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

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Current Questions and Controversies in the Management of Lung Cancer

An Interactive Meet The Professor Series

Lecia V Sequist, MD, MPH
Director, Center for Innovation in Early Cancer Detection
Massachusetts General Hospital Cancer Center
The Landry Family Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Commercial Support

This activity is supported by an educational grant from AstraZeneca Pharmaceuticals LP.

Dr Love — Disclosures

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Dr Sequist — Disclosures

Advisory Committee	AstraZeneca Pharmaceuticals LP, Genentech, a member of the Roche Group, Janssen Biotech Inc
Contracted Research	AstraZeneca Pharmaceuticals LP, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Genentech, a member of the Roche Group, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Novartis
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Patent Pending	In conjunction with Blueprint Medicines

Upcoming Live Webinars

Friday, August 28, 2020
12:00 PM – 1:00 PM ET

Exploring the Role of Immune Checkpoint Inhibitor Therapy and Other Novel Strategies in Gynecologic Cancers

Faculty
Michael J Birrer, MD, PhD

Moderator
Neil Love, MD

Monday, August 31, 2020
12:00 PM – 1:00 PM ET

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

Faculty
Joseph Mikhael, MD

Moderator
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Kerry Rogers, MD

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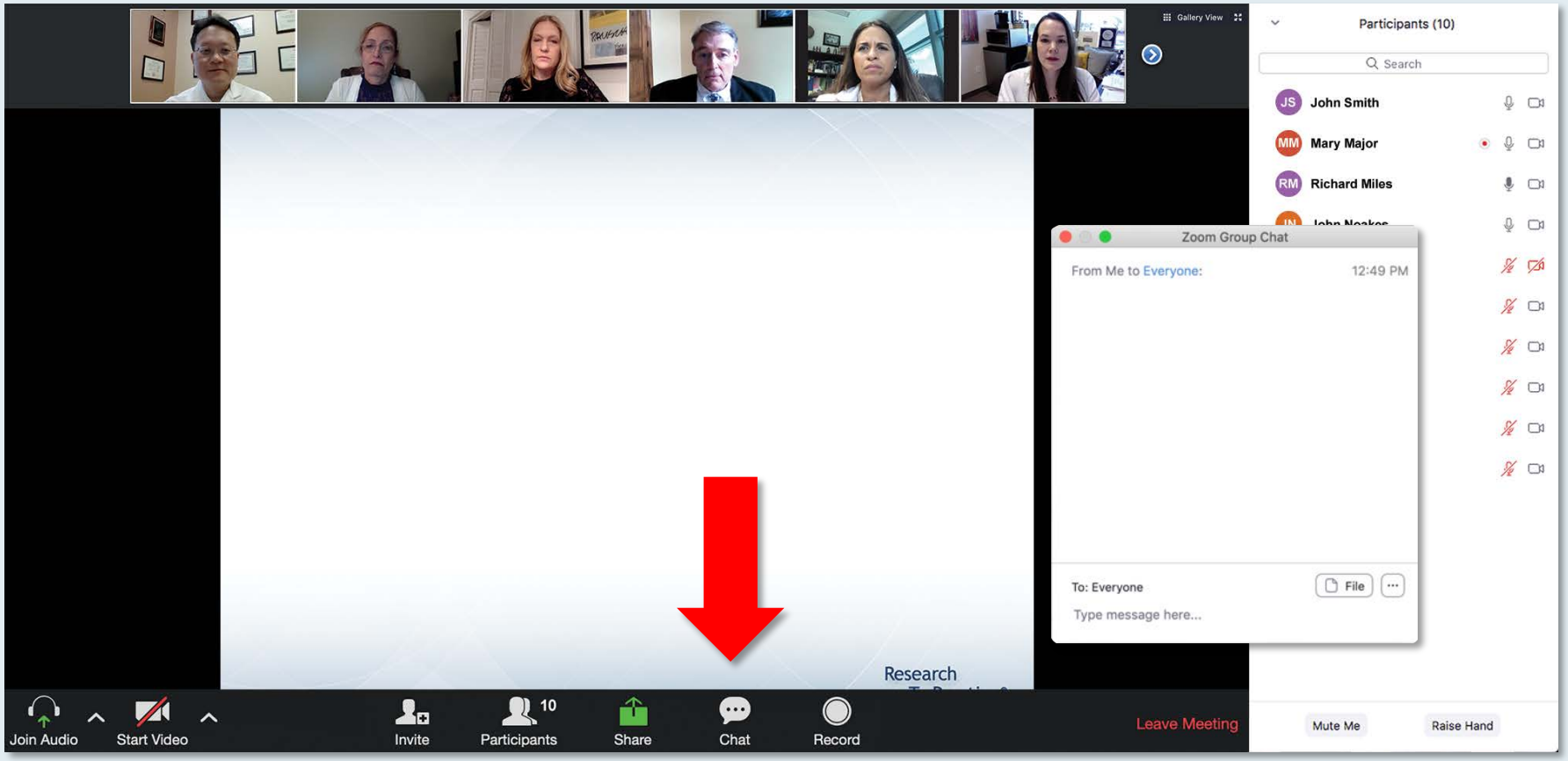
We Encourage Clinicians in Practice to Submit Questions



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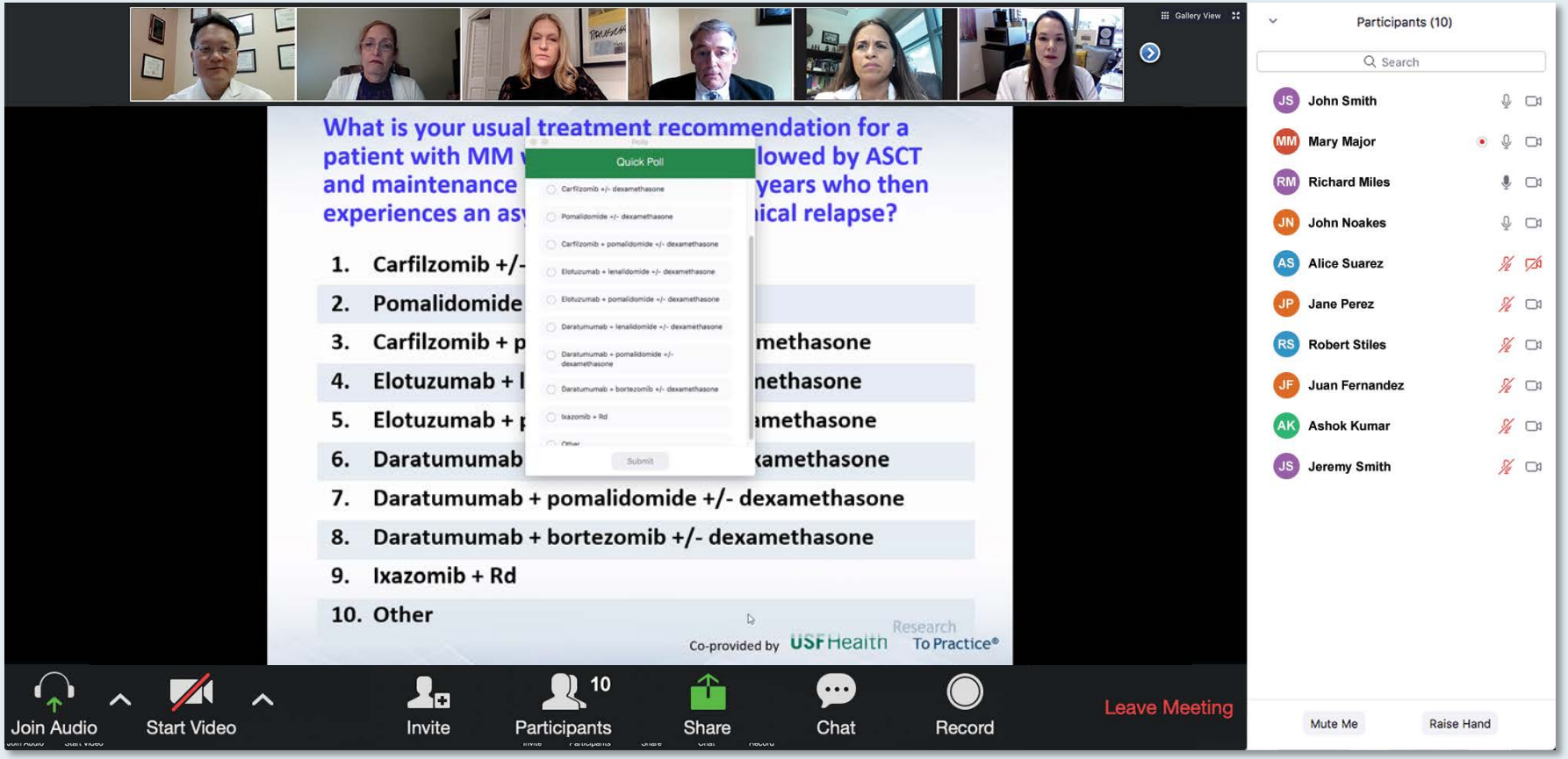
Familiarizing Yourself with the Zoom Interface

How to answer poll questions



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Thank you for joining us!

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

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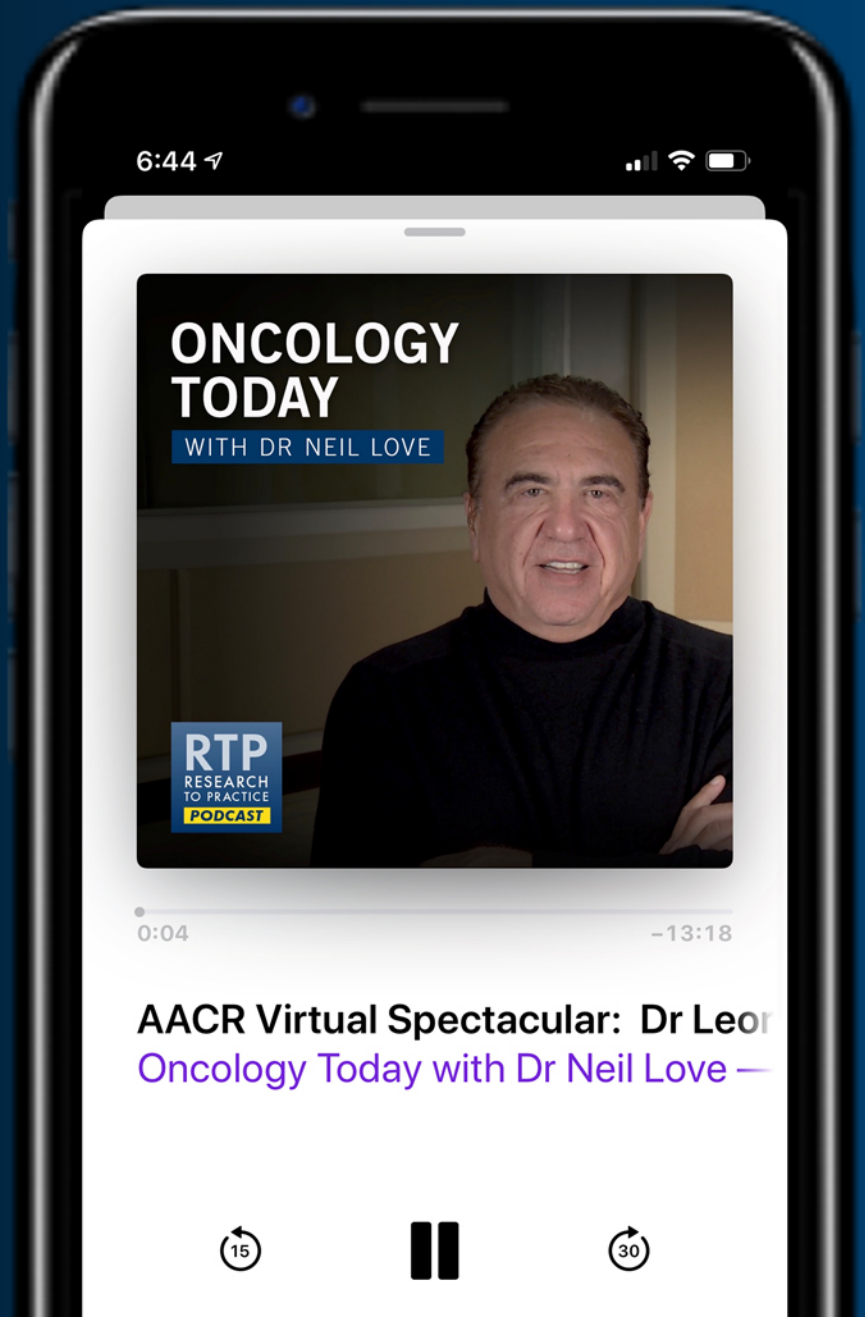

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Boston, Massachusetts

Meet The Professor Program Participating Faculty

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Houston, Texas

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Director, Thoracic Oncology
Research Program
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Faculty Development
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Medical Center
Nashville, Tennessee

Benjamin Levy, MD
Associate Professor
Johns Hopkins School of Medicine
Clinical Director
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Oncology Program
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Cancer Center at Sibley Memorial
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Program Director
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Sarah Cannon Research Institute
Nashville, Tennessee

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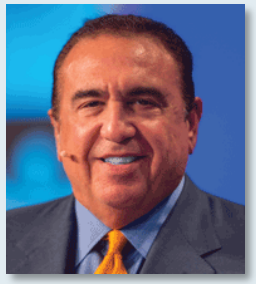
Meet The Professor Program Moderator



Project Chair
Neil Love, MD
Research To Practice
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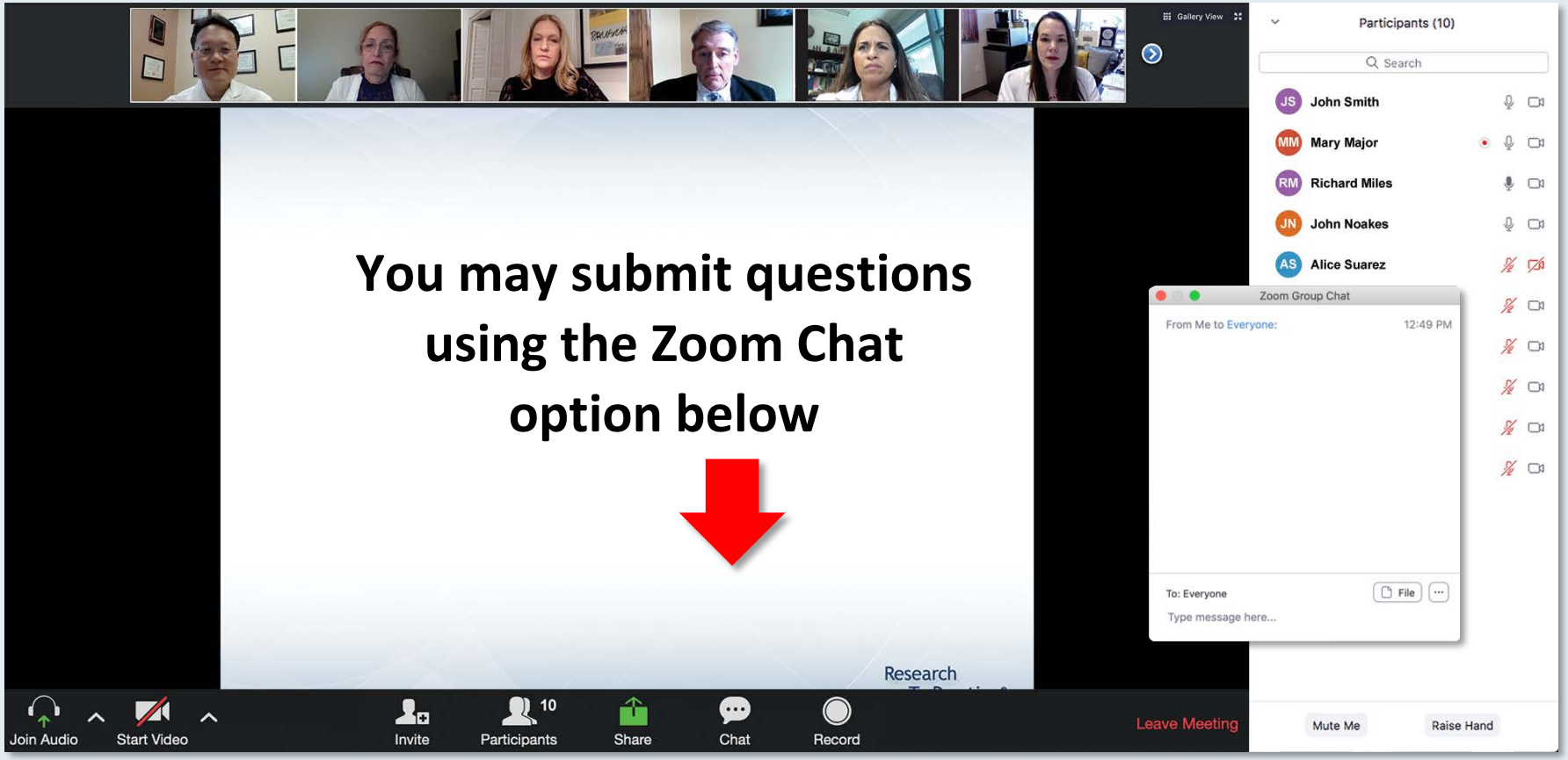
We Encourage Clinicians in Practice to Submit Questions



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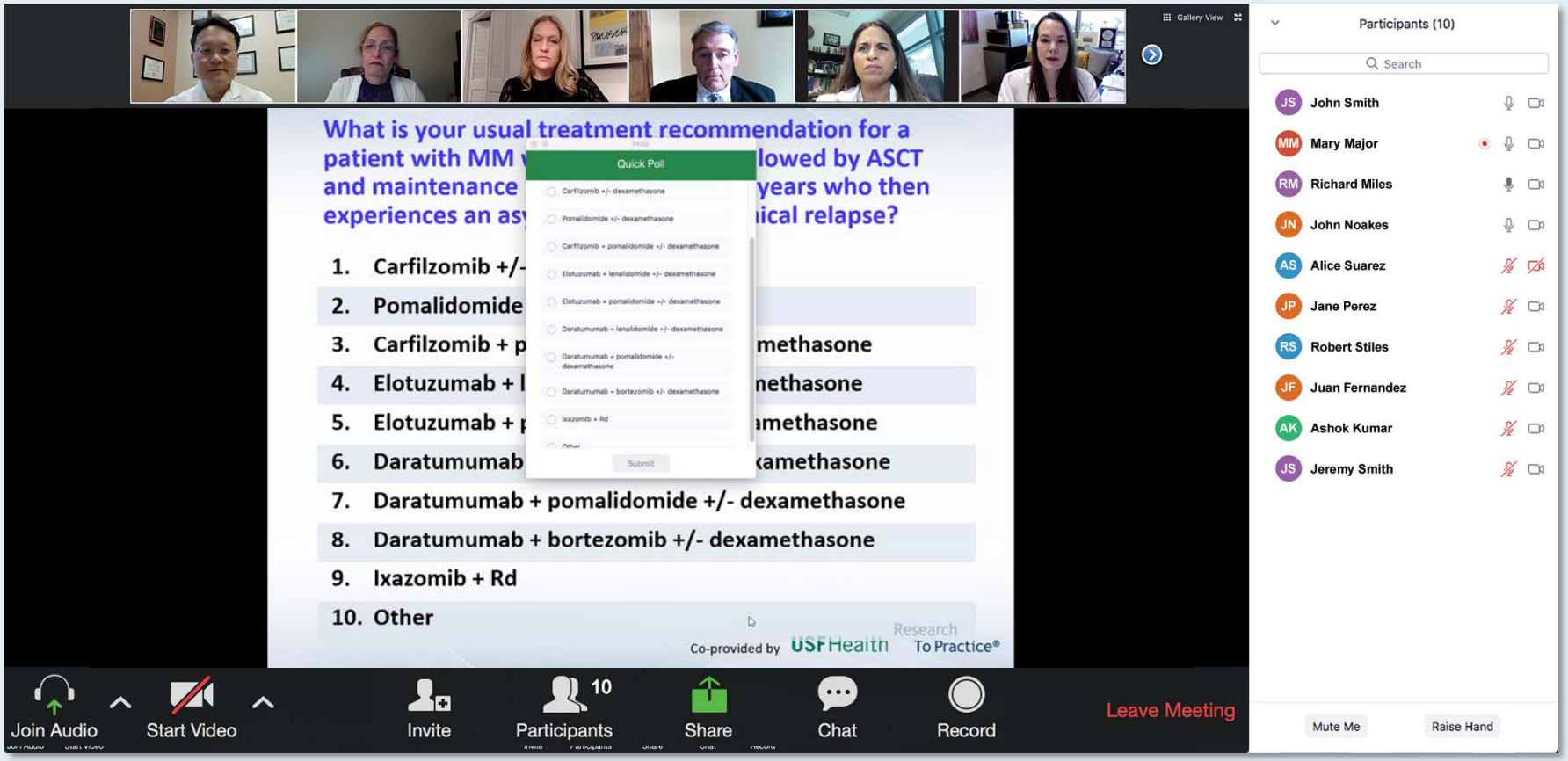

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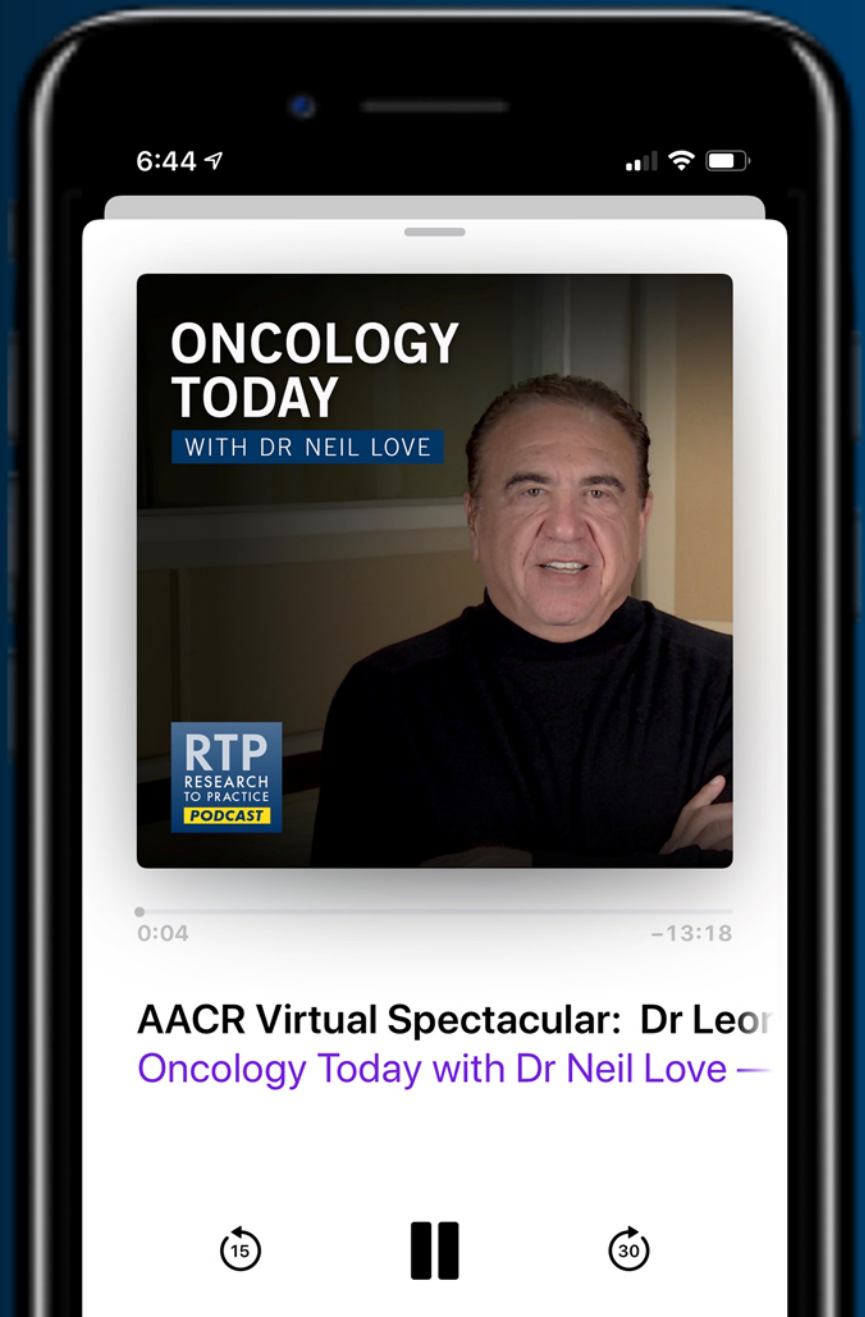

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Consulting Oncologist

Warren S Brenner, MD
Lynn Cancer Institute
Boca Raton, Florida

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Meet The Professor with Dr Sequist

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

- A 66-year-old woman with metastatic adenocarcinoma of the lung, PD-L1 100% – Dr Brenner

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- A 57-year-old man with locally advanced NSCLC, PD-L1 90% – Dr Brenner

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Case Presentation – Dr Brenner: 66-year-old woman with metastatic adenocarcinoma of the lung, PD-L1 100%

Warren S Brenner, MD

- Large RLL mass with metastatic disease to the right axilla, right lateral chest wall, periportal, peripancreatic, retroperitoneal, aortocaval and periaortic lymph nodes
- Initial axillary biopsy: Metastatic, poorly differentiated adenocarcinoma
- Molecular profiling: PD-L1 100%, TMB 9 mut/Mb, no actionable mutations, KRAS mutation, ALK mutation variant of uncertain significance
- Comorbidities: Psoriatic arthritis, hypertension, history of probable ischemic colitis, atrial fibrillation, hypothyroidism
- June 25, 2020: Carboplatin/pemetrexed
  - Hospitalization, probable aspiration pneumonia; profound weakness, pancytopenia and possible small stroke → recovered after 3 weeks
- Pemetrexed/pembrolizumab

Questions

- What is the best front-line treatment for patients with adenocarcinoma of the lung with a high PD-L1?
- In a patient with a history of psoriatic arthritis, currently controlled, would the faculty use a checkpoint inhibitor (CI)? Are there situations where they would use a CI in patients with autoimmune disease?

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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

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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	0.56
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] Gadgeel S et al. *J Clin Oncol* 2020;38(14):1505-17. [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 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)."

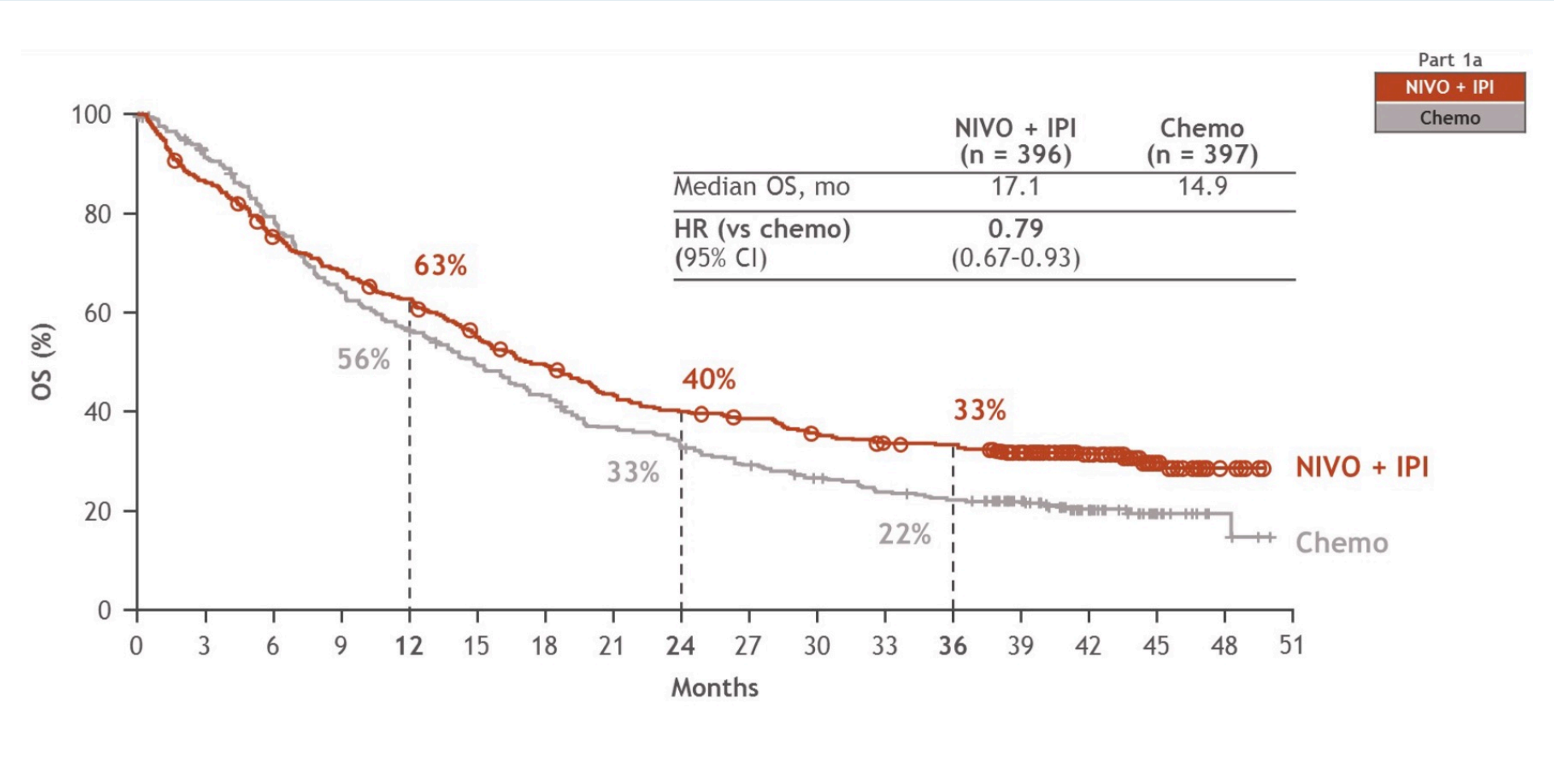
https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-nivolumab-plus-ipilimumab-first-line-mnsclc-pd-l1-tumor-expression-1

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.

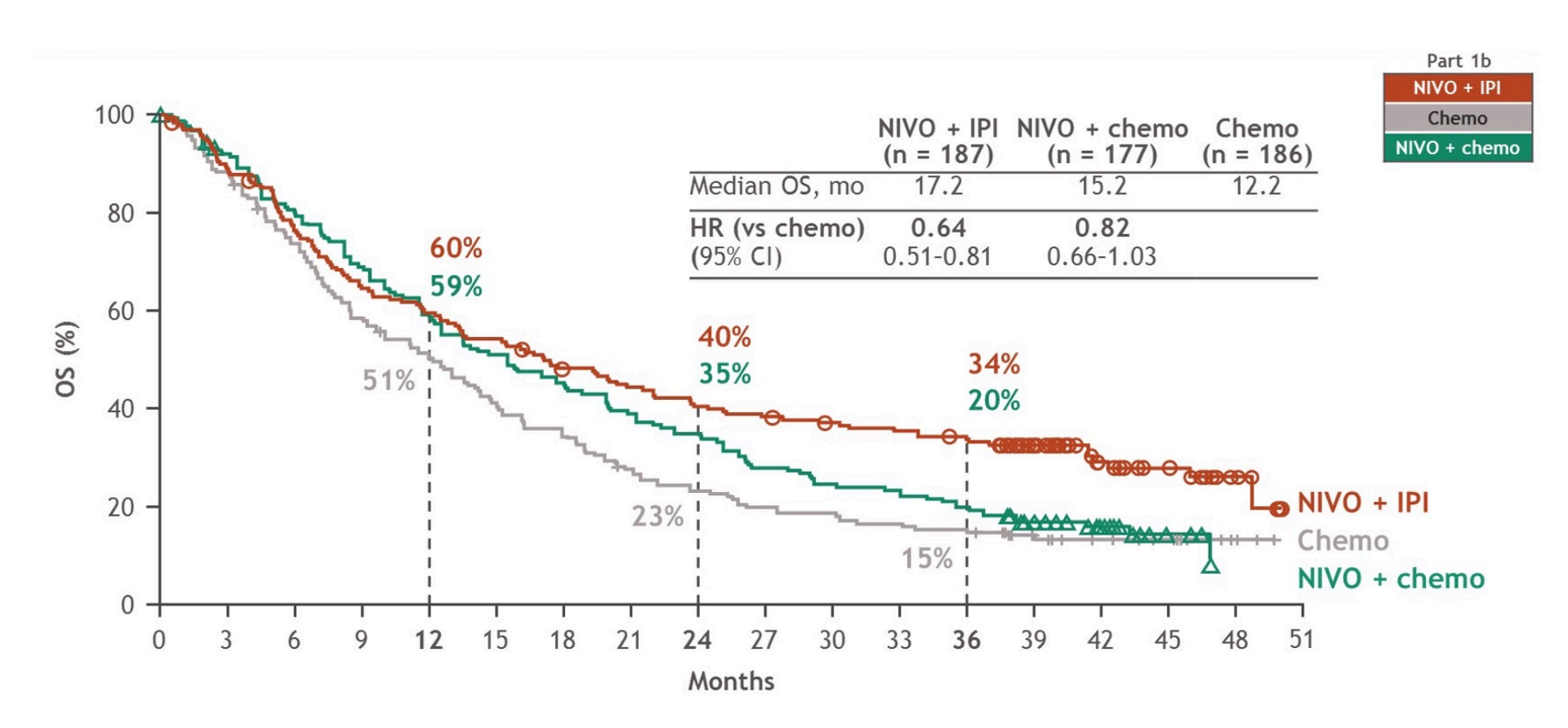
ASCO 2020;Abstract 9500.

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.

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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)."

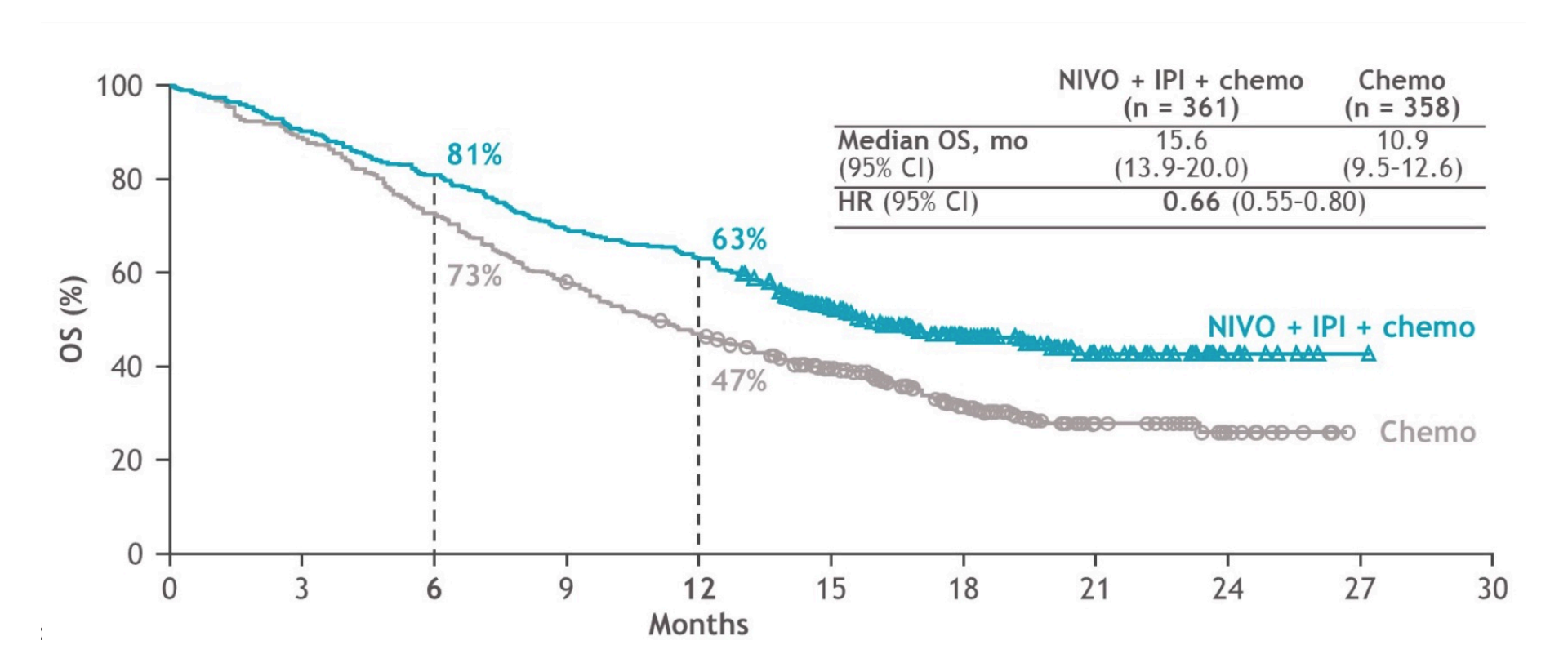
https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-nivolumab-plus-ipilimumab-and-chemotherapy-first-line-treatment-metastatic-nsclc

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.

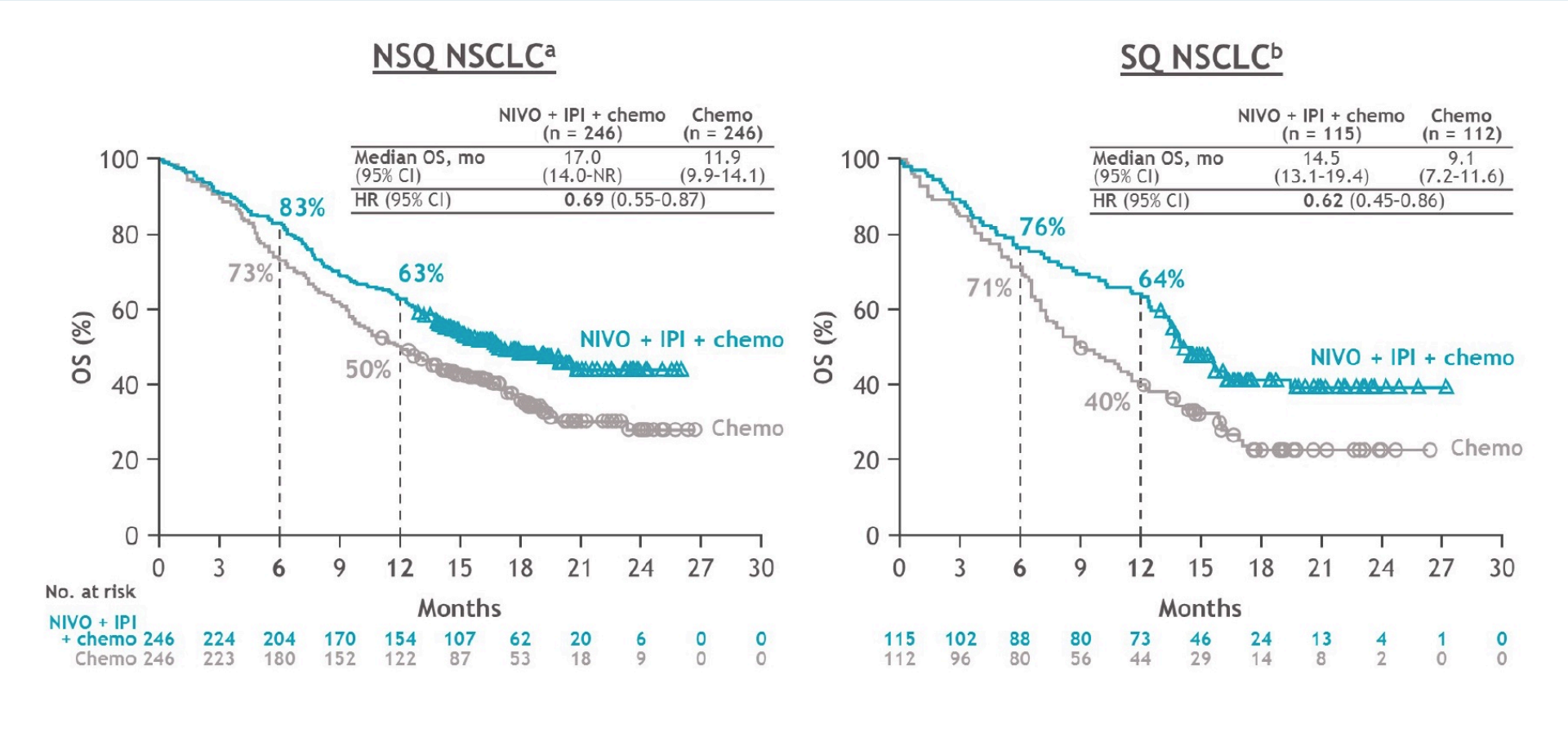
ASCO 2020;Abstract 9501.

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.

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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 Sequist

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

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Case Presentation – Dr Brenner: 81-year-old woman with metastatic adenocarcinoma of the lung, EGFR exon 19 mutation

Warren S Brenner, MD

- December 2015: Diagnosed with mediastinal LAD and bone disease
- Erlotinib 100 mg daily, increased to 150 mg daily January 2016
  - June 2016: Decreased back to 100 mg daily
- July 2018: Disease progression, with development of hoarseness, left vocal cord paralysis, and evidence of progressive mediastinal and subcarinal lymph nodes
- Liquid biopsy: T790M mutation
- Osimertinib, discontinued after 10 days due to rash requiring steroids
- September 2018: Re-initiation of osimertinib, dose-reduced 40 mg
- June 2020: Disease progression

Questions

- What are the options for a patient with an EGFR-mutated lung cancer who has progressed on osimertinib and now has progressive disease? Chemo alone? Chemo + CI?
- What is the role for rebiopsy of these patients to look for new acquired mutations? Liquid versus tumor biopsy?

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Case Presentation – Dr Brenner: 93-year-old man with adenocarcinoma of the lung with brain metastases, MET exon 14 skipping mutation

Warren S Brenner, MD

- Capmatinib
- Developed pneumonia, and possible pneumonitis and passed away

Questions

- Does the faculty have any experience with capmatinib? Any pearls regarding its management?
- In patients with MET exon 14 skipping mutations, should we use capmatinib in the front-line setting or in the relapse setting? Are there any particular toxicities we should be aware of?

Comments and Questions: Management of metastatic NSCLC with an EGFR exon 20 mutation

Dr Warren S Brenner

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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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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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Key Data Sets

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

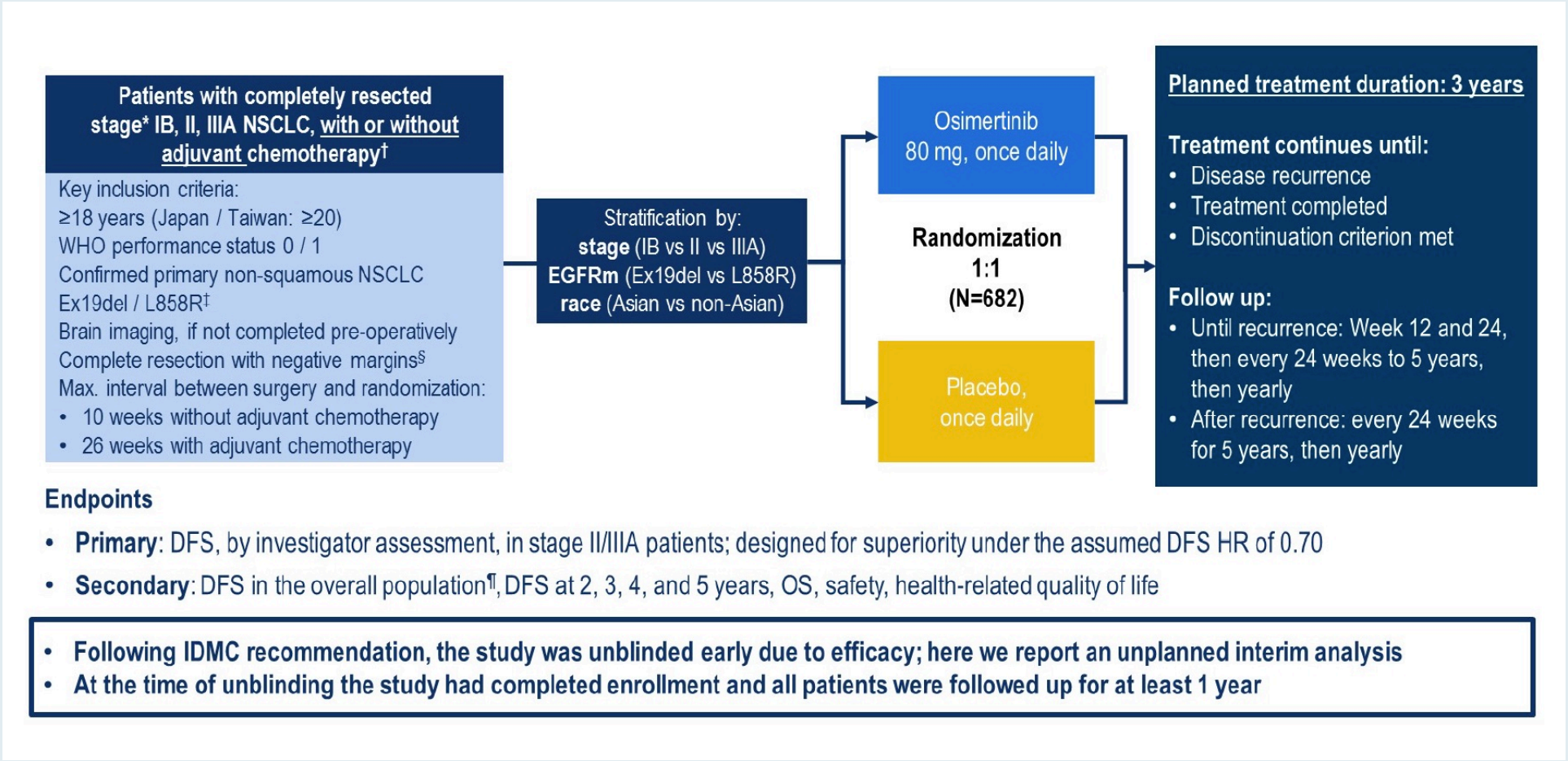
Herbst RS et al.

ASCO 2020;Abstract LBA5.

Discussion of LBA5

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

ADAURA Phase III Trial Schema



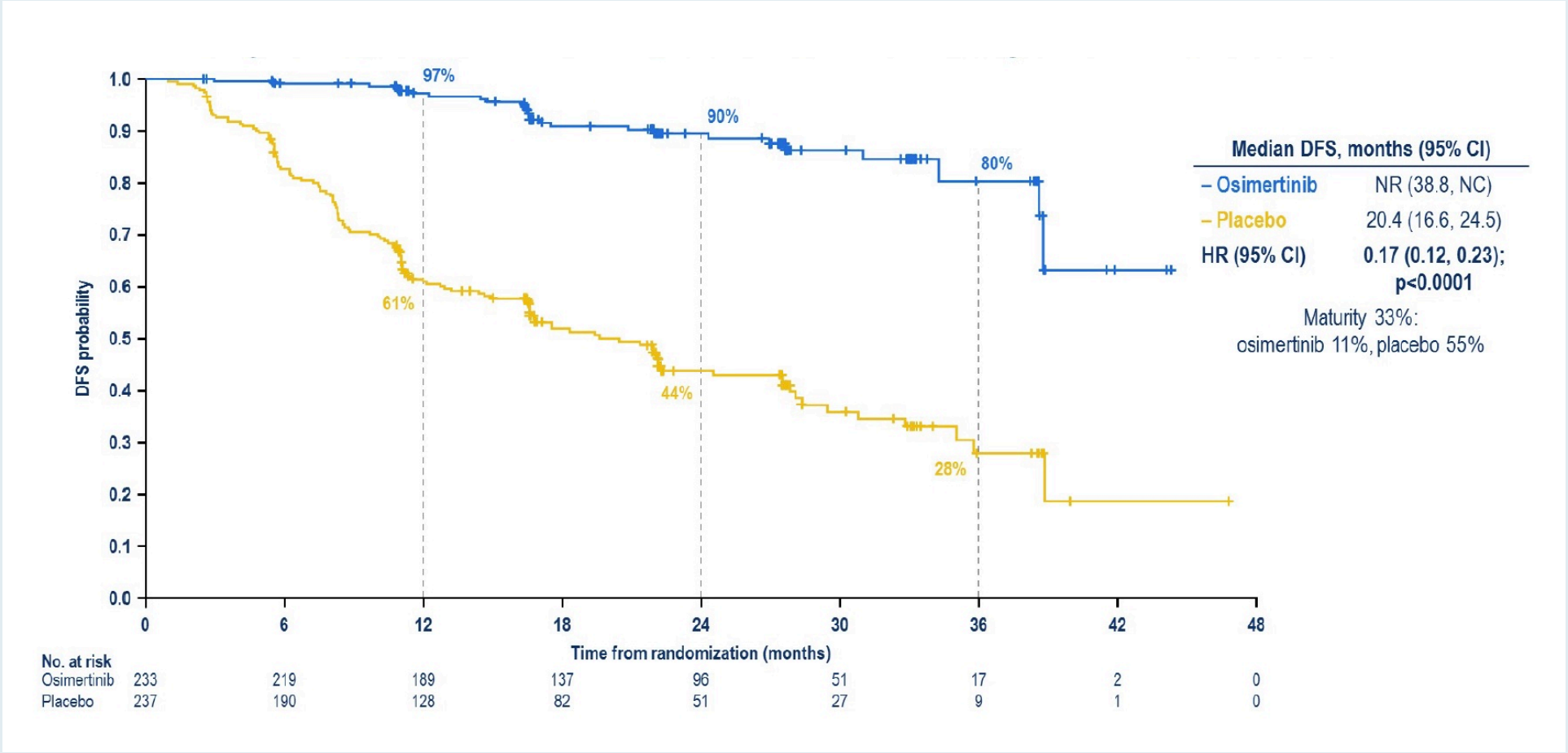
Endpoints

- **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.

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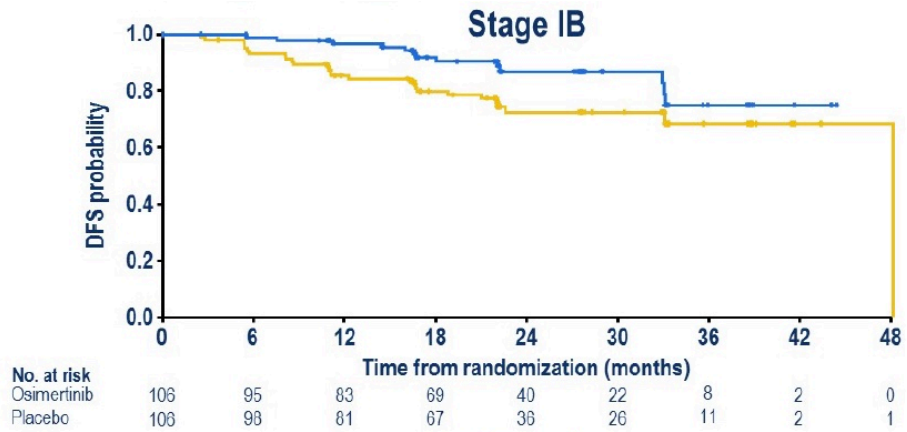
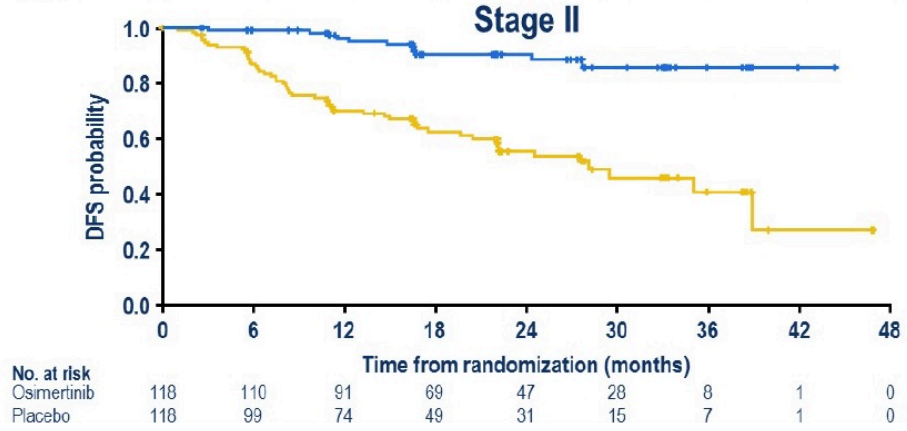
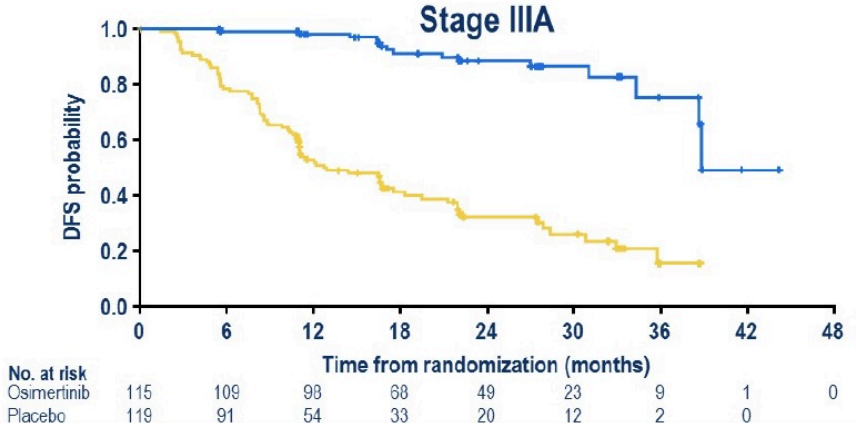
ADAURA: DFS by Stage



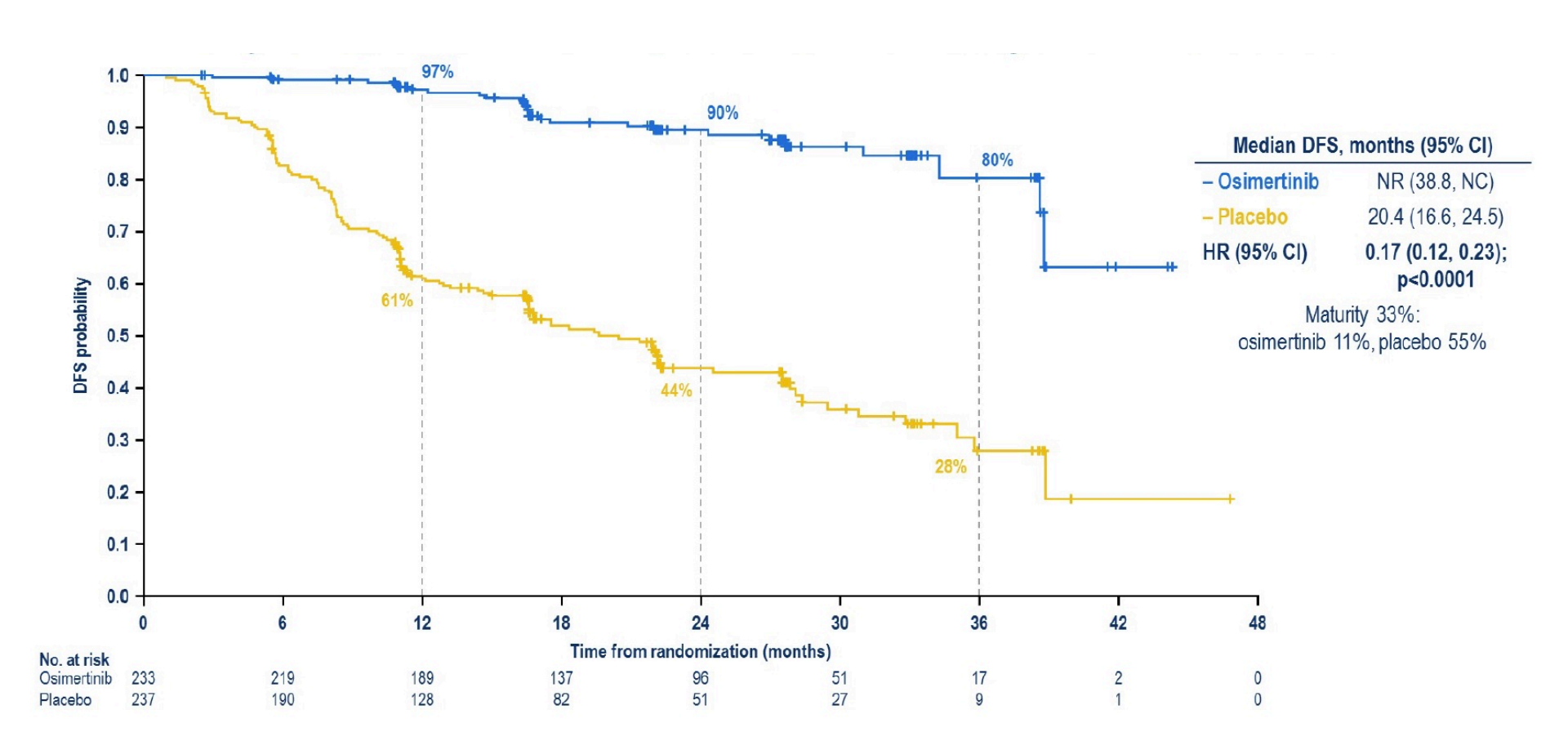


	Stage IB	Stage II	Stage IIIA
2 year DFS rate, % (95% CI)			
– Osimertinib	87 (77, 93)	91 (82, 95)	88 (79, 94)
– Placebo	73 (62, 81)	56 (45, 65)	32 (23, 42)
Overall HR (95% CI)	0.50 (0.25, 0.96)	0.17 (0.08, 0.31)	0.12 (0.07, 0.20)



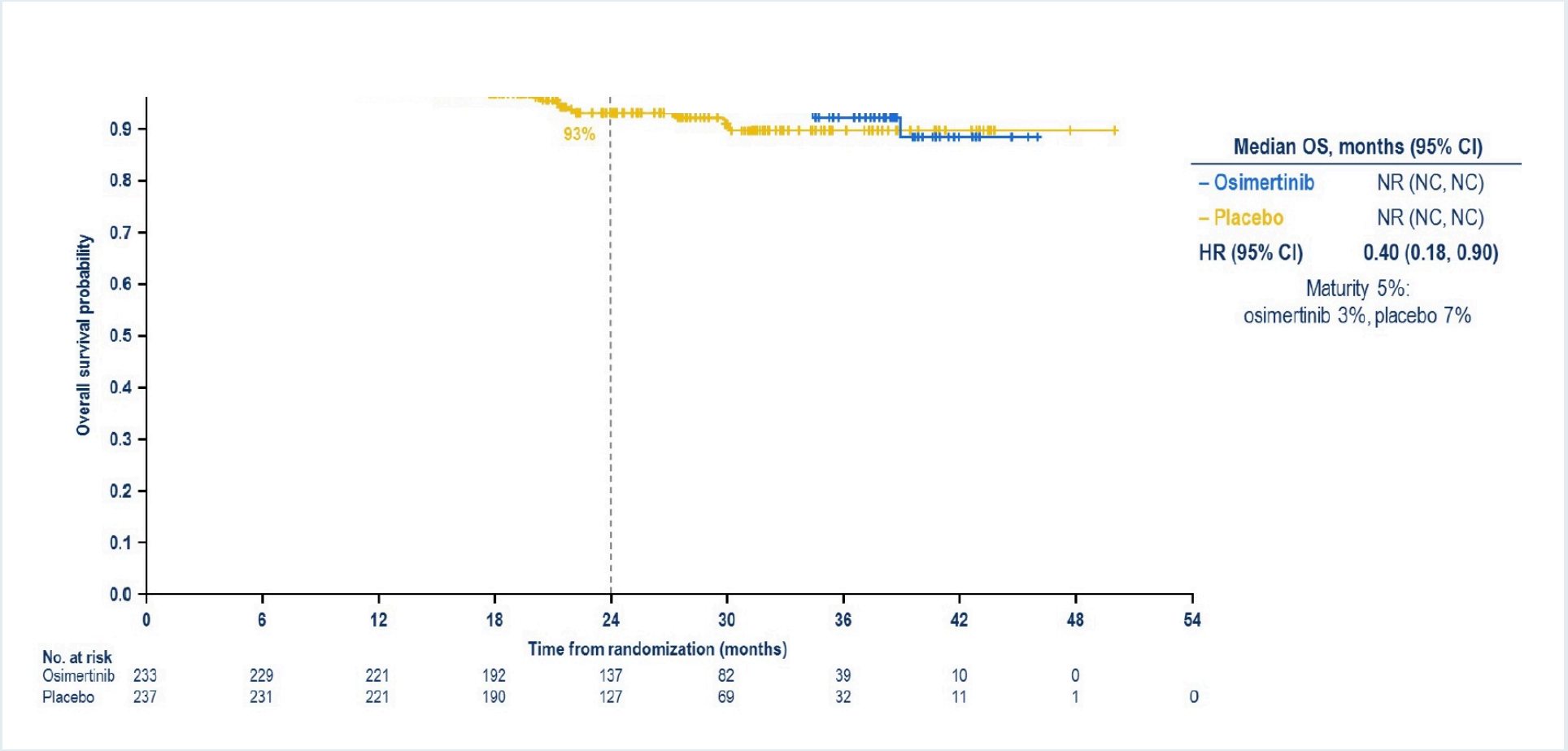
Herbst RS et al. ASCO 2020;Abstract LBA5.

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.

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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.

FDA Approves Ramucirumab with Erlotinib for First-Line Metastatic NSCLC

Press Release — May 29, 2020

"On May 29, 2020, the Food and Drug Administration approved ramucirumab in combination with erlotinib for first-line treatment of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations.

Efficacy was evaluated in RELAY (NCT02411448), a multinational, randomized, double-blind, placebo-controlled, multicenter study in patients with previously untreated metastatic NSCLC whose tumors have EGFR exon 19 deletion or exon 21 (L858R) substitution mutations. A total of 449 patients were randomized (1:1) to receive either ramucirumab 10 mg/kg or placebo every 2 weeks as an intravenous infusion, in combination with erlotinib 150 mg orally once daily, until disease progression or unacceptable toxicity."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-ramucirumab-plus-erlotinib-first-line-metastatic-nsclc

FDA Approves Brigatinib for ALK-Positive Metastatic NSCLC

Press Release — May 22, 2020

"On May 22, 2020, the Food and Drug Administration approved brigatinib for adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

The FDA also approved the Vysis ALK Break Apart FISH Probe Kit as a companion diagnostic for brigatinib.

Efficacy was investigated in ALTA 1L (NCT02737501), a randomized (1:1), open-label, multicenter trial in adult patients with advanced ALK-positive NSCLC who had not previously received an ALK-targeted therapy. The trial required patients to have an ALK rearrangement based on a local standard of care testing. A subset of the clinical samples was retrospectively tested with the Vysis ALK Break Apart FISH Probe Kit.

The recommended brigatinib dose is 90 mg orally once daily for the first 7 days; then increase to 180 mg orally once daily."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-brigatinib-alk-positive-metastatic-nsclc

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

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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

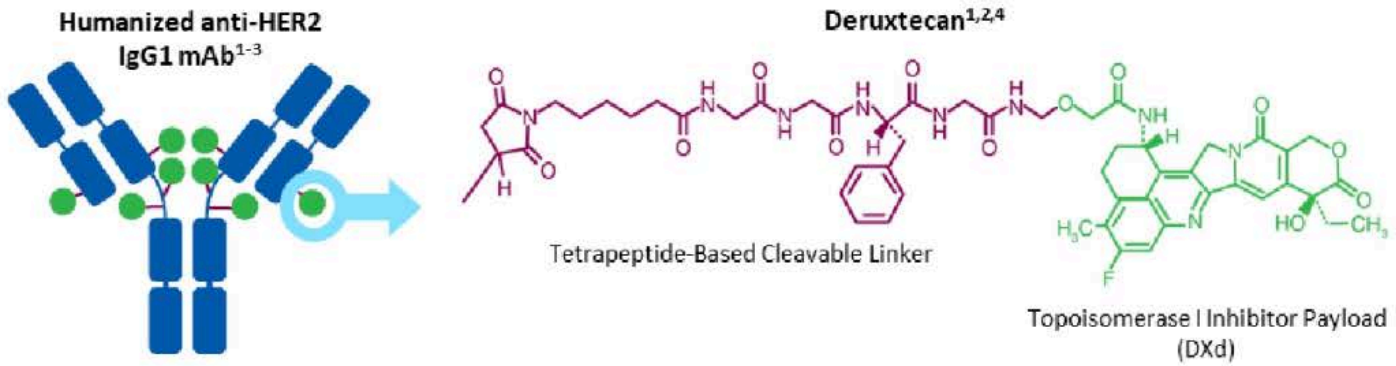
Trastuzumab Deruxtecan (T-DXd; DS-8201) in Patients with HER2-Mutated Metastatic Non-Small Cell Lung Cancer (NSCLC): Interim Results of DESTINY-Lung01

Smit EF et al.
ASCO 2020;Abstract 9504.

Antibody-Drug Conjugate
Trastuzumab Deruxtecan

T-DXd is an ADC with 3 components:

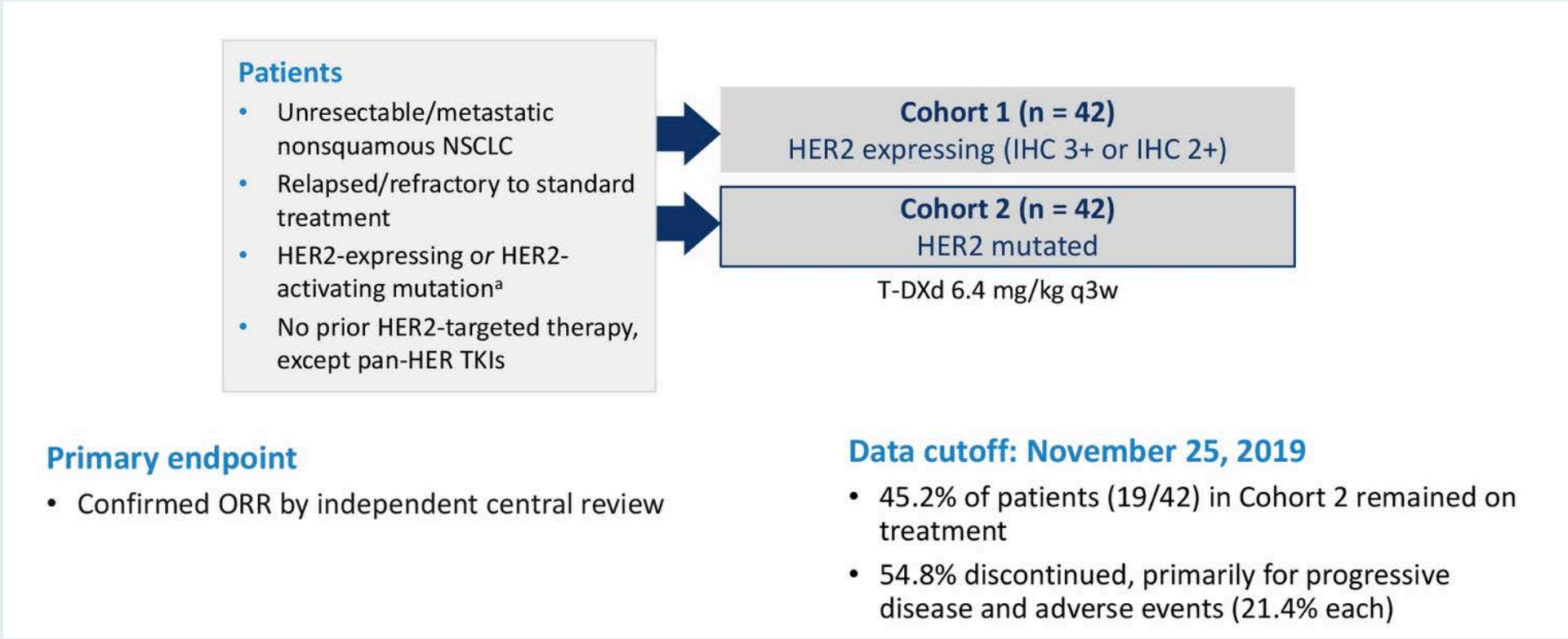
- A humanized anti-HER2 IgG1 mAb with the same amino acid sequence as trastuzumab
- A topoisomerase I inhibitor payload, an exatecan derivative
- A tetrapeptide-based cleavable linker



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

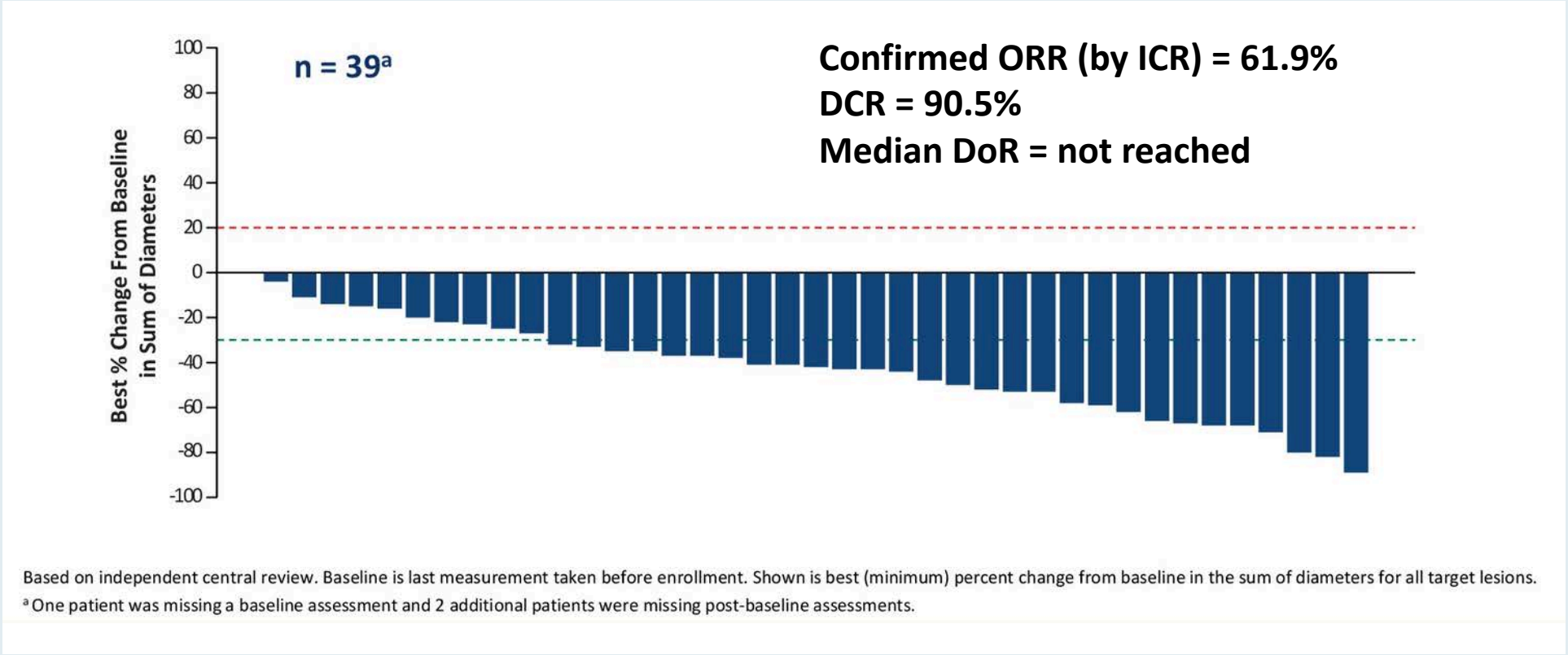
Smit EF et al. *Proc ASCO* 2020;Abstract 9504.

DESTINY-Lung01: Phase II Study Design



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

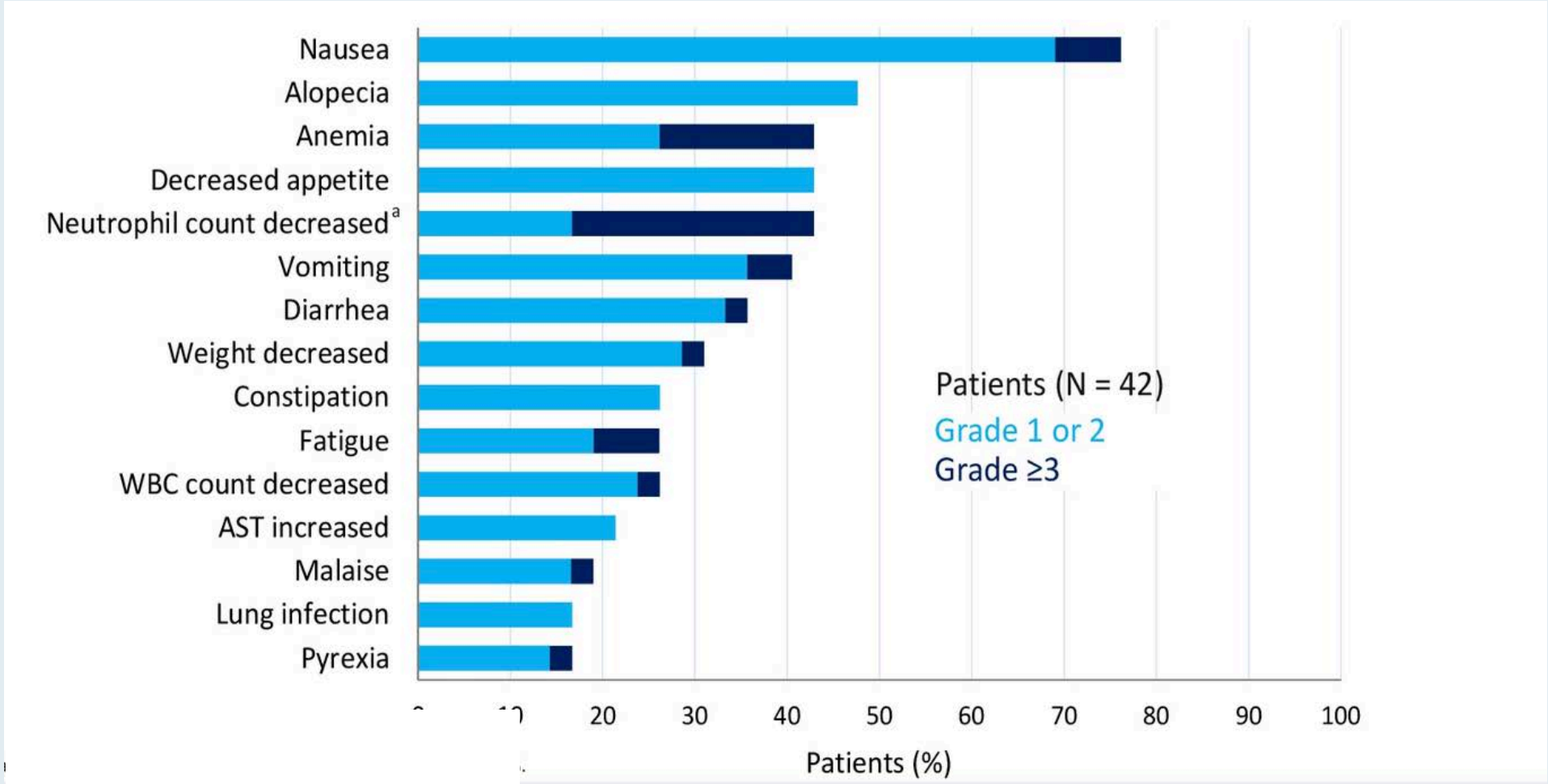
DESTINY-Lung01: Efficacy



- 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.

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.

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

Meet The Professor with Dr Sequist

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

- A 66-year-old woman with metastatic adenocarcinoma of the lung, PD-L1 100% – Dr Brenner

Module 2: Management of Metastatic NSCLC with Targetable Mutations

- An 81-year-old woman with metastatic adenocarcinoma of the lung, EGFR exon 19 mutation – Dr Brenner
- A 93-year-old man with adenocarcinoma of the lung, MET exon 14 skipping mutation – Dr Brenner

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

- A 55-year-old woman with small cell lung cancer – Dr Brenner

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

- A 57-year-old man with locally advanced NSCLC, PD-L1 90% – Dr Brenner

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Case Presentation – Dr Brenner: 55-year-old woman with small cell lung cancer

Warren S Brenner, MD

- August 2019: SCLC involving the RUL, with bulky right hilar lymphadenopathy encasing the pulmonary arteries, infrahilar lymphadenopathy, right paratracheal prevascular lymphadenopathy
- September 2019: Cisplatin/etoposide → concurrent hyperfractionated radiation and chemotherapy
- March 2020: Recurrence of disease, with small brain lesion, and T8 bone lesion
  - April 2020: Stereotactic radiation therapy to brain lesion
  - May 2020: Radiation therapy to T8 thoracic lesion
- May 2020: Progression of disease in the chest and mediastinum
- June 3, 2020: Ipilimumab/nivolumab, with ipilimumab 1 mg/kg, nivolumab 3 mg/kg
- June 18, 2020: New small multifocal brain metastases and progressive disease in bones

Questions

- In platinum-refractory SCLC, what is the treatment of choice?
- What is the role of the new agent, lurbinectedin, that was recently approved?
- Do we use checkpoint inhibitors? What is the role of dual checkpoint inhibitors?
- Should we use high-dose ipilimumab or lower-dose ipilimumab?

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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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

FDA Approves Durvalumab for Extensive-Stage Small Cell Lung Cancer

Press Release — March 27, 2020

"On March 27, 2020, the Food and Drug Administration approved durvalumab in combination with etoposide and either carboplatin or cisplatin as first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).

Efficacy of this combination in patients with previously untreated ES-SCLC was investigated in CASPIAN, a randomized, multicenter, active-controlled, open-label, trial (NCT03043872). The evaluation was based on the comparison of patients randomized to durvalumab plus chemotherapy vs. chemotherapy alone.

For ES-SCLC, durvalumab is to be administered prior to chemotherapy on the same day. The recommended durvalumab dose when administered with etoposide and either carboplatin or cisplatin is 1500 mg every 3 weeks prior to chemotherapy and then every 4 weeks as a single agent."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-extensive-stage-small-cell-lung-cancer

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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.

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.

Pembrolizumab or Placebo plus Etoposide and Platinum as First-Line Therapy for Extensive-Stage Small-Cell Lung Cancer: Randomized, Double-Blind, Phase III KEYNOTE-604 Study

Rudin CM et al.

J Clin Oncol 2020;38(21):2369-79.

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- A 57-year-old man with locally advanced NSCLC, PD-L1 90% – Dr Brenner

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Case Presentation – Dr Brenner: 57-year-old man with locally advanced NSCLC, PD-L1 90%

Warren S Brenner, MD

- September 2019: T1b N3 adenocarcinoma of the RUL, with contralateral supraclavicular lymph nodes, PD-L1 90%
  - NGS: Rearrangement in RET intron 11
- October 18, 2019: Induction carboplatin/paclitaxel
- December 17, 2019 – January 21, 2020: Concurrent RT with weekly carboplatin/paclitaxel
- April 2020: Repeat PET-CT, with excellent response
- April 7, 2020: Initiation of durvalumab

Questions

- Should we do NGS on earlier-stage lung cancer, especially given recent data of benefit with adjuvant osimertinib?
- Any correlation from PACIFIC trial regarding benefit of IO therapy and PD-L1 status?
- Any data regarding RET intron mutations?
- Are patients with actionable mutations less likely to benefit from maintenance IO therapy?

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

RTP RESEARCH TO PRACTICE

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

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

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Exploring the Role of Immune Checkpoint Inhibitor Therapy and Other Novel Strategies in Gynecologic Cancers

A Meet The Professor Series

Friday, August 28, 2020
12:00 PM – 1:00 PM ET

Faculty

Michael J Birrer, MD, PhD

Moderator

Neil Love, MD

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Thank you for joining us!

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