Thank you for joining us.
The program will commence momentarily.

Current Questions and Controversies in the Management of Lung Cancer

An Interactive Meet The Professor Series

Leora Horn, MD, MSc
Ingram Associate Professor of Cancer Research
Director, Thoracic Oncology Research Program
Assistant Vice Chairman for Faculty Development
Vanderbilt University Medical Center
Nashville, Tennessee

Commercial Support

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Dr Love — Disclosures

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Upcoming Live Webinars

Wednesday, August 19, 2020
12:00 PM – 1:00 PM ET

Clinical Investigator Perspectives on the Current and Future Management of Multiple Myeloma

Faculty
Noopur Raje, MD

Moderator
Neil Love, MD

Thursday, August 20, 2020
5:00 PM – 6:00 PM ET

Clinical Investigator Perspectives on the Current and Future Role of PARP Inhibition in the Management of Ovarian Cancer

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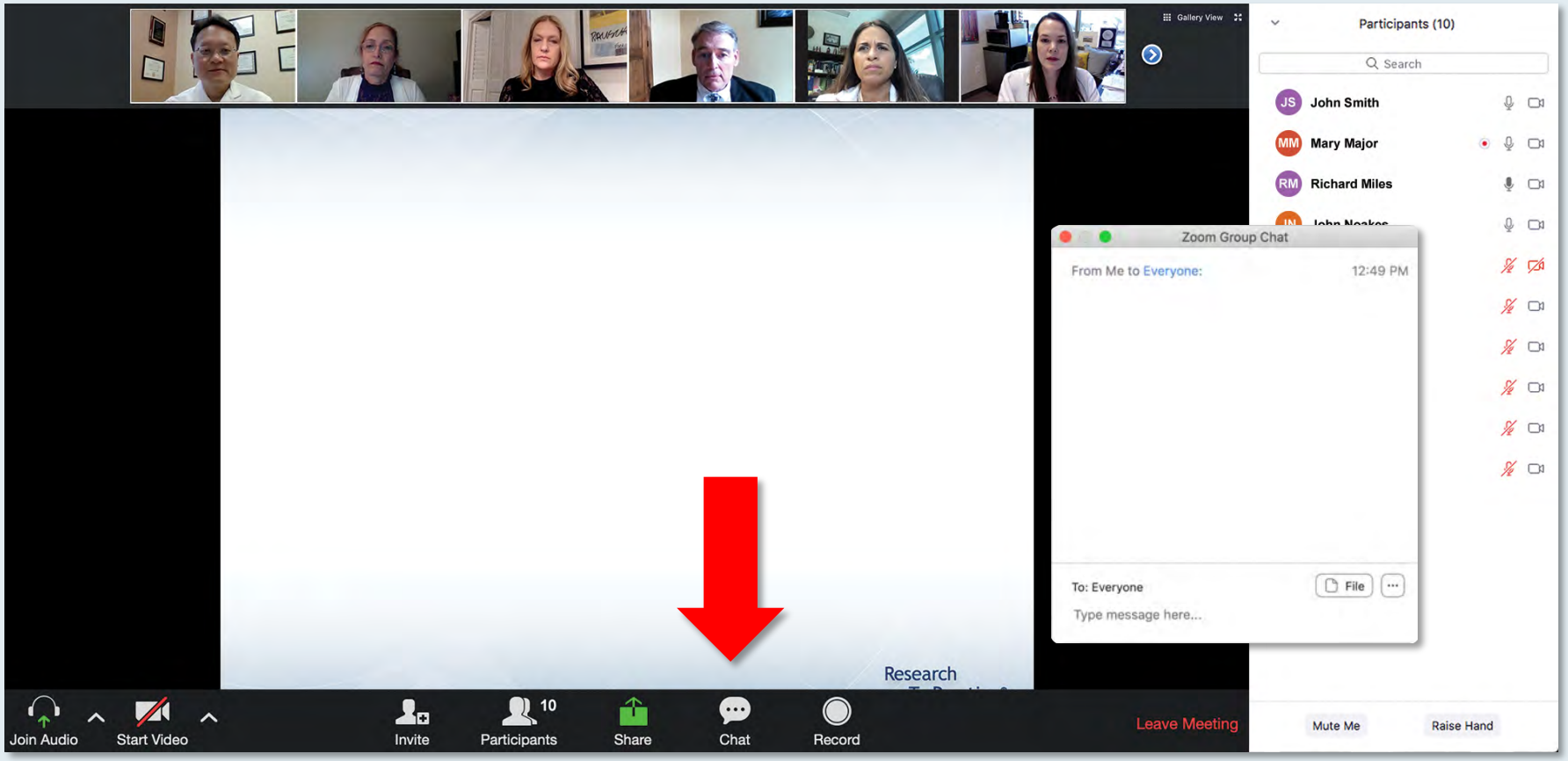
We Encourage Clinicians in Practice to Submit Questions



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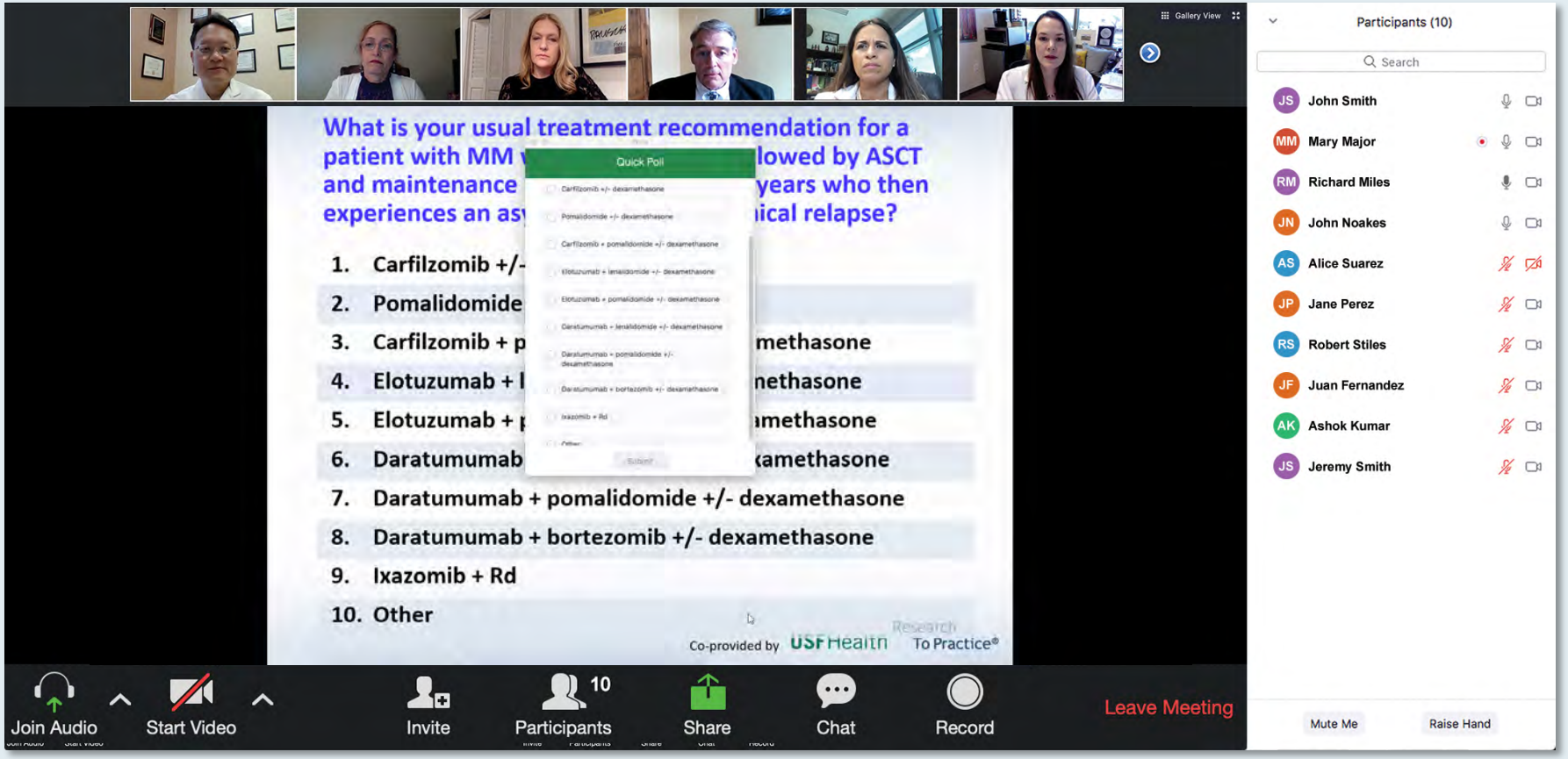
Familiarizing yourself with the Zoom interface

How to answer poll questions



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Meet The Professor Program Participating Faculty

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The University of Texas
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Corey J Langer, MD
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Associate Professor
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Division of Oncology
Department of Medicine
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Stanford University
Palo Alto, California

Lecia V Sequist, MD, MPH
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Massachusetts General Hospital Cancer Center
The Landry Family Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Nathan A Pennell, MD, PhD
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

David R Spigel, MD
Chief Scientific Officer
Program Director
Lung Cancer Research
Sarah Cannon Research Institute
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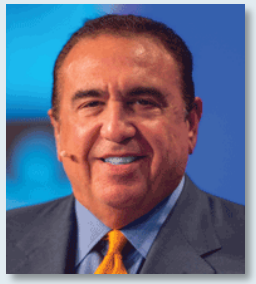
Meet The Professor Program Moderator



Project Chair
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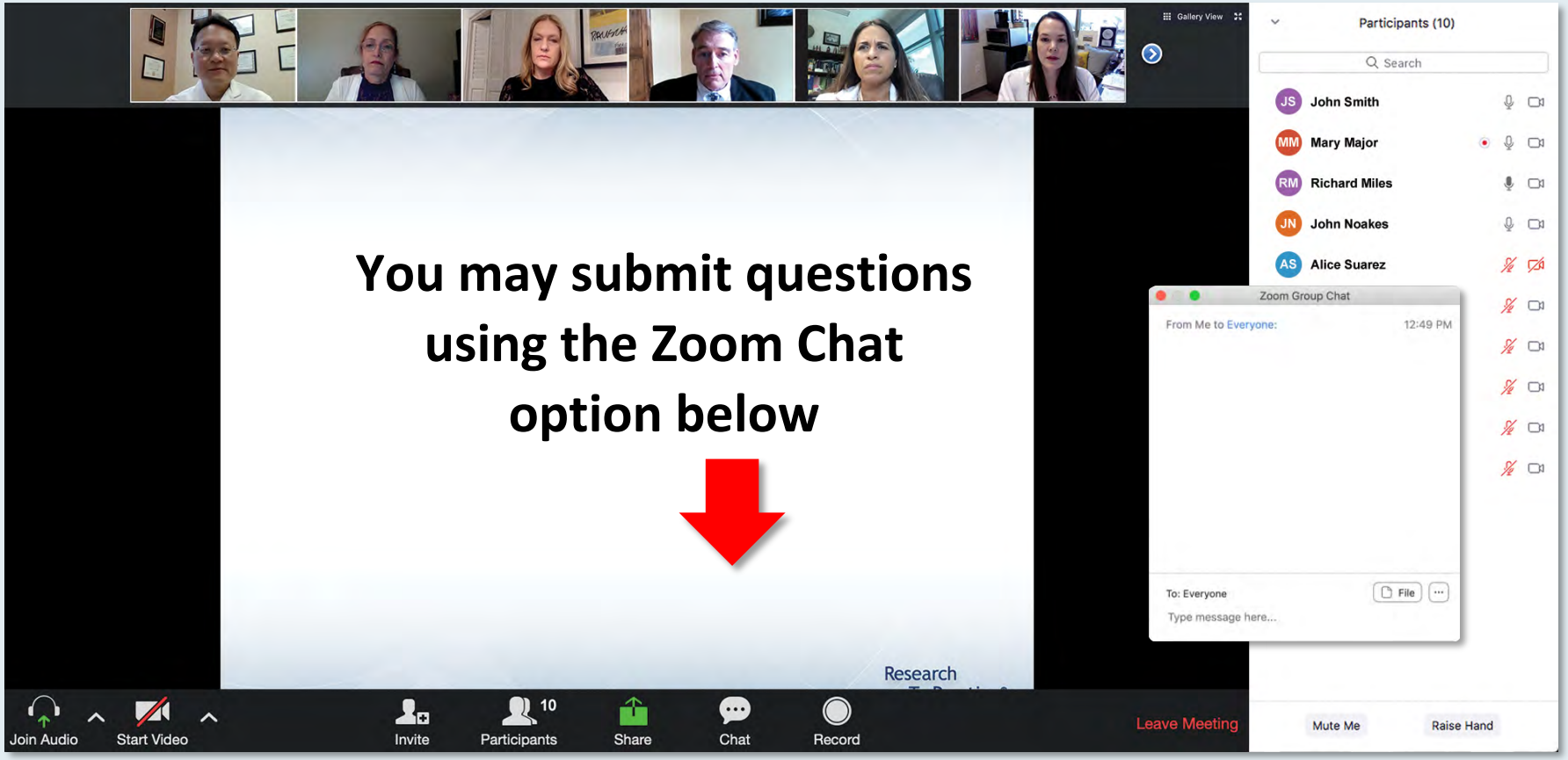

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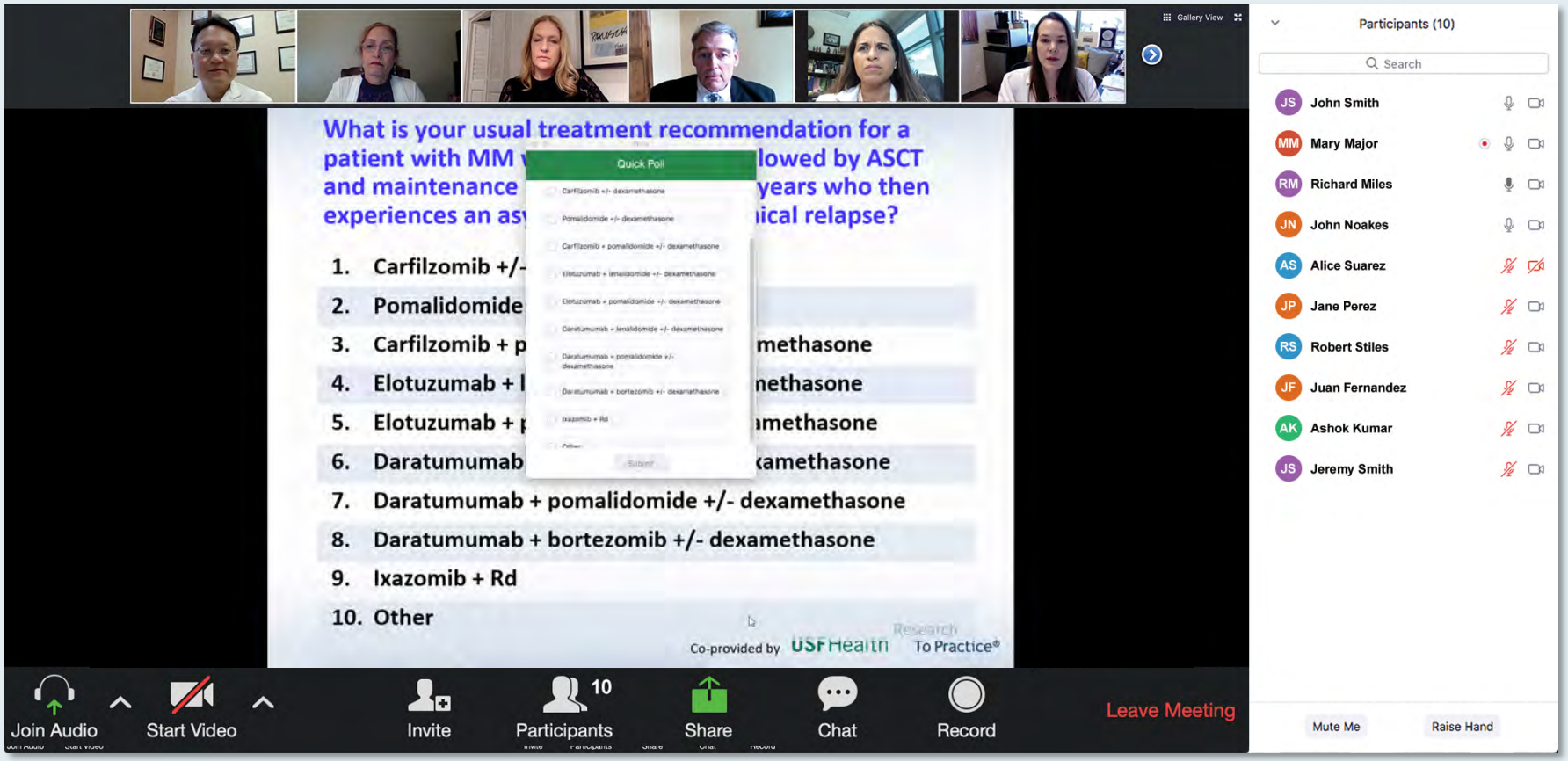

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Contributing Oncologists

Matthew Gubens, MD, MS
Associate Professor, Thoracic Medical Oncology
University of California, San Francisco
San Francisco, California

Sulfi Ibrahim, MD
Hematology/Oncology
Reid Health
Richmond, Indiana

Neil Morganstein, MD
Hematology Oncology
Atlantic Health System
Summit, New Jersey

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Meet The Professor with Dr Horn

Module 1: Management of Metastatic NSCLC with an EGFR Tumor Mutation

- A 67-year-old woman with metastatic adenocarcinoma of the lung – Dr Ibrahim

Module 2: Anti-PD-1/PD-L1 Antibodies Alone or in Combinations for Metastatic NSCLC

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- A 65-year-old man with locally advanced adenocarcinoma of the lung – Dr Gubens

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A 67-year-old former light smoker presents with symptomatic metastatic adenocarcinoma of the lung (PD-L1 level 50%). The patient requires urgent treatment but there is not enough tissue for NGS and the liquid biopsy is pending. How would you treat?

1. Pemetrexed/pembrolizumab/carboplatin
2. Pemetrexed
3. Other chemotherapy
4. Other checkpoint inhibitor
5. Other

Case Presentation — Dr Ibrahim: 67-year-old woman with metastatic adenocarcinoma of the lung

67-year-old woman with a very light history of smoking in her 20's presents with progressive dyspnea. Initially treated with antibiotics as an outpatient with worsening symptoms. Eventually admitted to the hospital with worsening dyspnea. Becomes oxygen dependent. Because she has infiltrates on imaging and not a mass, a diagnosis of lung malignancy is not considered for a few days and she has a work-up for other things like vasculitis. Eventually imaging shows bone lesion and oncology is consulted in the hospital. Biopsy done and patient is discharged home on oxygen. Biopsy positive for metastatic pulmonary adenocarcinoma, but tissue is insufficient for NGS.

I have her come in for plasma based NGS. Suggest she hold off on treatment because of strong possibility of finding a driver mutation. She calls me one morning and says she is more symptomatic and cannot hold on anymore. I admit her to the hospital that day and get a therapeutic thoracentesis for her symptoms of dyspnea. I treat her with one dose of Carboplatin and Pemetrexed in the hospital. She feels better and is discharged home the next day. That afternoon the plasma based NGS comes back showing the EGFR L858R mutation, and the next week she is started on osimertinib.

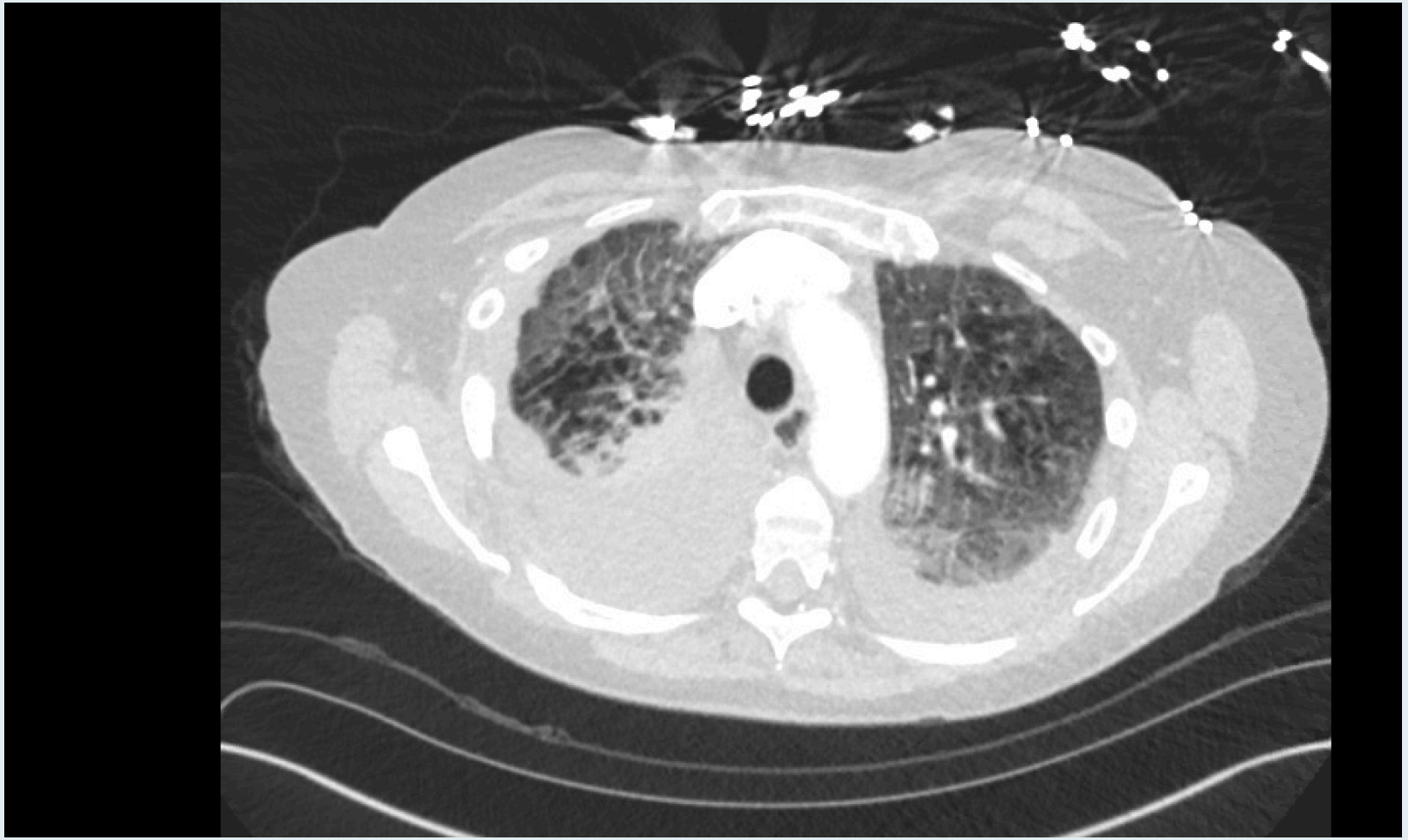
Sulfi Ibrahim, MD

Case Presentation — Dr Ibrahim: 67-year-old woman with metastatic adenocarcinoma of the lung (cont)

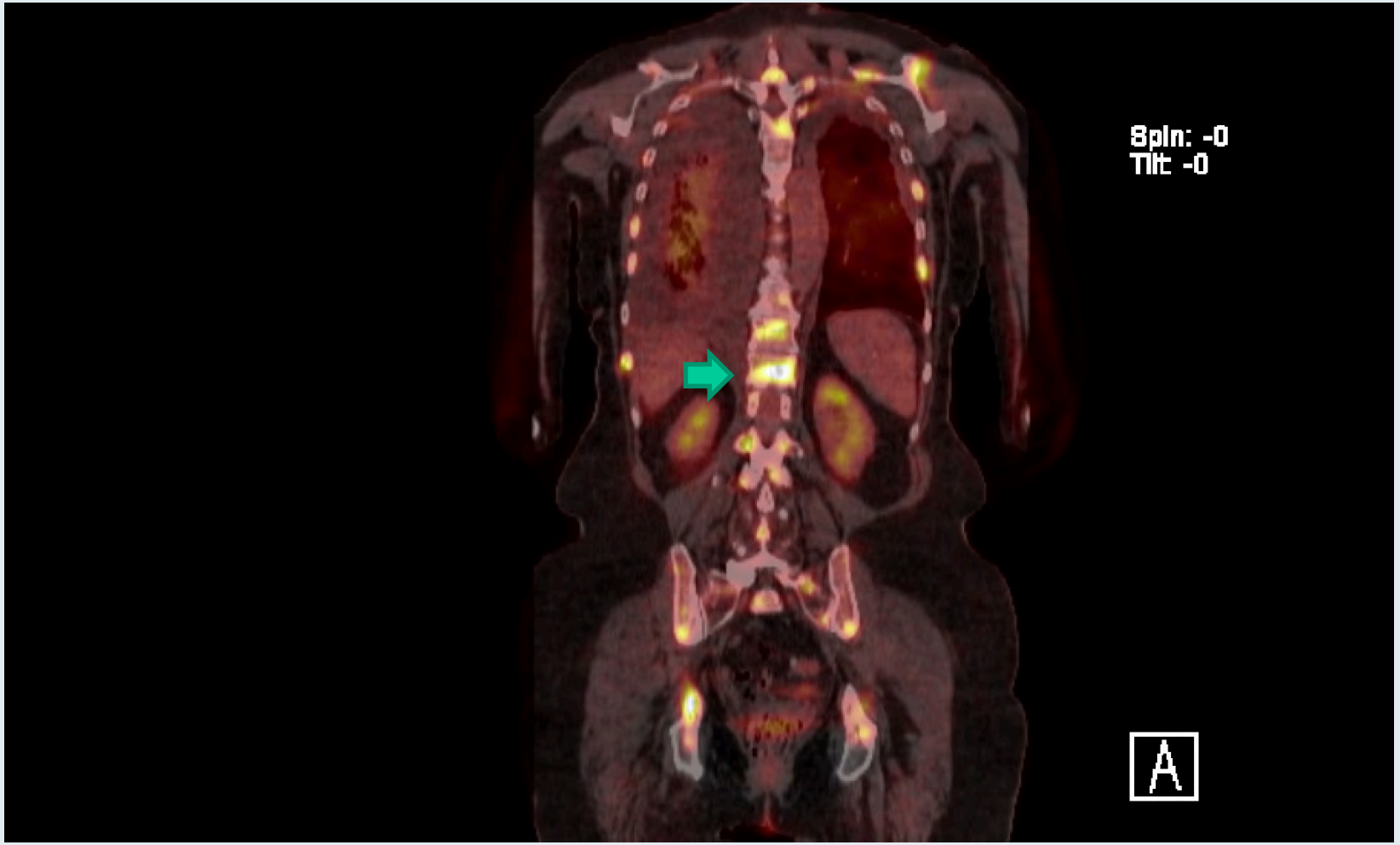
I had a virtual visit with her last week. She is tolerating Osimertinib well and reports she is now barely using her oxygen

Questions are regarding the management of a patient who needs treatment but does not have the time for the NGS to come back. Would you give her bevacizumab with the chemo given her pleural effusions and would you give her bevacizumab now with the osimertinib?

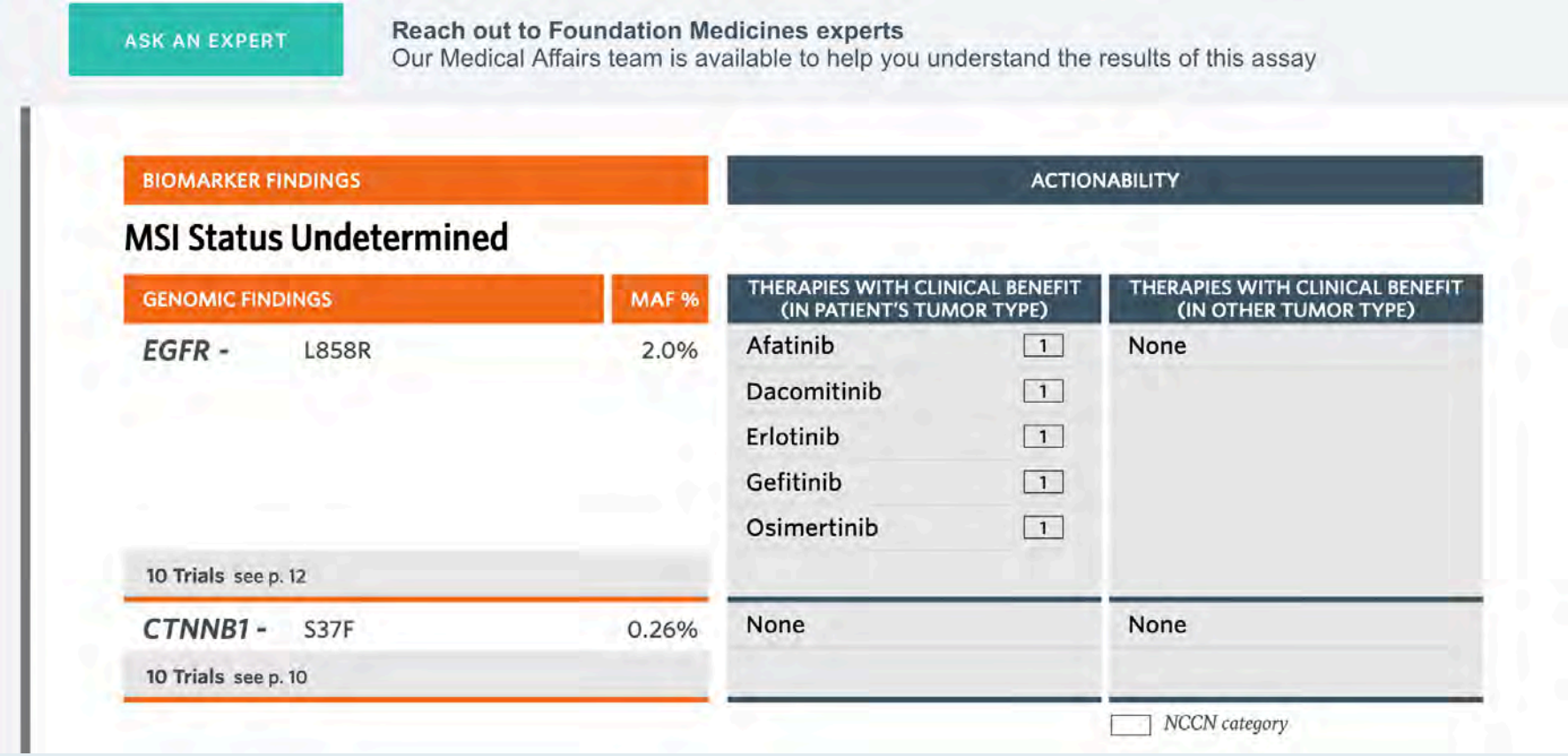
Case Presentation — Dr Ibrahim: 67-year-old woman with metastatic adenocarcinoma of the lung (cont) – CT scan showing left pleural effusion and infiltrates



Case Presentation — Dr Ibrahim: 67-year-old woman with metastatic adenocarcinoma of the lung (cont) – PET CT with bone lesion



Case Presentation — Dr Ibrahim: 67-year-old woman with metastatic adenocarcinoma of the lung (cont) – Plasma NGS



ASK AN EXPERT

Reach out to Foundation Medicines experts
Our Medical Affairs team is available to help you understand the results of this assay

BIOMARKER FINDINGS

MSI Status Undetermined

GENOMIC FINDINGS		MAF %	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
EGFR -	L858R	2.0%	Afatinib 1 Dacomitinib 1 Erlotinib 1 Gefitinib 1 Osimertinib 1	None
10 Trials see p. 12				
CTNNB1 -	S37F	0.26%	None	None
10 Trials see p. 10				

ACTIONABILITY

NCCN category

Regulatory and reimbursement issues aside, which adjuvant systemic therapy would you generally recommend for a patient with Stage IIB nonsquamous NSCLC and an EGFR exon 19 deletion?

1. Chemotherapy
2. Osimertinib
3. Chemotherapy followed by osimertinib
4. Other

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For a patient with metastatic nonsquamous NSCLC with an EGFR exon 19 deletion and a PD-L1 TPS of 60% who receives first-line osimertinib with response followed by disease progression, would you recommend repeat mutation testing? What treatment would you recommend if no further actionable mutations were identified?

	Recommend repeat testing?	Second-line treatment
 JOHN V HEYMACH, MD, PHD	Yes, tissue	Atezo/carbo/paclitaxel + bev
 LEORA HORN, MD, MSC	Yes, liquid; if negative, tissue	Carbo/pemetrexed
 COREY J LANGER, MD	Yes, liquid and tissue	Continue osimertinib, add carbo/pemetrexed/bev*
 BENJAMIN LEVY, MD	Yes, liquid and tissue	Atezo/carbo/paclitaxel + bev
 JOEL W NEAL, MD, PHD	Yes, tissue	Pembro/carbo/pemetrexed or Atezo/carbo/paclitaxel + bev
 NATHAN A PENNELL, MD, PHD	Yes, tissue	Pembro/carbo/pemetrexed
 DAVID R SPIGEL, MD	Yes, liquid	Continue osimertinib, add carbo/pemetrexed

Atezo = atezolizumab; carbo = carboplatin; bev = bevacizumab; pembro = pembrolizumab

* Atezo/carbo/paclitaxel + bev if very symptomatic

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Key Data Sets

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

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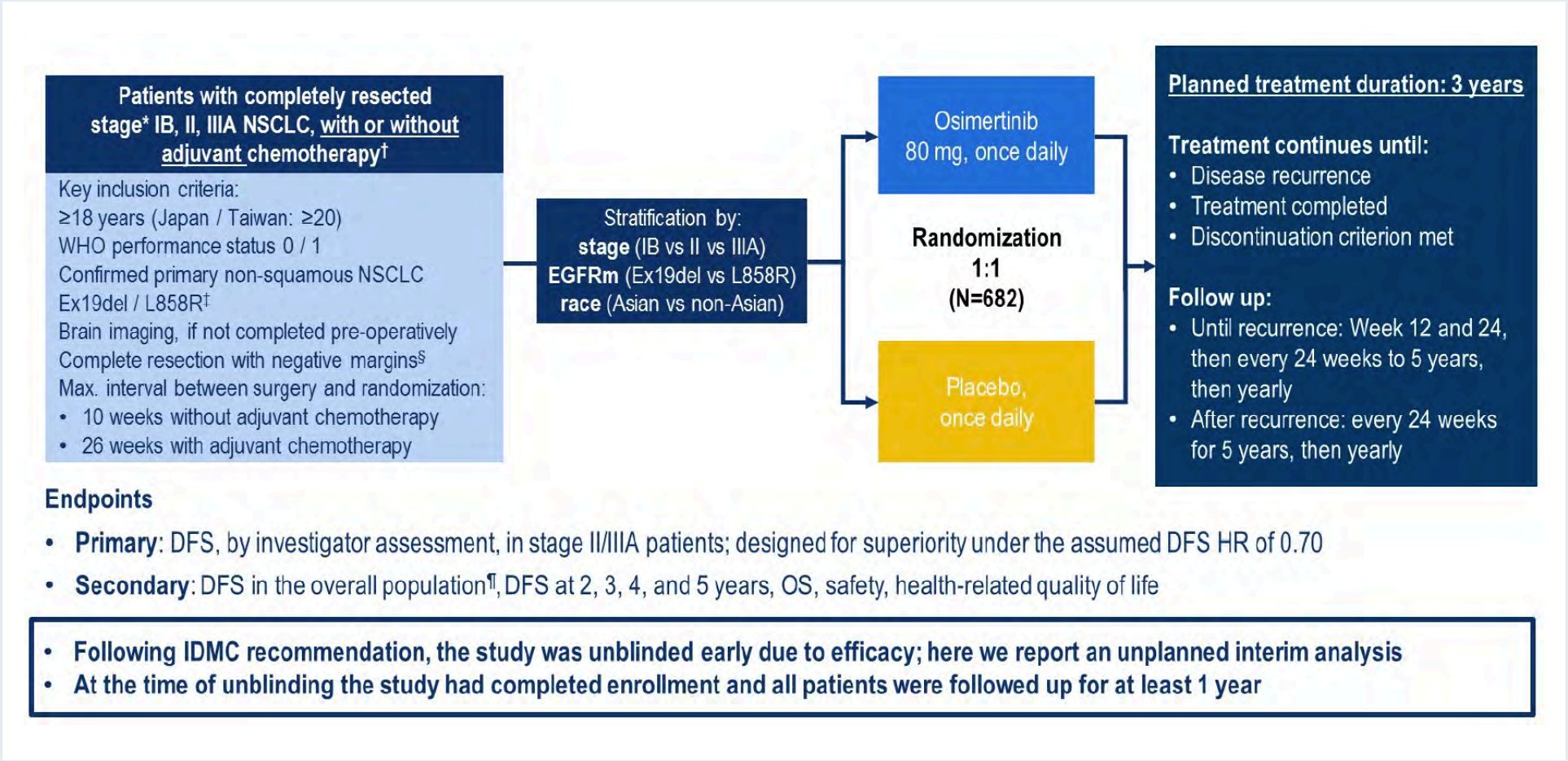
ADAURA Phase III Trial Schema



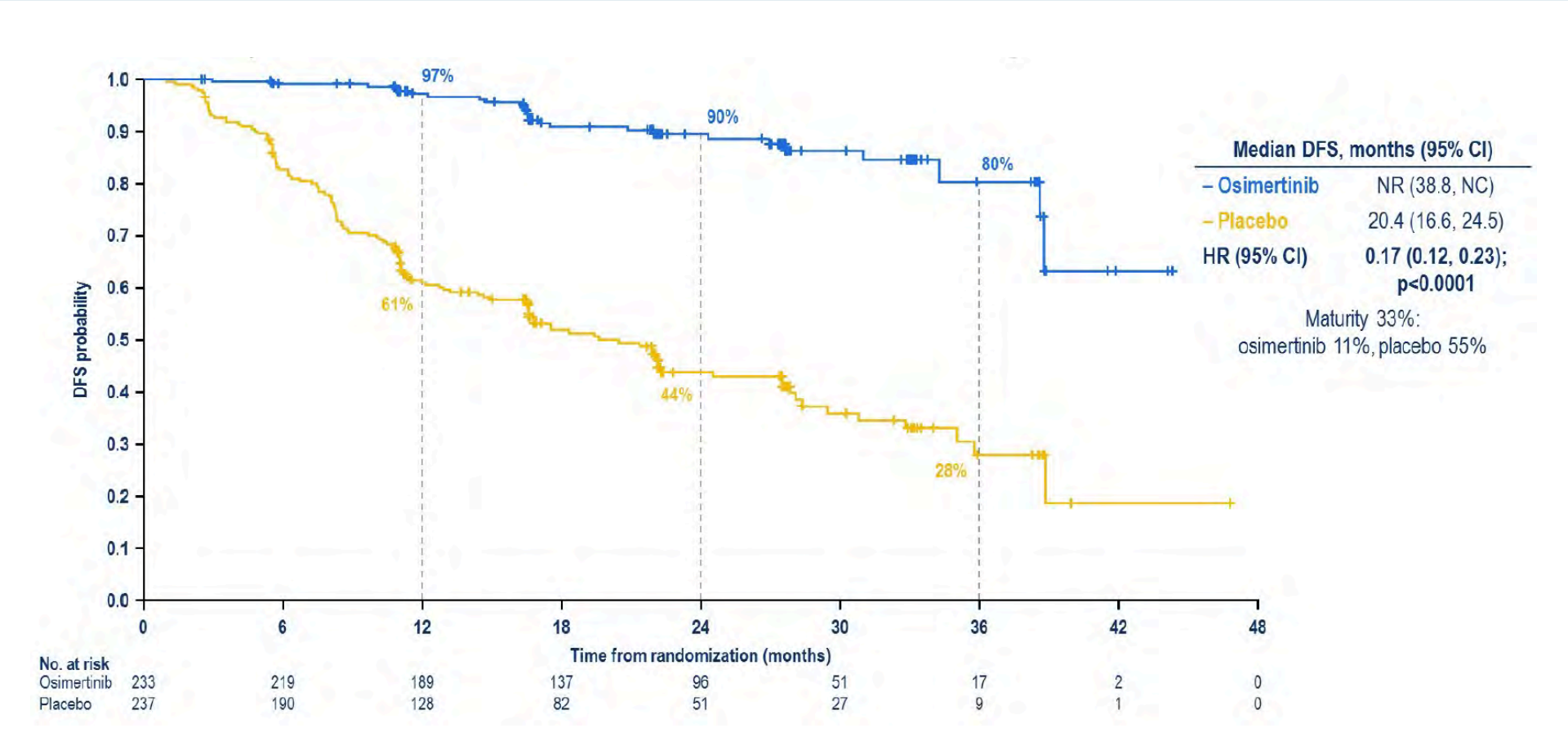
Endpoints

- **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**

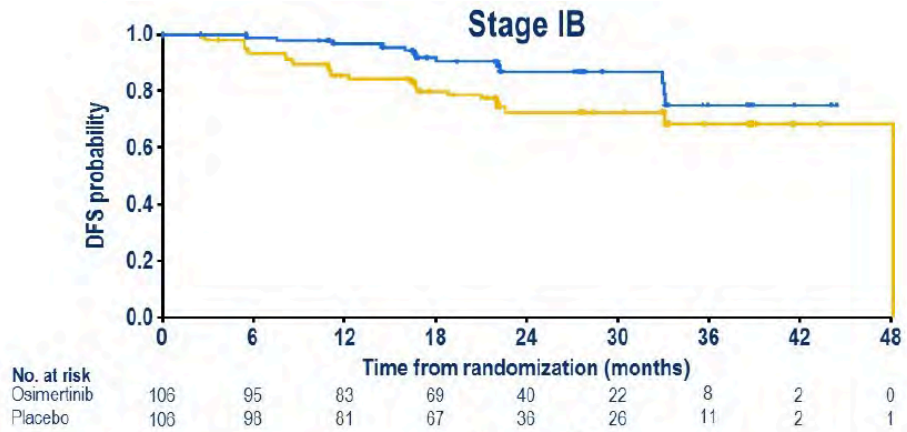
Herbst RS et al. ASCO 2020;Abstract LBA5.

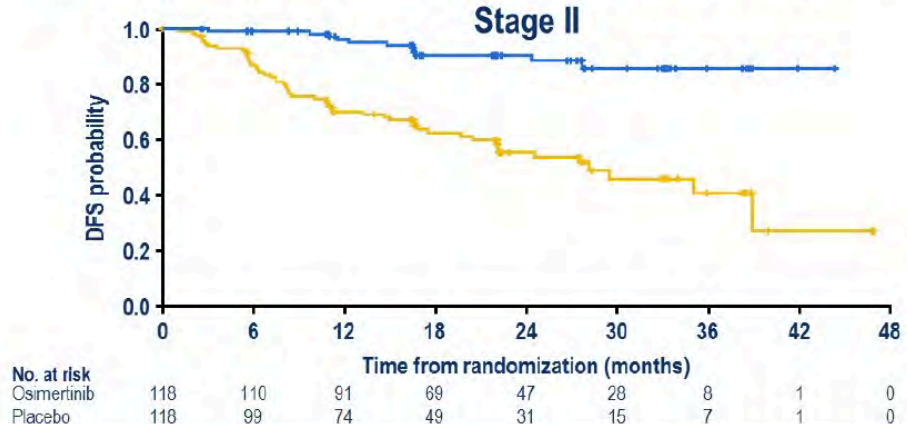
ADAURA Primary Endpoint: Inv-Assessed DFS (Stage II/IIIA)



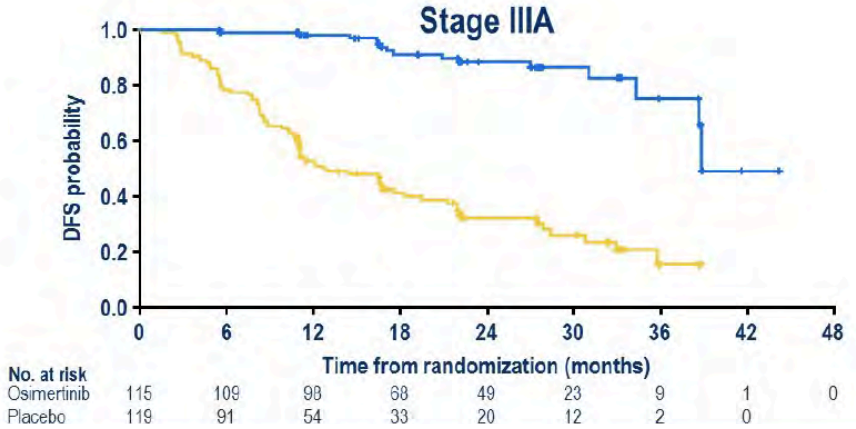
Herbst RS et al. ASCO 2020;Abstract LBA5.

ADAURA: DFS by Stage



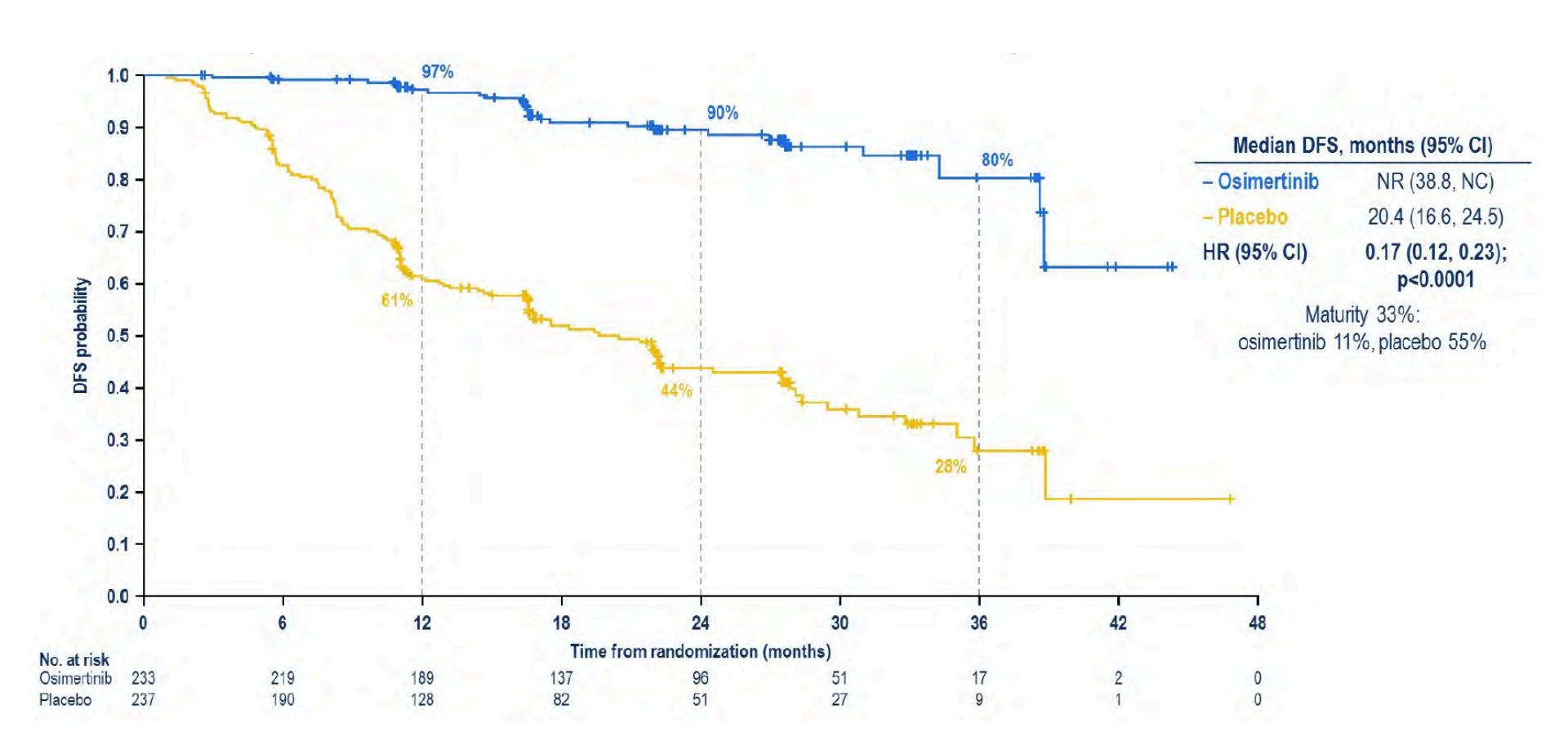


	Stage IB	Stage II	Stage IIIA
2 year DFS rate, % (95% CI)			
– Osimertinib	87 (77, 93)	91 (82, 95)	88 (79, 94)
– Placebo	73 (62, 81)	56 (45, 65)	32 (23, 42)
Overall HR (95% CI)	0.50 (0.25, 0.96)	0.17 (0.08, 0.31)	0.12 (0.07, 0.20)



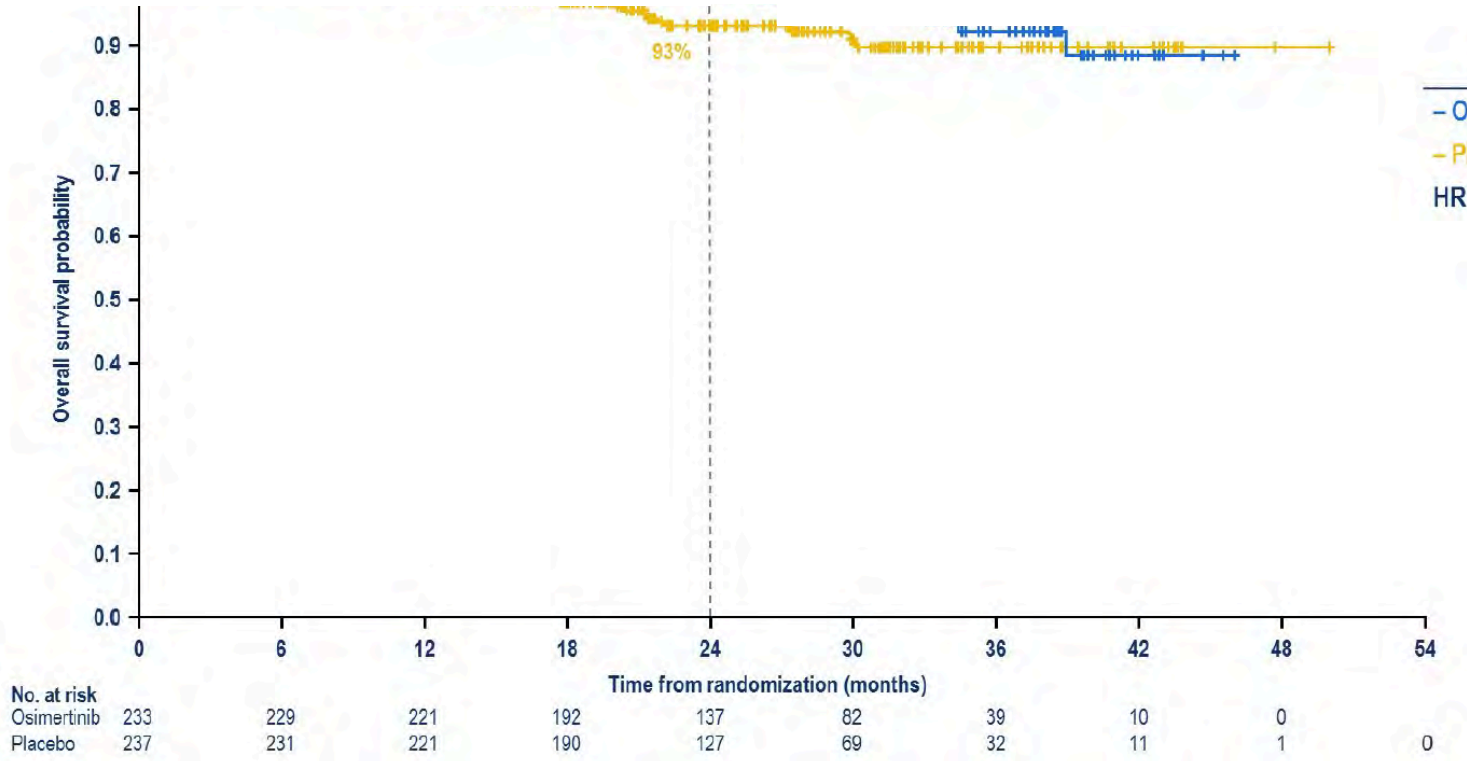
Herbst RS et al. ASCO 2020;Abstract LBA5.

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



Herbst RS et al. ASCO 2020;Abstract LBA5.

ADAURA: Early Snapshot of OS (Stage II/IIIA)



Herbst RS et al. ASCO 2020;Abstract LBA5.

ADAURA: Safety Summary

AE, any cause*, n (%)	Osimertinib (n=336)	Placebo (n=343)
Any AE	327 (97)	306 (89)
Any AE Grade ≥3	68 (20)	48 (14)
Any AE leading to death	0	1 (<1)
Any serious AE	54 (16)	44 (13)
Any AE leading to discontinuation	38 (11)	15 (4)
Any AE leading to dose reduction	25 (7)	2 (1)
AE, possibly causally related†, n (%)		
Any AE	303 (90)	190 (55)
Any AE Grade ≥3	32 (10)	9 (3)
Any AE leading to death	0	0
Any serious AE	9 (3)	2 (1)

Herbst RS et al. ASCO 2020;Abstract LBA5.

Phase II Randomized Trial of Carboplatin + Pemetrexed + Bevacizumab, +/- Atezolizumab in Stage IV Non-Squamous Non-Small Lung Cancer (NSCLC) Patients who Harbor a Sensitizing EGFR Mutation or Have Never Smoked

Bodor JN et al.

ASCO 2020;Abstract TPS9629.

Meet The Professor with Dr Horn

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Case Presentation — Dr Morganstein: A 59-year-old man with metastatic squamous cell carcinoma of the lung

- Locally advanced squamous cell cancer and solitary metastasis to abdominal wall, which was resected
- NGS: KRAS G12C mutation, PD-L1: 10%
- Carboplatin/*nab* paclitaxel/pembrolizumab, with excellent response
- Currently on pembrolizumab maintenance

Questions

- In limited-stage metastatic disease or metastatic Stage IV NED, is there any role for thoracic radiation as a consolidative measure?
- Where do we fit in first-line VEGF therapy? Is anybody using 4-drug therapy in the first-line setting?
- What does the KRAS G12C mutation mean? How often is that seen in clinical practice? Is there a prognostic significance to that? When AMG 510 comes out, where would that get sequenced?

Neil Morganstein, MD

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Would you offer a checkpoint inhibitor to a patient with metastatic NSCLC who had undergone a liver transplant in the past and had exhausted all treatment options?

1. Yes
2. No

Case Presentation — Dr Morganstein: A 72-year-old man with metastatic adenocarcinoma of the lung

- History of liver transplant 15 years ago
- Presented with stage IV adenocarcinoma with pleural and bone disease
- PD-L1: 80%
- NGS on tissue was normal
- Liquid biopsy: BRAF V600E at 0.2%
- Currently doing well on carboplatin and pemetrexed, with a plan for maintenance pemetrexed

Questions

- How do you deal with discordance between liquid biopsy and tissue NGS?
- How to interpret the percent positive on liquid biopsy?
- What is the role of BRAF inhibitor in first-line treatment and later lines?
- If he is running out of options is immunotherapy out of the question?

Neil Morganstein, MD

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Which first-line treatment regimen would you recommend for a patient with metastatic nonsquamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 10%? Of 60%?

	TPS of 10%		TPS of 60%	
	Age 65	Age 80	Age 65	Age 80
 JOHN V HEYMACH, MD, PHD	Pembro/carbo/pem	Pembro	Pembro	Pembro
 LEORA HORN, MD, MSC	Pembro/carbo/pem	Pembro or hospice	Pembro	Pembro
 COREY J LANGER, MD	Pembro/carbo/pem	Pembro	Pembro*	Pembro
 BENJAMIN LEVY, MD	Pembro/carbo/pem	Pembro	Pembro	Pembro
 JOEL W NEAL, MD, PHD	Pembro/carbo/pem	Pembro	Pembro +/- carbo/pem	Pembro
 NATHAN A PENNELL, MD, PHD	Pembro/carbo/pem	Pembro/carbo/pem†	Pembro	Pembro
 DAVID R SPIGEL, MD	Pembro/carbo/pem	Pembro/carbo/pem	Pembro	Pembro

Pem = pemetrexed

* If very symptomatic, pembro/carbo/pem; † Likely dose-reduced chemotherapy

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Which first-line treatment regimen would you recommend for a patient with metastatic squamous lung cancer, no identified targetable mutations and a PD-L1 TPS of 10%?
Of 60%?

	TPS of 10%		TPS of 60%	
	Age 65	Age 80	Age 65	Age 80
 JOHN V HEYMACH, MD, PHD	Pembro/carbo/ *nab*-P	Pembro	Pembro	Pembro
 LEORA HORN, MD, MSC	Pembro/carbo/ *nab*-P	Pembro/carbo/*nab*-P	Pembro	Pembro
 COREY J LANGER, MD	Pembro/carbo/*nab*-P	Pembro/carbo/*nab*-P	Pembro	Pembro
 BENJAMIN LEVY, MD	Pembro/carbo/ *nab*-P	Pembro/carbo/P	Pembro	Pembro
 JOEL W NEAL, MD, PHD	Pembro/carbo/ *nab*-P or P	Pembro/carbo/*nab*-P	Pembro +/- carbo/ *nab*-P or P	Pembro+/- carbo/ *nab*-P
 NATHAN A PENNELL, MD, PHD	Pembro/carbo/*nab*-P	Pembro/carbo/P	Pembro	Pembro
 DAVID R SPIGEL, MD	Pembro/carbo/*nab*-P	Pembro/carbo/*nab*-P	Pembro	Pembro

Nab-P = nanoparticle albumin-bound paclitaxel; P = paclitaxel

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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	Partial clinical response
 JOHN V HEYMACH, MD, PHD	2 years	Indefinitely or until PD/toxicity
 LEORA HORN, MD, MSC	2 years	2 years
 COREY J LANGER, MD	2 years (min)	2 years (min)
 BENJAMIN LEVY, MD	Indefinitely or until PD/toxicity	Indefinitely or until PD/toxicity
 JOEL W NEAL, MD, PHD	2 years	2 years
 NATHAN A PENNELL, MD, PHD	2 years	2 years
 DAVID R SPIGEL, MD	Likely 2 years but CR duration dependent	Indefinitely or until PD/toxicity

PD = progressive disease

RTP RESEARCH TO PRACTICE

Key Data Sets

FDA-Approved Immunotherapy Options for the First-Line Treatment of Metastatic NSCLC

Combination regimen	FDA approval	Pivotal study	Histologic type	HR (OS)
Pembrolizumab + Platinum and pemetrexed[1]	8/20/18	KEYNOTE-189	Nonsquamous	0.49
Pembrolizumab + Carboplatin, paclitaxel or *nab* paclitaxel[2]	10/30/18	KEYNOTE-407	Squamous	0.64
Atezolizumab + Carboplatin and paclitaxel and bevacizumab[3]	12/6/18	IMpower150	Nonsquamous	0.78
Atezolizumab + Carboplatin and *nab* paclitaxel[4]	12/3/19	IMpower130	Nonsquamous	0.79
Nivolumab + Ipilimumab[5]	5/15/20	CheckMate-227	PD-L1 TPS≥1, EGFR and/or ALK *wt*	0.62
Nivolumab + Ipilimumab and chemotherapy[6]	5/26/20	CheckMate-9LA	EGFR and/or ALK *wt*	0.69
Monotherapy	**FDA approval**	**Pivotal study**	**Histologic type**	**HR (OS)**
Pembrolizumab[7,8]	4/11/19 10/24/16	KEYNOTE-042 KEYNOTE-024	PD-L1 TPS≥1%	0.63
Atezolizumab[9]	5/18/20	IMpower110	PD-L1 TPS≥50, EGFR and/or ALK *wt*	0.59

[1] Gandhi L et al. *NEJM* 2018;378(22):2078-92. [2] Paz-Ares L et al. *NEJM* 2018;379(21):2040-51.
[3] Socinski MA et al. *NEJM* 2018;378(24):2288-301. [4] West H et al. *Lancet Oncol* 2019;20(7):924-37.
[5] Hellmann MD et al. *N Engl J Med* 2019;381(21):2020-31. [6] Reck M et al. ASCO 2020;Abstract 9501.
[7] Mok TSK et al. *Lancet* 2019;393(10183):1819-30. [8] Reck M et al. *J Clin Oncol* 2019;37(7):537-46.
[9] Spigel DR et al. ESMO 2019;Abstract LBA78

FDA approves nivolumab with ipilimumab for first-line mNSCLC (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).

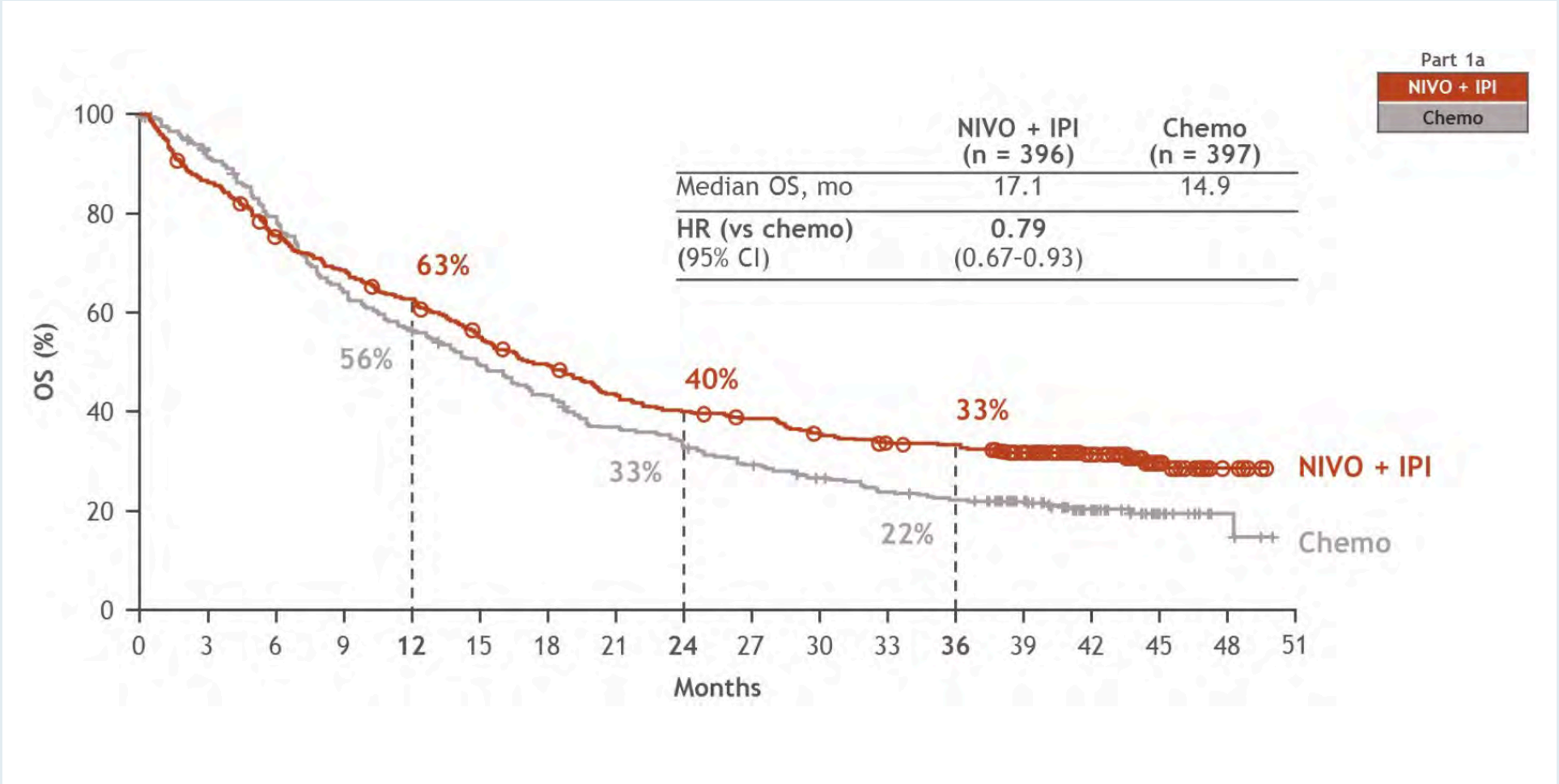
https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-nivolumab-plus-ipilimumab-first-line-mnsclc-pd-l1-tumor-expression-1

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.

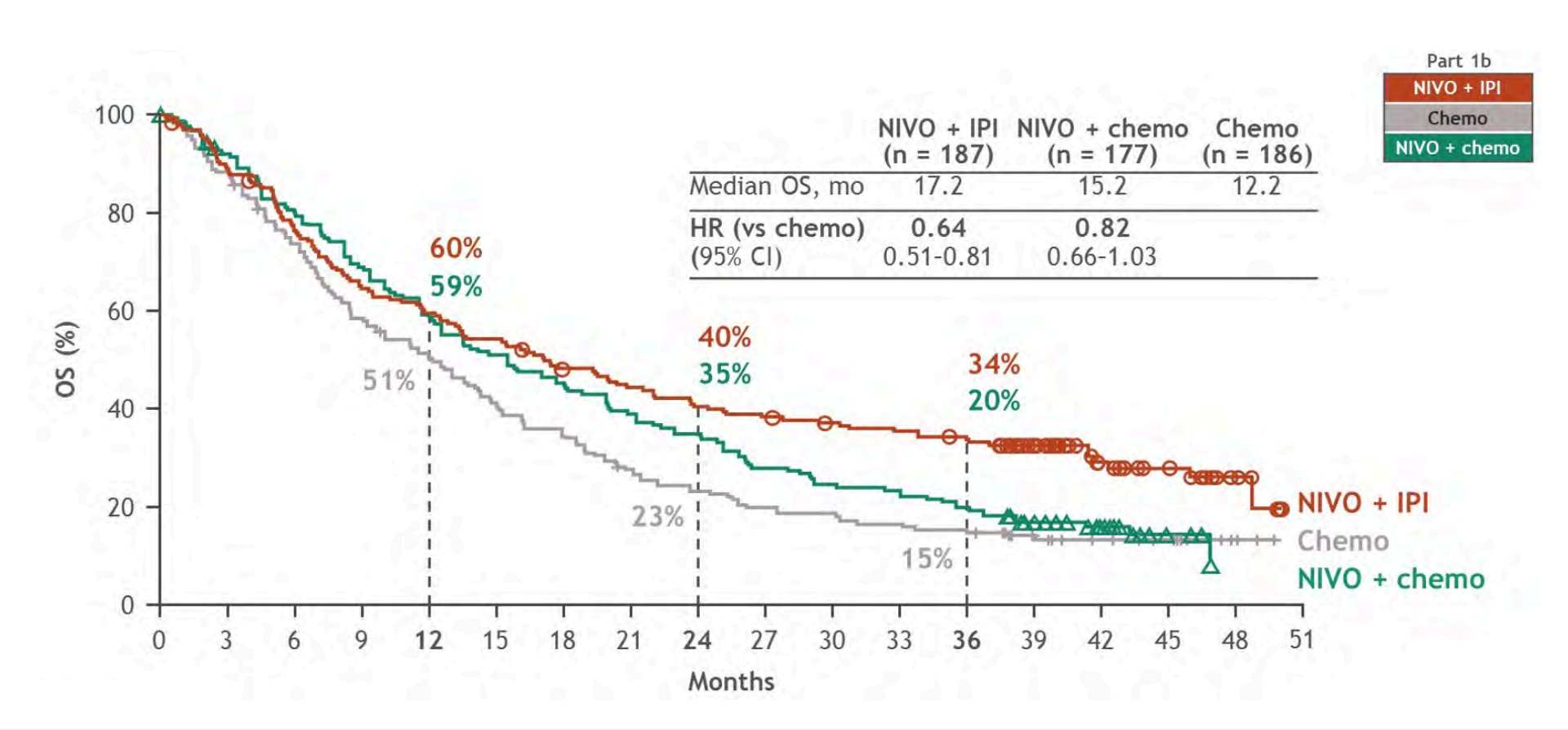
ASCO 2020;Abstract 9500.

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.

Landmark Analysis of OS by Response Status at 6 Months with PD-L1 ≥ 1% (IPI + Nivo vs Chemo)

	Ipi + Nivo (n = 295) versus Chemo (n = 306)			
Response status	Response at 6 mo	1-yr OS rate	2-yr OS rate	3-yr OS rate
CR or PR	39% vs 25%	90% vs 73%	76% vs 51%	70% vs 39%
SD	14% vs 18%	69% vs 54%	45% vs 38%	34% vs 33%
PD	46% vs 58%	44% vs 47%	22% vs 25%	19% vs 17%

Ramalingam SS et al. ASCO 2020;Abstract 9500.

CheckMate 227: Treatment-Related AEs

Select AE	Nivo/Ipi (n = 576)		Chemo (n = 570)	
	Any grade	Grade 3-4	Any grade	Grade 3-4
Diarrhea	17.0%	1.7%	9.6%	0.7%
Rash	17.0%	1.6%	5.3%	0
Fatigue	14.4%	1.7%	18.9%	1.4%
Decreased appetite	13.2%	0.7%	19.6%	1.2%
Nausea	9.9%	0.5%	36.1%	2.1%
Anemia	3.8%	1.4%	33.0%	11.6%
Neutropenia	0.2%	0	17.2%	9.5%

- Treatment-related serious **AEs (any grade)**: 24.5% (Nivo/Ipi) vs 13.9% (chemo)
- Treatment-related AEs leading to **discontinuation (any grade)**: 18.1% (Nivo/Ipi) vs 9.1% (chemo)
- Treatment-related **death (any grade)**: 1.4% (Nivo/Ipi) vs 1.1% (chemo)

Hellmann MD et al. *N Engl J Med* 2019;381(21):2020-31.

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).

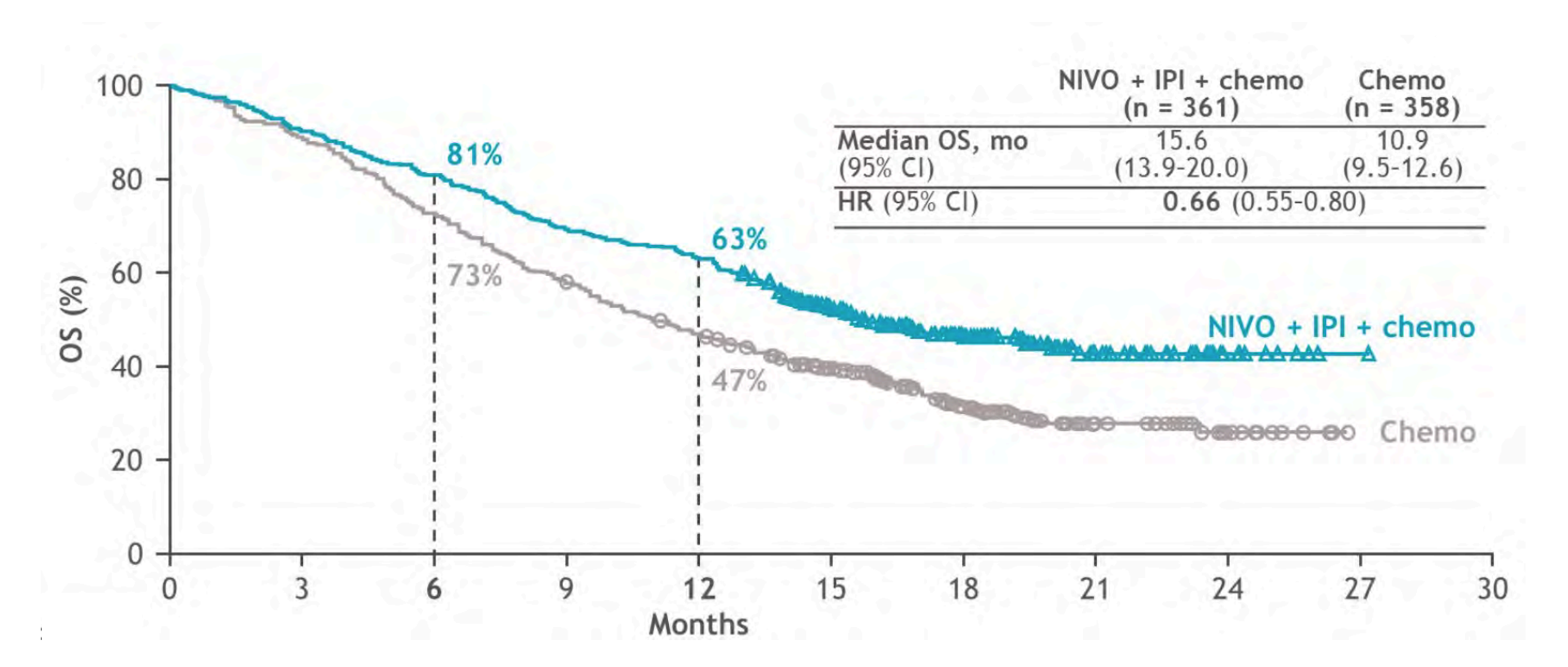
https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-nivolumab-plus-ipilimumab-and-chemotherapy-first-line-treatment-metastatic-nsclc

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.

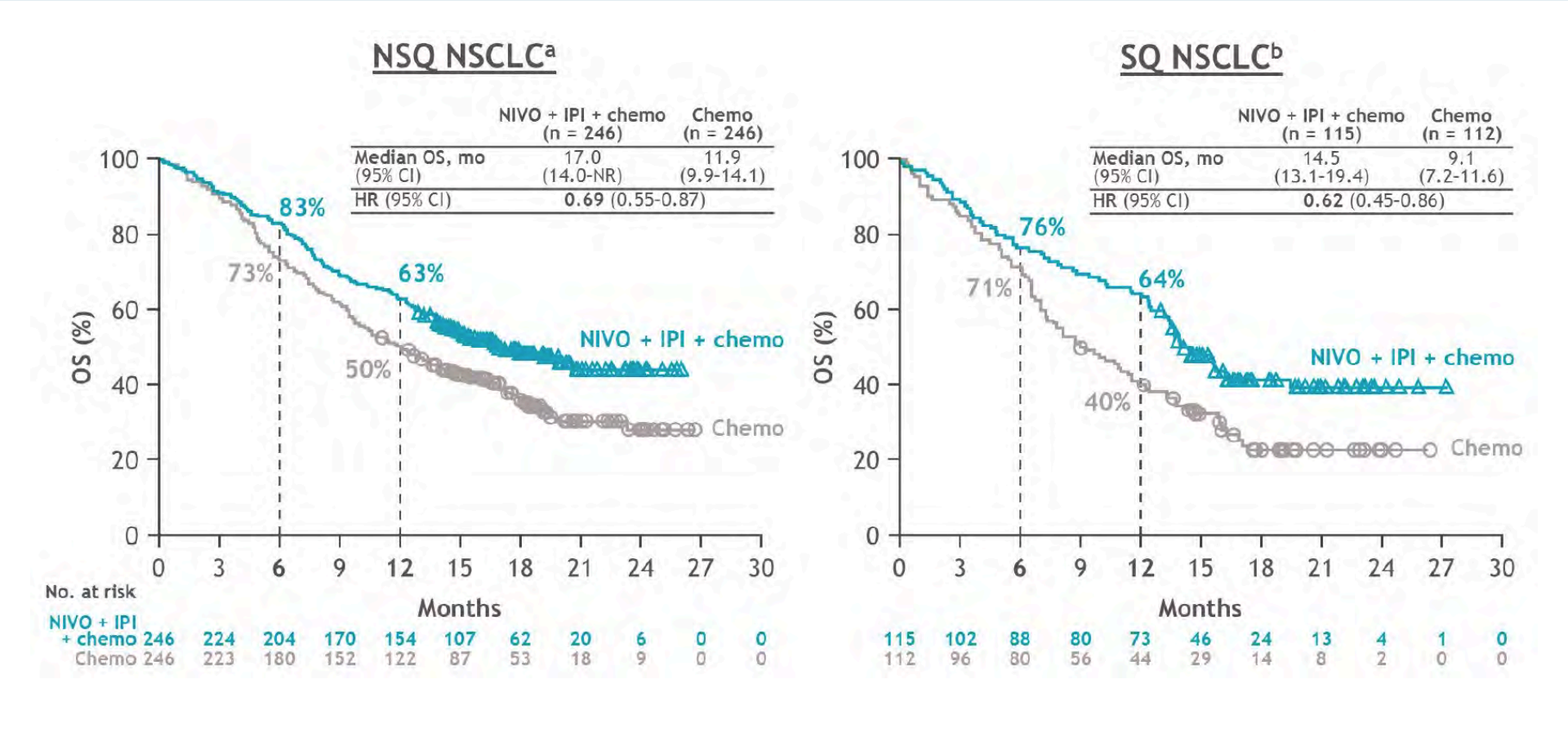
ASCO 2020;Abstract 9501.

CheckMate 9LA: Updated OS



Reck M et al. ASCO 2020;Abstract 9501.

CheckMate 9LA: Updated OS by Histology



Reck M et al. ASCO 2020;Abstract 9501.

CheckMate 9LA: Safety Summary

TRAE,[a] %	NIVO + IPI + chemo (n = 358)		Chemo (n = 349)	
	Any grade	Grade 3-4	Any grade	Grade 3-4
Any TRAE	92	47	88	38
TRAEs leading to discontinuation of any component of the regimen	19	16	7	5
Serious TRAEs	30	25.4	18	15
Treatment-related deaths[b]	2		2	

- Median (range) duration of therapy was 6.1 (0-23.5) months and 2.4 (0-24.0) months for NIVO + IPI + chemo versus chemo, respectively
- Most common any-grade TRAEs (≥ 15%) were nausea, anemia, asthenia and diarrhea

Reck M et al. ASCO 2020;Abstract 9501.

Meet The Professor with Dr Horn

Module 1: Management of Metastatic NSCLC with an EGFR Tumor Mutation

- A 67-year-old woman with metastatic adenocarcinoma of the lung – Dr Ibrahim

Module 2: Anti-PD-1/PD-L1 Antibodies Alone or in Combinations for Metastatic NSCLC

- A 59-year-old man with metastatic squamous cell carcinoma of the lung – Dr Morganstein
- A 72-year-old man with metastatic adenocarcinoma of the lung – Dr Morganstein

Module 3: First-Line Treatment of Extensive-Stage Small Cell Lung Cancer

- A 64-year-old man with extensive-stage small cell lung cancer – Dr Ibrahim

Module 4: Checkpoint Inhibition in the Management of Locally Advanced NSCLC

- A 65-year-old man with locally advanced adenocarcinoma of the lung – Dr Gubens

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Case Presentation — Dr Ibrahim: A 64-year-old man with extensive-stage small cell lung cancer

64-year-old gentleman who presented with symptoms of dyspnea and a palpable left supraclavicular lymph node. Biopsy of supraclavicular node consistent with metastatic small cell lung cancer. Also found to have a left adrenal lesion on PET scan that is hypermetabolic

Started on the IMpower 133 regimen of Carboplatin, Etoposide and Atezolizumab for extensive stage small cell lung cancer. Has good improvement in symptoms with four cycles of therapy, and follow-up imaging shows a good response to therapy. Has prophylactic cranial radiation and is on maintenance Atezolizumab for about four months when he develops disease progression in the mediastinum and adrenal gland

Gets second and third line therapy with weekly Paclitaxel and Topotecan with no response

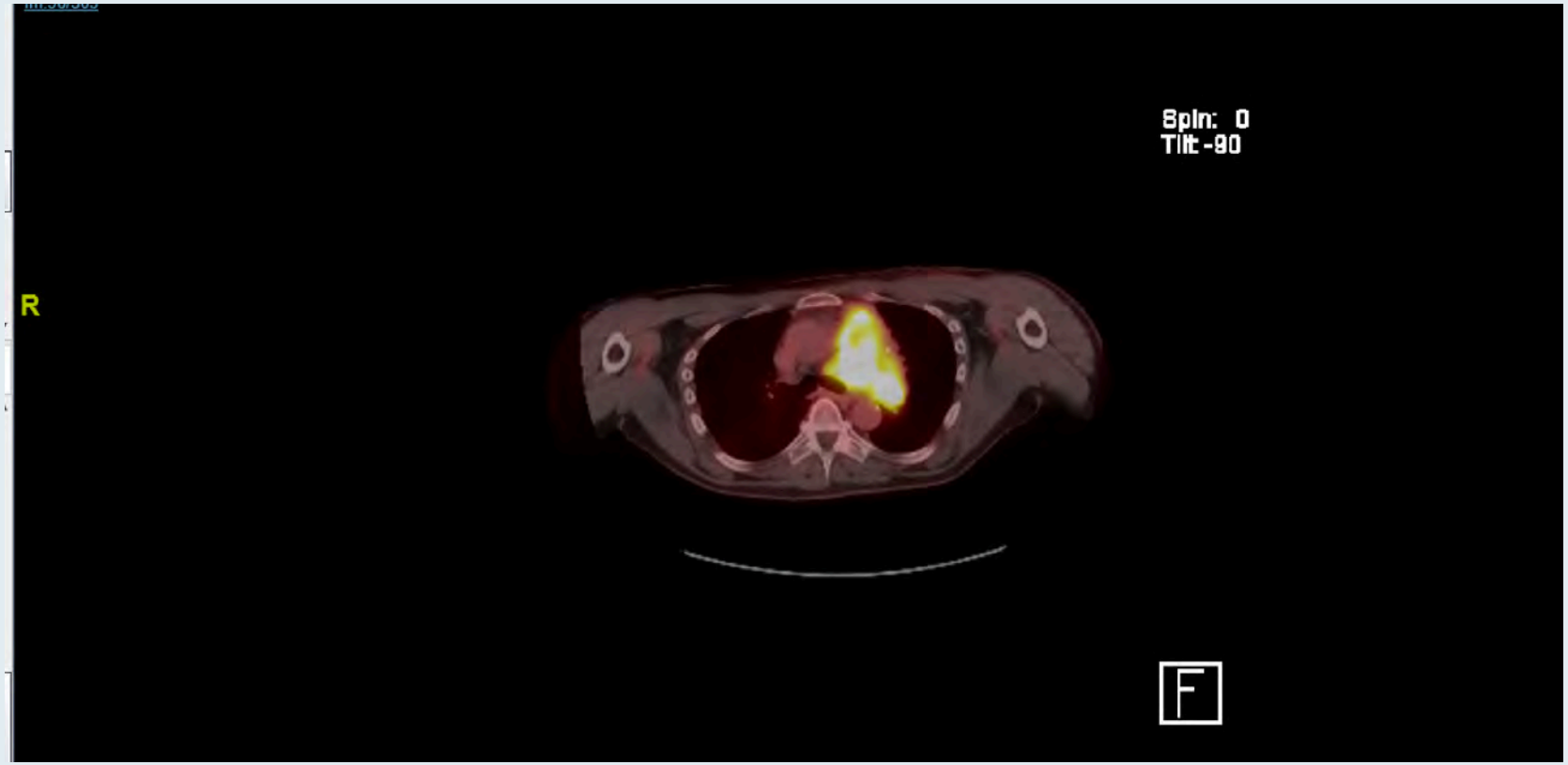
Was started Lurbinectedin three weeks ago. I got it for him on an expanded access program just prior to FDA approval. Has had one cycle with no toxicity issues that he has called us about

Questions:

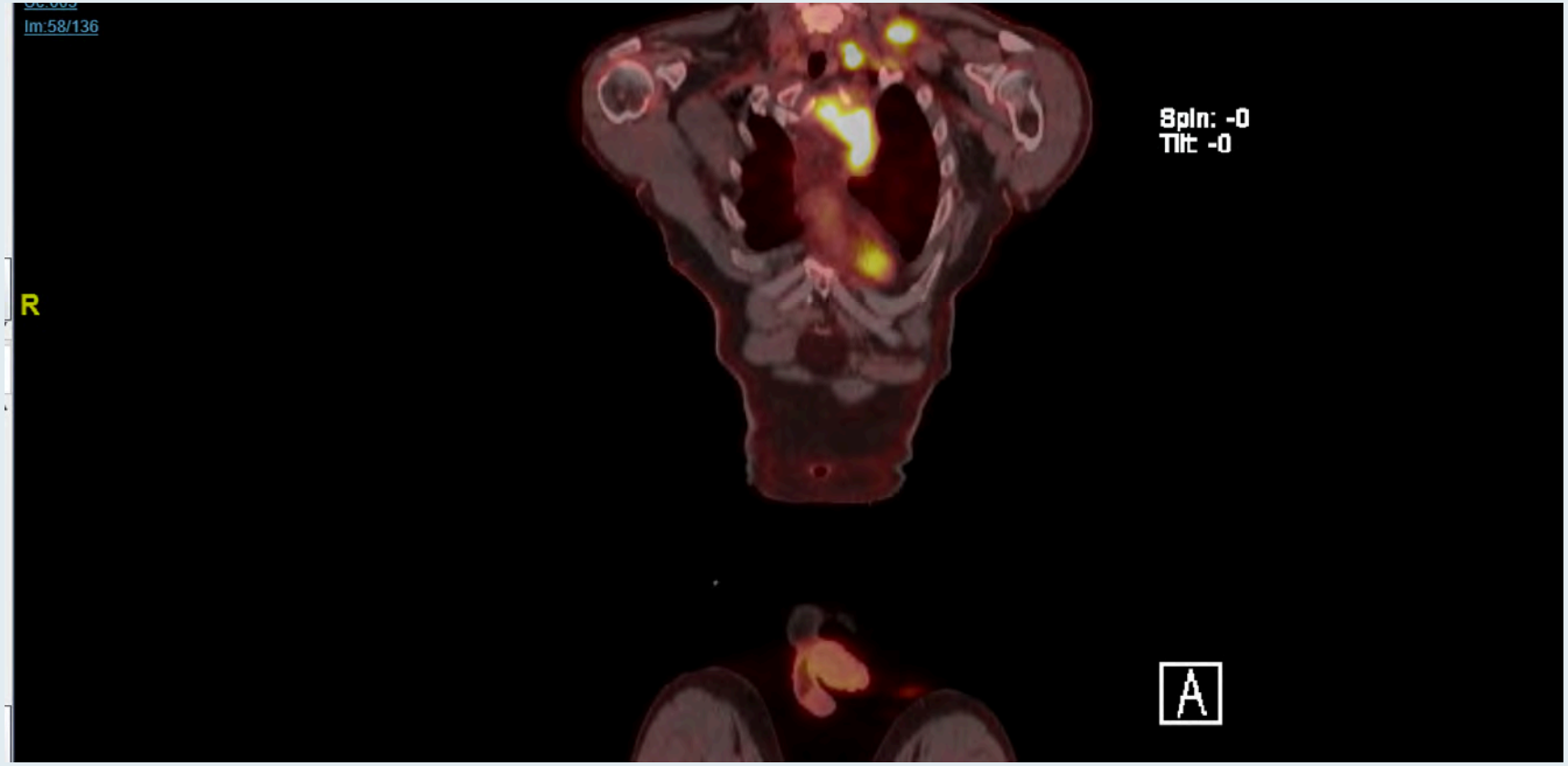
- Is Lurbinectedin now the second line therapy for small cell? Any specific toxicity concerns? Further directions in the development of this agent?

Sulfi Ibrahim, MD

Case Presentation — Dr Ibrahim: A 64-year-old man with extensive-stage small cell lung cancer (cont) – Large left lung mass



Case Presentation — Dr Ibrahim: A 64-year-old man with extensive-stage small cell lung cancer (cont) – Large left lung mass and supraclavicular adenopathy



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 patient with extensive-stage SCLC?

	Age 65	Age 80
 JOHN V HEYMACH, MD, PHD	Carbo/etoposide + atezolizumab	Carbo/etoposide + atezolizumab
 LEORA HORN, MD, MSC	Carbo/etoposide + atezolizumab	Carbo/etoposide + atezolizumab
 COREY J LANGER, MD	Carbo/etoposide + atezolizumab or durvalumab	Carbo/etoposide + durvalumab
 BENJAMIN LEVY, MD	Carbo/etoposide + atezolizumab	Carbo/etoposide + atezolizumab
 JOEL W NEAL, MD, PHD	Carbo/etoposide + atezolizumab	Carbo/etoposide + atezolizumab or durvalumab
 NATHAN A PENNELL, MD, PHD	Carbo/etoposide + atezolizumab	Carbo/etoposide + atezolizumab
 DAVID R SPIGEL, MD	Carbo/etoposide + durvalumab	Carbo/etoposide + durvalumab

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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?

 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
 JOEL W NEAL, MD, PHD	Carboplatin/etoposide + atezolizumab or durvalumab
 NATHAN A PENNELL, MD, PHD	Carboplatin/etoposide
 DAVID R SPIGEL, MD	Carboplatin/etoposide + durvalumab

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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?

 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
 JOEL W NEAL, MD, PHD	Carboplatin/etoposide + atezolizumab or durvalumab
 NATHAN A PENNELL, MD, PHD	Carboplatin/etoposide/atezolizumab
 DAVID R SPIGEL, MD	Carboplatin/etoposide + durvalumab

SIADH = syndrome of inappropriate antidiuretic hormone secretion

RTP RESEARCH TO PRACTICE

Key Data Sets

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.

Randomized Phase II Clinical Trial of Cisplatin/Carboplatin and Etoposide (CE) Alone or in Combination with Nivolumab as Frontline Therapy for Extensive-Stage Small Cell Lung Cancer (ES-SCLC): ECOG-ACRIN EA5161

Leal T et al.

ASCO 2020;Abstract 9000.

KEYNOTE-604: Pembrolizumab (Pembro) or Placebo Plus Etoposide and Platinum (EP) as First-Line Therapy for Extensive-Stage (ES) Small-Cell Lung Cancer (SCLC)

Rudin CM et al.

ASCO 2020;Abstract 9001.

Durvalumab +/- Tremelimumab + Platinum-Etoposide in First-Line Extensive-Stage SCLC (ES-SCLC): Updated Results from the Phase III CASPIAN Study

Paz-Ares LG et al.

ASCO 2020;Abstract 9002.

Meet The Professor with Dr Horn

Module 1: Management of Metastatic NSCLC with an EGFR Tumor Mutation

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- A 65-year-old man with locally advanced adenocarcinoma of the lung – Dr Gubens

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What additional treatment, if any, would you recommend to a patient who had just completed chemoradiation therapy for unresectable Stage IIIB adenocarcinoma and had an ALK fusion mutation?

1. None
2. Durvalumab
3. Durvalumab followed by an ALK inhibitor
4. Durvalumab + ALK inhibitor
5. ALK inhibitor

Case Presentation — Dr Gubens: A 65-year-old man with a modest smoking history and locally advanced adenocarcinoma of the lung

- Stage III adenocarcinoma of the lung, with multi-station mediastinal nodes involved; No distant disease
- Chemoradiation, with response
- Molecular profiling: ALK fusion alteration
- Consolidation durvalumab x 1 year
- Currently, under surveillance

Matthew Gubens, MD, MS

RTP RESEARCH TO PRACTICE

Should PD-L1 levels generally be tested in patients with locally advanced NSCLC? In general, do you recommend durvalumab as consolidation treatment for patients with locally advanced NSCLC who have no disease progression after chemoradiation therapy?

		Recommend consolidation durvalumab?		
	Test for PD-L1?	PD-L1 ≤1%	EGFR mutation	ALK rearrangement
 JOHN V HEYMACH, MD, PHD	No	Yes	Yes	Yes
 LEORA HORN, MD, MSC	No	Yes	No	No
 COREY J LANGER, MD	Yes	Yes	Yes	Yes
 BENJAMIN LEVY, MD	Yes	Yes	Yes	Yes
 JOEL W NEAL, MD, PHD	Yes	Yes	Yes	No
 NATHAN A PENNELL, MD, PHD	No	Yes	Yes	Yes
 DAVID R SPIGEL, MD	No	Yes	Yes	Yes

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A patient who successfully received chemoradiation therapy for locally advanced NSCLC is about to start durvalumab. Pretreatment imaging shows changes consistent with radiation effect. Would you use durvalumab?

In general, would you recommend consolidation durvalumab for similar patients who are experiencing mild esophagitis or mildly symptomatic pneumonitis?

	Radiation effect	Mild esophagitis	Mildly symptomatic pneumonia
 JOHN V HEYMACH, MD, PHD	Yes	Yes	No
 LEORA HORN, MD, MSC	Yes	Yes	No, wait until improvement
 COREY J LANGER, MD	Yes	Yes	Yes*
 BENJAMIN LEVY, MD	Yes	Yes	Yes
 JOEL W NEAL, MD, PHD	Yes	Yes	Yes
 NATHAN A PENNELL, MD, PHD	Yes	Yes	No
 DAVID R SPIGEL, MD	Yes	Yes	Yes

* If Grade 1 and do not require steroids

RTP RESEARCH TO PRACTICE

Key Data Sets

Real-World Rates of Pneumonitis After Consolidation Durvalumab

Real-World Survey of Pneumonitis/Radiation Pneumonitis in LA-NSCLC After Approval of Durvalumab: HOPE-005/CRIMSON Retrospective Cohort Study

- >80% developed pneumonitis
- More than half of them were asymptomatic, but 5% needed HOT and 1.5% developed fatal pneumonitis
- V20 was an independent risk factor for symptomatic pneumonitis (Grade ≥2)
- With careful consideration, durvalumab-rechallenge could be an option after corticosteroid therapy for pneumonitis

Incidence of Pneumonitis in US Veterans with NSCLC Receiving Durvalumab After Chemoradiation Therapy

- In this real-world cohort, clinical significant pneumonitis was:
  - More frequent compared to clinical trial reports
    - Asymptomatic infiltrates on imaging: 39.8%
    - Clinically significant pneumonitis: 21.1%
      - Grade 2 (7.3%), Grade 3 (11.4%), Grade 4 (1.6%), Grade 5 (0.8%)
  - Not associated with increased risk of death

RTP RESEARCH TO PRACTICE

Saito et al. ASCO 2020; Abstract 9039. Thomas T et al. ASCO 2020; Abstract 9034.

Lorlatinib Significantly Improves Progression-Free Survival in First-Line ALK-Positive Lung Cancer

Press Release – August 5, 2020

The Phase 3 CROWN study of lorlatinib in people with previously untreated advanced anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) met its primary endpoint by demonstrating significantly improved progression-free survival (PFS), as compared to crizotinib. The results were reviewed by an independent Data Monitoring Committee (DMC) at a planned interim analysis. The safety profile for lorlatinib and crizotinib were consistent with what has been previously seen in clinical trials.

CROWN is a Phase 3, randomized, open-label, parallel 2-arm study in which 296 people with previously untreated advanced ALK-positive NSCLC were randomized 1:1 to receive lorlatinib monotherapy or crizotinib monotherapy. The primary endpoint of the CROWN trial is PFS based on blinded independent central review (BICR). Secondary endpoints include overall survival, PFS based on investigator's assessment, objective response (OR) based on BICR and on investigator's assessment; intracranial OR (IC-OR), IC time to progression, duration of response (DR), IC-DR, time to tumor response (TTR), IC-TTR (all by BICR); PFS2 based on investigator's assessment, and safety.

https://investors.pfizer.com/investor-news/press-release-details/2020/LORBRENA-lorlatinib-Significantly-Improves-Progression-Free-Survival-in-First-Line-ALK-Positive-Lung-Cancer/default.aspx

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

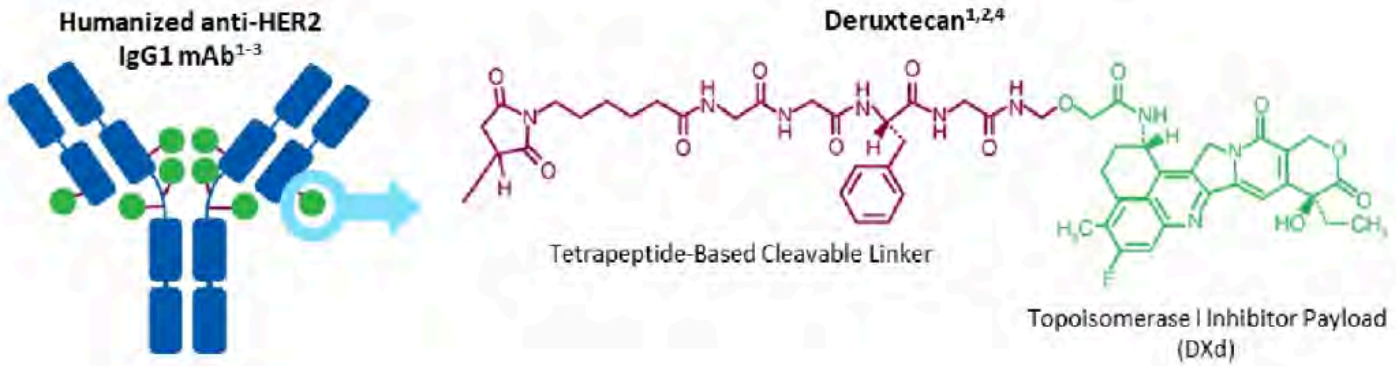
Smit EF et al.

ASCO 2020;Abstract 9504.

Antibody-Drug Conjugate
Trastuzumab Deruxtecan

T-DXd is an ADC with 3 components:

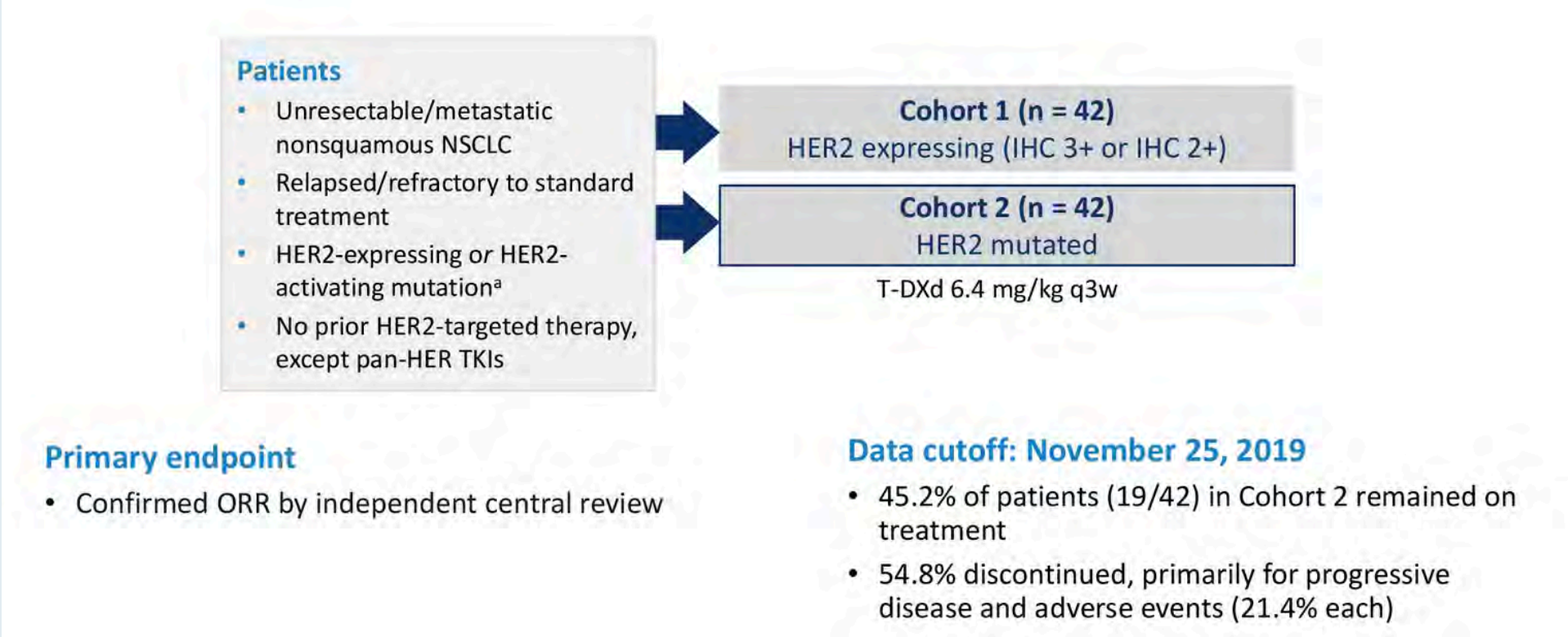
- A humanized anti-HER2 IgG1 mAb with the same amino acid sequence as trastuzumab
- A topoisomerase I inhibitor payload, an exatecan derivative
- A tetrapeptide-based cleavable linker



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

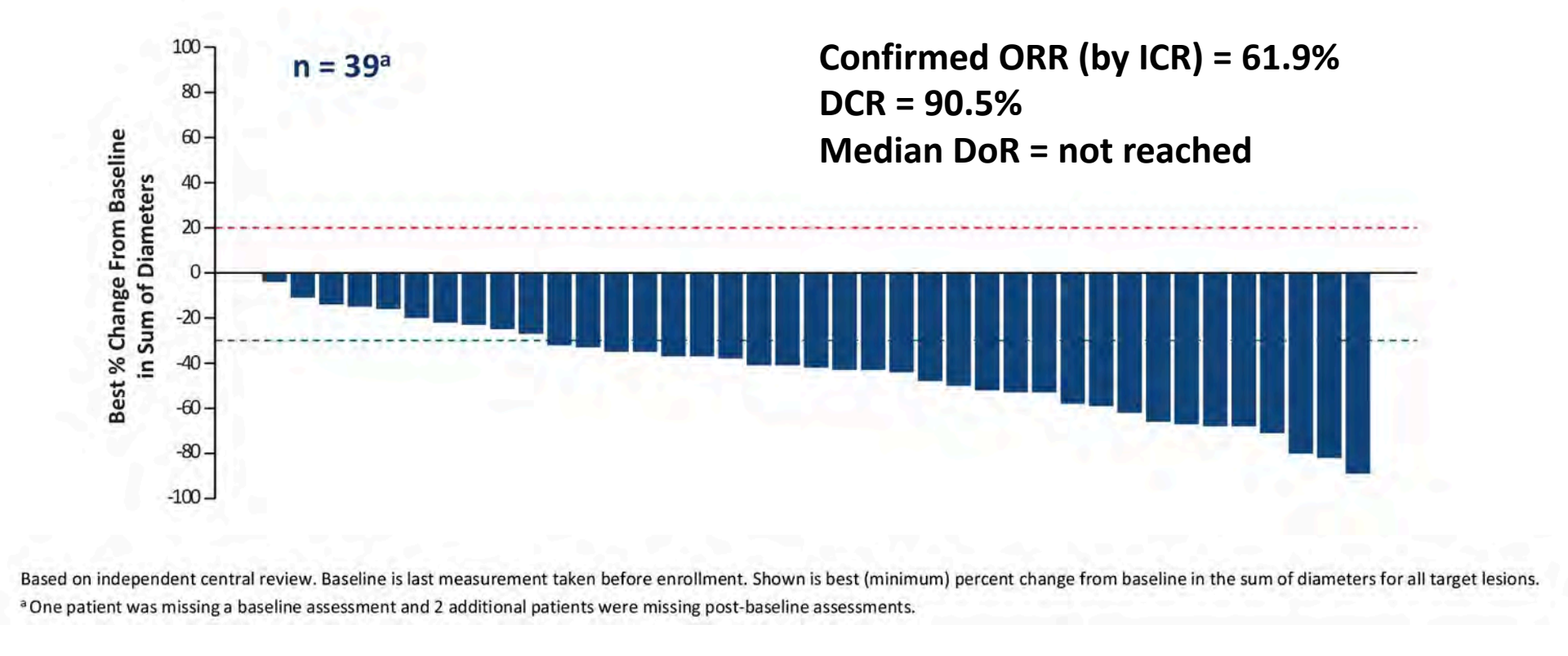
Smit EF et al. *Proc ASCO* 2020;Abstract 9504.

DESTINY-Lung01: Phase II Study Design



Smit EF et al. *Proc ASCO* 2020;Abstract 9504.

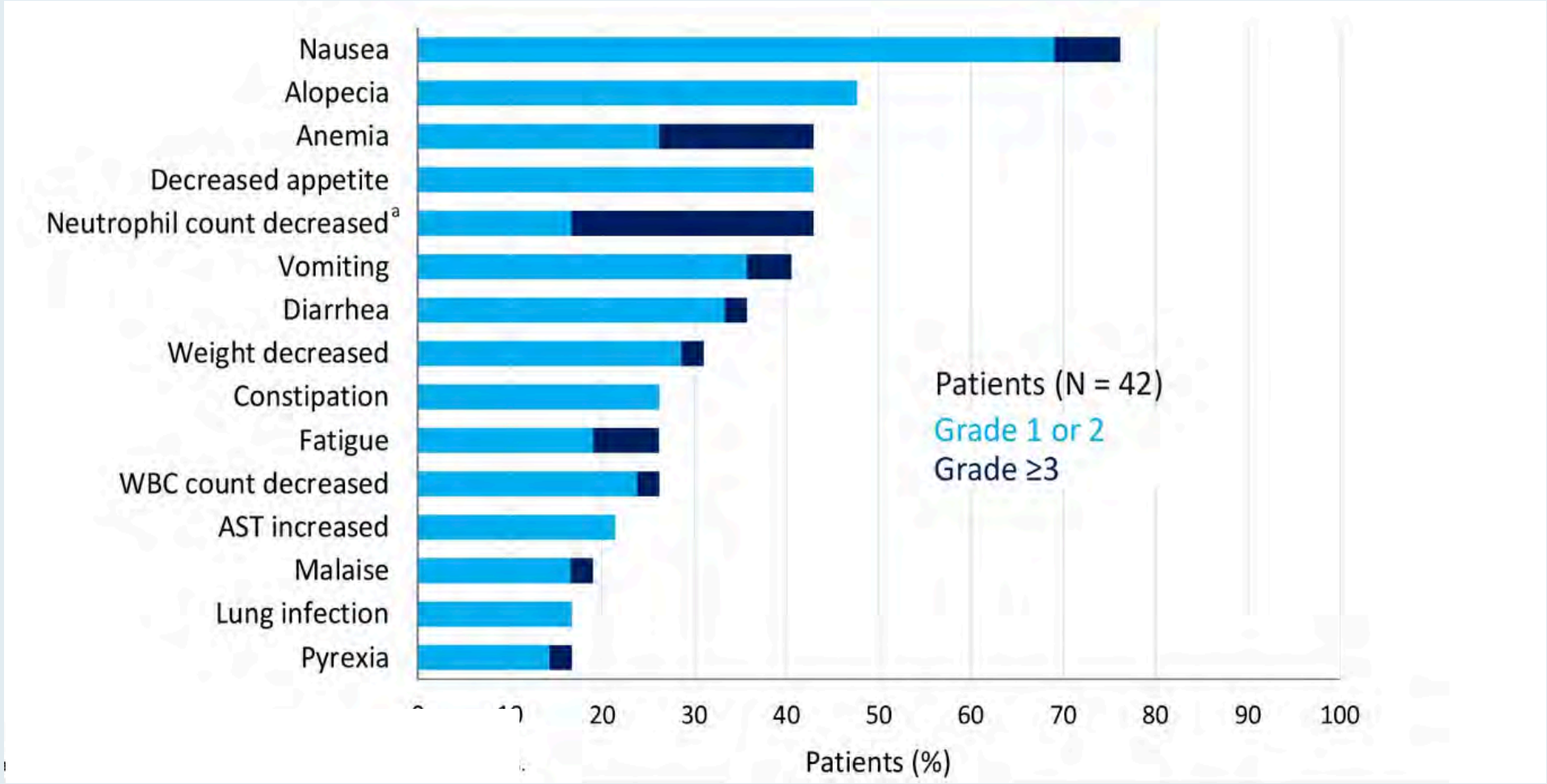
DESTINY-Lung01: Efficacy



- Median PFS = 14.0 mos

Smit EF et al. *Proc ASCO* 2020;Abstract 9504.

DESTINY-Lung01: Treatment-Emergent AEs



Smit EF et al. *Proc 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. *Proc ASCO* 2020;Abstract 9504.

Clinical Investigator Perspectives on the Current and Future Management of Multiple Myeloma

A Meet The Professor Series

Wednesday, August 19, 2020
12:00 PM – 1:00 PM ET

Faculty

Noopur Raje, MD

Moderator

Neil Love, MD

Co-provided by USF Health

RTP RESEARCH TO PRACTICE

Thank you for joining us!

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