSCLC
- Baseline plasma tumor mutation burden predicts response to pembrolizumab-based therapy
- ATOMIC registry study: Mechanisms of resistance to osimertinib for NSCLC with EGFR mutation
- Pembrolizumab after completion of locally ablative therapy for oligometastatic NSCLC
- Amivantamab, an EGFR-MET bispecific antibody, combined with lazertinib, a third-generation TKI, for advanced NSCLC with EGFR mutation
- Identifying successful biomarkers for patients with NSCLC

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Module 1: Cases from Drs Bachow and Naidoo

Module 2: Lung Cancer Journal Club with Dr Bauml (cont)

- Early tumor and nodal responses in locally advanced NSCLC predict outcomes with concurrent proton- and chemotherapy
- Thoracic imaging of NSCLC treated with anti-PD-1 therapy
- Real-world treatment patterns and survival for patients with NSCLC and BRAF V600 mutations
- Next-generation sequencing of cerebrospinal fluid: How can a liquid be like a solid?
- High-dose osimertinib for CNS progression of NSCLC with EGFR mutation
- Management of lung cancer during the COVID-19 pandemic
- Outcomes for patients with NSCLC and brain metastases treated with pembrolizumab-based therapy

Module 3: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

Module 4: Key Papers and Recent Approvals

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Research

JAMA Oncology | Original Investigation

Clinical Implications of Plasma-Based Genotyping With the Delivery of Personalized Therapy in Metastatic Non–Small Cell Lung Cancer

Charu Aggarwal, MD, MPH; Jeffrey C. Thompson, MD; Taylor A. Black, BA; Sharyn I. Katz, MD, MTR; Ryan Fan, BA; Stephanie S. Yee, MS; Austin L. Chien, BA; Tracey L. Evans, MD; Joshua M. Bauml, MD; Evan W. Alley, MD, PhD; Christine A. Ciunci, MD, MSCE; Abigail T. Berman, MD, MSCE; Roger B. Cohen, MD; David B. Lieberman, MS, LCGC; Krishna S. Majmundar, BS; Samantha L. Savitch, BA; Jennifer J. D. Morrissette, PhD; Wei-Ting Hwang, PhD; Kojo S. J. Elenitoba-Johnson, MD; Corey J. Langer, MD; Erica L. Carpenter, MBA, PhD

JAMA Oncol 2019;5(2):173-80.

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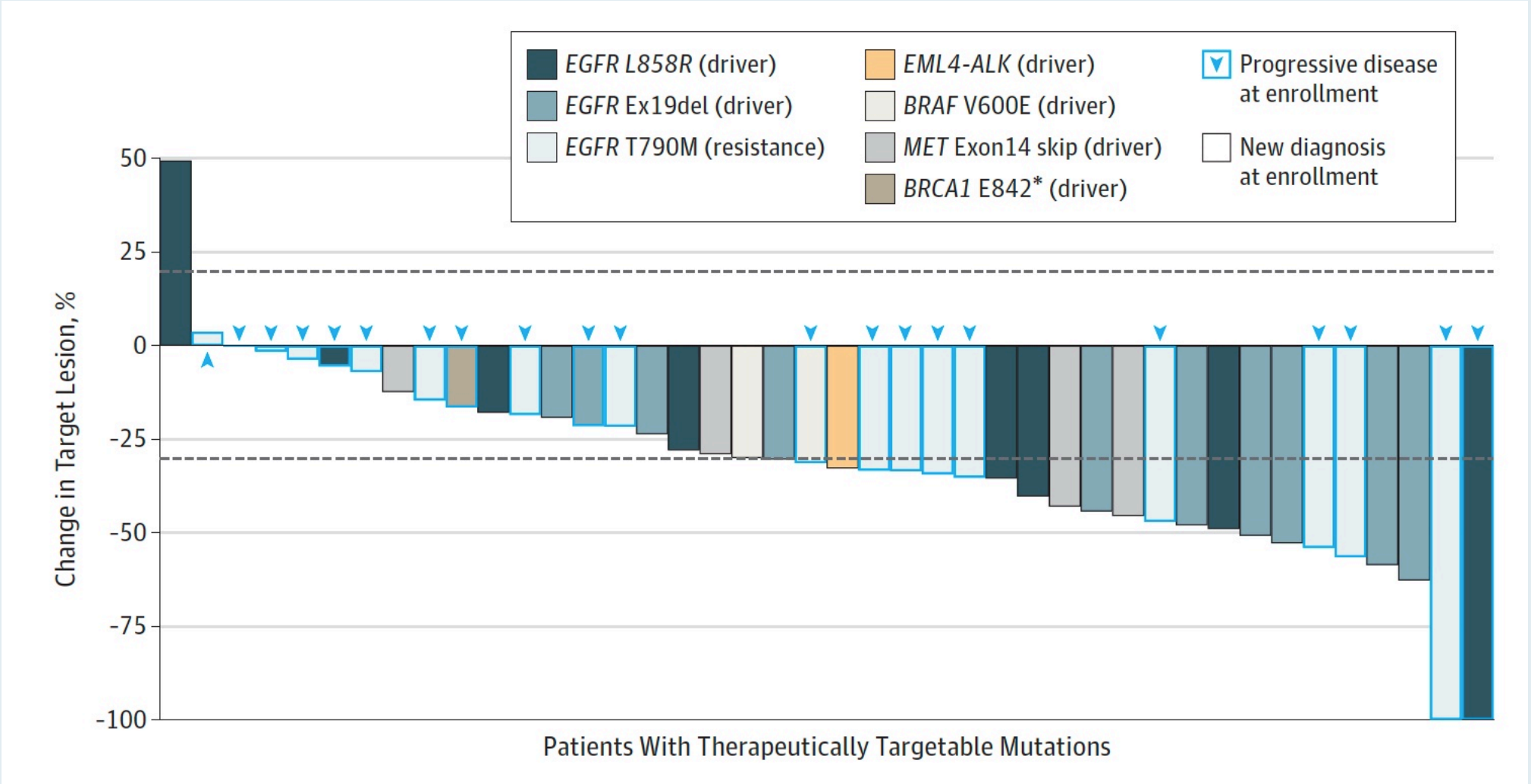
Response to Plasma-Indicated Targeted Therapy as Measured by Response Evaluation Criteria in Solid Tumors



Aggarwal C et al. *JAMA Oncol* 2019;5(2):173-80.

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Clin Cancer Res 2020;26(10):2354-61.

Baseline plasma tumor mutation burden predicts response to pembrolizumab-based therapy in patients with metastatic non-small cell lung cancer

Charu Aggarwal, MD, MPH[1], Jeffrey C. Thompson, MD, MTR[2], Austin L. Chien, BA[1], Katie J. Quinn, PhD[4], Wei-Ting Hwang, PhD[6], Taylor A. Black, BA[1], Stephanie S. Yee, MS[1], Theresa E. Christensen, BA[1], Michael J. LaRiviere, MD[3], Benjamin A. Silva[1], Kimberly C. Banks, MBA, MS[4], Rebecca J. Nagy, MS[4], Elena Helman, PhD[4], Abigail T. Berman, MD, MSCE[3], Christine A. Ciunci, MD, MSCE[1], Aditi P. Singh, MD[1], Jeffrey S. Wasser, MD[5], Joshua M. Bauml, MD[1], Corey J. Langer, MD[1], Roger B. Cohen, MD[1], Erica L. Carpenter, MBA, PhD[1]

Multicenter Analysis of Mechanisms of Resistance to Osimertinib (O) in EGFR Mutated NSCLC: An ATOMIC Registry Study

Bauml JM et al.

IASLC 2020;Abstract FP14.06.

Research

JAMA Oncology | Original Investigation

Pembrolizumab After Completion of Locally Ablative Therapy for Oligometastatic Non–Small Cell Lung Cancer
A Phase 2 Trial

Joshua M. Bauml, MD; Rosemarie Mick, MS; Christine Ciunci, MD, MSCE; Charu Aggarwal, MD, MPH; Christiana Davis, MD; Tracey Evans, MD; Charuhas Deshpande, MD; Linda Miller, RN; Pooja Patel, BA, BS; Evan Alley, MD, PhD; Christina Knepley, CRNP; Faith Mutale, CRNP; Roger B. Cohen, MD; Corey J. Langer, MD

JAMA Oncol 2019;5(9):1283-90.

Amivantamab (JNJ-61186372), an EGFR-MET Bispecific Antibody, in Combination with Lazertinib, a 3rd-Generation Tyrosine Kinase Inhibitor (TKI), in Advanced EGFR NSCLC

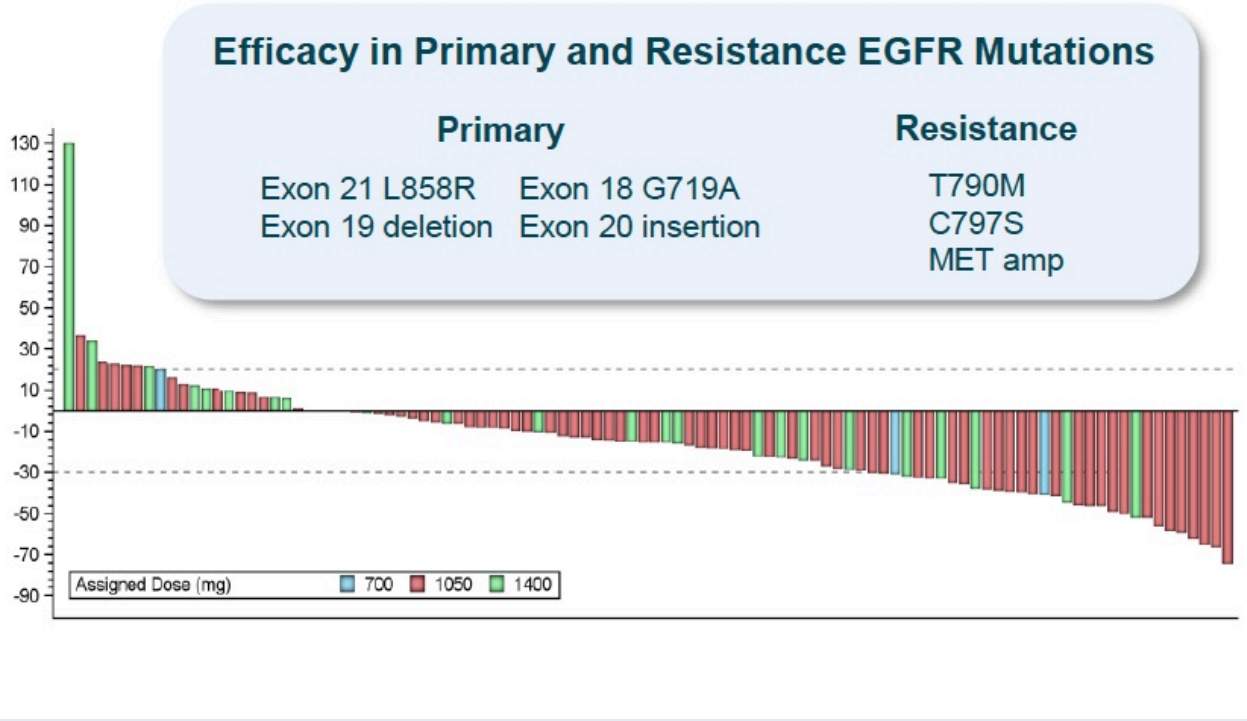
Cho BC et al.

ESMO 2020;Abstract 1258O.

Amivantamab

Amivantamab
(am-e-van-tuh-mab)

- Fully human bispecific (Duobody®) antibody that targets EGFR and MET
- Has immune cell-directing activity[1]
- Demonstrated clinical activity across diverse EGFRm NSCLC[2]
- Granted FDA Breakthrough Therapy Designation for EGFRm Exon20ins NSCLC post-chemotherapy



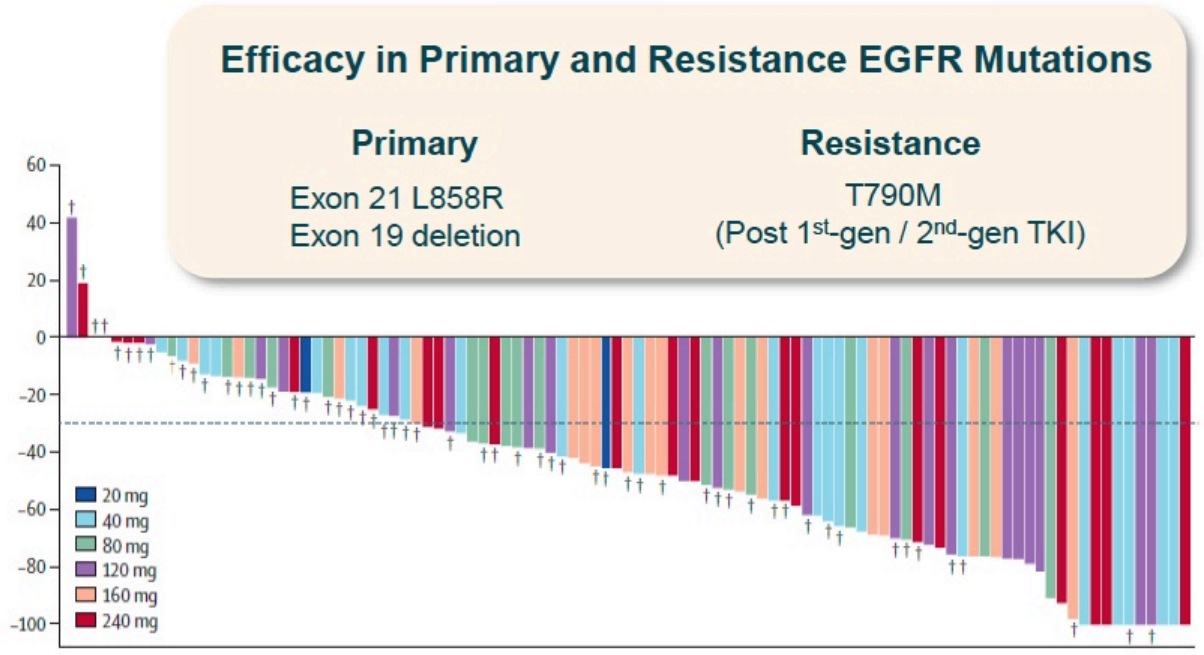
Cho BC et al. ESMO 2020;Abstract 1258O.

RTP RESEARCH TO PRACTICE

Lazertinib

Lazertinib

- Potent 3rd-gen TKI with efficacy seen in activating EGFR mutations, T790M, and CNS disease[3-4]
- Low rates of EGFR-related toxicity such as rash and diarrhea[3]
- Safety profile that supports combination with other anti-EGFR molecules



Cho BC et al. ESMO 2020;Abstract 1258O.

RTP RESEARCH TO PRACTICE

Conclusions: Amivantamab in Combination with Lazertinib

Amivantamab can be safely combined with lazertinib

- No dose-limiting toxicities identified during dose escalation
- Combination dose tolerated, with low rates of treatment discontinuation (6%) and grade ≥3 TRAE (11%)
- 65% of patients experienced IRR, all grade 1 – 2, occurring with the first infusion

Amivantamab with lazertinib is efficacious in advanced EGFRm NSCLC

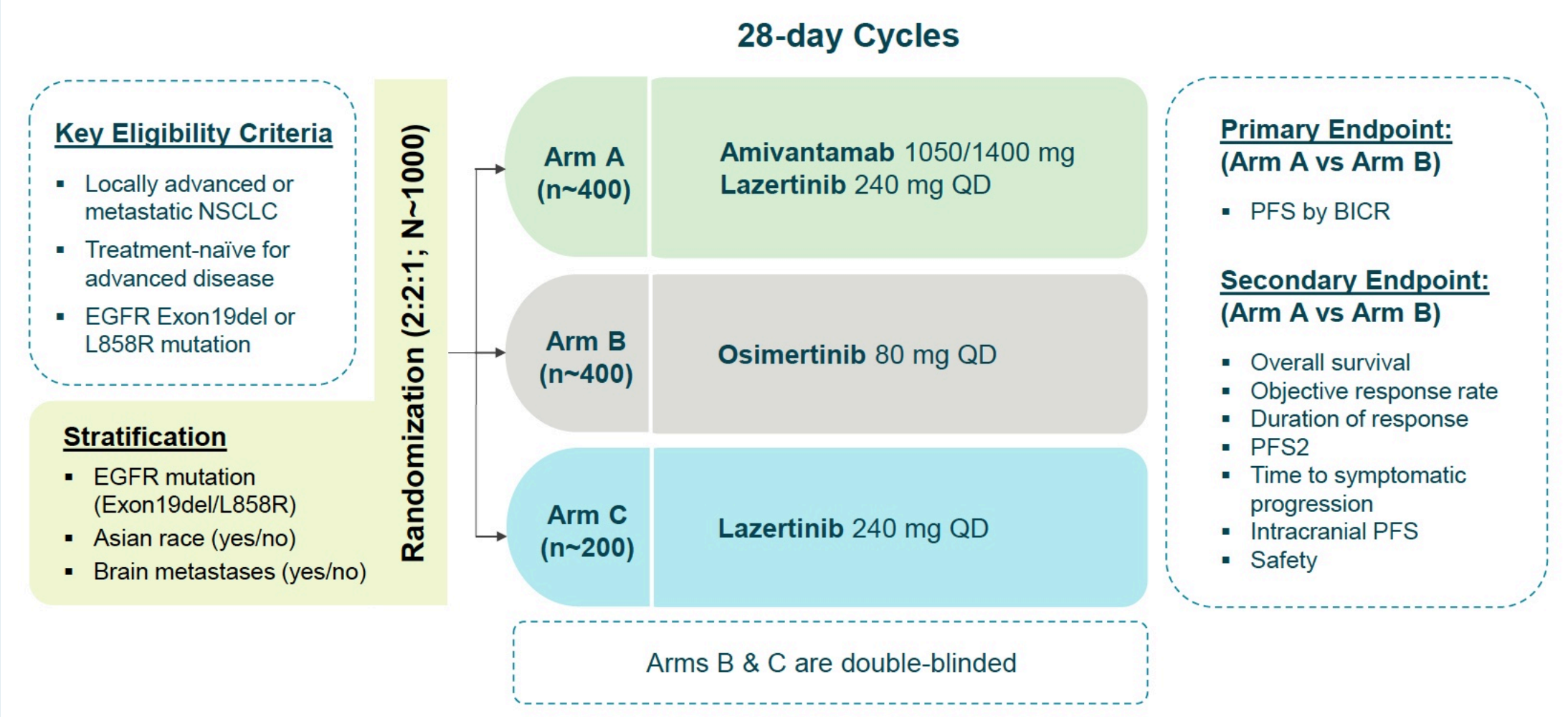
- 100% ORR in treatment-naïve cohort
- 36% ORR in osimertinib-resistant, chemo-naïve cohort
  - Analysis of efficacy by mechanism of resistance is ongoing

New studies with amivantamab + lazertinib combination started:

- Phase 3 MARIPOSA[a] study in frontline EGFRm NSCLC vs osimertinib
- Phase 2 CHRYSALIS-2 study in osimertinib-resistant and chemotherapy-relapsed setting

Cho BC et al. ESMO 2020;Abstract 1258O.

Phase III MARIPOSA Study (NCT04487080)

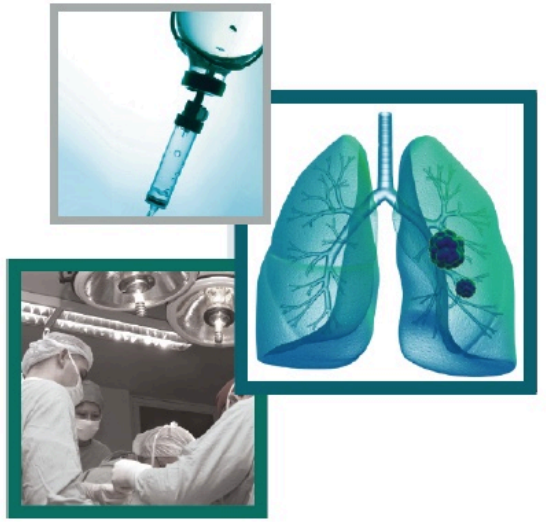


Cho BC et al. ESMO 2020;Abstract 1258O.

Editorial

Lung Cancer Manag 2019;8(3):LMT17.

Lung Cancer Management



Identifying successful biomarkers for patients with non-small-cell lung cancer

Alex Friedlaender[1], Joshua Bauml[2], Giuseppe Luigi Banna[3] & Alfredo Addeo*,[1]

[1]Department of Oncology, University Hospital of Geneva (HUG), 12052, Switzerland

[2]Abramson Cancer Center, Perelman Center for Advanced Medicine, University of Pennsylvania, Philadelphia, PA 191043, USA

[3]Oncology Department, United Lincolnshire Hospital Trust, Lincoln, LN2 5QY, UK

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"There are several new biomarkers in their infancy: the role and importance of TILs, immune gene signatures, interferon gamma related mRNA-based signatures, T-cell exhaustion profiling, myeloid-derived suppressor cells or the neutrophil-to-lymphocyte ratio at baseline, HLA diversity and the microbiota."

Int J Radiat Oncol Biol Phys 2020;106(2):358-68.

International Journal of Radiation Oncology biology • physics

www.redjournal.org

Clinical Investigation

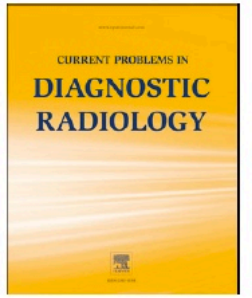
Early Tumor and Nodal Response in Patients with Locally Advanced Non-Small Cell Lung Carcinoma Predict for Oncologic Outcomes in Patients Treated with Concurrent Proton Therapy and Chemotherapy

Amardeep S. Grewal, MD,* Eun Jeong Min, PhD,† Qi Long, PhD,† Sharonjit K. Grewal, MD,* Varsha Jain, MD,* William P. Levin, MD,* Keith A. Cengel, MD, PhD,* Samuel Swisher-McClure, MD, MSHP,* Charu Aggarwal, MD,‡ Joshua M. Bauml, MD,‡ Aditi Singh, MD,‡ Christine Ciunci, MD,‡ Roger B. Cohen, MD,‡ Corey Langer, MD,‡ Steven J. Feigenberg, MD,* and Abigail T. Berman, MD, MSCE*

Current Problems in Diagnostic Radiology 48 (2019) 142–147

Current Problems in Diagnostic Radiology

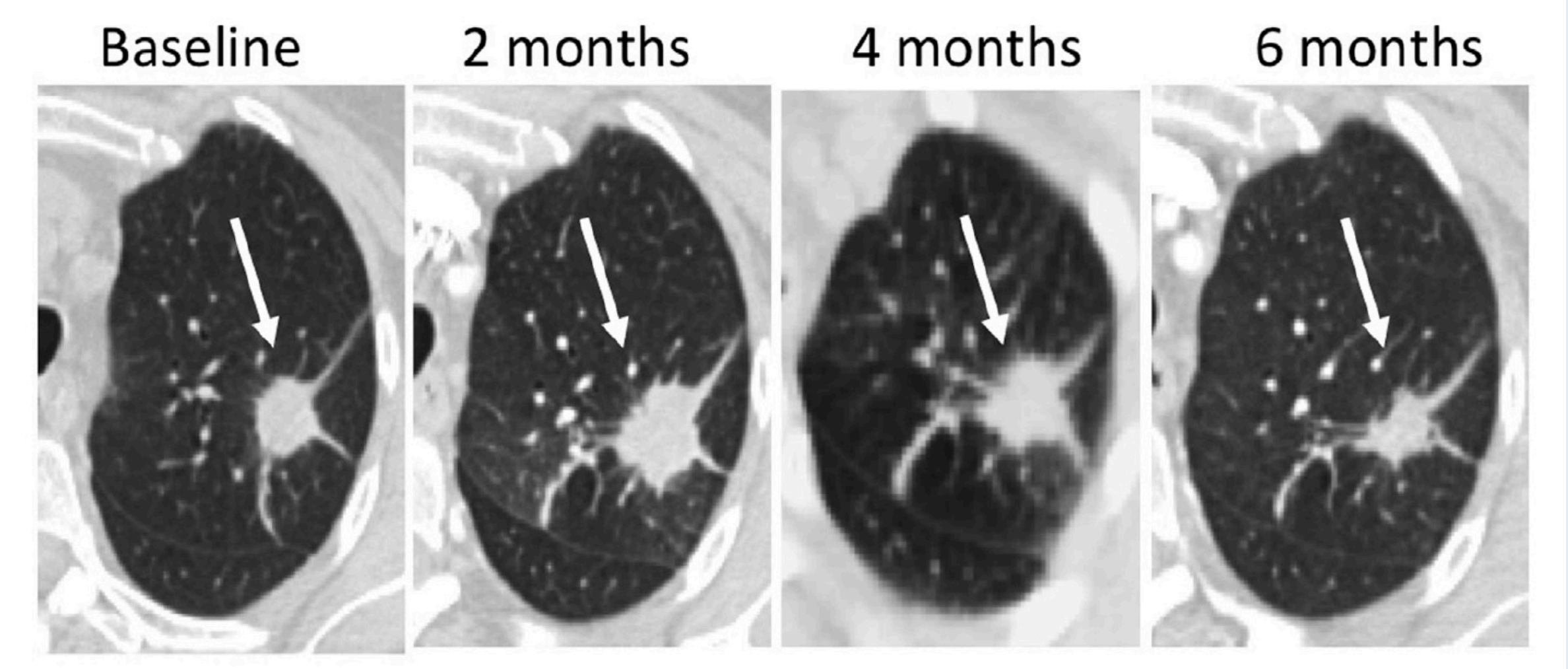
journal homepage: www.cpdrjournal.com



Thoracic Imaging of Non-Small Cell Lung Cancer Treated With Anti-programmed Death Receptor-1 Therapy

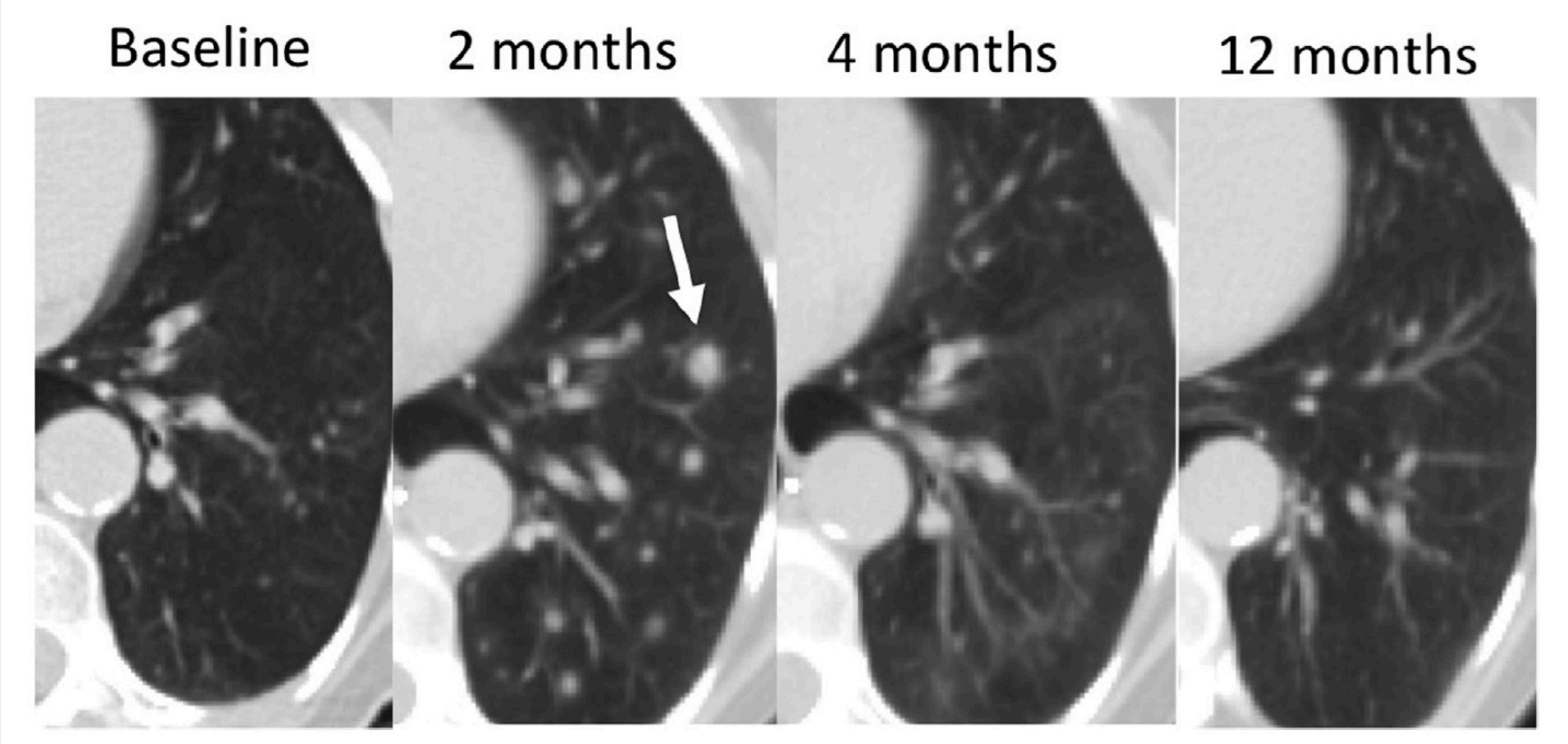
Mark Hammer, MD[a,b], Stephen Bagley, MD[c], Charu Aggarwal, MD, MPH[c], Joshua Bauml, MD[c], Arun C. Nachiappan, MD[b], Charles B. Simone II, MD[d], Corey Langer, MD[c], Sharyn I. Katz, MD, MTR[b,*]

Radiologic Pseudoprogression on CT Manifesting as Enlargement of the Primary Tumor During Nivolumab Therapy



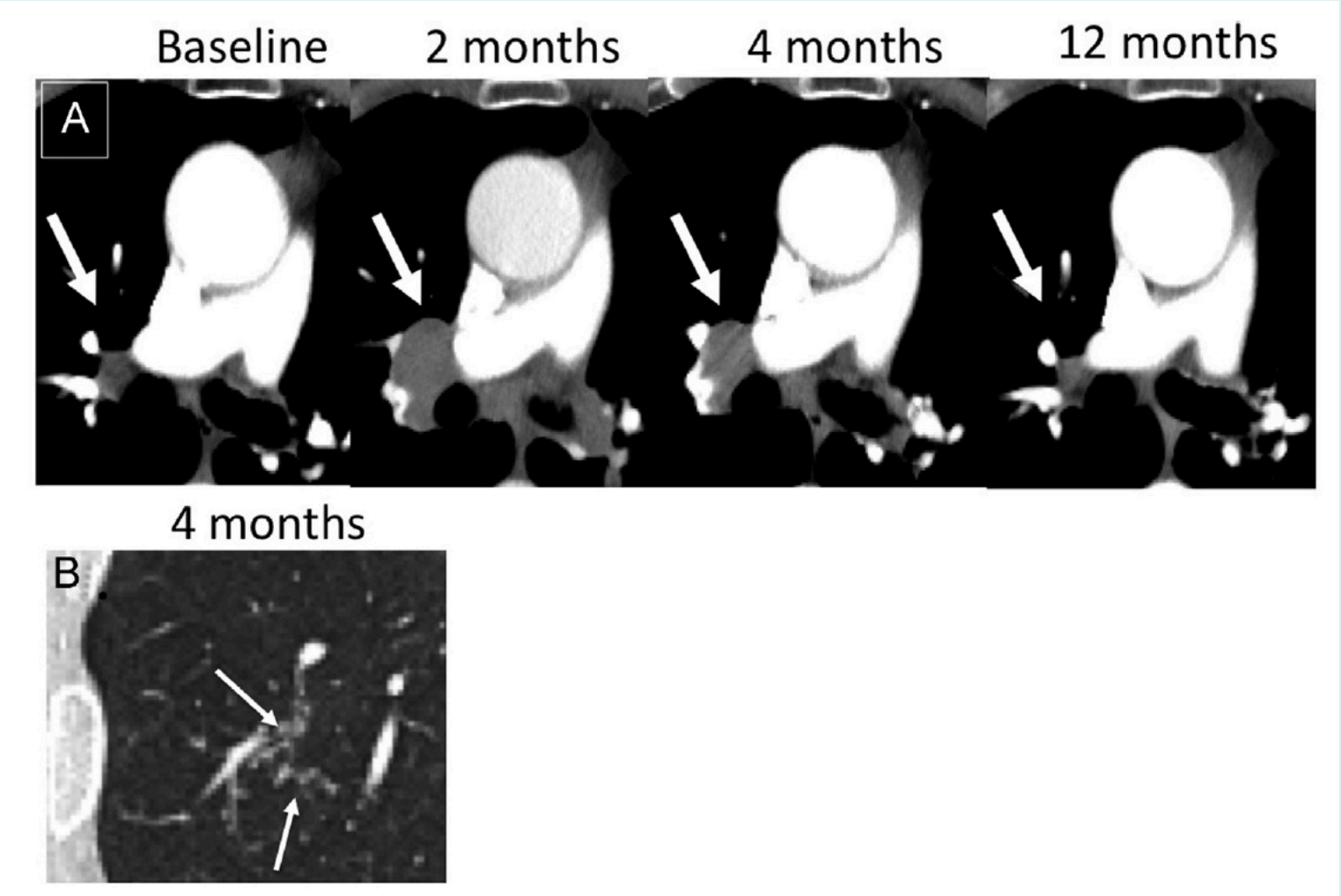
Hammer M et al. *Curr Probl Diagn Radiol* 2019;48(2):142-7.

Radiologic Pseudoprogression on CT Manifesting as New Lesions During Nivolumab Therapy



Hammer M et al. *Curr Probl Diagn Radiol* 2019;48(2):142-7.

Sarcoid-Like Drug Reaction in a Patient with NSCLC Receiving Pembrolizumab



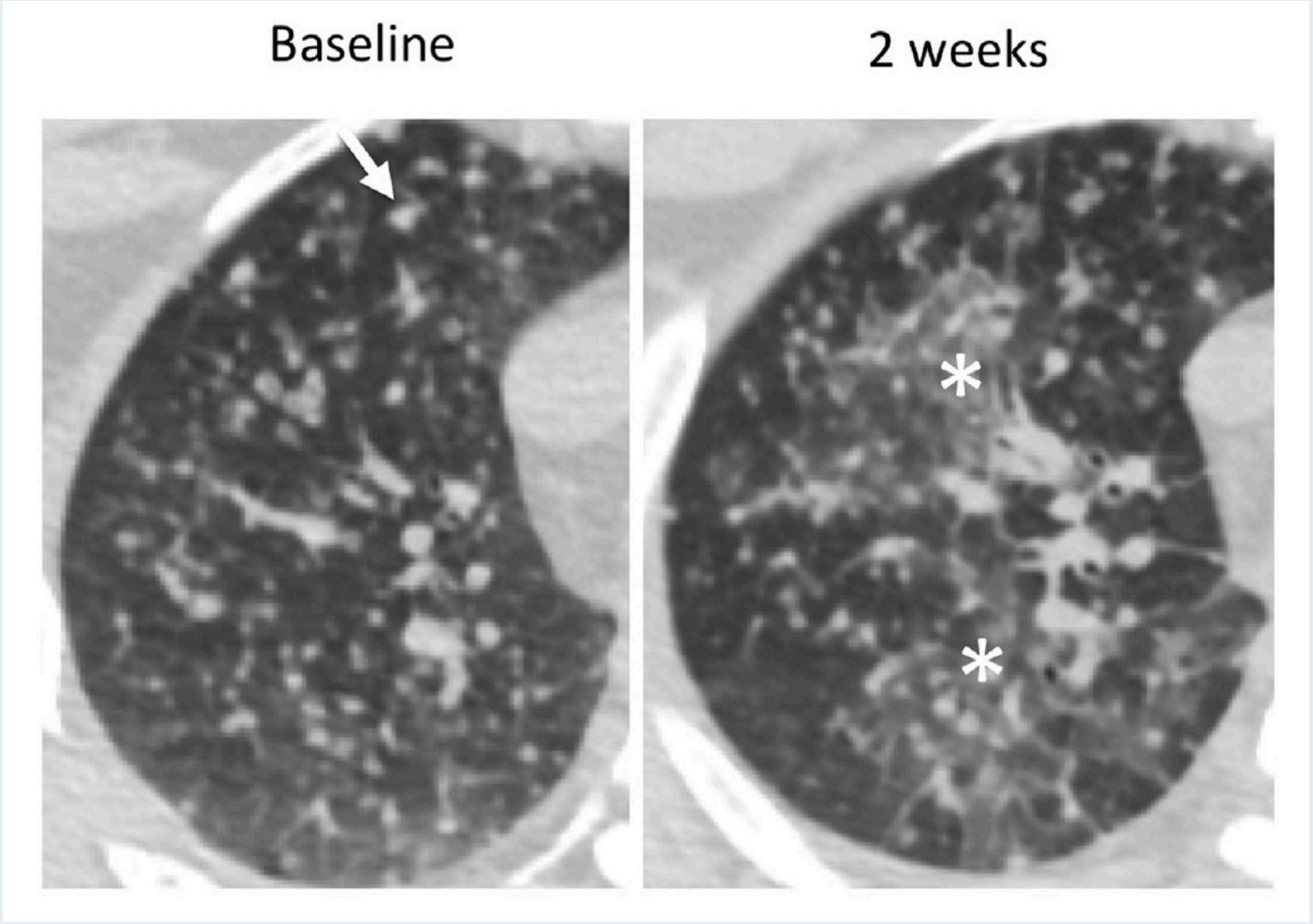
Developed new bilateral hilar lymphadenopathy (thick arrows) at reimaging at 2 months of pembrolizumab therapy

At 4 months of therapy, this adenopathy increased in size and was accompanied by new perilymphatic nodularity (thin arrows), which was suspicious for lymphangitic carcinomatosis

Hammer M et al. *Curr Probl Diagn Radiol* 2019;48(2):142-7.

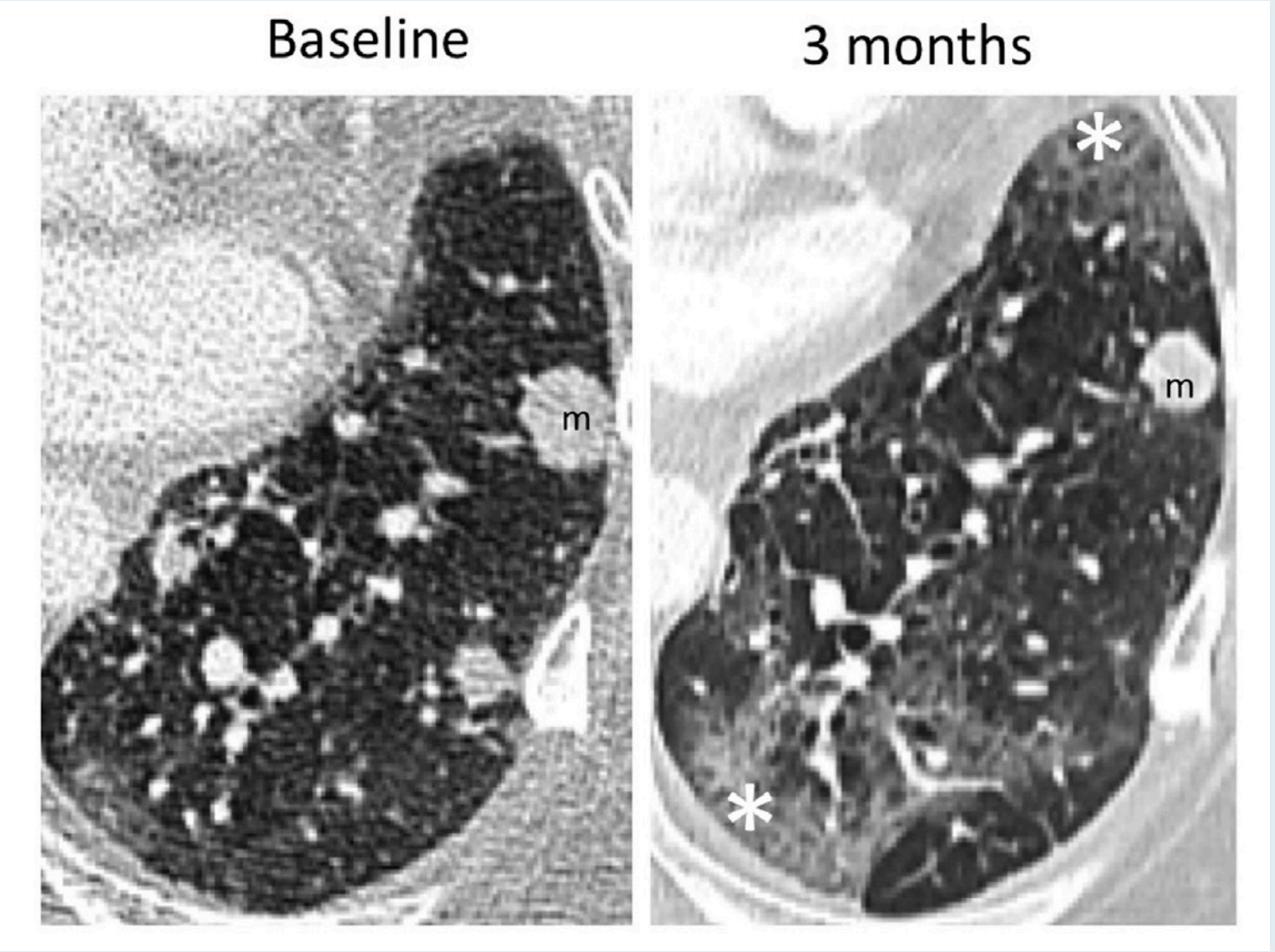
RTP RESEARCH TO PRACTICE

Pneumonitis Manifesting as Ground Glass Opacities at 2 Weeks of Therapy with Nivolumab



Hammer M et al. *Curr Probl Diagn Radiol* 2019;48(2):142-7.

Pneumonitis Manifesting as Ground Glass Opacities at 2 Months of Therapy with Nivolumab



Hammer M et al. *Curr Probl Diagn Radiol* 2019;48(2):142-7.

Lung Cancer 128 (2019) 74–90

Contents lists available at ScienceDirect

Lung Cancer

journal homepage: www.elsevier.com/locate/lungcan

Real-world treatment patterns and survival of patients with BRAF V600-mutated metastatic non-small cell lung cancer

Leora Horn[a], Joshua Bauml[b], Patrick M. Forde[c], Keith L. Davis[d,*], Nathaniel J. Myall[e], Medha Sasane[f,1], Anand Dalal[f], Ken Culver[f], Antoinette J. Wozniak[g], Christina S. Baik[h], Alex Mutebi[f,2], Pingkuan Zhang[f], Heather A. Wakelee[e], Bruce E. Johnson[i]

High-Dose Osimertinib for CNS Progression in EGFR+ Non-Small Cell Lung Cancer (NSCLC): A Multi-institutional Experience

Piper-Vallillo A et al.

ASCO 2020;Abstract 9586.

care delivery reviews

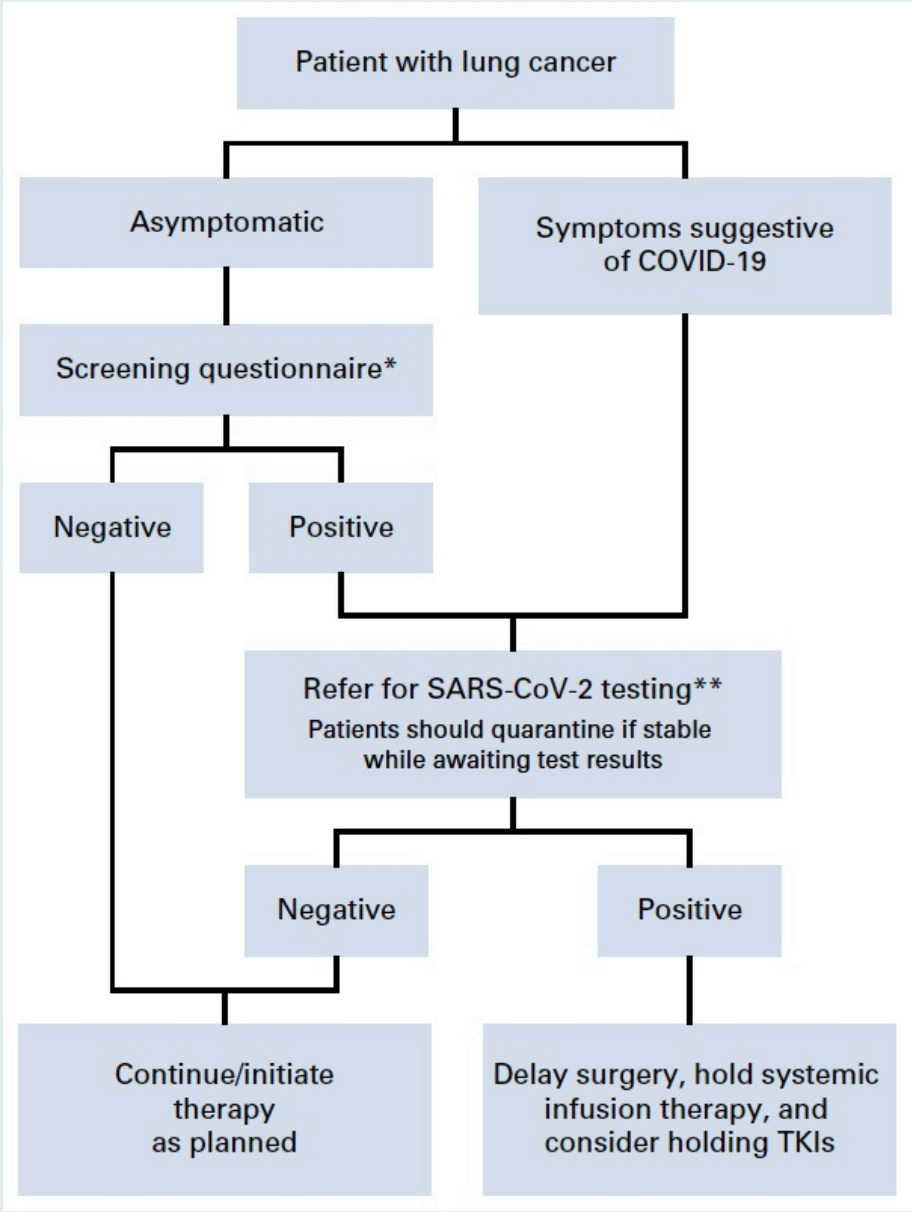
Management of Lung Cancer During the COVID-19 Pandemic

Aditi P. Singh, MD[1,2]; Abigail T. Berman, MD[2,3]; Melina E. Marmarelis, MD[1,2]; Andrew R. Haas, MD, PhD[4]; Steven J. Feigenberg, MD[2,3]; Jennifer Braun, RN, BSN, MHA[2]; Christine A. Ciunci, MD[1,2]; Joshua M. Bauml, MD[1,2]; Roger B. Cohen, MD[1,2]; John C. Kucharczuk, MD[5]; Lawrence N. Shulman, MD[1,2]; Corey J. Langer, MD[1,2]; and Charu Aggarwal, MD, MPH[1,2]

JCO Oncol Pract 2020;16:579-86.

RTP RESEARCH TO PRACTICE

Algorithm for Treating Lung Cancer During the COVID-19 Pandemic



Singh AP et al. *JCO Oncol Pract* 2020;16(9):579-86.

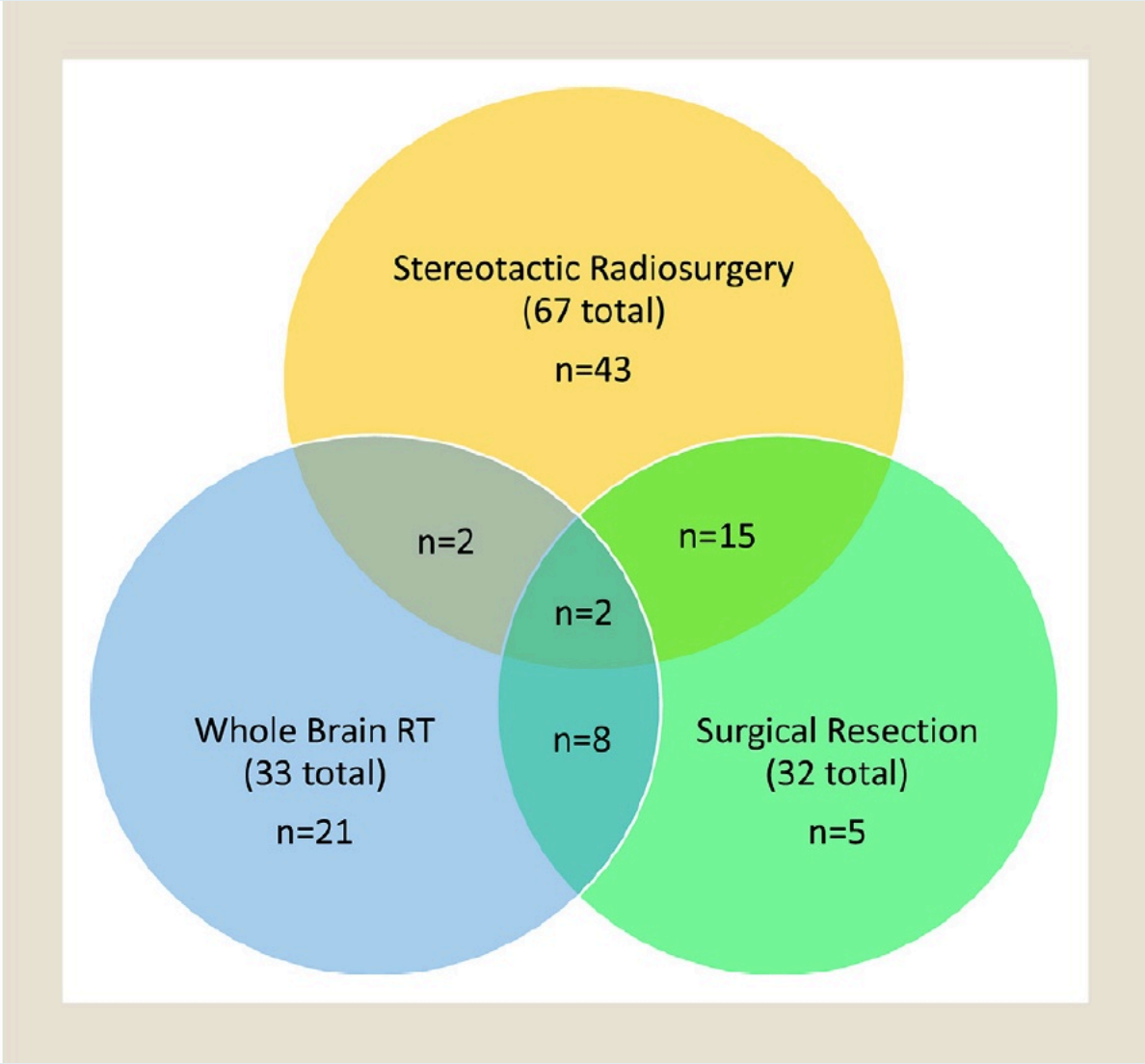
Original Study

Clinical Lung Cancer 2020;22(1):58-66

Outcomes in Patients With Non–small-cell Lung Cancer With Brain Metastases Treated With Pembrolizumab-based Therapy

Lova Sun,[1] Christiana W. Davis,[1] Wei-Ting Hwang,[3] Seth Jeffries,[1] Lydia Frenzel Sulyok,[1] Melina E. Marmarelis,[1] Aditi P. Singh,[1] Abigail T. Berman,[2] Steven J. Feigenberg,[2] William Levin,[2] Christine A. Ciunci,[1] Joshua M. Bauml,[1] Roger B. Cohen,[1] Corey J. Langer,[1] Charu Aggarwal[1]

Details of Prior Local Therapy in Patients with Metastatic Non-Small Cell Lung Cancer with Treated Brain Metastases (n = 96)



Sun L et al. *Clin Lung Cancer* 2021;22(1):58-66.e3.

Meet The Professor with Dr Bauml

Module 1: Cases from Drs Bachow and Naidoo

Module 2: Lung Cancer Journal Club with Dr Bauml

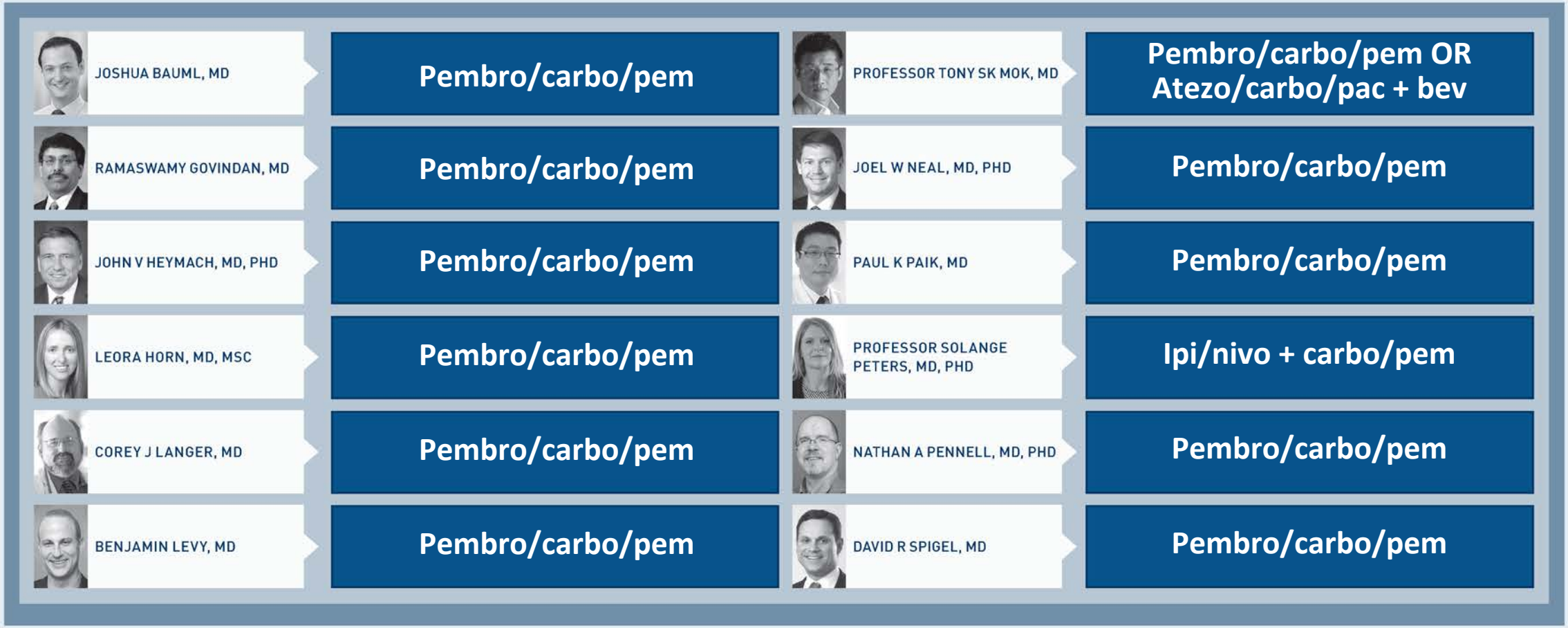
- Clinical implications of plasma-based genotyping for personalized therapy in metastatic NSCLC
- Baseline plasma tumor mutation burden predicts response to pembrolizumab-based therapy
- ATOMIC registry study: Mechanisms of resistance to osimertinib for NSCLC with EGFR mutation
- Pembrolizumab after completion of locally ablative therapy for oligometastatic NSCLC
- Amivantamab, an EGFR-MET bispecific antibody, combined with lazertinib, a third-generation TKI, for advanced NSCLC with EGFR mutation
- Identifying successful biomarkers for patients with NSCLC
- Early tumor and nodal responses in locally advanced NSCLC predict outcomes with concurrent proton- and chemotherapy
- Thoracic imaging of NSCLC treated with anti-PD-1 therapy
- Real-world treatment patterns and survival for patients with NSCLC and BRAF V600 mutations
- Next-generation sequencing of cerebrospinal fluid: How can a liquid be like a solid?
- High-dose osimertinib for CNS progression of NSCLC with EGFR mutation
- Management of lung cancer during the COVID-19 pandemic
- Outcomes for patients with NSCLC and brain metastases treated with pembrolizumab-based therapy

Module 3: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

Module 4: Key Papers and Recent Approvals

RTP
RESEARCH
TO PRACTICE

Which first-line treatment regimen would you recommend for a 65-year-old patient with metastatic nonsquamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 10%?



Pembro = pembrolizumab; carbo = carboplatin; pem = pemetrexed; atezo = atezolizumab; pac = paclitaxel; bev = bevacizumab; ipi = ipilimumab; nivo = nivolumab

RTP RESEARCH TO PRACTICE

Which first-line treatment regimen would you recommend for an 80-year-old patient with metastatic nonsquamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 10%?

 JOSHUA BAUML, MD	Pembro/carbo/pem	 PROFESSOR TONY SK MOK, MD	Pembro
 RAMASWAMY GOVINDAN, MD	Pembro	 JOEL W NEAL, MD, PHD	Pembro
 JOHN V HEYMACH, MD, PHD	Pembro	 PAUL K PAIK, MD	Pembro/carbo/pem
 LEORA HORN, MD, MSC	Pembro or Hospice	 PROFESSOR SOLANGE PETERS, MD, PHD	Pembro/carbo/pem
 COREY J LANGER, MD	Pembro	 NATHAN A PENNELL, MD, PHD	Pembro/carbo/pem*
 BENJAMIN LEVY, MD	Pembro	 DAVID R SPIGEL, MD	Pembro/carbo/pem

* Likely dose-reduced chemotherapy

Which first-line treatment regimen would you recommend for a 65-year-old patient with metastatic nonsquamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 60%?

 JOSHUA BAUML, MD	Pembro	 PROFESSOR TONY SK MOK, MD	Pembro
 RAMASWAMY GOVINDAN, MD	Pembro/carbo/pem	 JOEL W NEAL, MD, PHD	Pembro +/- carbo/pem
 JOHN V HEYMACH, MD, PHD	Pembro	 PAUL K PAIK, MD	Pembro
 LEORA HORN, MD, MSC	Pembro	 PROFESSOR SOLANGE PETERS, MD, PHD	Pembro
 COREY J LANGER, MD	Pembro*	 NATHAN A PENNELL, MD, PHD	Pembro
 BENJAMIN LEVY, MD	Pembro	 DAVID R SPIGEL, MD	Pembro

* If very symptomatic, pembro/carbo/pem

RTP RESEARCH TO PRACTICE

Which first-line treatment regimen would you recommend for an 80-year-old patient with metastatic nonsquamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 60%?

 JOSHUA BAUML, MD	Pembro	 PROFESSOR TONY SK MOK, MD	Pembro
 RAMASWAMY GOVINDAN, MD	Pembro	 JOEL W NEAL, MD, PHD	Pembro
 JOHN V HEYMACH, MD, PHD	Pembro	 PAUL K PAIK, MD	Pembro
 LEORA HORN, MD, MSC	Pembro	 PROFESSOR SOLANGE PETERS, MD, PHD	Pembro
 COREY J LANGER, MD	Pembro	 NATHAN A PENNELL, MD, PHD	Pembro
 BENJAMIN LEVY, MD	Pembro	 DAVID R SPIGEL, MD	Pembro

RTP RESEARCH TO PRACTICE

Which first-line treatment regimen would you recommend for a 65-year-old patient with metastatic squamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 10%?

 JOSHUA BAUML, MD	Pembro/carbo/pac	 PROFESSOR TONY SK MOK, MD	Pembro/carbo/*nab*-P or Pembro/carbo/pac
 RAMASWAMY GOVINDAN, MD	Pembro/carbo/*nab*-P	 JOEL W NEAL, MD, PHD	Pembro/carbo/ *nab*-P or pac
 JOHN V HEYMACH, MD, PHD	Pembro/carbo/*nab*-P	 PAUL K PAIK, MD	Pembro/carbo/pac
 LEORA HORN, MD, MSC	Pembro/carbo/*nab*-P	 PROFESSOR SOLANGE PETERS, MD, PHD	Ipi/nivo + carbo/pac
 COREY J LANGER, MD	Pembro/carbo/*nab*-P	 NATHAN A PENNELL, MD, PHD	Pembro/carbo/*nab*-P
 BENJAMIN LEVY, MD	Pembro/carbo/*nab*-P	 DAVID R SPIGEL, MD	Pembro/carbo/*nab*-P

Nab-P = nanoparticle albumin-bound paclitaxel

Which first-line treatment regimen would you recommend for an 80-year-old patient with metastatic squamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 10%?

 JOSHUA BAUML, MD	Pembro/carbo/pac
 RAMASWAMY GOVINDAN, MD	Pembro
 JOHN V HEYMACH, MD, PHD	Pembro
 LEORA HORN, MD, MSC	Pembro/carbo/*nab*-P
 COREY J LANGER, MD	Pembro/carbo/*nab*-P
 BENJAMIN LEVY, MD	Pembro/carbo/pac
 PROFESSOR TONY SK MOK, MD	Pembro
 JOEL W NEAL, MD, PHD	Pembro/carbo/*nab*-P
 PAUL K PAIK, MD	Pembro/carbo/pac
 PROFESSOR SOLANGE PETERS, MD, PHD	Pembro/carbo/pac
 NATHAN A PENNELL, MD, PHD	Pembro/carbo/pac
 DAVID R SPIGEL, MD	Pembro/carbo/*nab*-P

RTP RESEARCH TO PRACTICE

Which first-line treatment regimen would you recommend for a 65-year-old patient with metastatic squamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 60%?

 JOSHUA BAUML, MD	Pembro	 PROFESSOR TONY SK MOK, MD	Pembro or Atezo
 RAMASWAMY GOVINDAN, MD	Pembro/carbo/*nab*-P	 JOEL W NEAL, MD, PHD	Pembro +/- carbo/ *nab*-P or pac
 JOHN V HEYMACH, MD, PHD	Pembro	 PAUL K PAIK, MD	Pembro
 LEORA HORN, MD, MSC	Pembro	 PROFESSOR SOLANGE PETERS, MD, PHD	Pembro
 COREY J LANGER, MD	Pembro	 NATHAN A PENNELL, MD, PHD	Pembro
 BENJAMIN LEVY, MD	Pembro	 DAVID R SPIGEL, MD	Pembro

RTP RESEARCH TO PRACTICE

Which first-line treatment regimen would you recommend for an 80-year-old patient with metastatic squamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 60%?

 JOSHUA BAUML, MD	Pembro	 PROFESSOR TONY SK MOK, MD	Pembro or Atezo
 RAMASWAMY GOVINDAN, MD	Pembro	 JOEL W NEAL, MD, PHD	Pembro +/- carbo/ *nab*-P
 JOHN V HEYMACH, MD, PHD	Pembro	 PAUL K PAIK, MD	Pembro
 LEORA HORN, MD, MSC	Pembro	 PROFESSOR SOLANGE PETERS, MD, PHD	Pembro
 COREY J LANGER, MD	Pembro	 NATHAN A PENNELL, MD, PHD	Pembro
 BENJAMIN LEVY, MD	Pembro	 DAVID R SPIGEL, MD	Pembro

RTP RESEARCH TO PRACTICE

How long would you continue treatment for a patient with metastatic NSCLC who is receiving an anti-PD-1/PD-L1 antibody and at first evaluation is tolerating it well and has a complete clinical response?

 JOSHUA BAUML, MD	Indefinitely or until PD/toxicity
 RAMASWAMY GOVINDAN, MD	2 years
 JOHN V HEYMACH, MD, PHD	2 years
 LEORA HORN, MD, MSC	2 years
 COREY J LANGER, MD	2 years (min)
 BENJAMIN LEVY, MD	Indefinitely or until PD/toxicity
 PROFESSOR TONY SK MOK, MD	2 years
 JOEL W NEAL, MD, PHD	2 years
 PAUL K PAIK, MD	Indefinitely or until PD/toxicity
 PROFESSOR SOLANGE PETERS, MD, PHD	2 years (discuss unknowns)
 NATHAN A PENNELL, MD, PHD	2 years
 DAVID R SPIGEL, MD	Likely 2 years but CR duration dependent

RTP RESEARCH TO PRACTICE

How long would you continue treatment for a patient with metastatic NSCLC who is receiving an anti-PD-1/PD-L1 antibody and at first evaluation is tolerating it well and has a partial clinical response?

 JOSHUA BAUML, MD	Indefinitely or until PD/toxicity	 PROFESSOR TONY SK MOK, MD	2 years
 RAMASWAMY GOVINDAN, MD	Indefinitely or until PD/toxicity	 JOEL W NEAL, MD, PHD	2 years
 JOHN V HEYMACH, MD, PHD	Indefinitely or until PD/toxicity	 PAUL K PAIK, MD	Indefinitely or until PD/toxicity
 LEORA HORN, MD, MSC	2 years	 PROFESSOR SOLANGE PETERS, MD, PHD	Indefinitely or until PD/toxicity
 COREY J LANGER, MD	2 years (min)	 NATHAN A PENNELL, MD, PHD	2 years
 BENJAMIN LEVY, MD	Indefinitely or until PD/toxicity	 DAVID R SPIGEL, MD	Indefinitely or until PD/toxicity

RTP RESEARCH TO PRACTICE

What is your preferred second-line treatment for a patient with extensive-stage small cell cancer of the lung with metastases and disease progression on chemotherapy/atezolizumab?

1. Topotecan or irinotecan
2. Lurbinectedin
3. Nivolumab/ipilimumab
4. Pembrolizumab
5. Nivolumab
6. Other

Regulatory and reimbursement issues aside, what would be your preferred first-line treatment regimen for a 65-year-old patient with extensive-stage SCLC?

 JOSHUA BAUML, MD	Carbo/etoposide + atezolizumab
 RAMASWAMY GOVINDAN, MD	Carbo/etoposide + atezolizumab
 JOHN V HEYMACH, MD, PHD	Carbo/etoposide + atezolizumab
 LEORA HORN, MD, MSC	Carbo/etoposide + atezolizumab
 COREY J LANGER, MD	Carbo/etoposide + atezolizumab or durvalumab
 BENJAMIN LEVY, MD	Carbo/etoposide + atezolizumab
 PROFESSOR TONY SK MOK, MD	Carbo/etoposide + atezolizumab
 JOEL W NEAL, MD, PHD	Carbo/etoposide + atezolizumab
 PAUL K PAIK, MD	Carbo/etoposide + atezolizumab
 PROFESSOR SOLANGE PETERS, MD, PHD	Carbo/etoposide + atezolizumab or durvalumab
 NATHAN A PENNELL, MD, PHD	Carbo/etoposide + atezolizumab
 DAVID R SPIGEL, MD	Carbo/etoposide + durvalumab

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, what would be your preferred first-line treatment regimen for an 80-year-old patient with extensive-stage SCLC?

 JOSHUA BAUML, MD	Carbo/etoposide + atezolizumab
 RAMASWAMY GOVINDAN, MD	Carbo/etoposide + atezolizumab
 JOHN V HEYMACH, MD, PHD	Carbo/etoposide + atezolizumab
 LEORA HORN, MD, MSC	Carbo/etoposide + atezolizumab
 COREY J LANGER, MD	Carbo/etoposide + durvalumab
 BENJAMIN LEVY, MD	Carbo/etoposide + atezolizumab
 PROFESSOR TONY SK MOK, MD	Carbo/etoposide OR Carbo/etoposide + atezolizumab or durvalumab
 JOEL W NEAL, MD, PHD	Carbo/etoposide + atezolizumab or durvalumab
 PAUL K PAIK, MD	Carbo/etoposide + atezolizumab
 PROFESSOR SOLANGE PETERS, MD, PHD	Carbo/etoposide + atezolizumab or durvalumab
 NATHAN A PENNELL, MD, PHD	Carbo/etoposide + atezolizumab
 DAVID R SPIGEL, MD	Carbo/etoposide + durvalumab

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, what would be your preferred first-line treatment regimen for a 65-year-old patient with extensive-stage SCLC and neurologic paraneoplastic syndrome causing moderate to severe proximal myopathy?

 JOSHUA BAUML, MD	Carboplatin/etoposide
 RAMASWAMY GOVINDAN, MD	Carboplatin/etoposide
 JOHN V HEYMACH, MD, PHD	Carboplatin/etoposide
 LEORA HORN, MD, MSC	Carboplatin/etoposide
 COREY J LANGER, MD	Carboplatin/etoposide + atezolizumab or durvalumab
 BENJAMIN LEVY, MD	Carboplatin/etoposide
 PROFESSOR TONY SK MOK, MD	Carboplatin/etoposide
 JOEL W NEAL, MD, PHD	Carboplatin/etoposide + atezolizumab or durvalumab
 PAUL K PAIK, MD	Carboplatin/etoposide
 PROFESSOR SOLANGE PETERS, MD, PHD	Carboplatin/etoposide + atezolizumab or durvalumab
 NATHAN A PENNELL, MD, PHD	Carboplatin/etoposide
 DAVID R SPIGEL, MD	Carboplatin/etoposide + durvalumab

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, what would be your preferred first-line treatment for a 65-year-old patient with extensive-stage SCLC and symptomatic SIADH, in addition to standard treatment for SIADH?

 JOSHUA BAUML, MD	Carboplatin/etoposide + atezolizumab
 RAMASWAMY GOVINDAN, MD	Carboplatin/etoposide + atezolizumab
 JOHN V HEYMACH, MD, PHD	Carboplatin/etoposide + atezolizumab or durvalumab
 LEORA HORN, MD, MSC	Carboplatin/etoposide + atezolizumab
 COREY J LANGER, MD	Carboplatin/etoposide + atezolizumab or durvalumab
 BENJAMIN LEVY, MD	Carboplatin/etoposide + atezolizumab
 PROFESSOR TONY SK MOK, MD	Carbo/etoposide OR Carbo/etoposide + atezolizumab or durvalumab
 JOEL W NEAL, MD, PHD	Carboplatin/etoposide + atezolizumab or durvalumab
 PAUL K PAIK, MD	Carboplatin/etoposide + atezolizumab
 PROFESSOR SOLANGE PETERS, MD, PHD	Carboplatin/etoposide + atezolizumab or durvalumab
 NATHAN A PENNELL, MD, PHD	Carboplatin/etoposide + atezolizumab
 DAVID R SPIGEL, MD	Carboplatin/etoposide + atezolizumab

SIADH = syndrome of inappropriate antidiuretic hormone secretion

RTP RESEARCH TO PRACTICE

Meet The Professor with Dr Bauml

Module 1: Cases from Drs Bachow and Naidoo

Module 2: Lung Cancer Journal Club with Dr Bauml

- Clinical implications of plasma-based genotyping for personalized therapy in metastatic NSCLC
- Baseline plasma tumor mutation burden predicts response to pembrolizumab-based therapy
- ATOMIC registry study: Mechanisms of resistance to osimertinib for NSCLC with EGFR mutation
- Pembrolizumab after completion of locally ablative therapy for oligometastatic NSCLC
- Amivantamab, an EGFR-MET bispecific antibody, combined with lazertinib, a third-generation TKI, for advanced NSCLC with EGFR mutation
- Identifying successful biomarkers for patients with NSCLC
- Early tumor and nodal responses in locally advanced NSCLC predict outcomes with concurrent proton- and chemotherapy
- Thoracic imaging of NSCLC treated with anti-PD-1 therapy
- Real-world treatment patterns and survival for patients with NSCLC and BRAF V600 mutations
- Next-generation sequencing of cerebrospinal fluid: How can a liquid be like a solid?
- High-dose osimertinib for CNS progression of NSCLC with EGFR mutation
- Management of lung cancer during the COVID-19 pandemic
- Outcomes for patients with NSCLC and brain metastases treated with pembrolizumab-based therapy

Module 3: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

Module 4: Key Papers and Recent Approvals

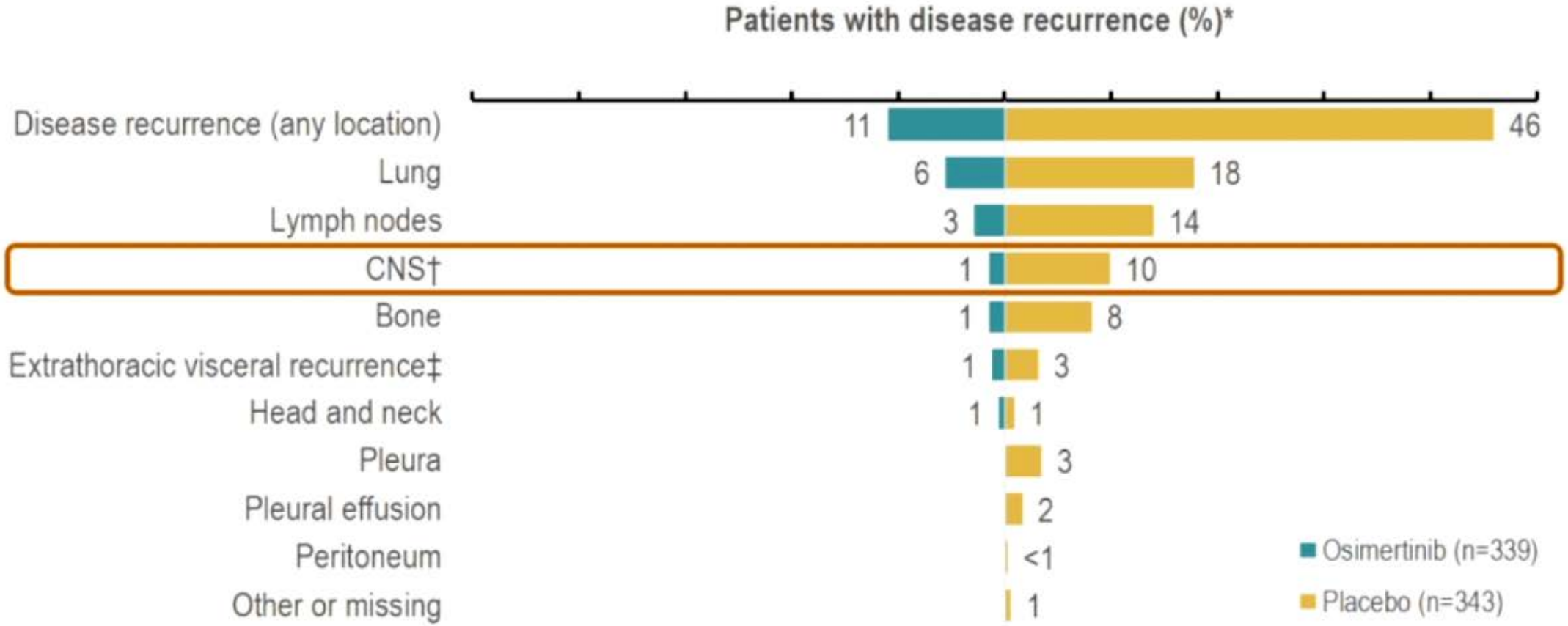
RTP RESEARCH TO PRACTICE

Osimertinib Adjuvant Therapy in Patients (pts) with Resected EGFR Mutated (EGFRm) NSCLC (ADAURA): Central Nervous System (CNS) Disease Recurrence

Tsuboi M et al.

ESMO 2020;Abstract LBA1.

ADAURA: Sites of Disease Recurrence



Tsuboi M et al. ESMO 2020;Abstract LBA1.

RTP RESEARCH TO PRACTICE

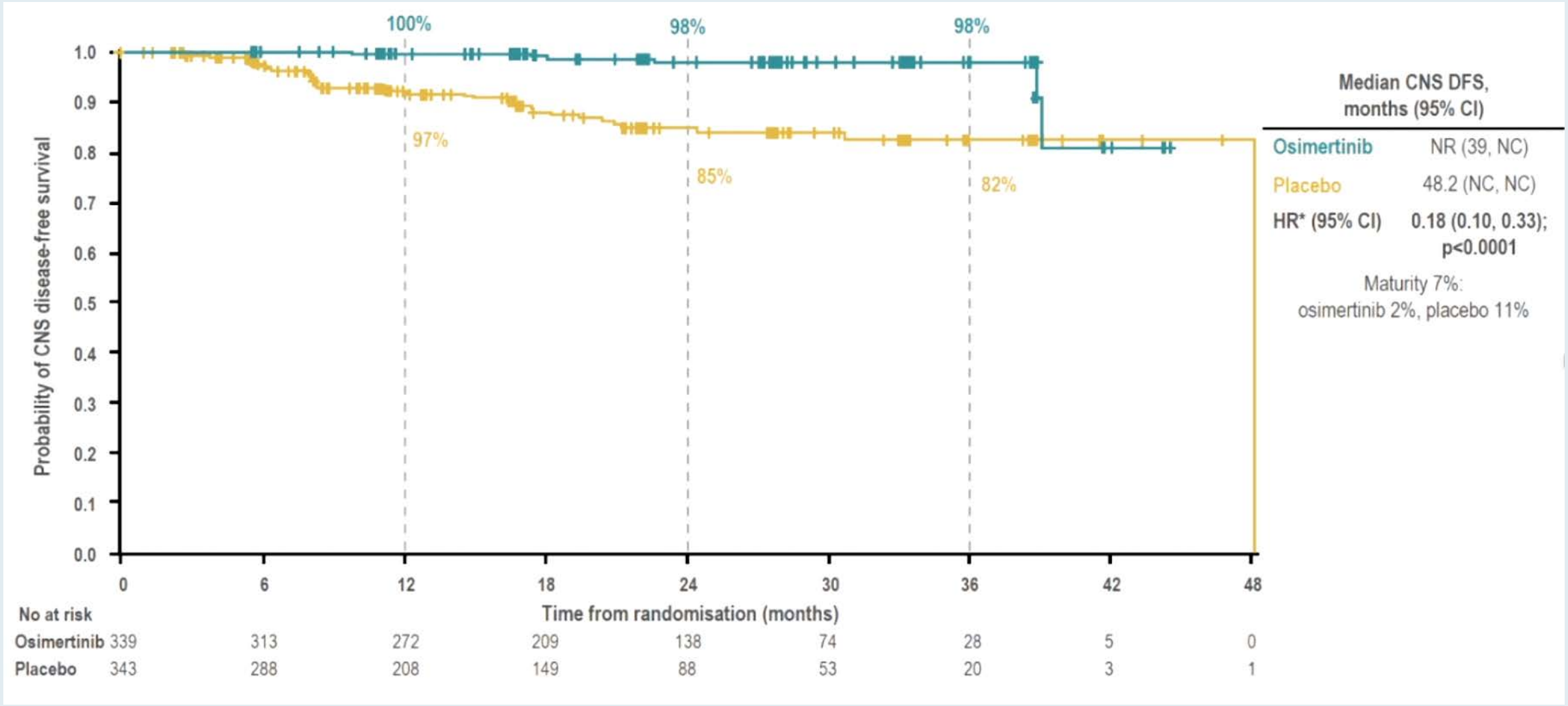
ADAURA: CNS DFS Events

- Overall, 45 patients (osimertinib n=6, placebo n=39) had CNS DFS events

	Overall population	
Patients, n (%)	**Osimertinib n=339**	**Placebo n=343**
CNS DFS events:	6 (2%)	39 (11%)
CNS recurrence	4 (1%)	33 (10%)
Death	2 (1%)	6 (2%)

Tsuboi M et al. ESMO 2020;Abstract LBA1.

ADAURA: CNS DFS in Overall Population



Tsuboi M et al. ESMO 2020;Abstract LBA1.

RTP RESEARCH TO PRACTICE

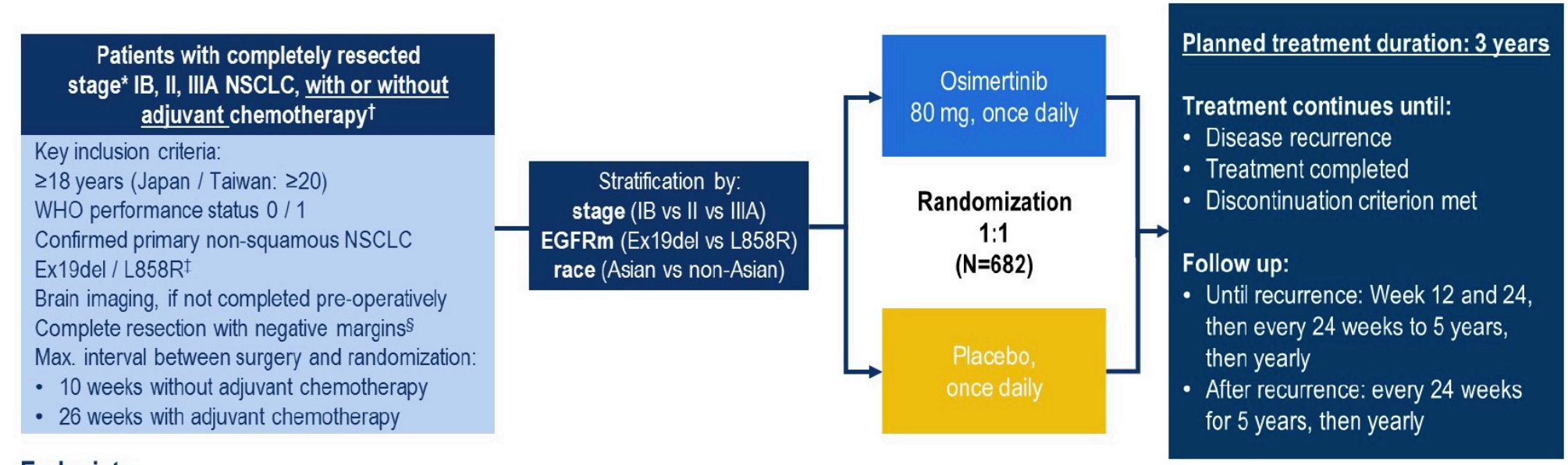
Osimertinib as Adjuvant Therapy in Patients (pts) with Stage IB–IIIA EGFR Mutation Positive (EGFRm) NSCLC After Complete Tumor Resection: ADAURA

Herbst RS et al.
ASCO 2020;Abstract LBA5.

Discussion of LBA5

Discussant: David R Spigel, MD, FASCO | Sarah Cannon Research Institute

ADAURA Phase III Trial Schema



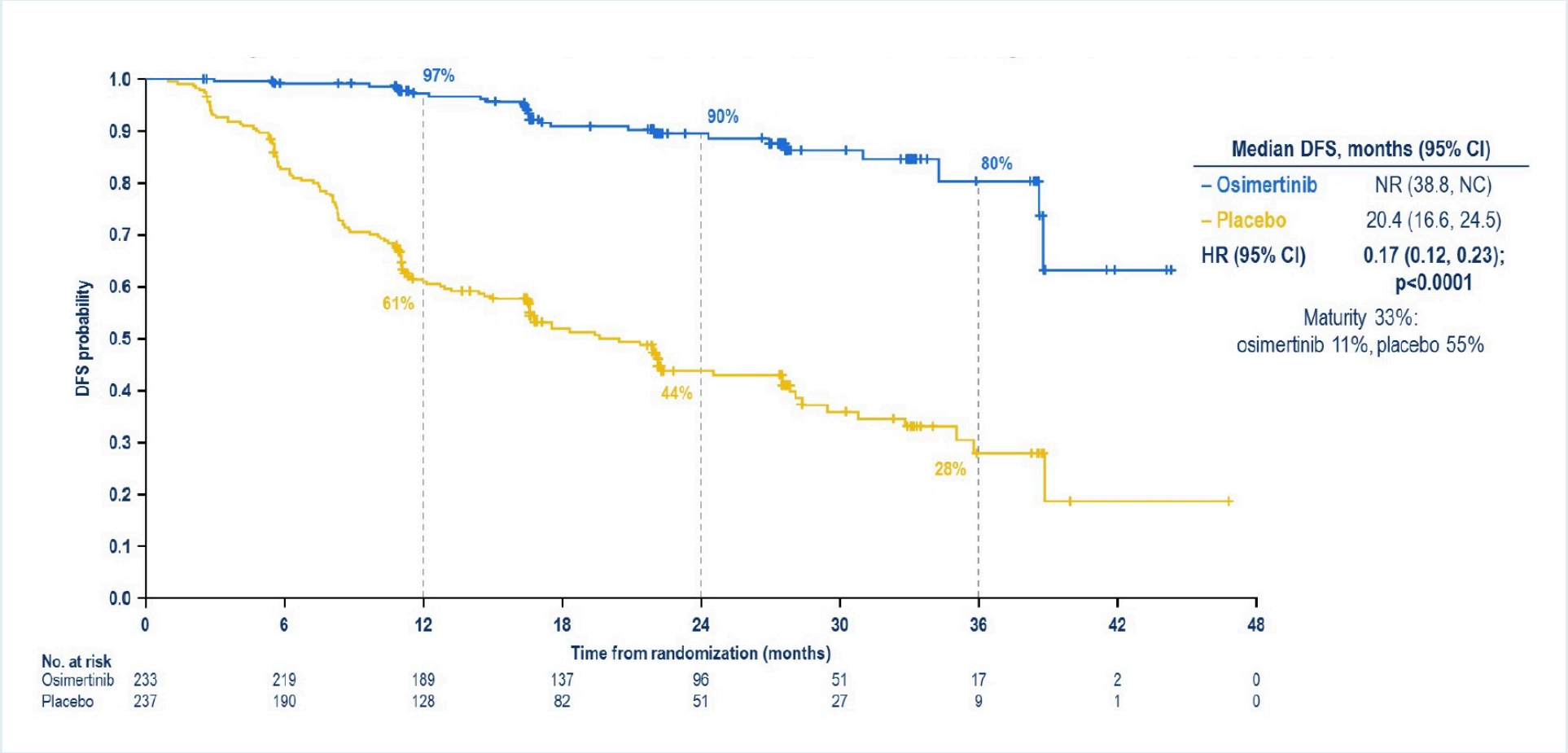
Endpoints

- **Primary**: DFS, by investigator assessment, in stage II/IIIA patients; designed for superiority under the assumed DFS HR of 0.70
- **Secondary**: DFS in the overall population¶, DFS at 2, 3, 4, and 5 years, OS, safety, health-related quality of life

- **Following IDMC recommendation, the study was unblinded early due to efficacy; here we report an unplanned interim analysis**
- **At the time of unblinding the study had completed enrollment and all patients were followed up for at least 1 year**

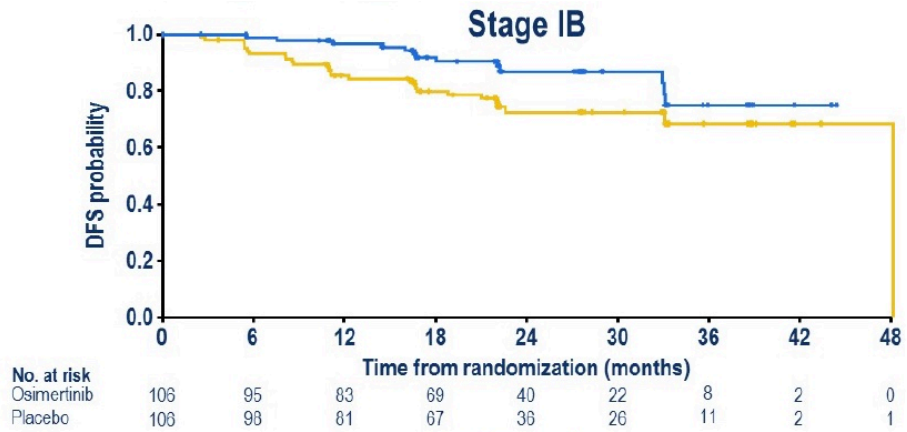
Herbst RS et al. ASCO 2020;Abstract LBA5.

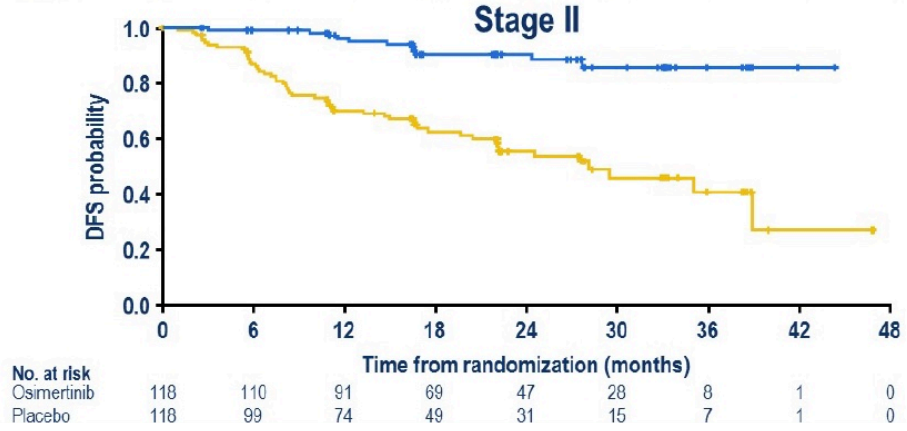
ADAURA Primary Endpoint: Inv-Assessed DFS (Stage II/IIIA)



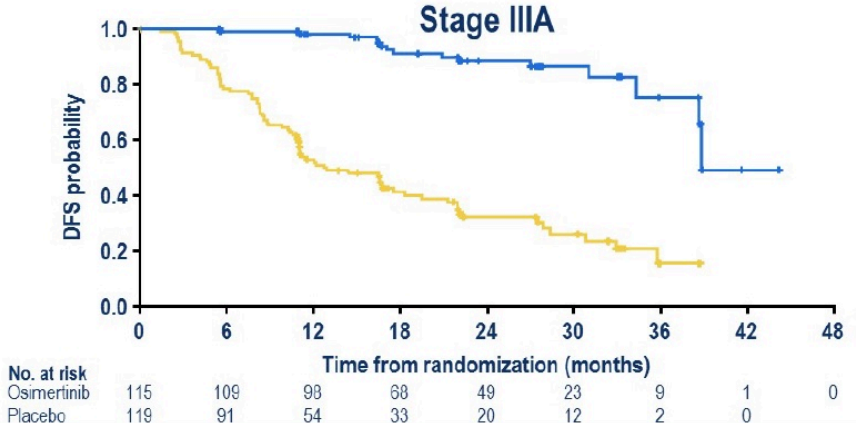
Herbst RS et al. ASCO 2020;Abstract LBA5.

ADAURA: DFS by Stage



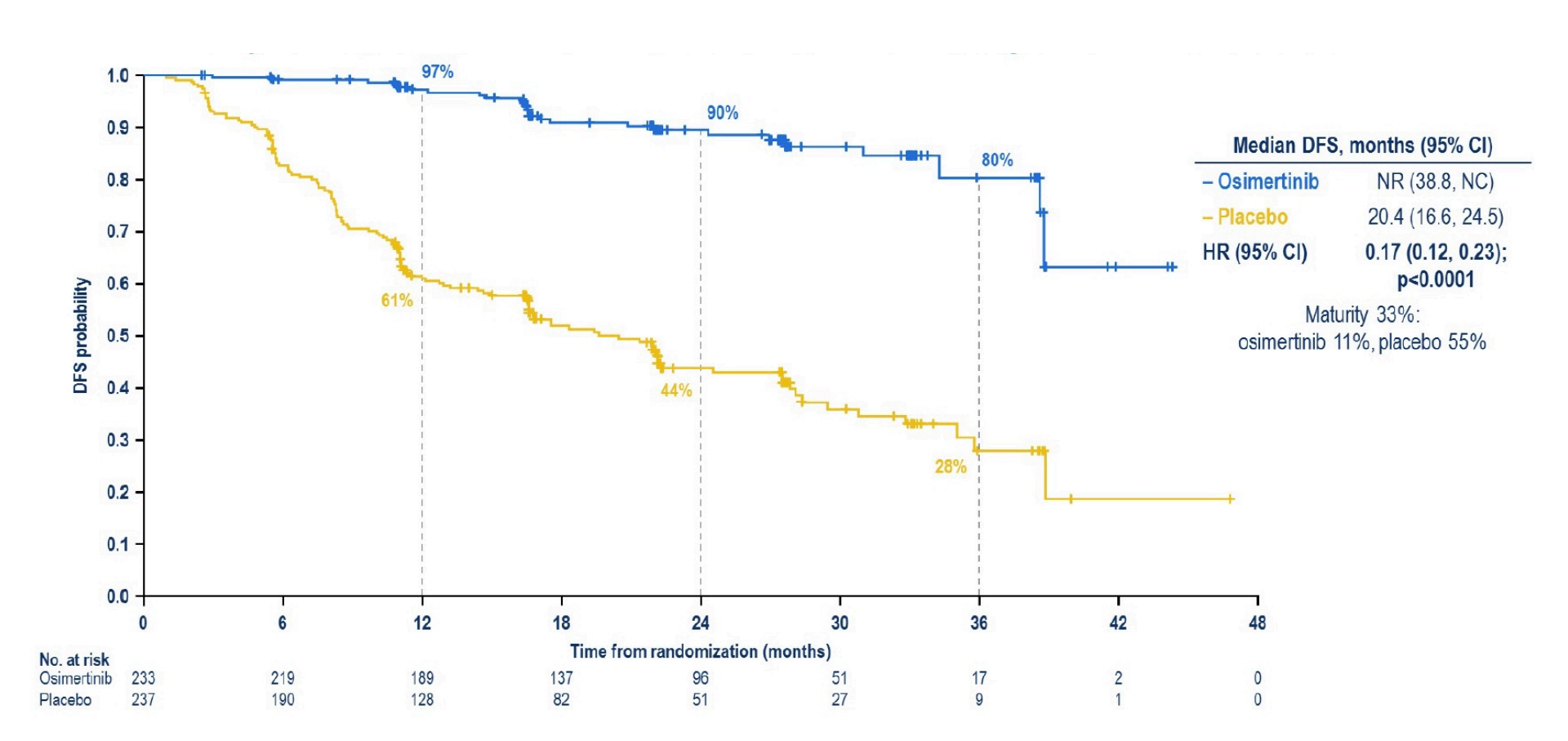


	Stage IB	Stage II	Stage IIIA
2 year DFS rate, % (95% CI)			
– Osimertinib	87 (77, 93)	91 (82, 95)	88 (79, 94)
– Placebo	73 (62, 81)	56 (45, 65)	32 (23, 42)
Overall HR (95% CI)	0.50 (0.25, 0.96)	0.17 (0.08, 0.31)	0.12 (0.07, 0.20)



Herbst RS et al. ASCO 2020;Abstract LBA5.

ADAURA Secondary Endpoint: Inv-Assessed DFS in the Overall Population (Stage IB/II/IIIA)



Herbst RS et al. ASCO 2020;Abstract LBA5.

FDA Approves Nivolumab with Ipilimumab for First-Line Metastatic NSCLC (PD-L1 Tumor Expression ≥1%)

Press Release — May 15, 2020

"The Food and Drug Administration approved the combination of nivolumab plus ipilimumab as first-line treatment for patients with metastatic non-small cell lung cancer whose tumors express PD-L1(≥1%), as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Efficacy was investigated in CHECKMATE-227 (NCT02477826), a randomized, open-label, multi-part trial in patients with metastatic or recurrent NSCLC and no prior anticancer therapy. In Part 1a of the trial, 793 patients with PD-L1 tumor expression ≥1% were randomized to receive either the combination of nivolumab plus with ipilimumab (n=396) or platinum-doublet chemotherapy (n=397)."

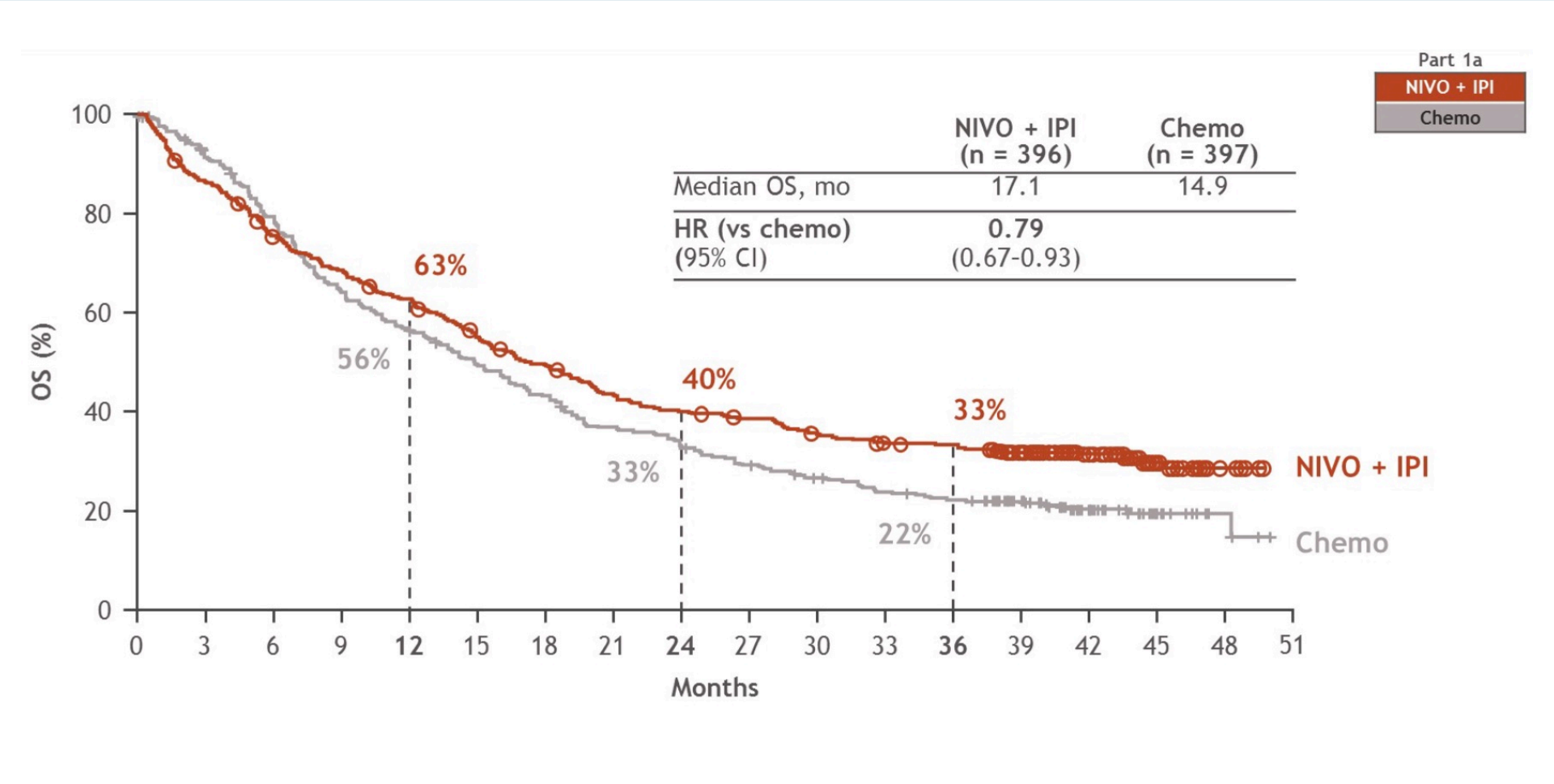
https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-nivolumab-plus-ipilimumab-first-line-mnsclc-pd-l1-tumor-expression-1

Nivolumab + Ipilimumab versus Platinum-Doublet Chemotherapy as First-Line Treatment for Advanced Non-Small Cell Lung Cancer: Three-Year Update from CheckMate 227 Part 1

Ramalingam SS et al.

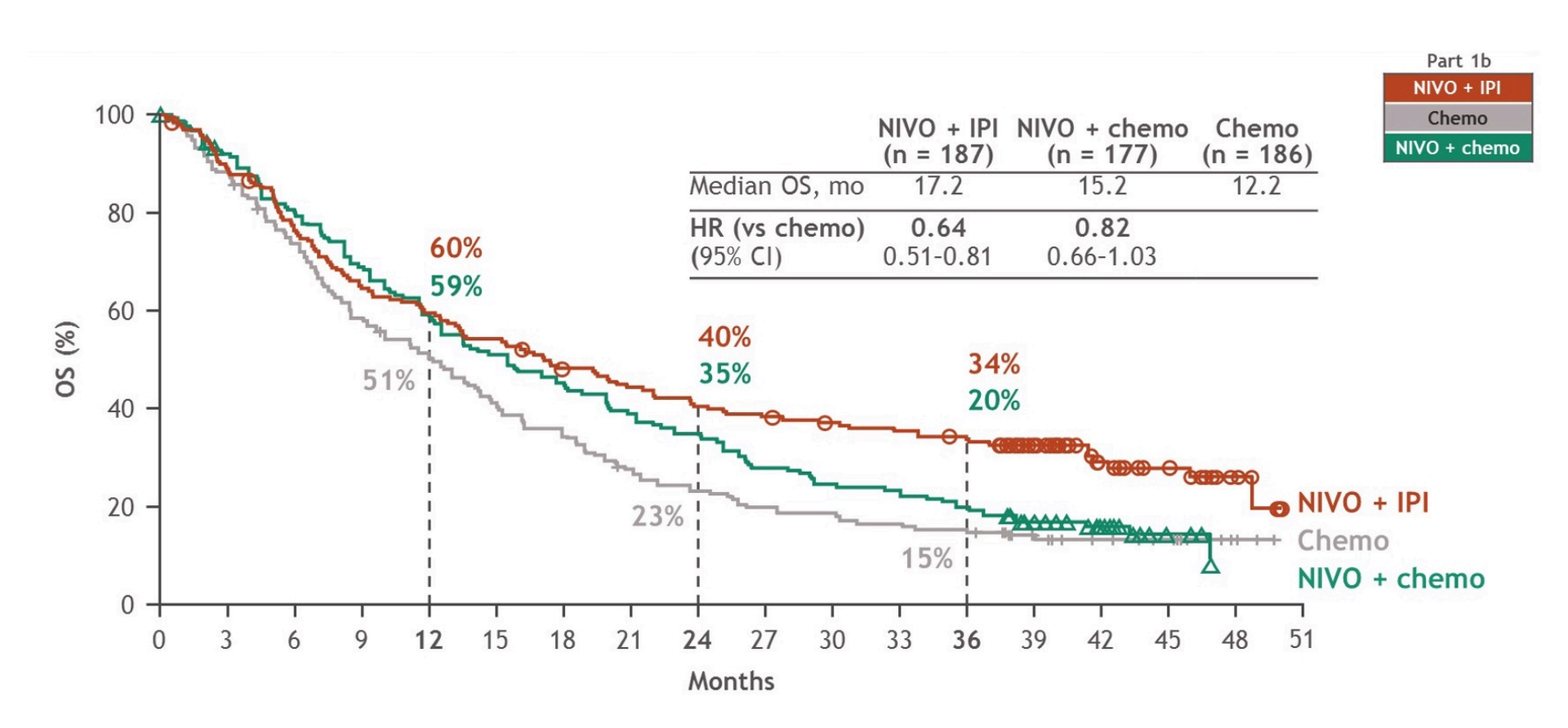
ASCO 2020;Abstract 9500.

3-Year Update: OS with IPI + Nivo vs Chemo (PD-L1 ≥1%)



Ramalingam SS et al. ASCO 2020;Abstract 9500.

3-Year Update: OS with IPI + Nivo vs Chemo vs Nivo + Chemo (PD-L1 <1%)



Ramalingam SS et al. ASCO 2020;Abstract 9500.

RTP RESEARCH TO PRACTICE

FDA Approves Nivolumab with Ipilimumab and Chemotherapy for First-Line Treatment of Metastatic NSCLC

Press Release — May 26, 2020

"The Food and Drug Administration approved the combination of nivolumab plus ipilimumab and 2 cycles of platinum-doublet chemotherapy as first-line treatment for patients with metastatic or recurrent non-small cell lung cancer (NSCLC), with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Efficacy was investigated in CHECKMATE-9LA (NCT03215706), a randomized, open-label trial in patients with metastatic or recurrent NSCLC. Patients were randomized to receive either the combination of nivolumab plus ipilimumab and 2 cycles of platinum-doublet chemotherapy (n=361) or platinum-doublet chemotherapy for 4 cycles (n=358)."

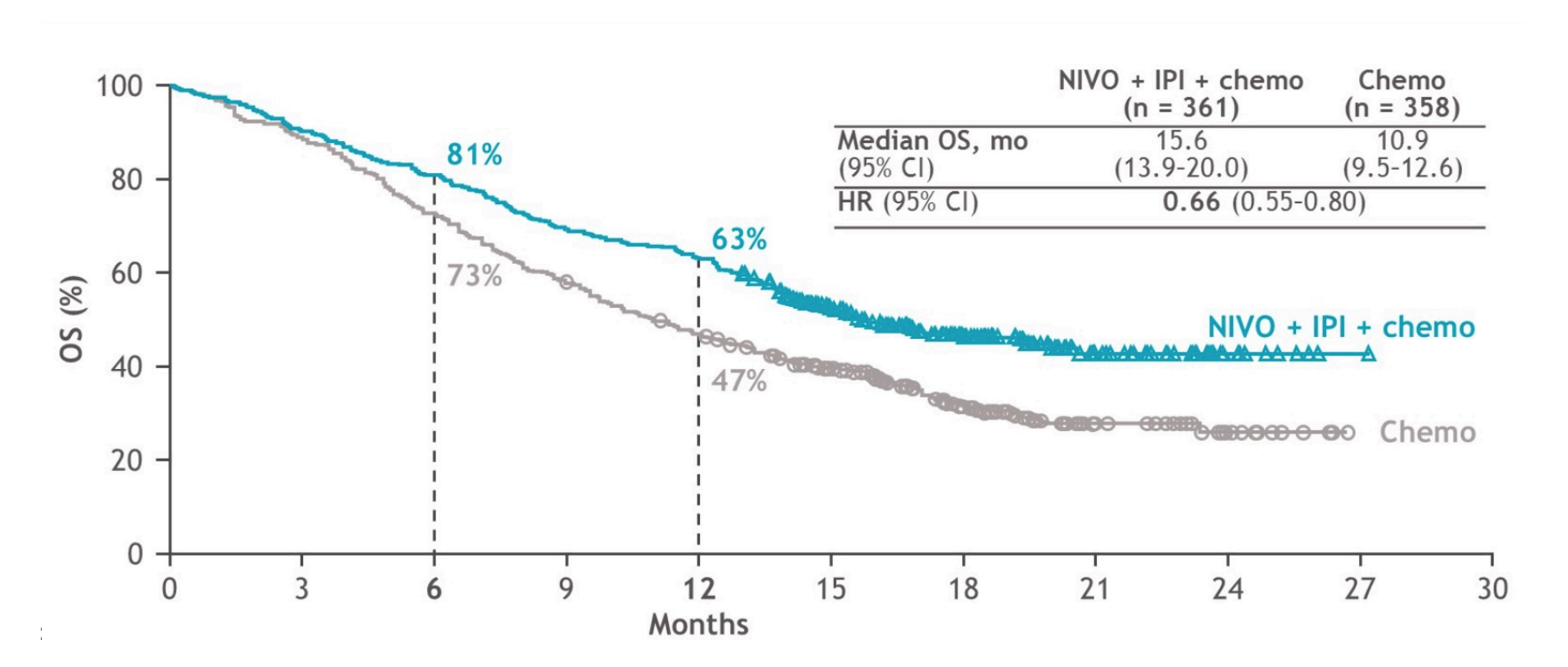
https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-nivolumab-plus-ipilimumab-and-chemotherapy-first-line-treatment-metastatic-nsclc

Nivolumab (NIVO) + Ipilimumab (IPI) + 2 Cycles of Platinum-Doublet Chemotherapy (Chemo) vs 4 Cycles Chemo as First-Line (1L) Treatment (tx) for Stage IV/Recurrent Non-Small Cell Lung Cancer (NSCLC): CheckMate 9LA

Reck M et al.

ASCO 2020;Abstract 9501.

CheckMate 9LA: Updated OS



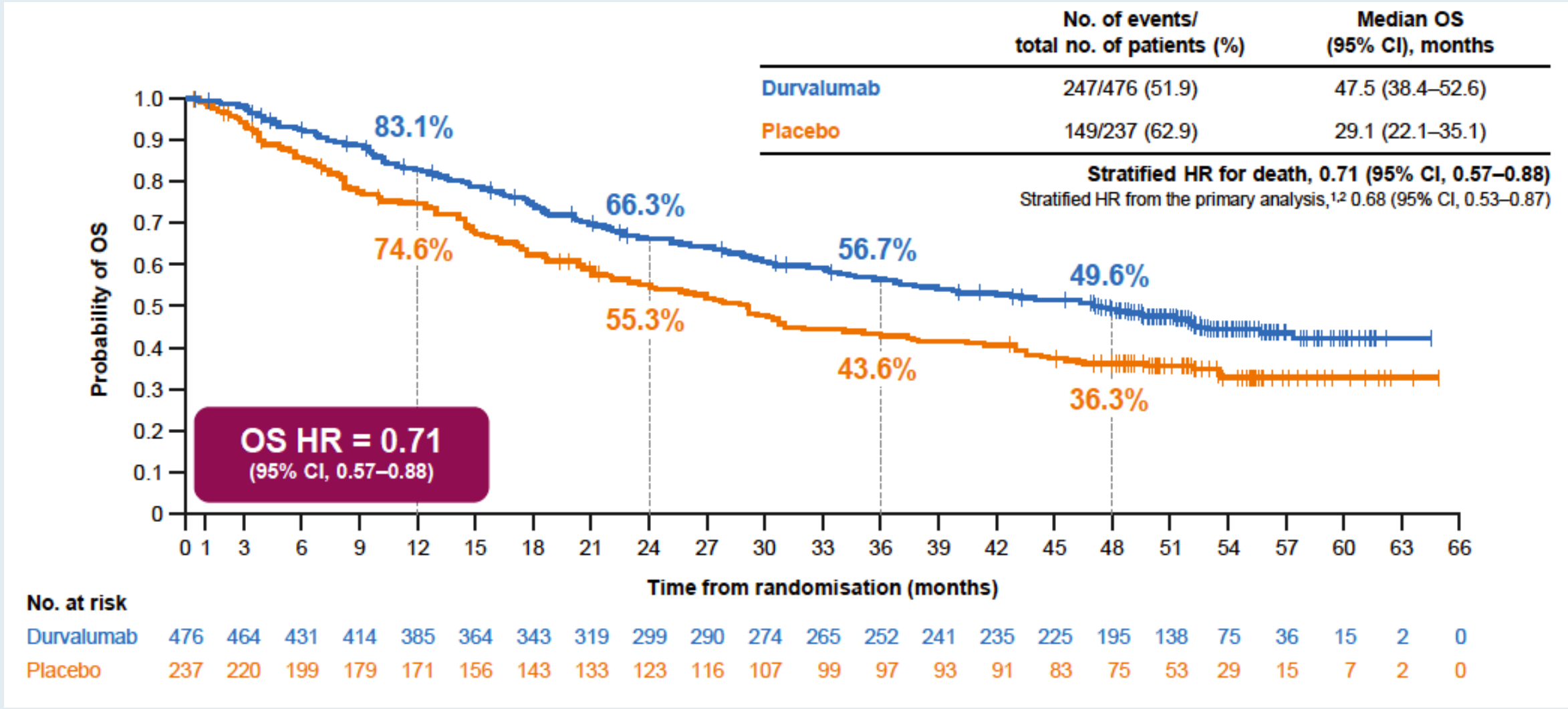
Reck M et al. ASCO 2020;Abstract 9501.

Durvalumab After Chemoradiotherapy in Stage III NSCLC: 4-Year Survival Update from the Phase III PACIFIC Trial

Faivre-Finn C et al.

ESMO 2020;Abstract LBA49.

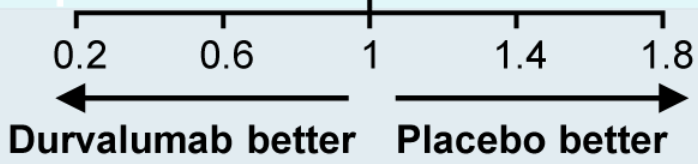
PACIFIC: 4-Year Overall Survival – Intent-To-Treat Population

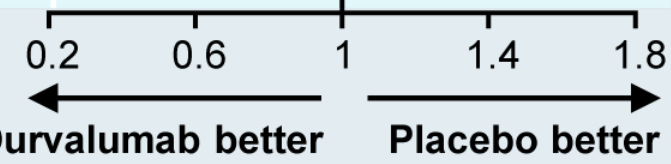


Faivre-Finn C et al. ESMO 2020;Abstract LBA49.

PACIFIC: Updated Outcomes by EGFR Status

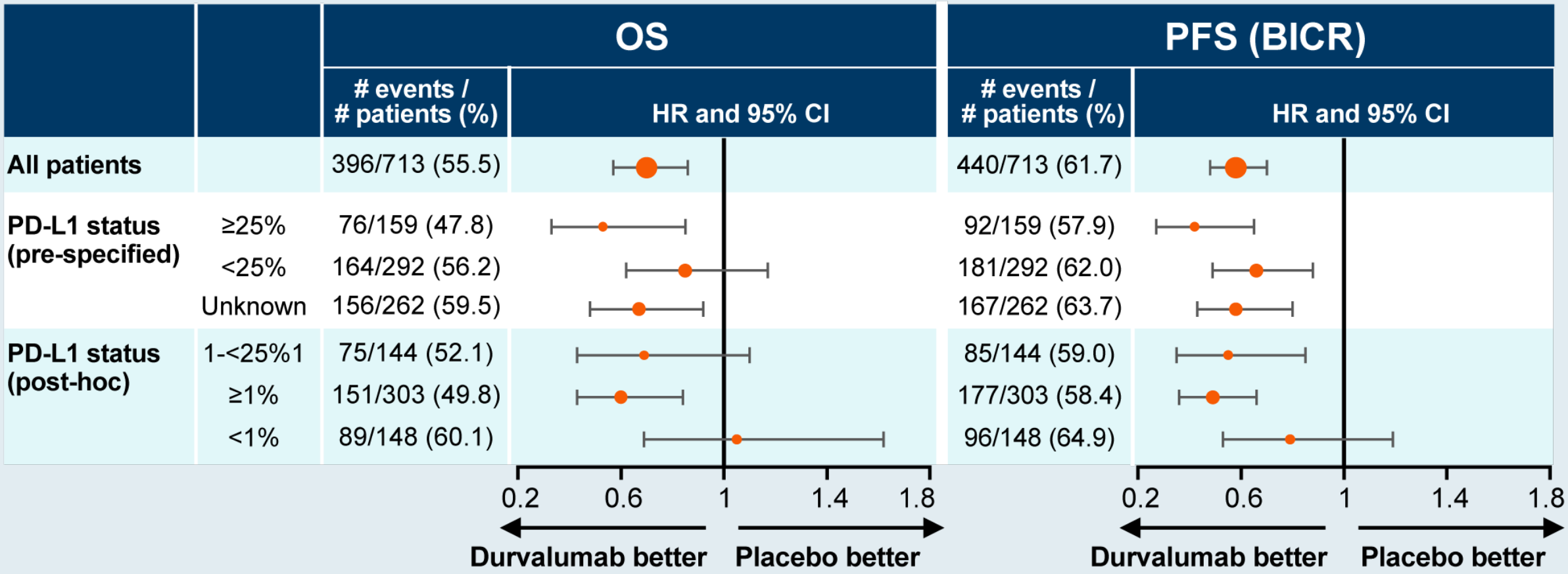
		OS		PFS (BICR)	
		# events / # patients (%)	HR and 95% CI	# events / # patients (%)	HR and 95% CI
***EGFR* mutation**	Positive	24/43 (55.8)		32/43 (74.4)	
	Negative	261/482 (54.1)		290/482 (60.2)	
	Unknown	111/188 (59.0)		118/188 (62.8)	





Faivre-Finn C et al. ESMO 2020;Abstract LBA49.

PACIFIC: Updated Outcomes by PD-L1 Status



- Important facts regarding PD-L1 status:
  - PD-L1 testing was not required and 37% of all randomised patients had unknown PD-L1 status
  - PD-L1 status was determined from tumour tissue obtained pre-CRT (getting a sample post-CRT medically not feasible)
  - PDL1 expression-level cutoff of 1% was part of an unplanned post-hoc analysis requested by the EMA

Faivre-Finn C et al. ESMO 2020;Abstract LBA49.

Characteristics of the First 615 Patients Enrolled in Pacific R: A Study of the First Real-World Data on Unresectable Stage III NSCLC Patients Treated with Durvalumab After Chemoradiotherapy

Girard N et al.

ESMO 2020;Abstract 1242P.

Pacific R: Biomarker Status

Biomarker evaluated	Tested, n (%)	Positive, n (%)	Inconclusive, n (%)
PD-L1 expression	442 (71.9)	324 (73.3)	27 (6.1)
EGFR mutation	262 (42.8)	19 (7.3)	7 (2.7)
ALK translocation	256 (41.9)	6 (2.3)	12 (4.7)
BRAF mutation	164 (26.8)	14 (8.5)	5 (3.0)
KRAS mutation	180 (29.5)	44 (24.4)	6 (3.3)

Girard N et al. ESMO 2020;Abstract 1242P.

Accelerated Approval of Lurbinectedin for Metastatic SCLC

Press Release – June 15, 2020

"On June 15, 2020, the Food and Drug Administration granted accelerated approval to lurbinectedin for adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

Efficacy was demonstrated in the PM1183-B-005-14 trial (Study B-005; NCT02454972), a multicenter open-label, multi-cohort study enrolling 105 patients with metastatic SCLC who had disease progression on or after platinum-based chemotherapy. Patients received lurbinectedin 3.2 mg/m^2 by intravenous infusion every 21 days until disease progression or unacceptable toxicity.

The recommended lurbinectedin dose is 3.2 mg/m^2 every 21 days."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-lurbinectedin-metastatic-small-cell-lung-cancer.

RTP RESEARCH TO PRACTICE

FDA Grants Accelerated Approval to Tepotinib for Metastatic Non-Small Cell Lung Cancer

Press Release – February 3, 2021

"The Food and Drug Administration granted accelerated approval to tepotinib for adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

Efficacy was demonstrated in the VISION trial (NCT02864992), a multicenter, non-randomized, open-label, multicohort study enrolling 152 patients with advanced or metastatic NSCLC with MET exon 14 skipping alterations. Patients received tepotinib 450 mg orally once daily until disease progression or unacceptable toxicity."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-tepotinib-metastatic-non-small-cell-lung-cancer

FDA Grants Approval of Pralsetinib for the Treatment of Metastatic NSCLC with RET Fusion

Press Release – September 7, 2020

"The Food and Drug Administration has approved pralsetinib for the treatment of adults with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test. This indication was approved under the FDA's Accelerated Approval programme, based on data from the phase I/II ARROW study. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Pralsetinib is a once-daily, oral precision therapy designed to selectively target RET alterations, including fusions and mutations.

The approval is based on the results from the phase I/II ARROW study, in which pralsetinib produced durable clinical responses in people with RET fusion-positive NSCLC with or without prior therapy, and regardless of RET fusion partner or central nervous system involvement. Pralsetinib demonstrated an overall response rate (ORR) of 57% ... and complete response (CR) rate of 5.7% in the 87 people with NSCLC previously treated with platinum-based chemotherapy. In the 27 people with treatment-naïve NSCLC, the ORR was 70%, with an 11% CR rate."

https://www.globenewswire.com/news-release/2020/09/07/2089388/0/en/Roche-announces-FDA-approval-of-Gavreto-pralsetinib-for-the-treatment-of-adults-with-metastatic-RET-fusion-positive-non-small-cell-lung-cancer.html

RTP RESEARCH TO PRACTICE

FDA Approves Selpercatinib for Lung and Thyroid Cancer with RET Gene Mutations or Fusions

Press Release – May 8, 2020

"On May 8, 2020, the Food and Drug Administration granted accelerated approval to selpercatinib for the following indications:

- Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC);
- Adult and pediatric patients ≥12 years of age with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy;
- Adult and pediatric patients ≥12 years of age with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

Efficacy was investigated in a multicenter, open-label, multi-cohort clinical trial (LIBRETTO-001) in patients whose tumors had RET alterations."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-selpercatinib-lung-and-thyroid-cancers-ret-gene-mutations-or-fusions

FDA Grants Accelerated Approval to Capmatinib for Metastatic Non-Small Cell Lung Cancer

Press Release – May 6, 2020

"On May 6, 2020, the Food and Drug Administration granted accelerated approval to capmatinib for adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

The FDA also approved the FoundationOne CDx assay as a companion diagnostic for capmatinib.

Efficacy was demonstrated in the GEOMETRY mono-1 trial (NCT02414139), a multicenter, non-randomized, open-label, multicohort study enrolling 97 patients with metastatic NSCLC with confirmed MET exon 14 skipping.

The recommended capmatinib dose is 400 mg orally twice daily with or without food."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-capmatinib-metastatic-non-small-cell-lung-cancer

Trastuzumab Deruxtecan (T-DXd; DS-8201) in Patients with HER2-Mutated Metastatic Non-Small Cell Lung Cancer (NSCLC): Interim Results of DESTINY-Lung01

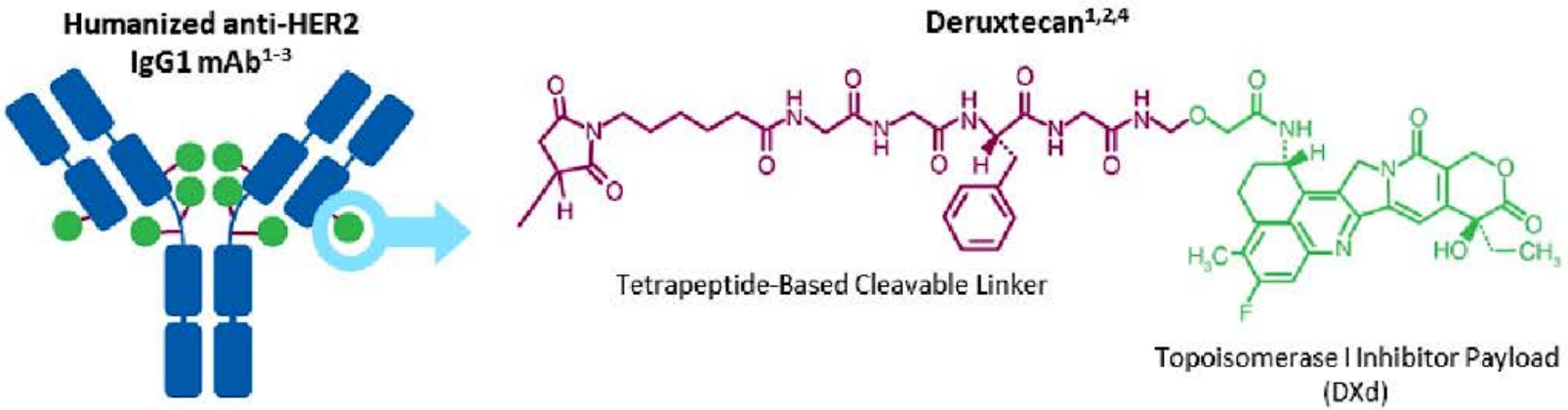
Smit EF et al.

ASCO 2020;Abstract 9504.

Antibody-Drug Conjugate
Trastuzumab Deruxtecan

T-DXd is an ADC with 3 components:

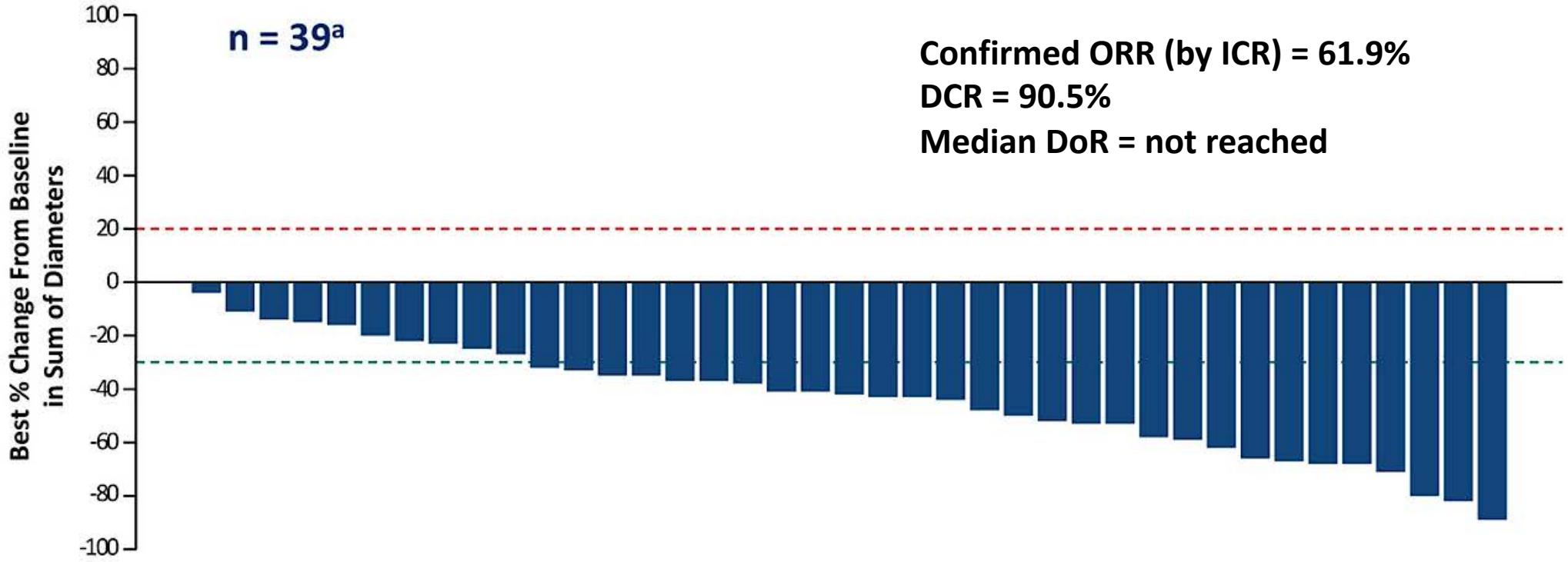
- A humanized anti-HER2 IgG1 mAb with the same amino acid sequence as trastuzumab
- A topoisomerase I inhibitor payload, an exatecan derivative
- A tetrapeptide-based cleavable linker



Payload mechanism of action: topoisomerase I inhibitor
High potency of payload
High drug to antibody ratio ≈ 8
Payload with short systemic half-life
Stable linker-payload
Tumor-selective cleavable linker
Membrane-permeable payload

Smit EF et al. ASCO 2020;Abstract 9504.

DESTINY-Lung01: Efficacy

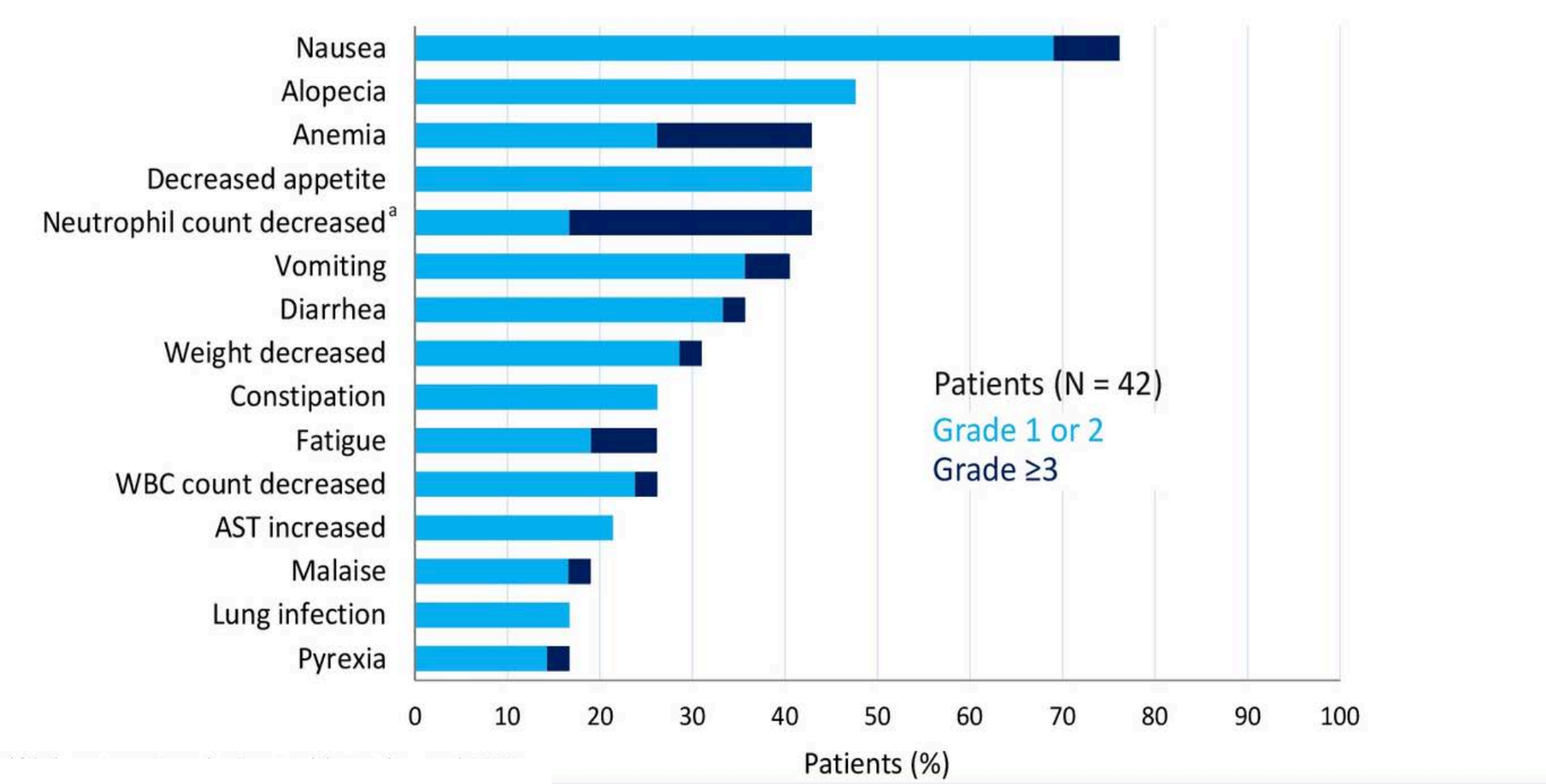


Based on independent central review. Baseline is last measurement taken before enrollment. Shown is best (minimum) percent change from baseline in the sum of diameters for all target lesions.
[a] One patient was missing a baseline assessment and 2 additional patients were missing post-baseline assessments.

- Median PFS = 14.0 months

Smit EF et al. ASCO 2020;Abstract 9504.

DESTINY-Lung01: Treatment-Emergent AEs



Smit EF et al. ASCO 2020;Abstract 9504.

RTP RESEARCH TO PRACTICE

DESTINY-Lung01: AEs of Special Interest – Interstitial Lung Disease

	All Patients (N = 42)					
n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade/ Total
Interstitial lung disease	0[a]	5 (11.9)	0	0	0	5 (11.9)

- Median time to onset of investigator-reported ILD was at 86 days (range, 41-255 days)
- 4 patients had drug withdrawn and 1 had drug interrupted
- All patients received steroid treatment
- 2 patients recovered, 1 recovered with sequelae, 1 was recovering, and 1 had not recovered by data-cutoff
- No grade 5 ILD was observed in this cohort

Smit EF et al. ASCO 2020;Abstract 9504.

Year in Review — Clinical Investigators Provide Perspectives on the Most Relevant New Publications, Data Sets and Advances in Oncology:

Breast Cancer

Tuesday, February 9, 2021
5:00 PM – 6:00 PM ET

Faculty

Harold Burstein, MD
Lisa Carey, MD

Moderator

Neil Love, MD

RESEARCH TO PRACTICE
2021
YEAR IN REVIEW

Current Concepts and Recent Advances in Oncology: A Daylong Clinical Summit Hosted in Partnership with North Carolina Oncology Association (NCOA) and South Carolina Oncology Society (SCOS)

Saturday, February 13, 2021
8:30 AM – 4:30 PM ET

Faculty

Courtney D DiNardo, MD, MSCE
Robert Dreicer, MD, MS
Justin F Gainor, MD
Sara Hurvitz, MD
Ian E Krop, MD, PhD
John M Pagel, MD, PhD
Alexander Perl, MD
Daniel P Petrylak, MD
Philip A Philip, MD, PhD, FRCP
Paul G Richardson, MD
Mitchell R Smith, MD, PhD
Eric Van Cutsem, MD, PhD
Peter Voorhees, MD
Heather Wakelee, MD

Moderator

Neil Love, MD

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Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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