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

Targeted Therapy for Lung Cancer

Tuesday, January 26, 2021
5:00 PM – 6:00 PM ET

Faculty

Joel W Neal, MD, PhD
Paul K Paik, MD

Moderator

Neil Love, MD

RTP Year in Review 2020

YiR Targeted Therapy for Lung Cancer Faculty

Joel W Neal, MD, PhD
Associate Professor of Medicine, Division of Oncology
Stanford Cancer Institute, Stanford University
Palo Alto, California

Paul K Paik, MD
Associate Attending Physician
Clinical Director, Thoracic Oncology Service
Memorial Sloan Kettering Cancer Center
New York, New York

Commercial Support

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Dr Love — Disclosures

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Data and Safety Monitoring Board/Committee	Iovance Biotherapeutics

Dr Paik — Disclosures

Advisory Committee	Calithera Biosciences, EMD Serono Inc, Xencor
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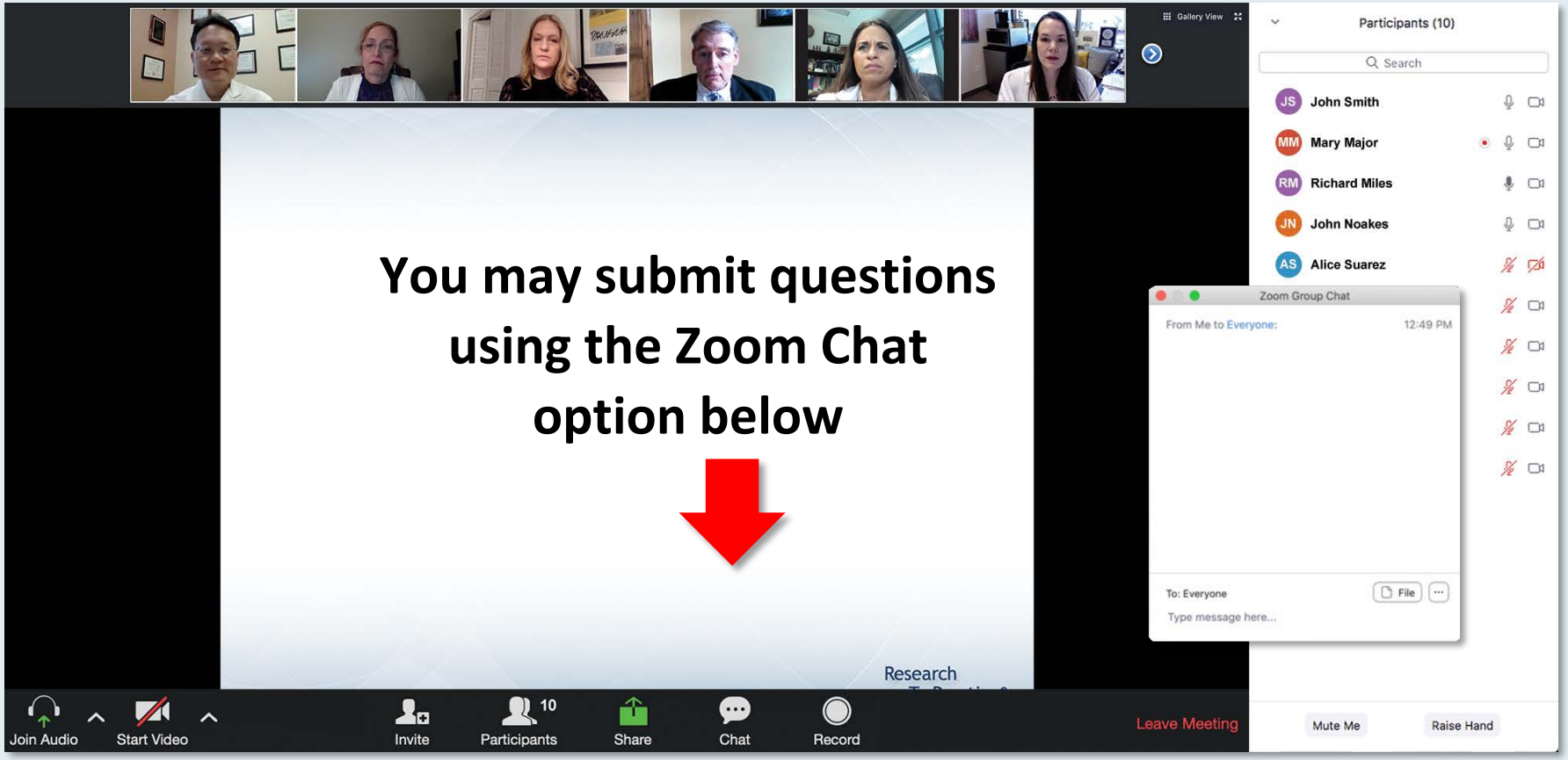
We Encourage Clinicians in Practice to Submit Questions



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Familiarizing Yourself with the Zoom Interface

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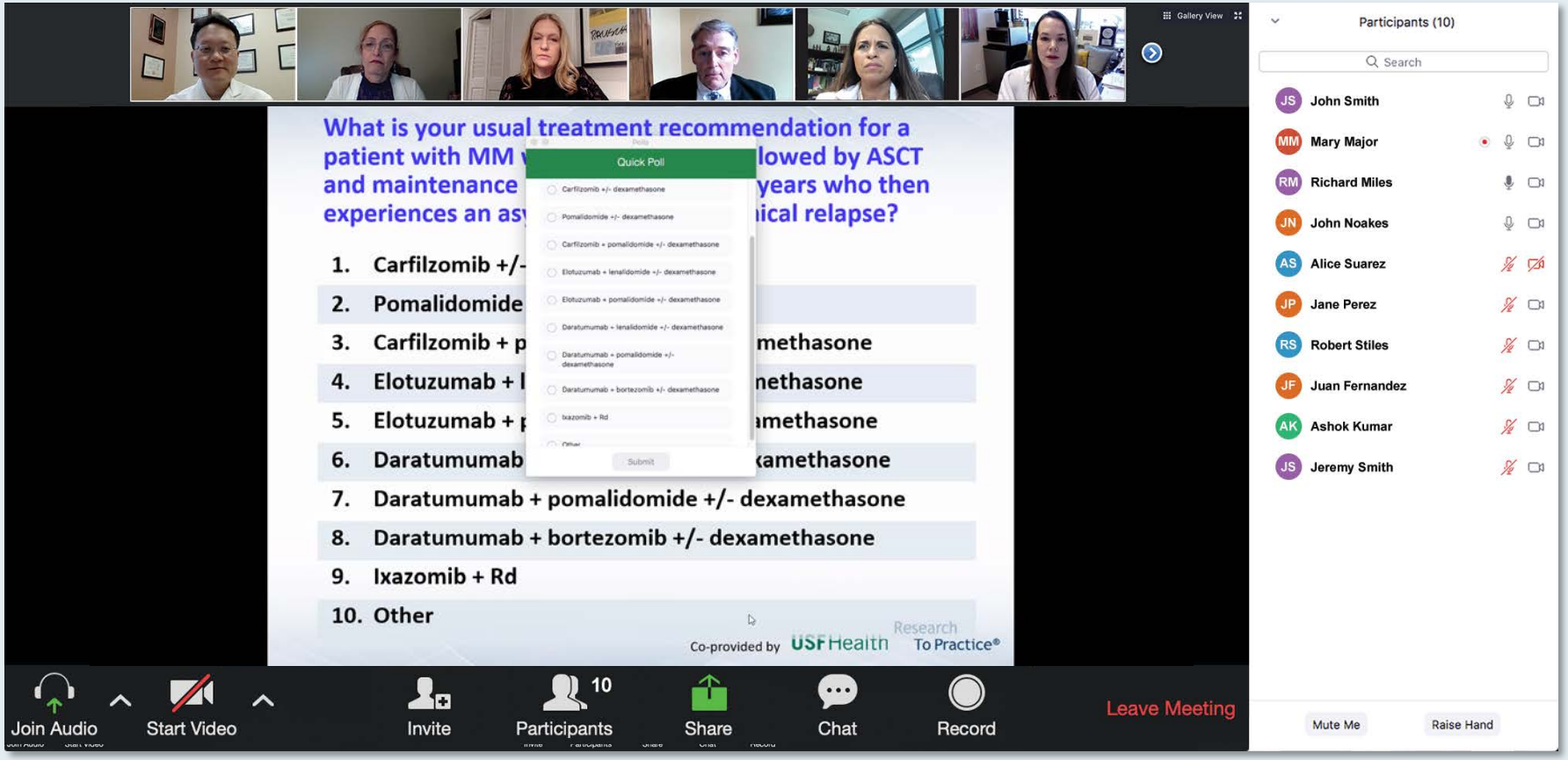

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The Role of Immunotherapy Combination Approaches in the Management of Metastatic Non-Small Cell Lung Cancer

DR STEPHEN LIU

GEORGETOWN UNIVERSITY HOSPITAL

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Cases from the Community: Investigators Discuss Emerging Research and Actual Patients with Hepatocellular Carcinoma (Part 1 of a 3-Part Series)

Wednesday, January 27, 2021
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Bladder Cancer and Renal Cell Carcinoma

Tuesday, February 2, 2021
5:00 PM – 6:00 PM ET

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Sumanta K Pal, MD
David I Quinn, MBBS, PhD

Moderator

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RTP Year in Review 2020

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

Part 2 — Hodgkin and Non-Hodgkin Lymphoma

Wednesday, February 3, 2021
5:00 PM – 6:00 PM ET

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John P Leonard, MD
Michael E Williams, MD, ScM

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RTP RESEARCH TO PRACTICE

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Yelena Y Janjigian, MD
Rutika Mehta, MD, MPH
Zev Wainberg, MD, MSc

Moderator

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RESEARCH TO PRACTICE

Meet The Professor
Management of Lung Cancer

Friday, February 5, 2021
12:00 PM - 1:00 PM ET

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Joshua Bauml, 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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Module 1: Non-Small Cell Lung Cancer (NSCLC)

- **Key Relevant Data Sets**
  - CheckMate 9LA: Nivolumab + ipilimumab + platinum-doublet chemotherapy
  - CheckMate 227 Part 1: Three-year update
  - KEYNOTE-189: Updated analysis
  - IMpower110: First-line atezolizumab
  - KEYNOTE-024: Five-year overall survival update
  - EMPOWER-Lung 1: Cemiplimab monotherapy vs platinum-doublet chemotherapy
  - PACIFIC: Three-year overall survival with durvalumab

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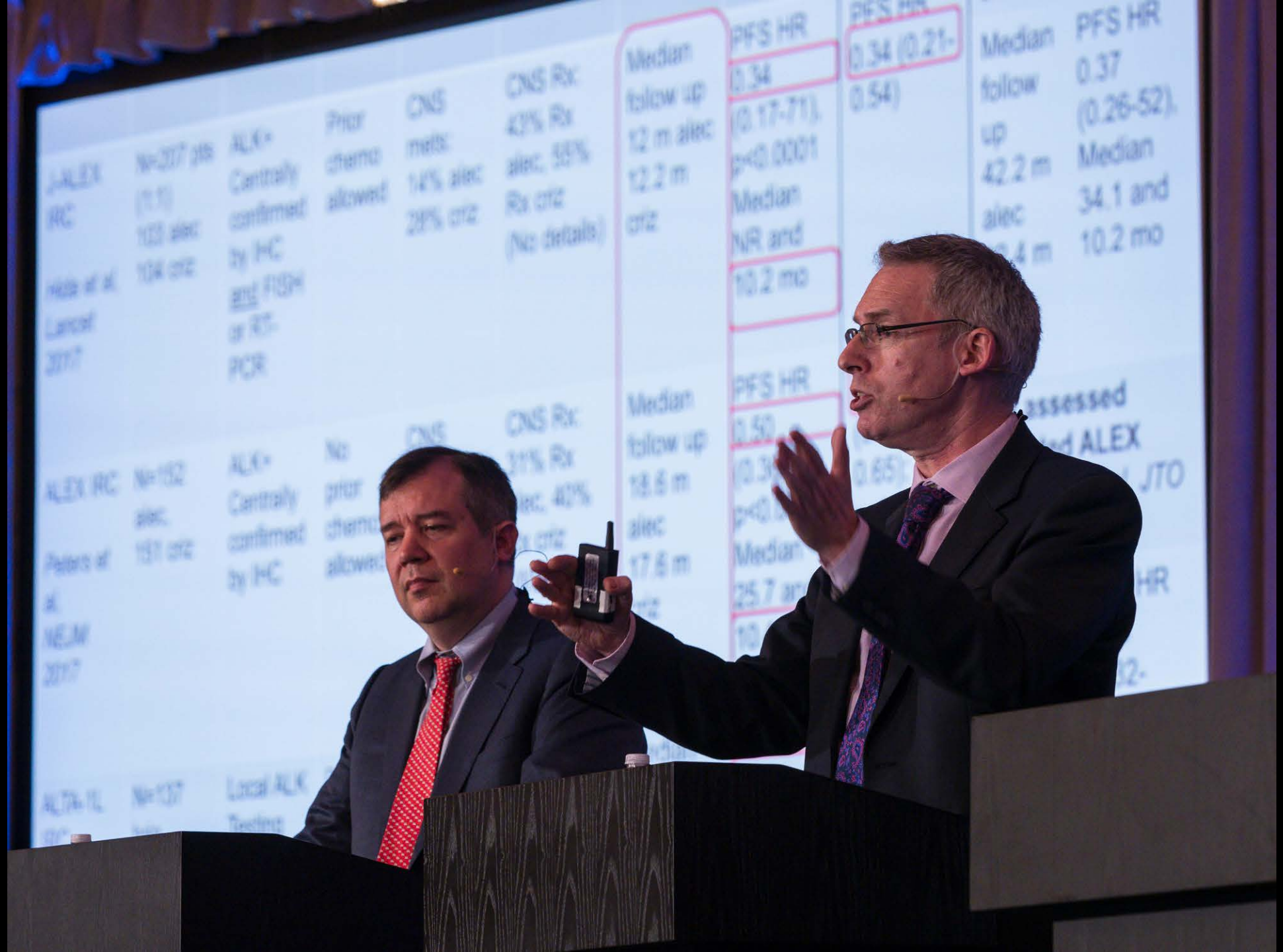
with an NTRK gene fusion?
32%
5%
10%
3%


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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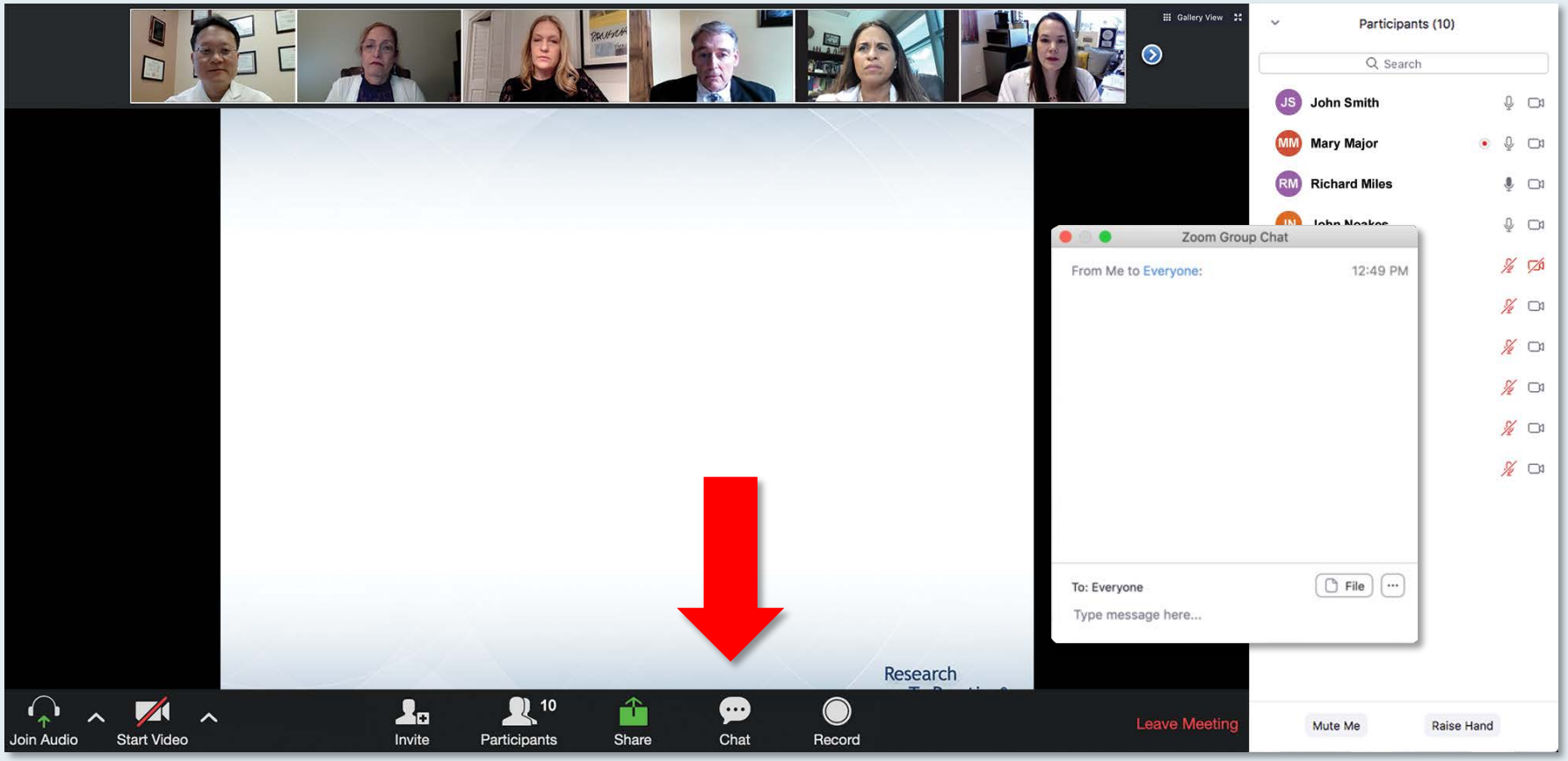

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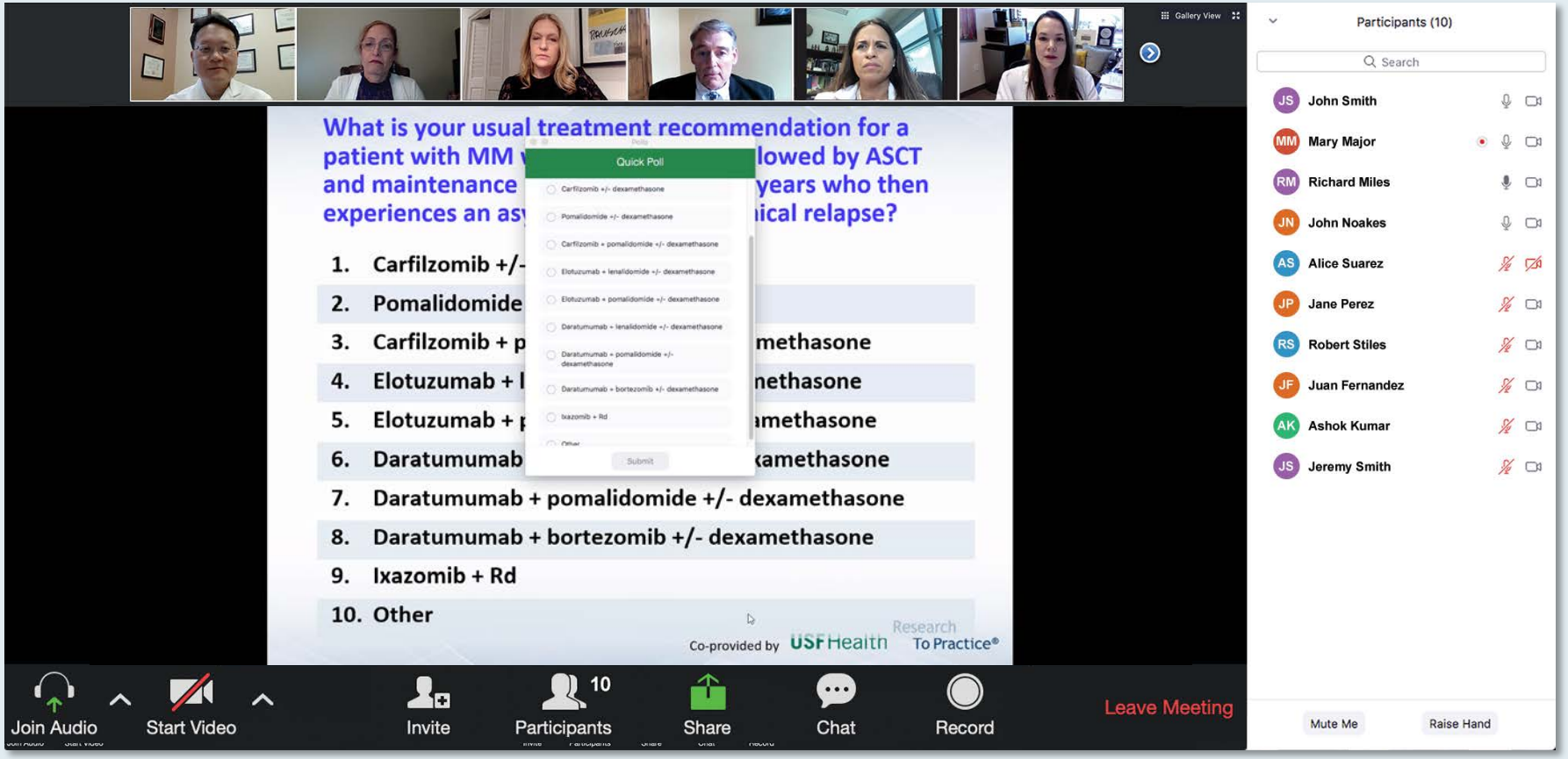

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Margaret A Deutsch, MD
Medical Oncologist
Duke Cancer Center Raleigh
Raleigh, North Carolina

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Agenda

Case Presentation: Dr Deutsch – 67-year-old man

Module 1: ROS1 Rearrangements

Module 2: EGFR Exon 19 Deletion; Exon 21 (L858R) Point Mutation

Module 3: EGFR Exon 20 Insertion

Module 4: HER2 Amplification/Mutation

Module 5: ALK Rearrangement

Module 6: NTRK Gene Fusion

Module 7: RET Fusions

Module 8: MET Exon 14 Skipping Mutations

Module 9: KRAS G12C Mutation

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Case Presentation: A 67-year-old man, never smoker with symptomatic metastatic adenosquamous carcinoma of the lung

Margaret Deutsch, MD

- December 2020: Presents with left chest discomfort and shortness of breath
- January 2021: Pleural biopsy reveals adenosquamous carcinoma of the lung
  - PD-L1: >95% | ALK: Negative | EGFR: Pending | NGS: Pending
- MRI brain: Stable
- Carboplatin/pemetrexed/pembrolizumab x 3 weeks – 1 dose pembro

Agenda

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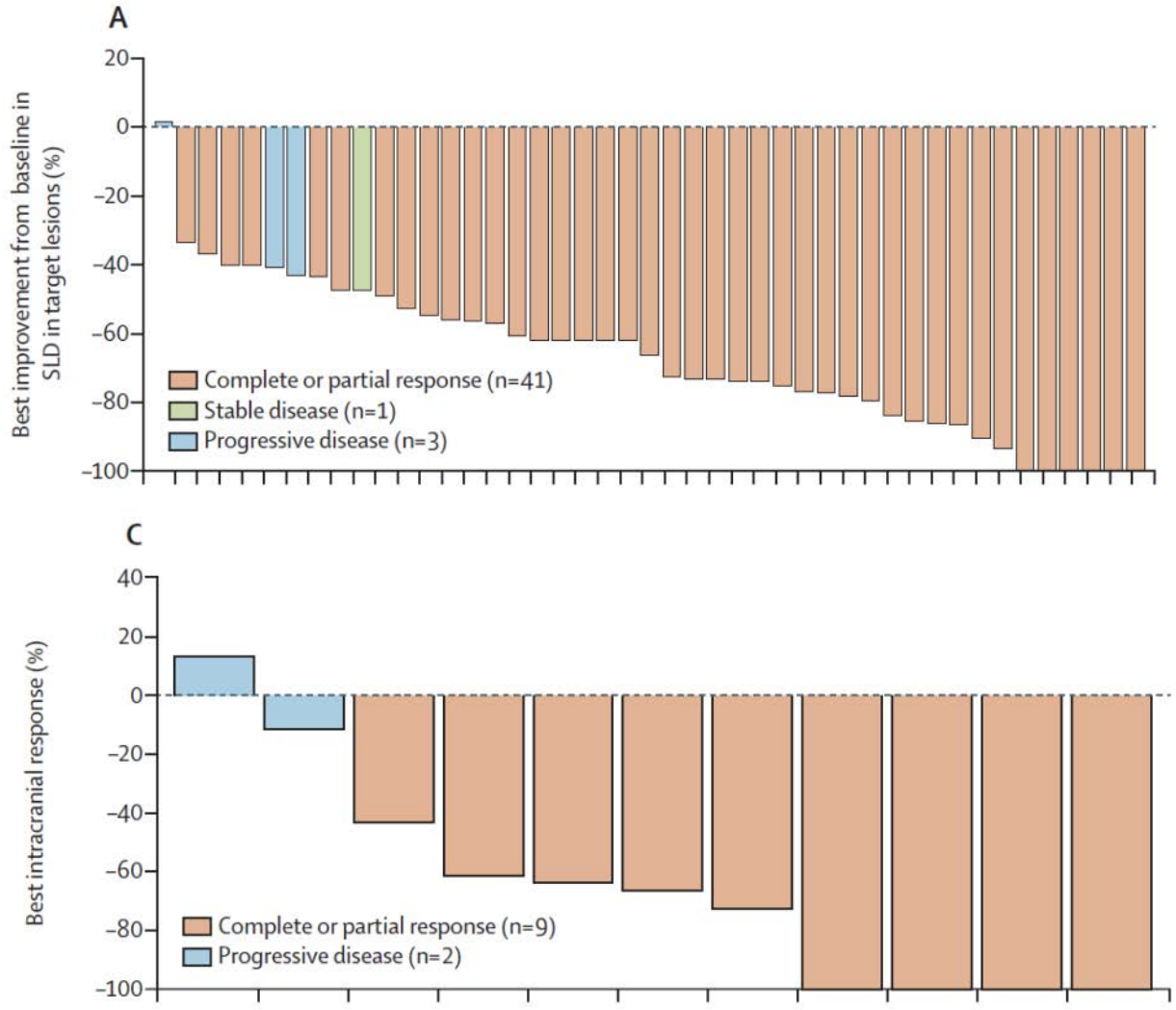
Module 1: ROS1 Rearrangements

- **Key Relevant Data Set**
  - Entrectinib: Integrated analysis of 3 Phase I/II trials

Entrectinib in ROS1+ lung cancer update



- ORR = 77% (64-88%)
- Median DOR = 24.6 months (11.4-34.8)
- Median PFS = 19 months (12.2-36.6)
- Intracranial ORR = 55% (32-77%)

Courtesy of Paul K Paik, MD

Drilon et al. Lancet Oncol 2020

For a patient with newly diagnosed metastatic adenocarcinoma of the lung with a ROS1 rearrangement and a PD-L1 tumor proportion score (TPS) of 10%, in which line of therapy would you most likely administer targeted treatment?

1. First line
2. Second line
3. Third line
4. After the third line

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Module 2: EGFR Exon 19 Deletion

- **Key Relevant Data Sets**
  - ADAURA: Adjuvant osimertinib for resected NSCLC
  - ADAURA: CNS disease recurrence
  - Patritumab deruxtecan: Novel HER3-directed antibody-drug conjugate

ADAURA Phase III double-blind study design

Patients with completely resected stage* IB, II, IIIA NSCLC, with or without adjuvant chemotherapy†

Key inclusion criteria:
≥18 years (Japan / Taiwan: ≥20)
WHO performance status 0 / 1
Confirmed primary non-squamous NSCLC
Ex19del / L858R‡
Brain imaging, if not completed pre-operatively
Complete resection with negative margins§
Max. interval between surgery and randomization:
- 10 weeks without adjuvant chemotherapy
- 26 weeks with adjuvant chemotherapy

Stratification by:
stage (IB vs II vs IIIA)
EGFRm (Ex19del vs L858R)
race (Asian vs non-Asian)

Randomization 1:1 (N=682)

- Osimertinib 80 mg, once daily
- Placebo, once daily

Planned treatment duration: 3 years

Treatment continues until:
- Disease recurrence
- Treatment completed
- Discontinuation criterion met

Follow up:
- Until recurrence: Week 12 and 24, then every 24 weeks to 5 years, then yearly
- After recurrence: every 24 weeks for 5 years, then yearly

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**

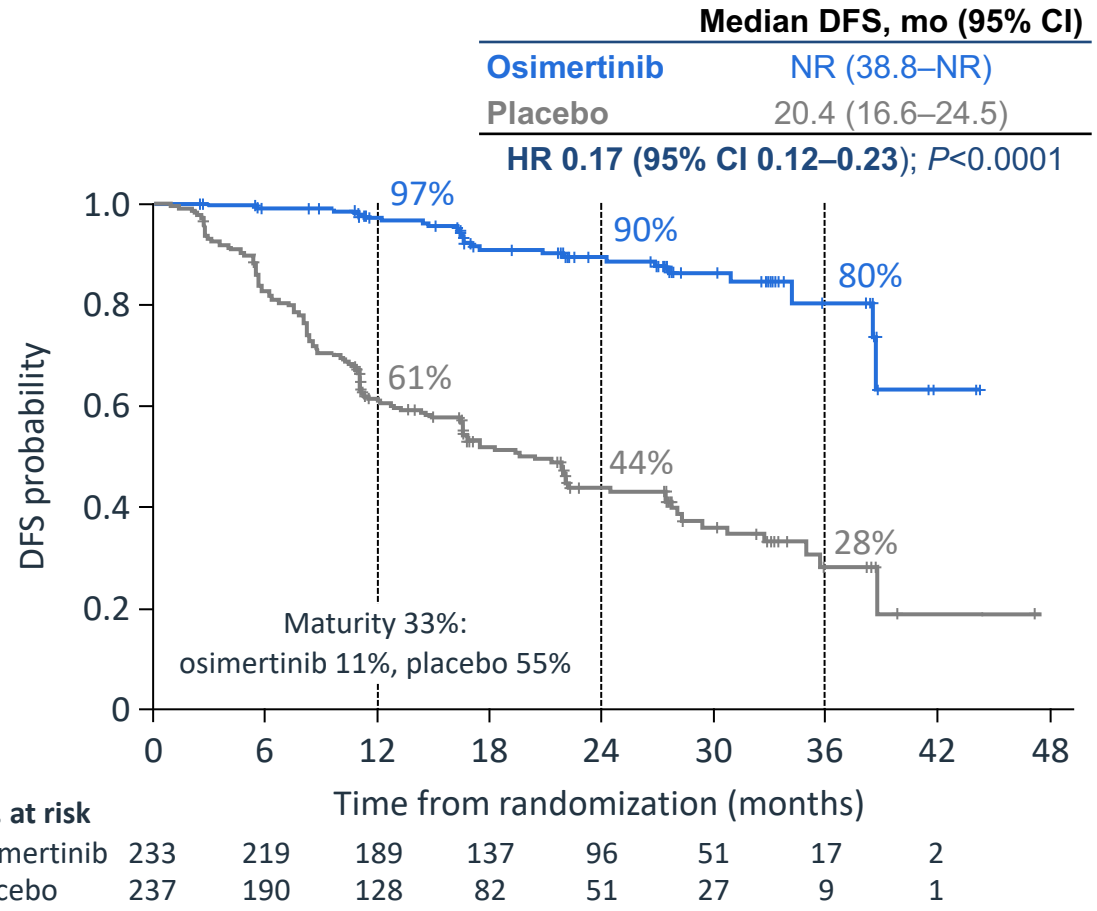
NCT02511106; ADAURA data cut-off: January 17, 2020. *AJCC 7th edition; †Prior, post, or planned radiotherapy was not allowed; ‡Centrally confirmed in tissue; §Patients received a CT scan after resection and within 28 days prior to treatment; ¶Stage IB / II / IIIA.
CT, computed tomography; Ex19del, exon 19 deletion;
IDMC, Independent Data Monitoring Committee; WHO, World Health Organization.

Herbst RS, et al. ASCO 2020. Abstract LBA5.

Courtesy of Joel W Neal, MD, PhD

ADAURA: Disease-free survival (DFS)

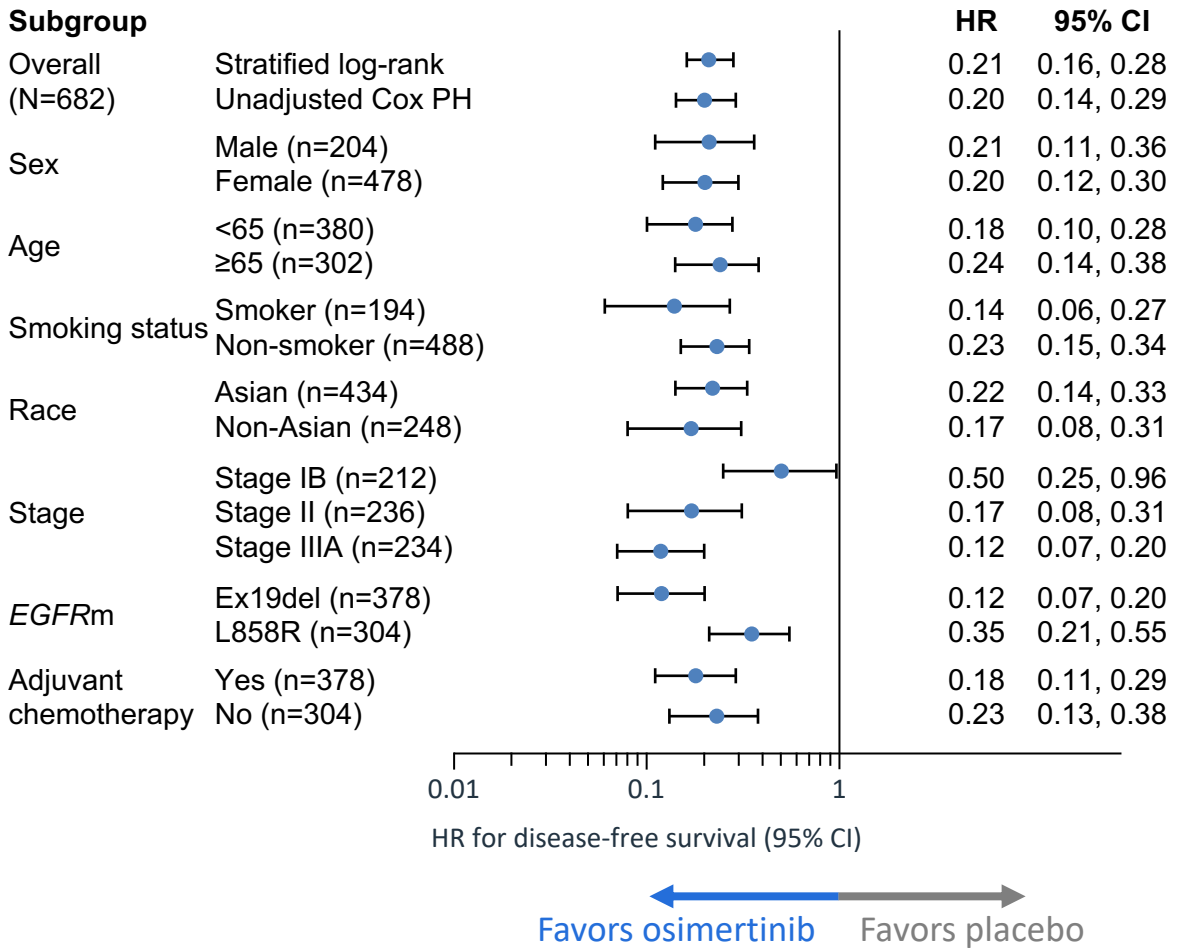
Primary endpoint: DFS in patients with Stage II/IIIA disease



No. at risk

Osimertinib	233	219	189	137	96	51	17	2
Placebo	237	190	128	82	51	27	9	1

DFS across subgroups in the overall population



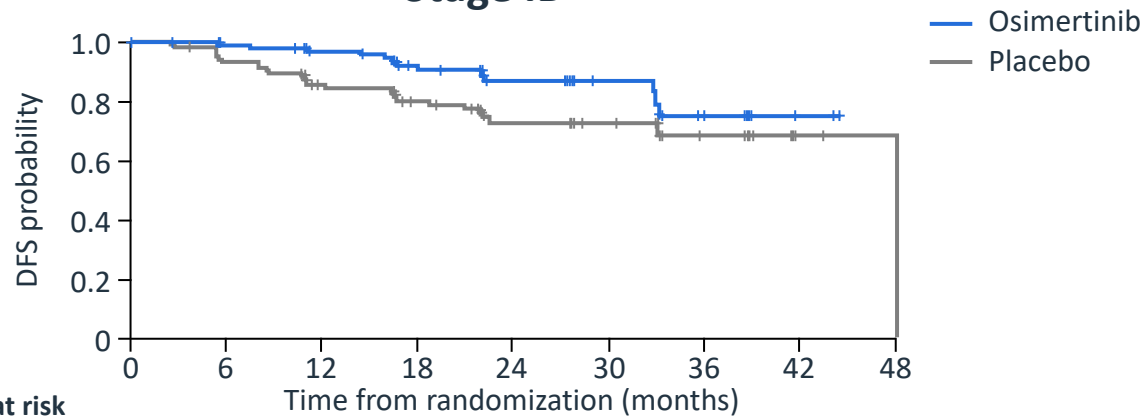
Data cutoff: January 17, 2020. NR, not reached

Herbst RS, et al. ASCO 2020. Abstract LBA5.

Courtesy of Joel W Neal, MD, PhD

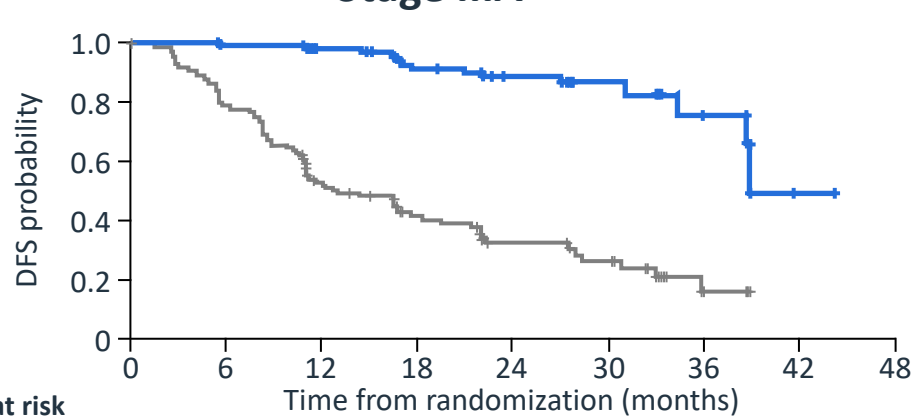
ADAURA: Disease-free survival by stage

Stage IB



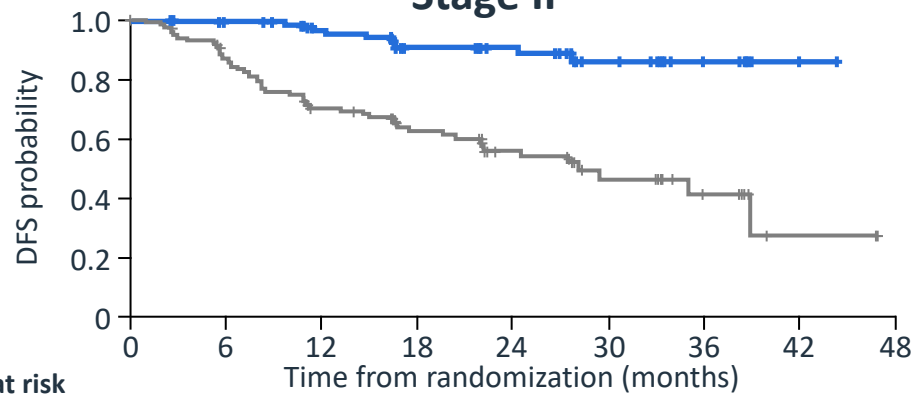
No. at risk									
Osimertinib	106	95	83	69	40	22	8	2	0
Placebo	106	98	81	67	36	26	11	2	1

Stage IIIA



No. at risk									
Osimertinib	115	109	98	68	49	23	9	1	0
Placebo	119	91	54	33	20	12	2	0	

Stage II



No. at risk									
Osimertinib	118	110	91	69	47	28	8	1	0
Placebo	118	99	74	49	31	15	7	1	0

2 Year DFS rate

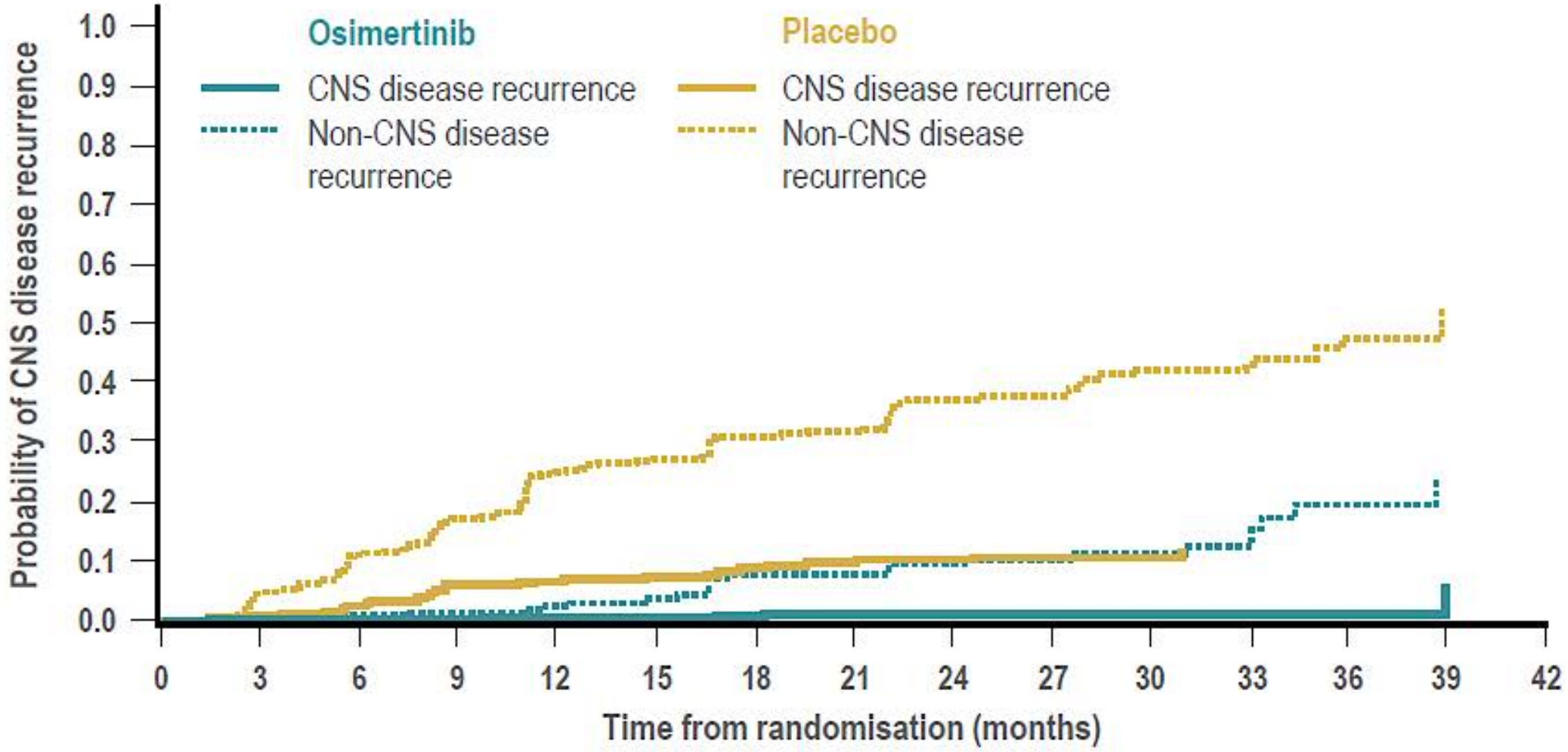
% (95% CI)	Stage IB	Stage II	Stage IIIA
Osimertinib	87 (77–93)	91 (82–95)	88 (79–94)
Placebo	73 (62–81)	56 (45–65)	32 (23–42)
Overall HR (95% CI)	**0.50 (0.25–0.96)**	**0.17 (0.08–0.31)**	**0.12 (0.07–0.20)**

Data cutoff: January 17, 2020.

Herbst RS, et al. ASCO 2020. Abstract LBA5.

Courtesy of Joel W Neal, MD, PhD

ADAURA: CNS Recurrence Risk

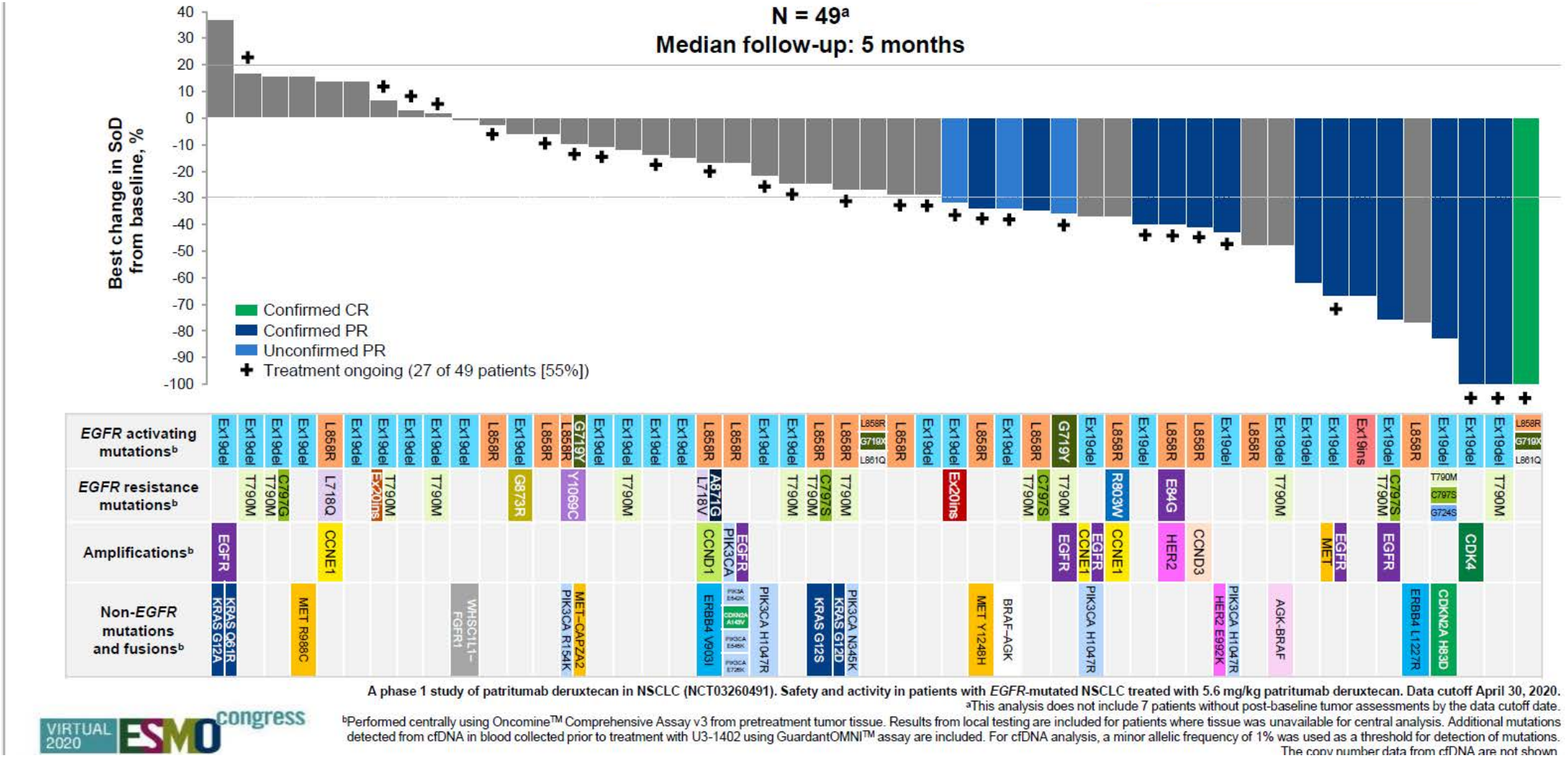


Tsuboi M ESMO 2020; Abstract LBA1

Courtesy of Joel W Neal, MD, PhD

Patritumab Deruxtecan in EGFR mutant NSCLC

This is a HER3 directed antibody-drug conjugate
Tested in 49 pts with EGFR+ NSCLC resistant to prior therapy



A phase 1 study of patritumab deruxtecan in NSCLC (NCT03260491). Safety and activity in patients with *EGFR*-mutated NSCLC treated with 5.6 mg/kg patritumab deruxtecan. Data cutoff April 30, 2020.

[a]This analysis does not include 7 patients without post-baseline tumor assessments by the data cutoff date.

[b]Performed centrally using Oncomine™ Comprehensive Assay v3 from pretreatment tumor tissue. Results from local testing are included for patients where tissue was unavailable for central analysis. Additional mutations detected from cfDNA in blood collected prior to treatment with U3-1402 using GuardantOMNI™ assay are included. For cfDNA analysis, a minor allelic frequency of 1% was used as a threshold for detection of mutations. The copy number data from cfDNA are not shown.

VIRTUAL 2020 ESMO congress

Yu ESMO 2020 LBA62

Courtesy of Joel W Neal, MD, PhD

Patritumab Deruxtecan in EGFR mutant NSCLC

AE's appear generally tolerable

Patritumab deruxtecan continued to demonstrate a manageable safety profile

- The most common grade ≥3 TEAEs were thrombocytopenia (16 patients [28%]) and neutropenia (11 patients [19%])
- TEAEs associated with discontinuation (9%) included fatigue (n = 2), decreased appetite (n = 1), ILD (n = 1), pneumonitis (n = 1), and URTI (n = 1)
  - There were no discontinuations due to thrombocytopenia or neutropenia
- Three (5.3%) ILD events were adjudicated by an independent central review committee as being related to treatment
- There were no treatment-related TEAEs associated with death

TEAEs (regardless of causality), n (%)	N = 57
TEAEs	57 (100)
Grade ≥3	38 (67)
Associated with discontinuation	5 (9)
Associated with dose reduction	10 (18)
Associated with dose interruption	17 (30)
Associated with death	3 (5)
Treatment-emergent SAEs	21 (37)
Grade ≥3	18 (32)
Treatment related	11 (19)

TEAEs in ≥20% of patients, n (%)	N = 57	
	All grades	Grade ≥3
Fatigue	33 (58)	5 (9)
Nausea	31 (54)	2 (4)
Thrombocytopenia[a]	30 (53)	16 (28)
Decreased appetite	20 (35)	1 (2)
Neutropenia[b]	19 (33)	11 (19)
Vomiting	17 (30)	1 (2)
Alopecia	17 (30)	NA
Anemia[c]	15 (26)	5 (9)
Constipation	14 (25)	0

Yu ESMO 2020 LBA62

Courtesy of Joel W Neal, MD, PhD

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

What would you most likely recommend as consolidation treatment for a patient with locally advanced NSCLC who has completed chemoradiation therapy and is found to have an EGFR activating mutation?

1. Durvalumab
2. Osimertinib
3. Durvalumab + osimertinib
4. Durvalumab followed by osimertinib
5. Other

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Module 8: MET Exon 14 Skipping Mutations

Module 9: KRAS G12C Mutation

Module 3: EGFR Exon 20 Insertion

- **Key Relevant Data Sets**
  - ECOG-ACRIN 5162: Osimertinib 160 mg
  - Amivantamab: Anti-EGFR-MET bispecific antibody

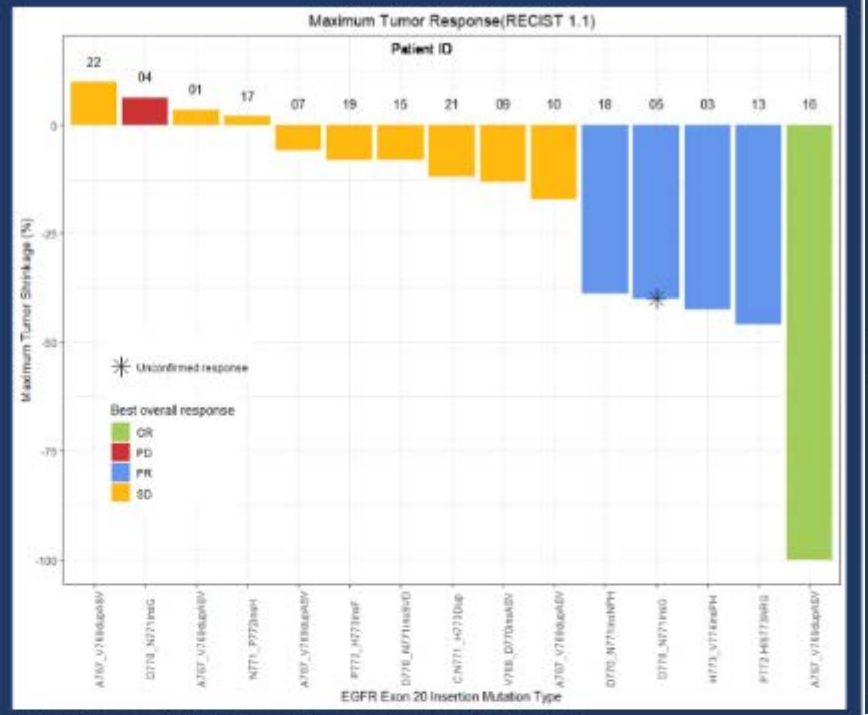
Osimertinib in EGFR Exon 20 insertion NSCLC

Exon 20 NSCLC comprises ~4% of EGFR+ NSCLC and is resistant to 1st and 2nd generation EGFR TKI therapy (Afatinib PFS ~3 months)

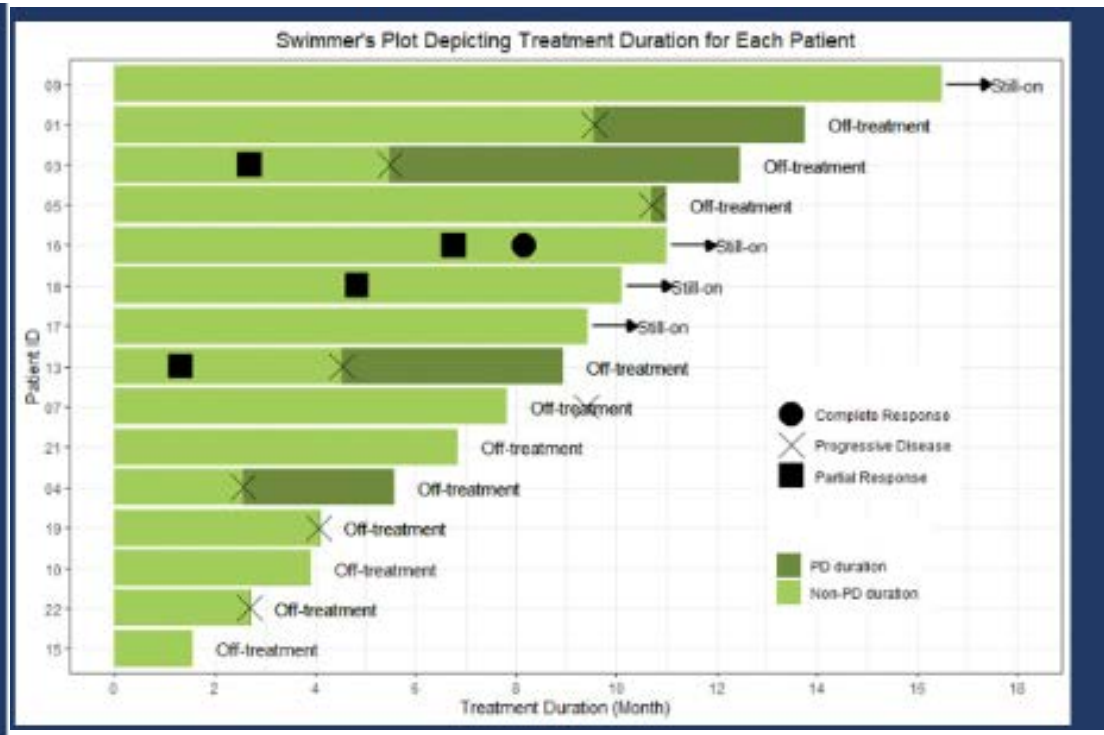
Fig 1. Waterfall Plot

OVERALL EFFICACY:

- **Confirmed ORR:** 4/17, 24%
- **DCR:** 14/17, 82%
- **mPFS:** 9.6 mo (95% CI, 4.1, 10.7)
- **mDOR:** NA (95% CI, 4.7, NA)



PR- partial response, SD- stable disease, PD- progressive disease, NA- not evaluable



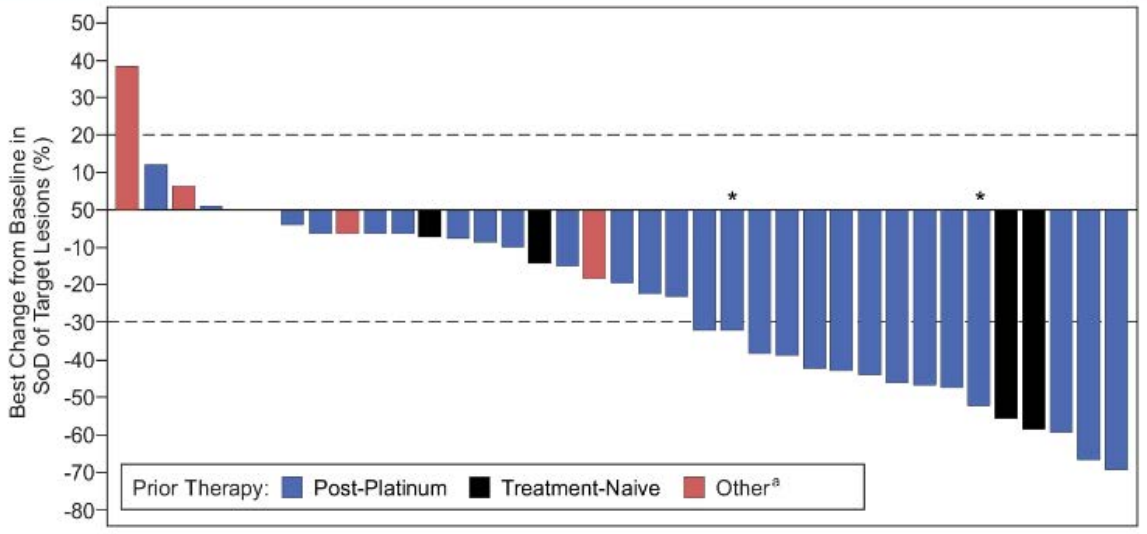
Pietrowska ASCO 2020 Abstract 9513

Courtesy of Joel W Neal, MD, PhD

Amivantamab in EGFR Exon 20 insertion NSCLC

Amivantamab is an EGFR/MET bispecific antibody
39 patients – RR 36% and PFS 8.3 months

Figure 2. Best Percentage Change from Baseline in Sum of Target Lesion Diameters

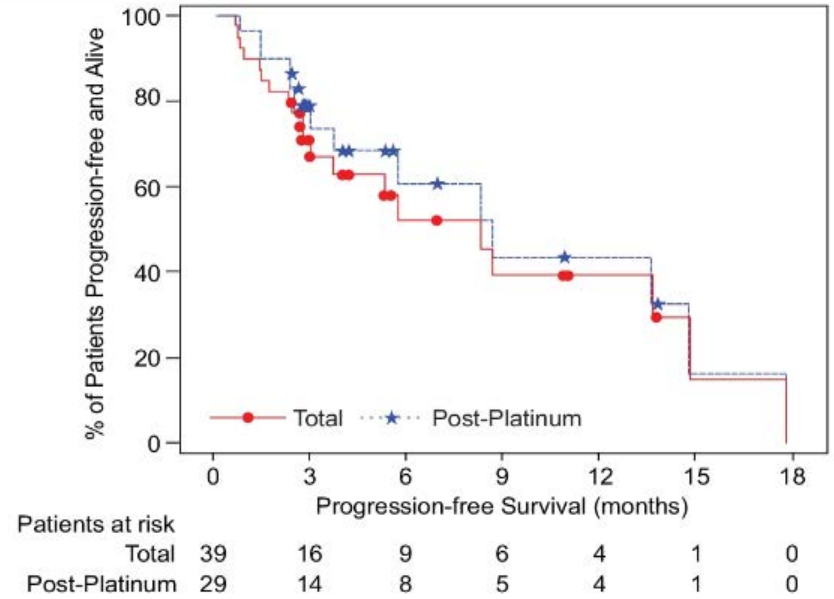


*Unconfirmed partial response. [a]2 patients treated with EGFR TKIs, 1 with bevacizumab plus radiation therapy, 1 with adjuvant immuno-oncology chemotherapy. 2 patients did not have post-baseline disease assessments and are not included in the plot. SoD=sum of diameters

- The overall response rate (ORR), confirmed responses only, was 36% (95% confidence interval [CI], 21–53), with 14/39 patients achieving a partial response.
- The ORR in post-platinum patients was 41% [95% CI, 24–61]).
- The clinical benefit rate (partial response or better or stable disease of at least 12 weeks [2 disease assessments]) was 67% (95% CI, 50–81) for all patients and 72% (95% CI, 53–87) for post-platinum patients.

- Median progression-free survival (mPFS) was 8.3 months (95% CI, 3.0–14.8) among all patients, with significant early censoring.
- Post-platinum patients had mPFS of 8.6 months (95% CI, 3.7–14.8).

Figure 5. Progression-free Survival



Park ASCO 2020 Abstract 9512

Courtesy of Joel W Neal, MD, PhD

Agenda

Case Presentation: Dr Deutsch – 67-year-old man

Module 1: ROS1 Rearrangements

Module 2: EGFR Exon 19 Deletion; Exon 21 (L858R) Point Mutation

Module 3: EGFR Exon 20 Insertion

Module 4: HER2 Amplification/Mutation

Module 5: ALK Rearrangement

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Module 7: RET Fusions

Module 8: MET Exon 14 Skipping Mutations

Module 9: KRAS G12C Mutation

Module 4: HER2 Amplification/Mutation

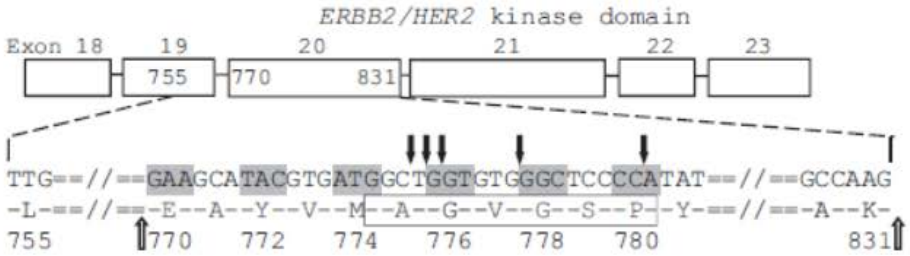
- **Key Relevant Data Set**
  - DESTINY-Lung01: Trastuzumab deruxtecan (T-DXd)

HER2 activating mutations in lung cancer

- **2-4% of lung cancers**
- **Most common *HER2* mutation is exon 20 insYVMA**
- **More common in women, never-smokers**

A

Schematic organization of *ERBB2* kinase domain



Wild-type sequence, exon 20

B

Spectrum of *ERBB2/HER2* mutations

Mut size	Total Cases (n = 25)	Nucleotide sequence*	CDS mutation (inserted sequence)	Amino acid mutation
12-bp ins	19 (76%)	TTG==//==GAAGCATACGTGATGGC**ATACGTGATGGC**TGGTGTGGGCTCCCCATAT -L-==//==-E--A--Y--V--M--A--**Y--V--M--A**--G--V--G--S--P--Y	c.2324_2325ins12 (ATACGTGATGGC duplication*)	p.Ala775_Gly776insTyrValMetAla

Memorial Sloan Kettering Cancer Center

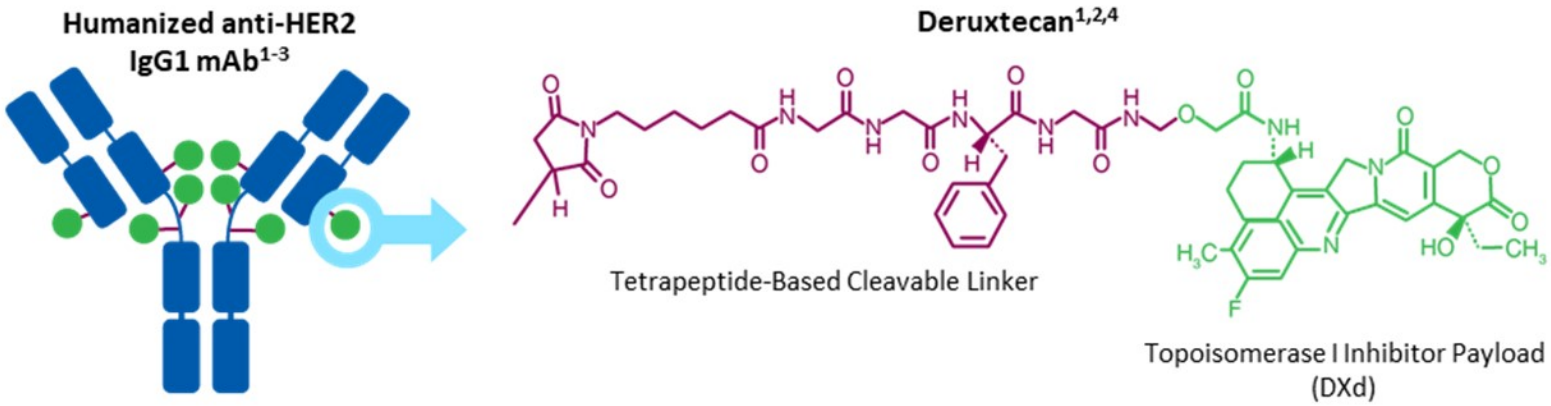
Courtesy of Paul K Paik, MD

Stephens et al. Nature. 2004
Arcila et al. Clin Cancer Res. 2012

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

The clinical relevance of these features is under investigation.
ADC, antibody-drug conjugate.

1. Nakada T, et al. *Chem Pharm Bull* (Tokyo). 2019;67(3):173-185. 2. Ogitani Y, et al. *Clin Cancer Res*. 2016;22(20):5097-5108. 3. Trail PA, et al. *Pharmacol Ther*. 2018;181:126-142. 4. Ogitani Y, et al. *Cancer Sci*. 2016;107(7):1039-1046.

DESTINY-1 trial

DESTINY-Lung01 Study Design

An open-label, multicenter, phase 2 study (NCT03505710)

Patients

- Unresectable/metastatic nonsquamous NSCLC
- Relapsed/refractory to standard treatment
- HER2-expressing *or* HER2-activating mutation[a]
- No prior HER2-targeted therapy, except pan-HER TKIs

Cohort 1 (n = 42)
HER2 expressing (IHC 3+ or IHC 2+)

Cohort 2 (n = 42)
HER2 mutated

T-DXd 6.4 mg/kg q3w

Primary endpoint

- Confirmed ORR by independent central review

Data cutoff: November 25, 2019

- 45.2% of patients (19/42) in Cohort 2 remained on treatment
- 54.8% discontinued, primarily for progressive disease and adverse events (21.4% each)

[a] Based on local assessment of archival tissue.

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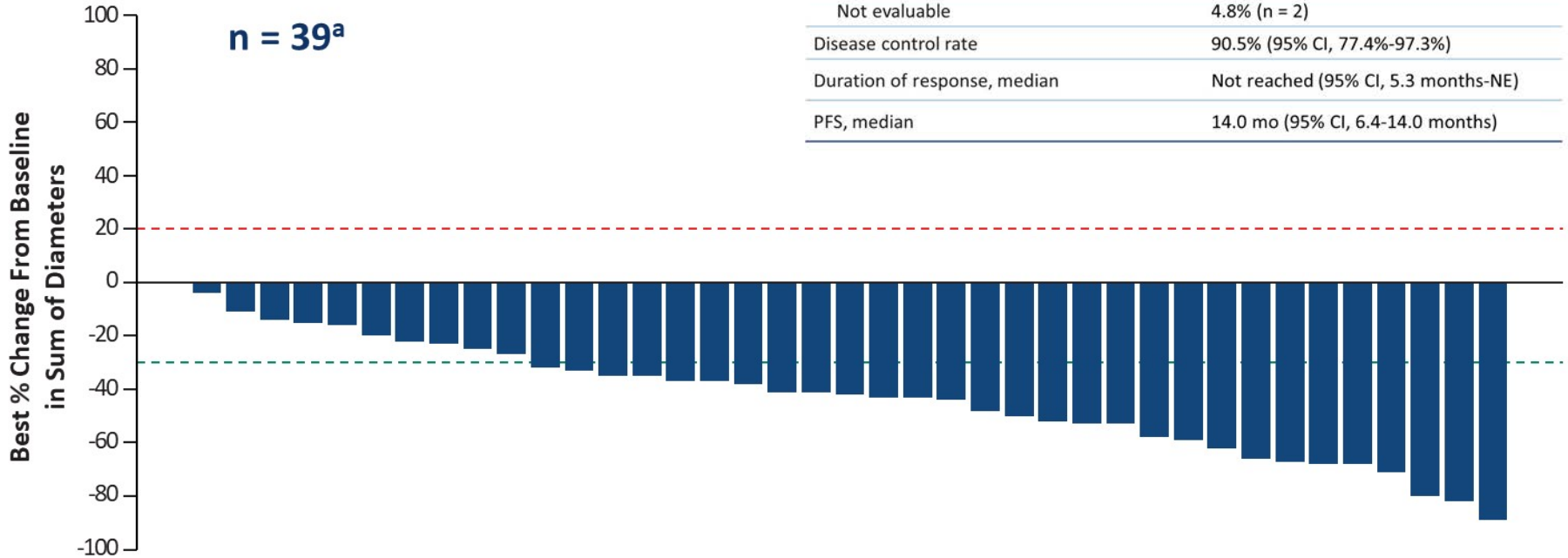
Courtesy of Paul K Paik, MD

Smit EF et al. ASCO 2020

DESTINY-1 efficacy

Best Change in Tumor Size

	Patients (N = 42)
Confirmed ORR by ICR	**61.9% (n = 26)** (95% CI, 45.6%-76.4%)
CR	2.4% (n = 1)
PR	59.5% (n = 25)
SD	28.6% (n = 12)
PD	4.8% (n = 2)
Not evaluable	4.8% (n = 2)
Disease control rate	90.5% (95% CI, 77.4%-97.3%)
Duration of response, median	Not reached (95% CI, 5.3 months-NE)
PFS, median	14.0 mo (95% CI, 6.4-14.0 months)



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.

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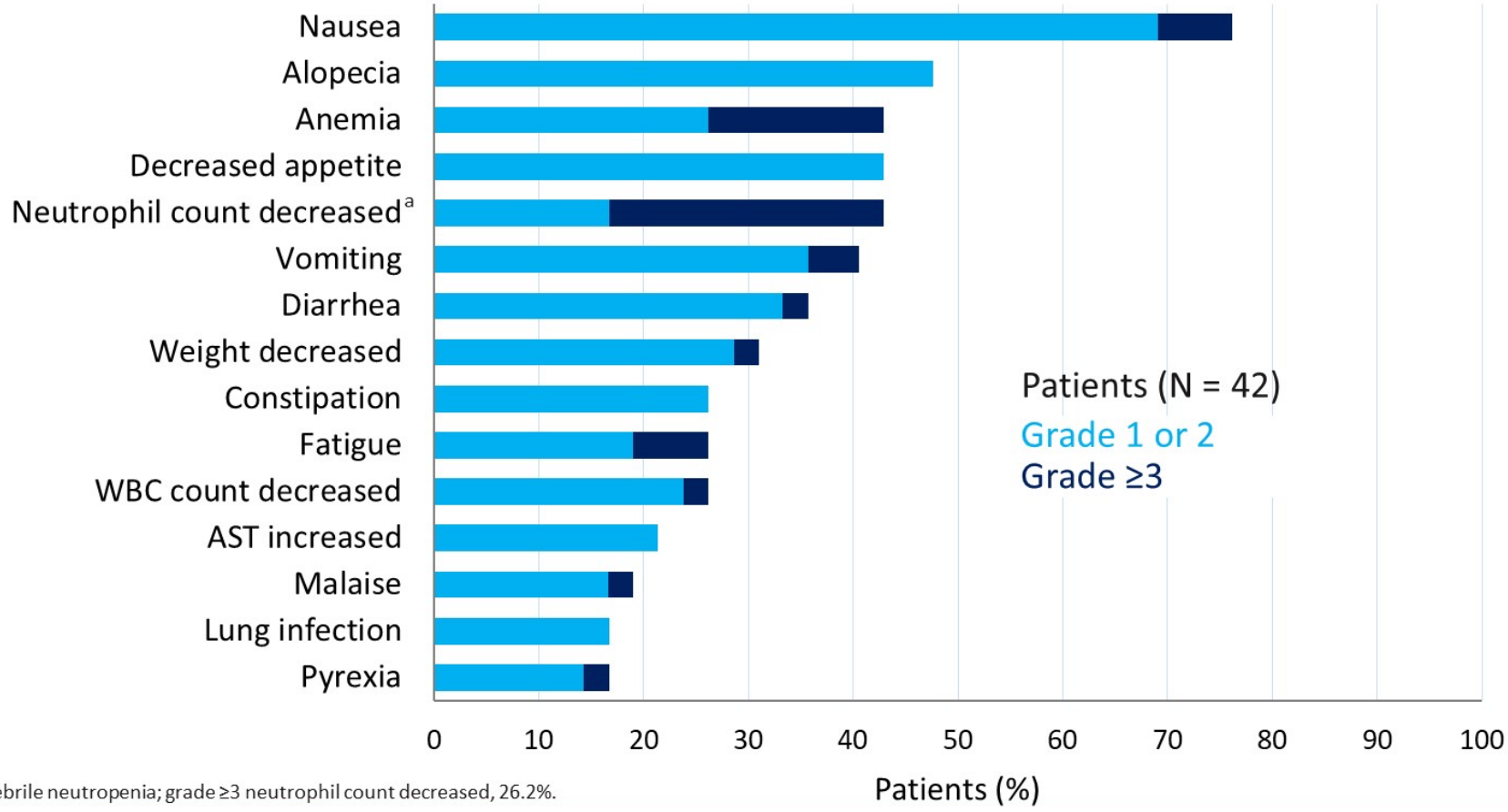
Smit EF et al. ASCO 2020

Trastuzumab deruxtecan side effects

Treatment-Emergent Adverse Events in >15% of Patients



[a] 2 patients had febrile neutropenia; grade ≥3 neutrophil count decreased, 26.2%.

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Courtesy of Paul K Paik, MD

Smit EF et al. ASCO 2020

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.

Regulatory and reimbursement issues aside, what would be your preferred first-line treatment for a patient with metastatic nonsquamous NSCLC with a HER2 mutation and a TPS of 10%?

1. Carboplatin/pemetrexed/pembrolizumab
2. Atezolizumab/carboplatin/taxane
3. Ipilimumab/nivolumab
4. Trastuzumab deruxtecan
5. Trastuzumab +/- pertuzumab
6. Pyrotinib
7. T-DM1
8. Neratinib
9. Other

Agenda

Case Presentation: Dr Deutsch – 67-year-old man

Module 1: ROS1 Rearrangements

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Module 7: RET Fusions

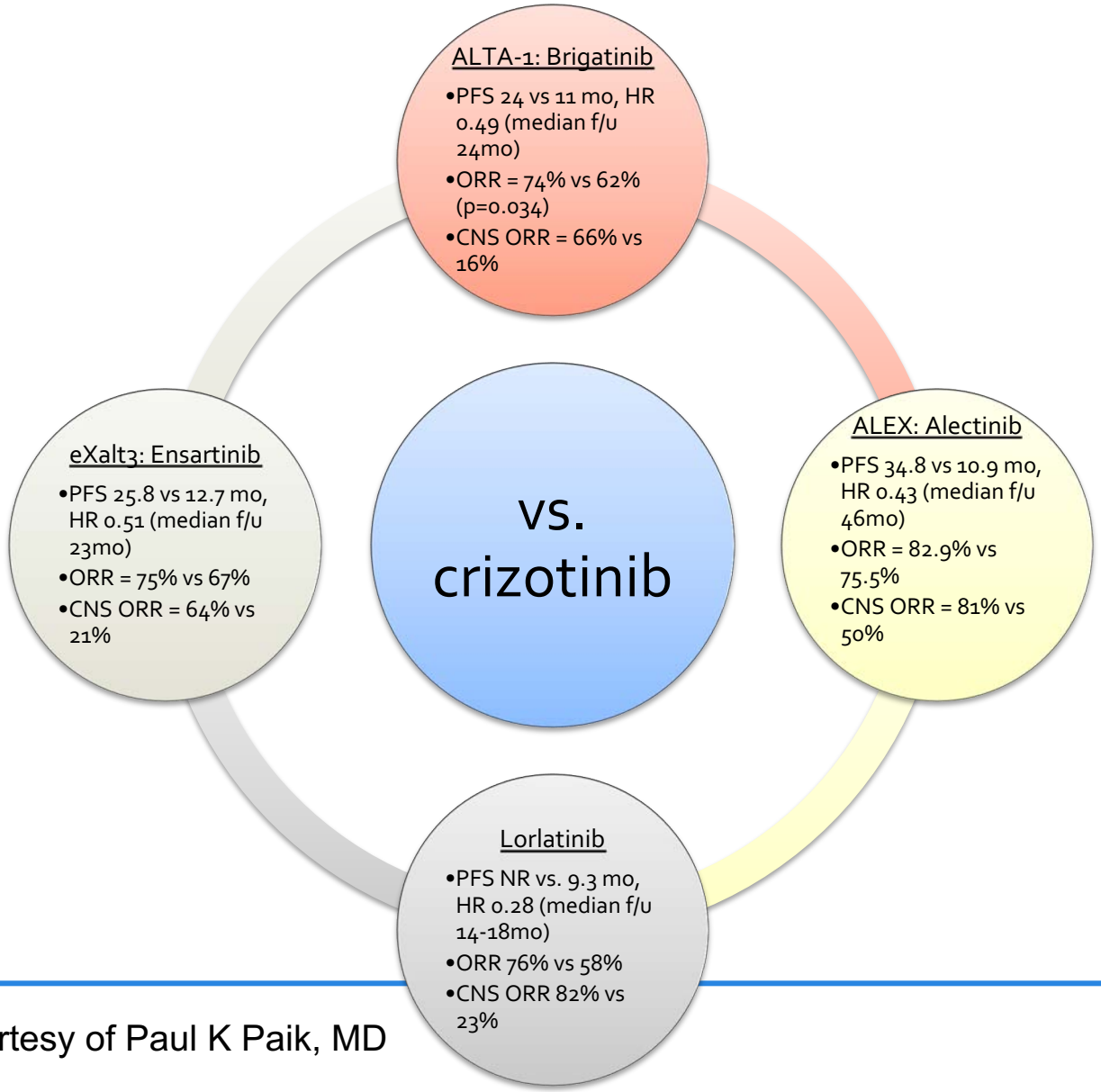
Module 8: MET Exon 14 Skipping Mutations

Module 9: KRAS G12C Mutation

Module 5: ALK Rearrangement

- **Key Relevant Data Sets**
  - ALTA-1L: Brigatinib vs crizotinib
  - eXalt3: Ensartinib vs crizotinib
  - ALEX: Updated OS and final PFS data
  - CROWN: First-line lorlatinib vs crizotinib

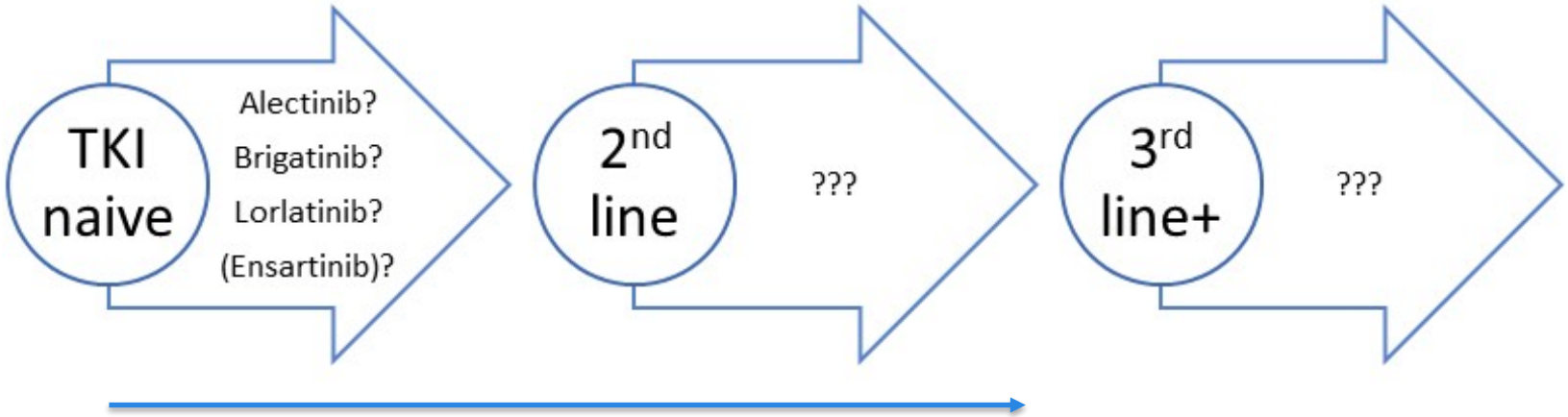
First-line ALK inhibitor trial readouts in 2020- are things clearer?



Courtesy of Paul K Paik, MD

Camidge et al. J Clin Oncol 2020
Mok et al. Ann Oncol 2020
Shaw NEJM 2020
Horn IASLC 2020

ALK+ lung cancer sequencing c. 2021



PFS ~ 30+ mo

Courtesy of Paul K Paik, MD

Which of the following ALK inhibitors is the most common first-line treatment used by lung cancer clinical investigators for metastatic nonsquamous NSCLC with an ALK rearrangement?

1. Crizotinib
2. Alectinib
3. Brigatinib
4. Lorlatinib
5. Ceritinib
6. I don’t know

Agenda

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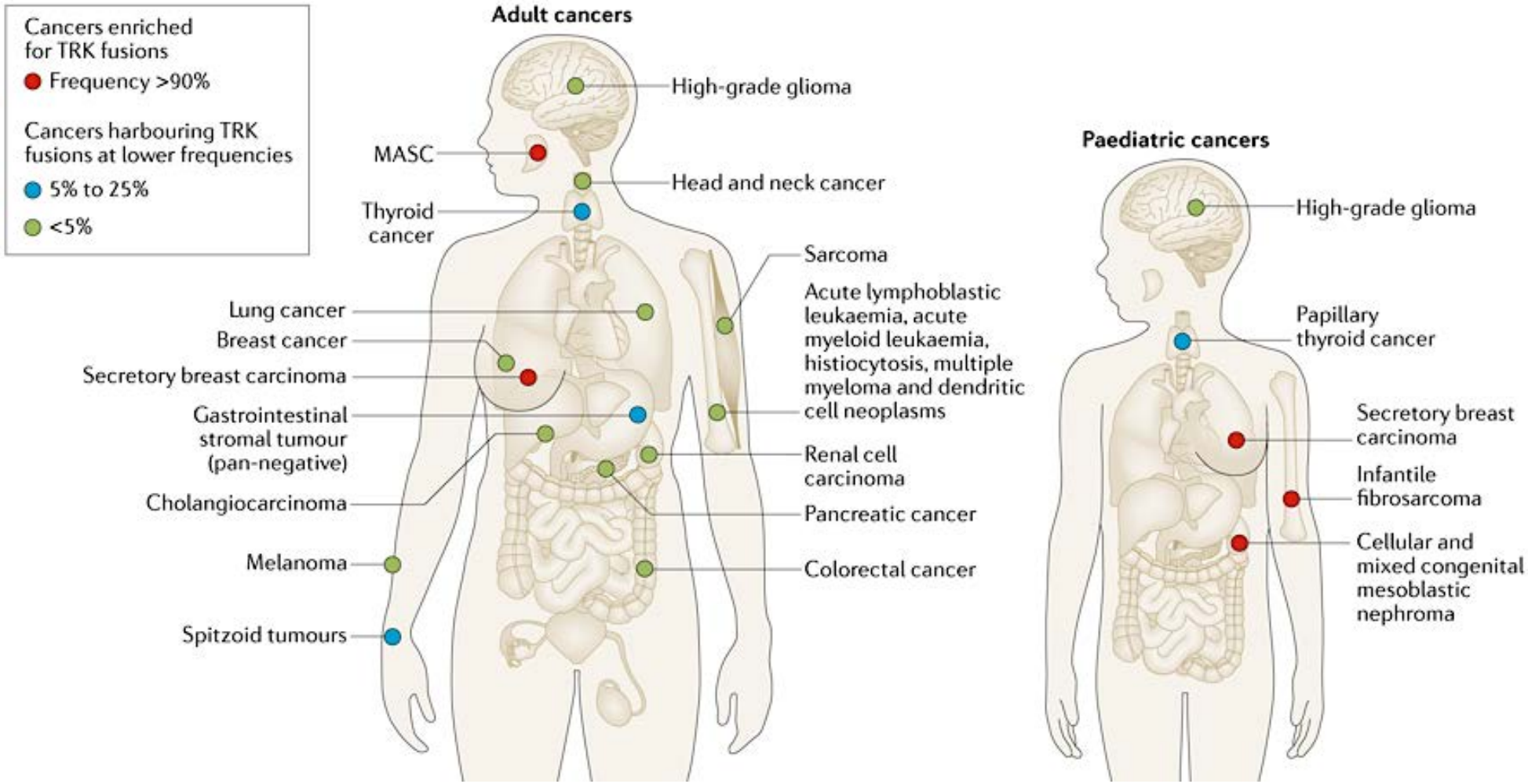
Module 6: NTRK Fusion

- **Key Relevant Data Sets**
  - Larotrectinib for TRK fusion
  - Entrectinib for solid tumors with NTRK fusion

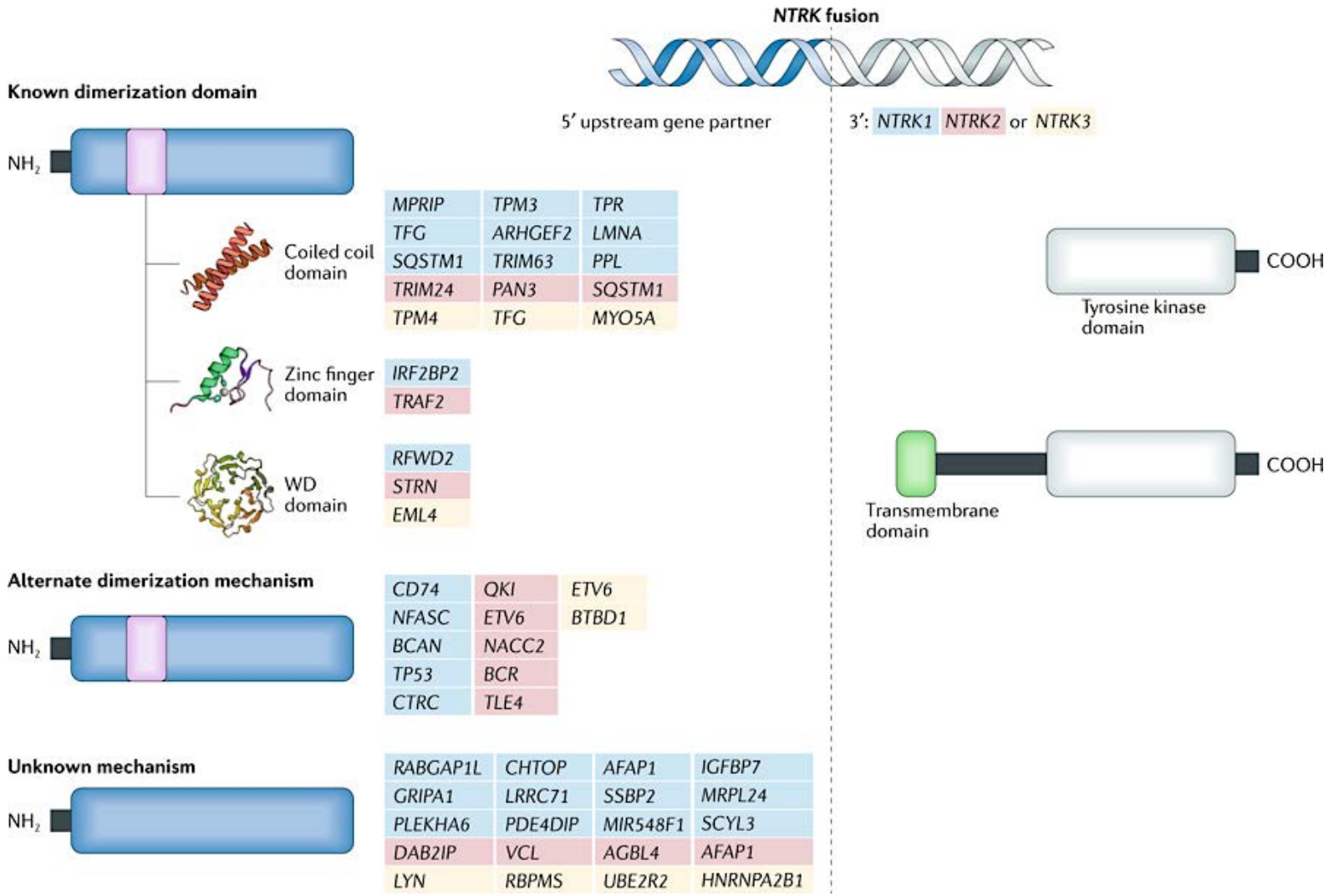
TRK fusions occur in multiple cancer types …



Courtesy of Paul K Paik, MD

Cocco et al, Nat Rev Clin Oncol 2018

… and have multiple partners leading to constitutive dimerization



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Courtesy of Paul K Paik, MD

Cocco et al, Nat Rev Clin Oncol 2018

First generation TRK inhibitors are highly effective

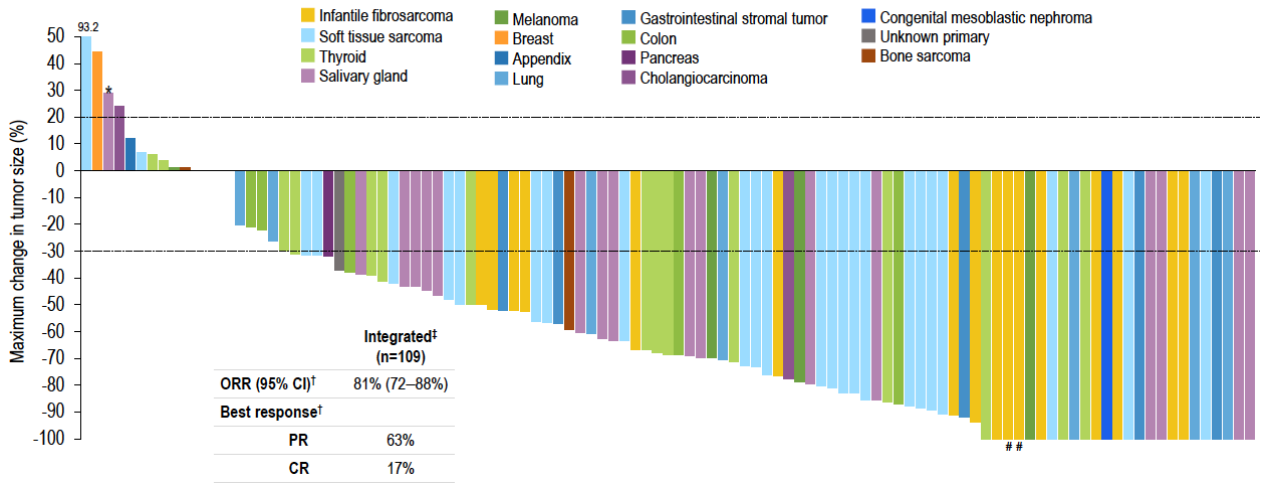
Larotrectinib

ORR 81%

(95% CI 72-88%, n=109)

Median DoR not reached

Median PFS not reached



FDA approved for NTRK fusion+ cancers November 2019

Entrectinib

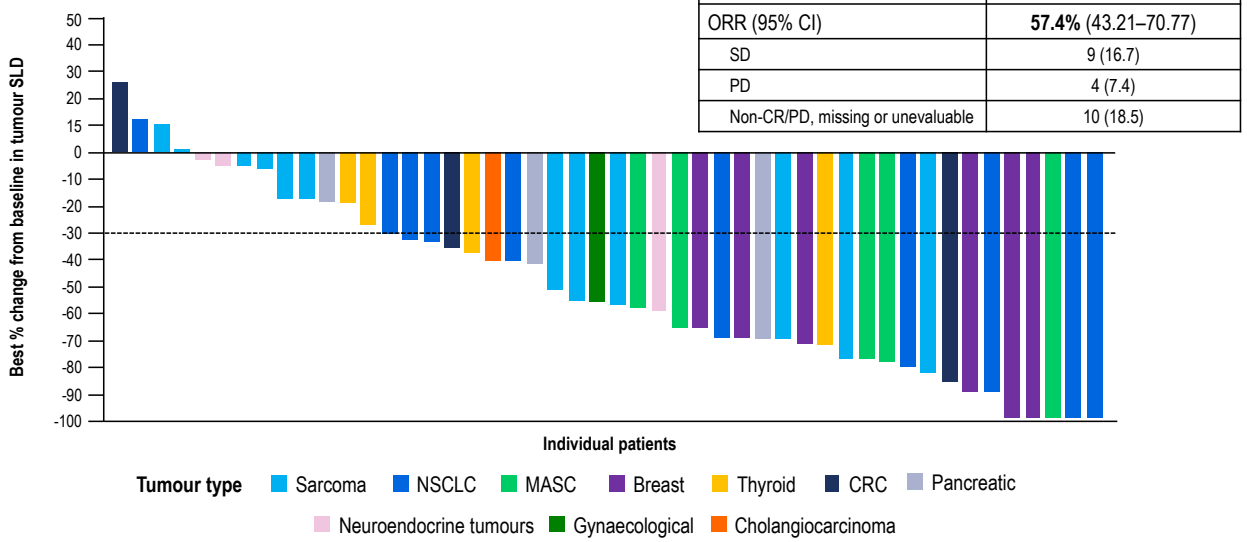
ORR 57%

(95% CI 43-71%, n=54)

Median DoR 10 mos

Median PFS 11 mos

	NTRK+ all patients (n=54)
ORR (95% CI)	**57.4%** (43.21–70.77)
SD	9 (16.7)
PD	4 (7.4)
Non-CR/PD, missing or unevaluable	10 (18.5)



FDA approved for NTRK fusion+ cancers August 2019

Memorial Sloan Kettering Cancer Center

Courtesy of Paul K Paik, MD

Drilon et al. NEJM 2018

Doebele et al. Lancet Oncol 2020

For a patient with metastatic nonsquamous NSCLC with an NTRK gene fusion and a PD-L1 TPS of 10%, in what line of therapy should targeted treatment (eg, larotrectinib, entrectinib) be used?

1. First line
2. Second line
3. Third line
4. Fourth line and beyond

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Module 7: RET Fusions

- **Key Relevant Data Sets**
  - ARROW: Pralsetinib – Registrational data set
  - Selpercatinib for disease with RET fusion

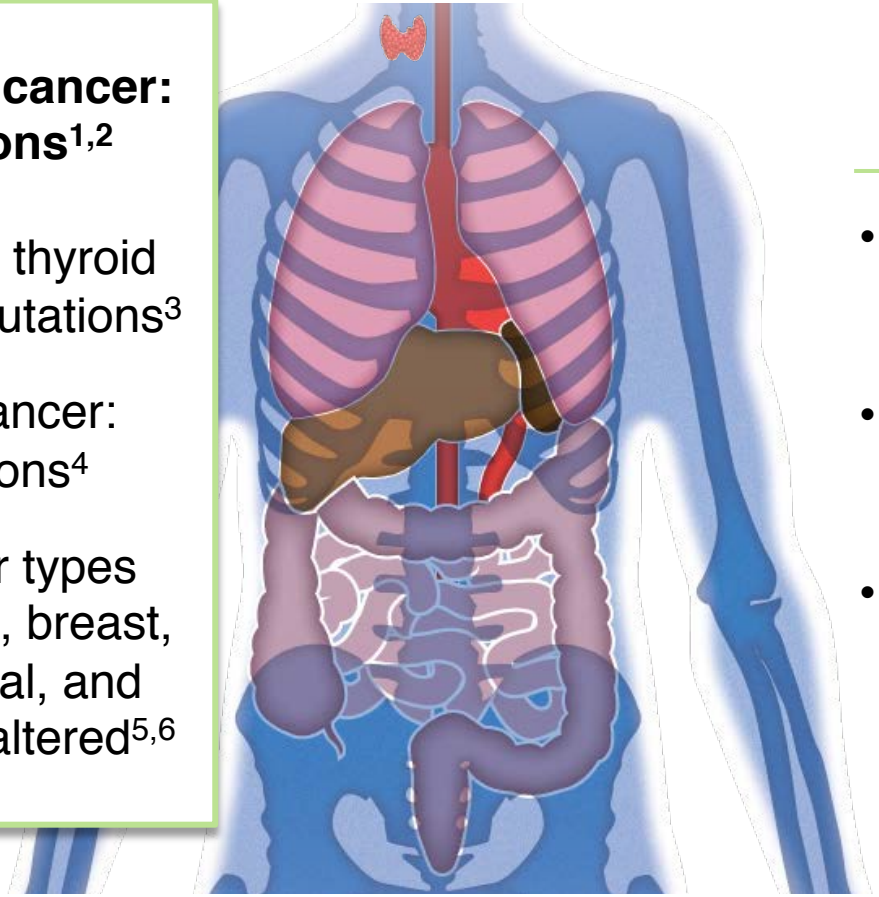
RET Alterations: Diverse Oncogenic Drivers Lacking Targeted Therapeutic Approach

Non-small cell lung cancer: ~1-2% RET fusions[1,2]

Advanced medullary thyroid cancer: ~90% RET mutations[3]

Papillary thyroid cancer: ~20% RET fusions[4]

Multiple other tumor types including esophageal, breast, melanoma, colorectal, and leukemia: <1% RET-altered[5,6]



NSCLC patients with RET fusions have not significantly benefited from existing therapy

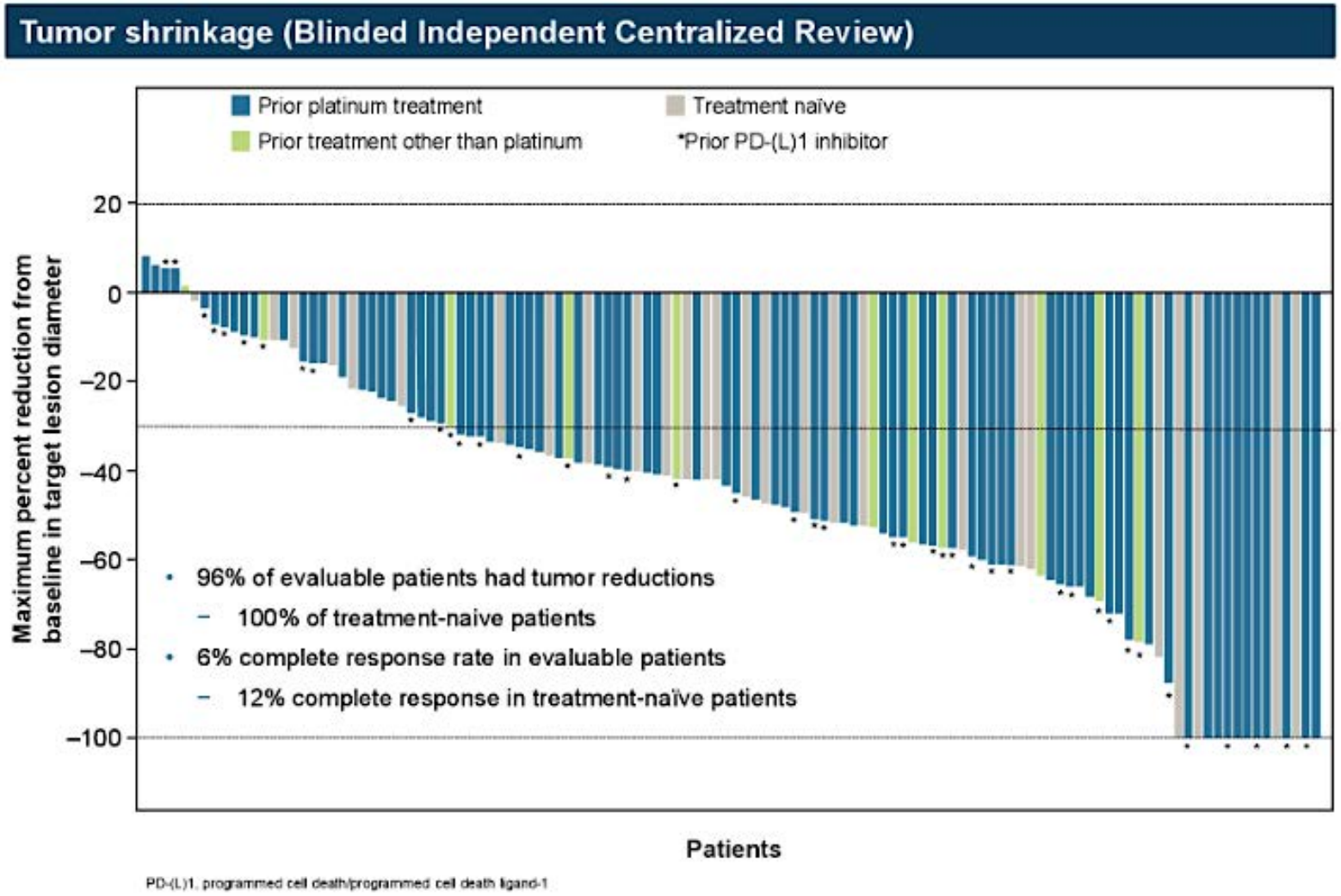
- Chemotherapy: nonspecific, low response rates, significant toxicity
- Checkpoint inhibition: Preliminary evidence for lack of benefit in RET-altered NSCLC[7]
- Multikinase inhibitors: ↓ activity, ↑ off-target toxicity[8,9]

NSCLC, non-small cell lung cancer; 1. Lipson, et al. *Nat Med* 2012; 2. Takeuchi, et al. *Nat Med* 2012; 3. Romei, et al. *Oncotarget* 2018; 4. Santoro, et al. *J Clin Invest* 1992; 5. Kato, et al. *Clin Cancer Res* 2017; 6. Ballerini, et al. *Leukemia* 2012; 7. Mazieres, et al. *JCO* 2018; 8. Drillon, et al. *Lancet* 2017; 9. Yoh, et al. *Lancet Respir Med* 2017

Courtesy of Justin F. Gainor MD

Pralsetinib in RET+ NSCLC

RET rearrangements are present in 1-2% of NSCLC
Best detected with FISH, DNA NGS or RNA-based assays



65% ORR (independent)

Median PFS not reached

56% (5/9) pts with intracranial response

Gainor ASCO 2020 Abstract 9515

Courtesy of Joel W Neal, MD, PhD

Pralsetinib in RET+ NSCLC

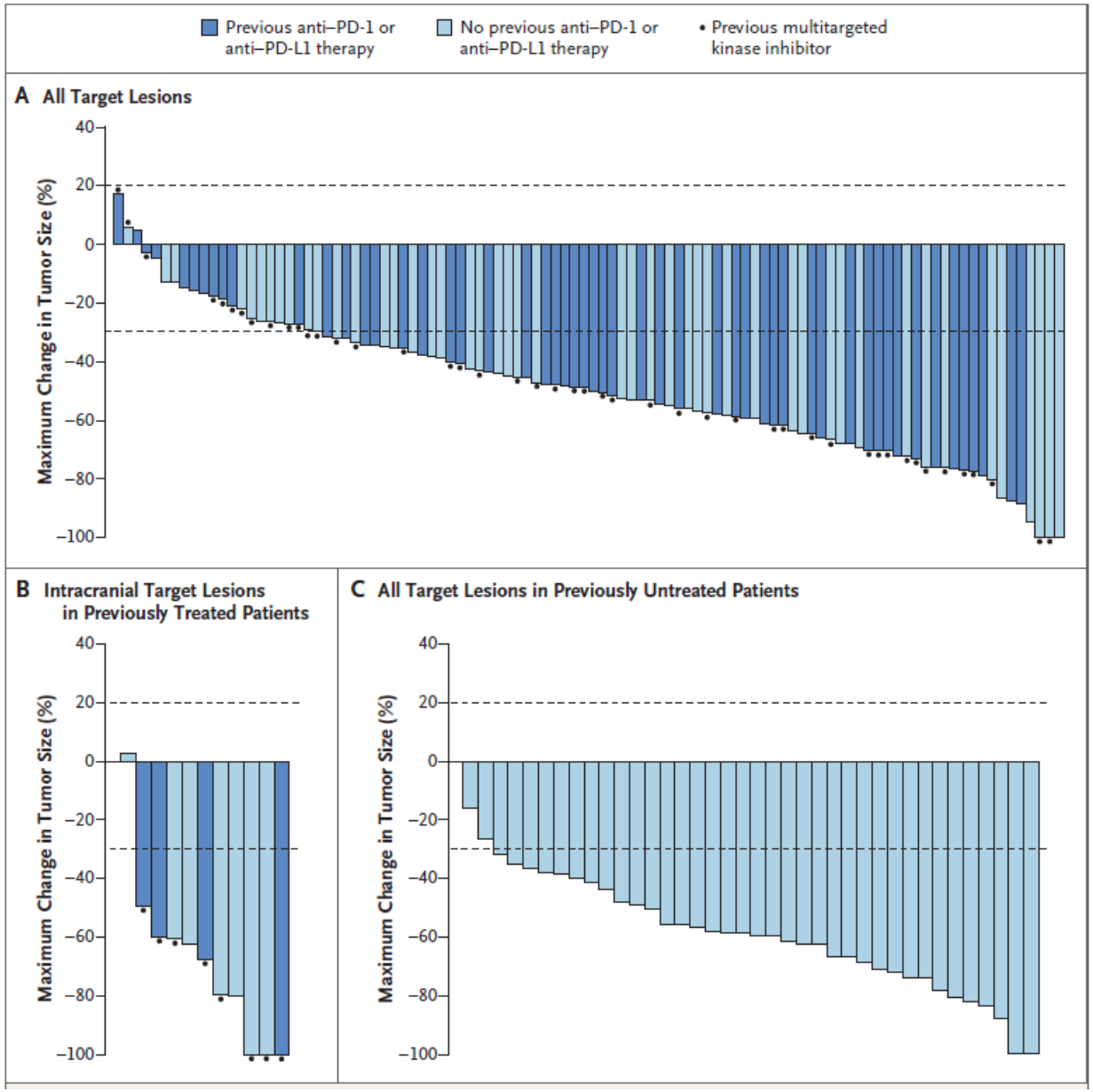
Note Transaminitis and pneumonitis

Treatment-related adverse events in ≥10% of patients (N=354, all tumor types)		
AE preferred term	All patients (n=354)	
	Any grade	Grade ≥3
AST increased	31%	2%
Anemia	22%	8%
ALT increased	21%	1%
Constipation	21%	1%
Hypertension	20%	10%
Neutropenia	19%	10%
Diarrhea	14%	1%
White blood cell count decreased	14%	3%
Dysgeusia	13%	0%
Blood creatinine increased	12%	0%
Fatigue	12%	1%
Neutrophil count decreased	12%	4%
Dry mouth	11%	0%
Hyperphosphatemia	11%	<1%
Asthenia	10%	1%

Gainor ASCO 2020 Abstract 9515

Courtesy of Joel W Neal, MD, PhD

Selpercatinib in RET+ NSCLC



Prior therapy:
64% ORR
PFS 16.5 mo

1st line:
85% ORR
PFS NR (?>18 mo)

Drilon NEJM 2020

Courtesy of Joel W Neal, MD, PhD

Selpercatinib in RET+ NSCLC

Note QT prolongation

Table 3. Adverse Events in 144 Patients with *RET* Fusion–Positive NSCLC Who Received Selpercatinib.*

Adverse Event	Adverse Events, Regardless of Attribution (N=144)					Treatment-Related Adverse Events (N=144)		
	Grade 1	Grade 2	Grade 3	Grade 4	Any Grade	Grade 3	Grade 4	Any Grade
	number of patients (percent)							
Any adverse event	8 (6)	47 (33)	69 (48)	14 (10)	144 (100)	39 (27)	2 (1)	131 (91)
Diarrhea	46 (32)	18 (12)	5 (3)	0	69 (48)	2 (1)	0	36 (25)
Dry mouth	48 (33)	11 (8)	0	0	59 (41)	0	0	52 (36)
Hypertension	3 (2)	22 (15)	20 (14)	0	45 (31)	13 (9)	0	25 (17)
Increased aspartate aminotransferase level	18 (12)	11 (8)	12 (8)	2 (1)	43 (30)	7 (5)	1 (1)	32 (22)
Fatigue	26 (18)	16 (11)	0	0	42 (29)	0	0	19 (13)
Increased alanine aminotransferase level	14 (10)	6 (4)	15 (10)	3 (2)	38 (26)	11 (8)	2 (1)	29 (20)
Constipation	33 (23)	3 (2)	2 (1)	0	38 (26)	1 (1)	0	16 (11)
Nausea	32 (22)	5 (3)	1 (1)	0	38 (26)	0	0	14 (10)
Peripheral edema	29 (20)	6 (4)	0	0	35 (24)	0	0	19 (13)
Urinary tract infection	4 (3)	21 (15)	7 (5)	0	32 (22)	0	0	0
Headache	21 (15)	7 (5)	2 (1)	0	30 (21)	0	0	6 (4)
Rash	20 (14)	6 (4)	2 (1)	0	28 (19)	2 (1)	0	17 (12)
Abdominal pain	18 (12)	8 (6)	1 (1)	0	27 (19)	0	0	5 (3)
Cough	24 (17)	3 (2)	0	0	27 (19)	0	0	3 (2)
Increased blood creatinine level	21 (15)	3 (2)	0	0	24 (17)	0	0	13 (9)
Dyspnea	15 (10)	6 (4)	3 (2)	0	24 (17)	0	0	4 (3)
Vomiting	17 (12)	6 (4)	1 (1)	0	24 (17)	1 (1)	0	5 (3)
Prolonged QT on electrocardiography	9 (6)	7 (5)	7 (5)	0	23 (16)	3 (2)	0	14 (10)
Pyrexia	14 (10)	8 (6)	1 (1)	0	23 (16)	1 (1)	0	8 (6)
Dry skin	19 (13)	3 (2)	0	0	22 (15)	0	0	13 (9)
Thrombocytopenia	13 (9)	6 (4)	3 (2)	0	22 (15)	2 (1)	0	15 (10)

Drilon NEJM 2020

Courtesy of Joel W Neal, MD, PhD

For a patient with metastatic nonsquamous NSCLC with a RET rearrangement and a PD-L1 TPS of 10%, in what line of therapy should targeted treatment (eg, selpercatinib, pralsetinib) be used?

1. First line
2. Second line
3. Third line
4. Fourth line and beyond

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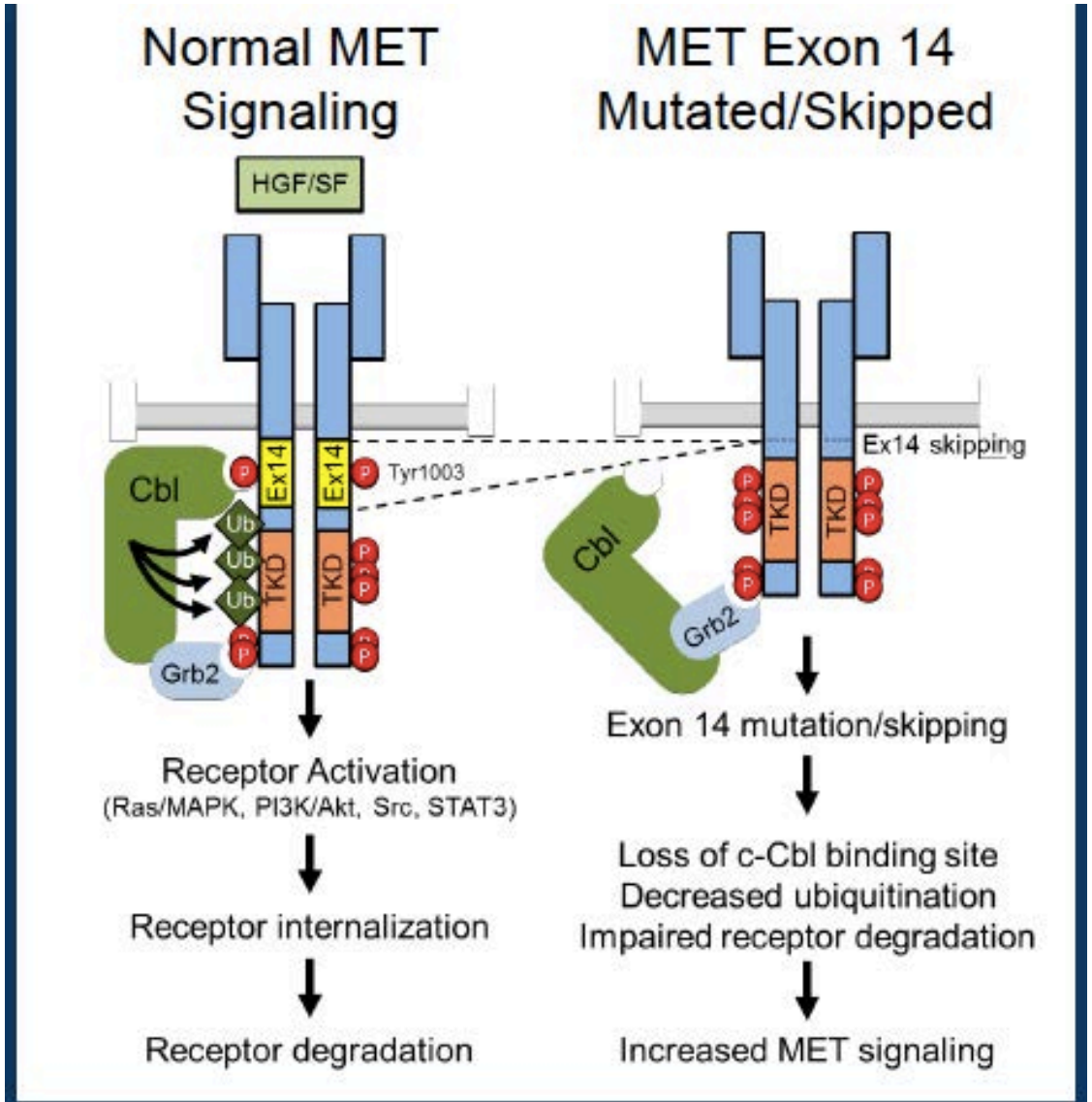
Module 9: KRAS G12C Mutation

Module 8: MET Exon 14 Skipping Mutations

- **Key Relevant Data Sets**
  - GEOMETRY mono-1: Capmatinib for MET exon 14 mutation or amplification
  - Tepotinib for MET exon 14 skipping mutations

Met Exon 14 NSCLC

MET exon 14 alterations are present in 3-4% of NSCLC
Best detected with DNA NGS or RNA-based assays

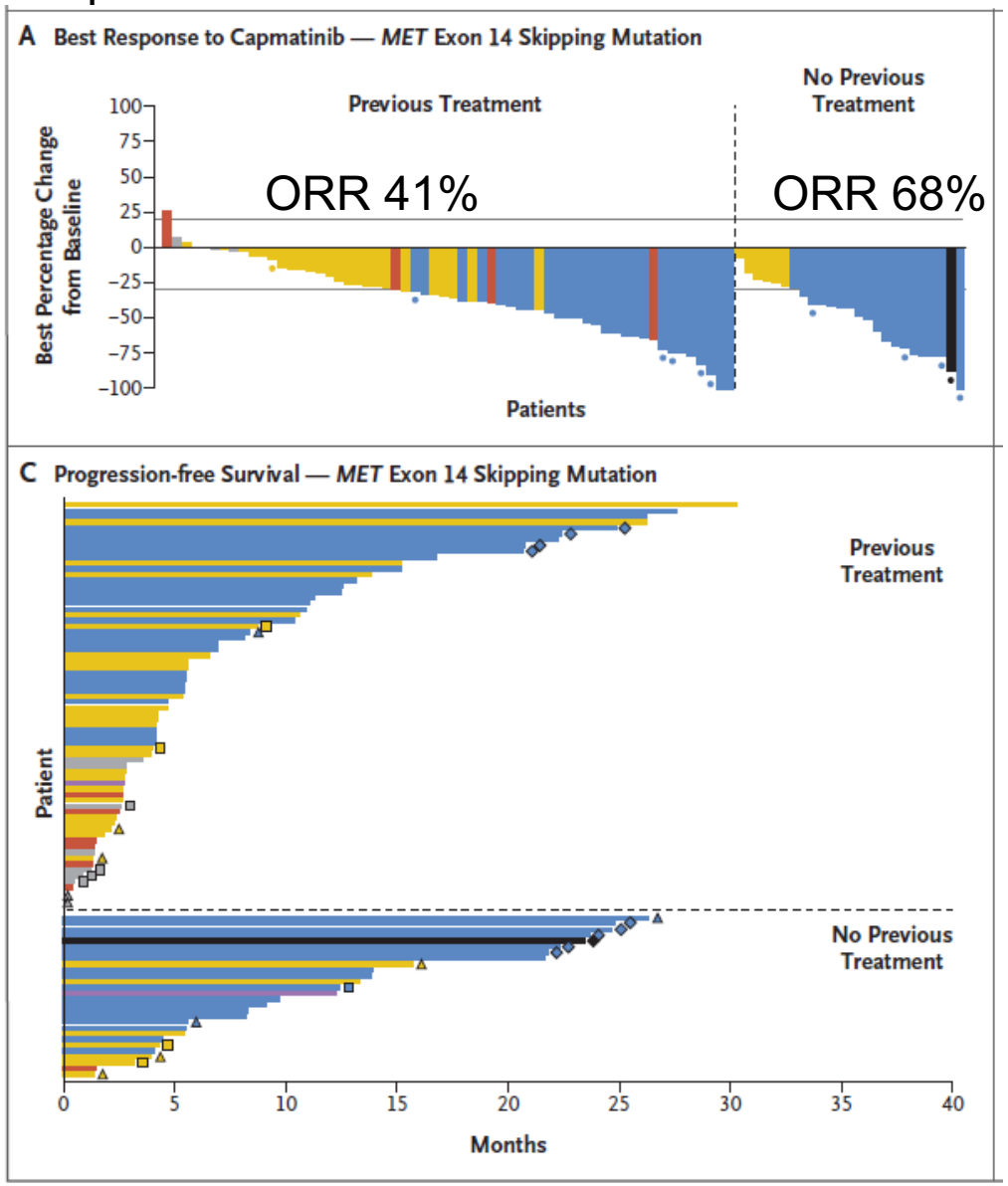


TCGA, *Nature*. 2014 Jul 31;511(7511):543-50.
Awad MM, et al, *J Clin Oncol*. 2016 Mar 1;34(7):721-30.
Paik PK, et al, *Cancer Discov*. 2015 Aug;5(8):842-9.
Frampton GM, et al, *Cancer Discov*. 2015 Aug;5(8):850-9.
Awad MM, et al, J Clin Oncol. 2016 Mar 10;34(8):879-81.

Courtesy of Joel W Neal, MD, PhD

Capmatinib in Met Exon 14 NSCLC

364 patients across all cohorts



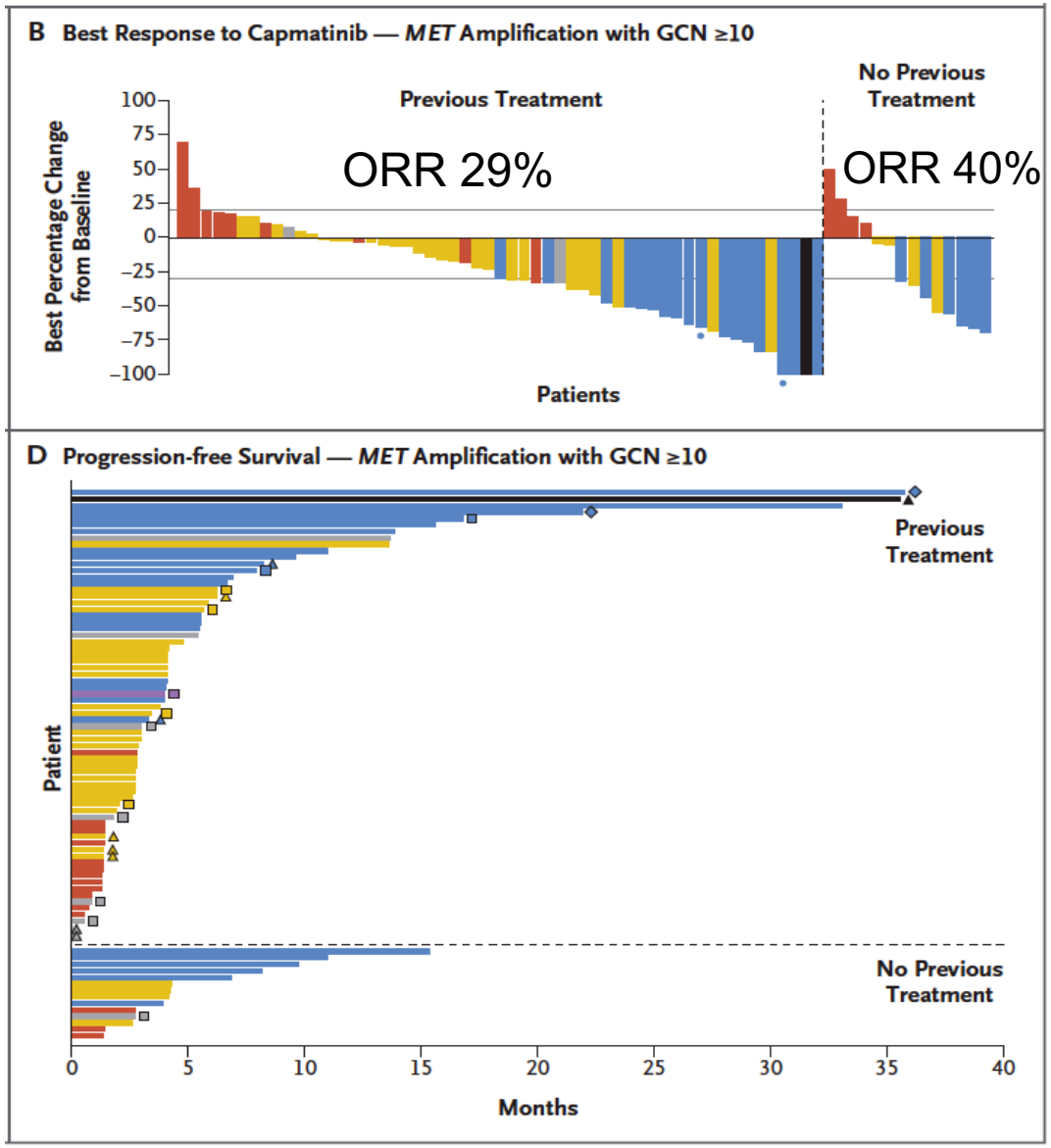
PFS
1L: 12.4 mos
2L/3L: 5.4 mos

54% (7/13) with intracranial response

Wolf NEJM. 2020

Courtesy of Joel W Neal, MD, PhD

Capmatinib in MET Amplification with Gene Copy Number ≥ 10



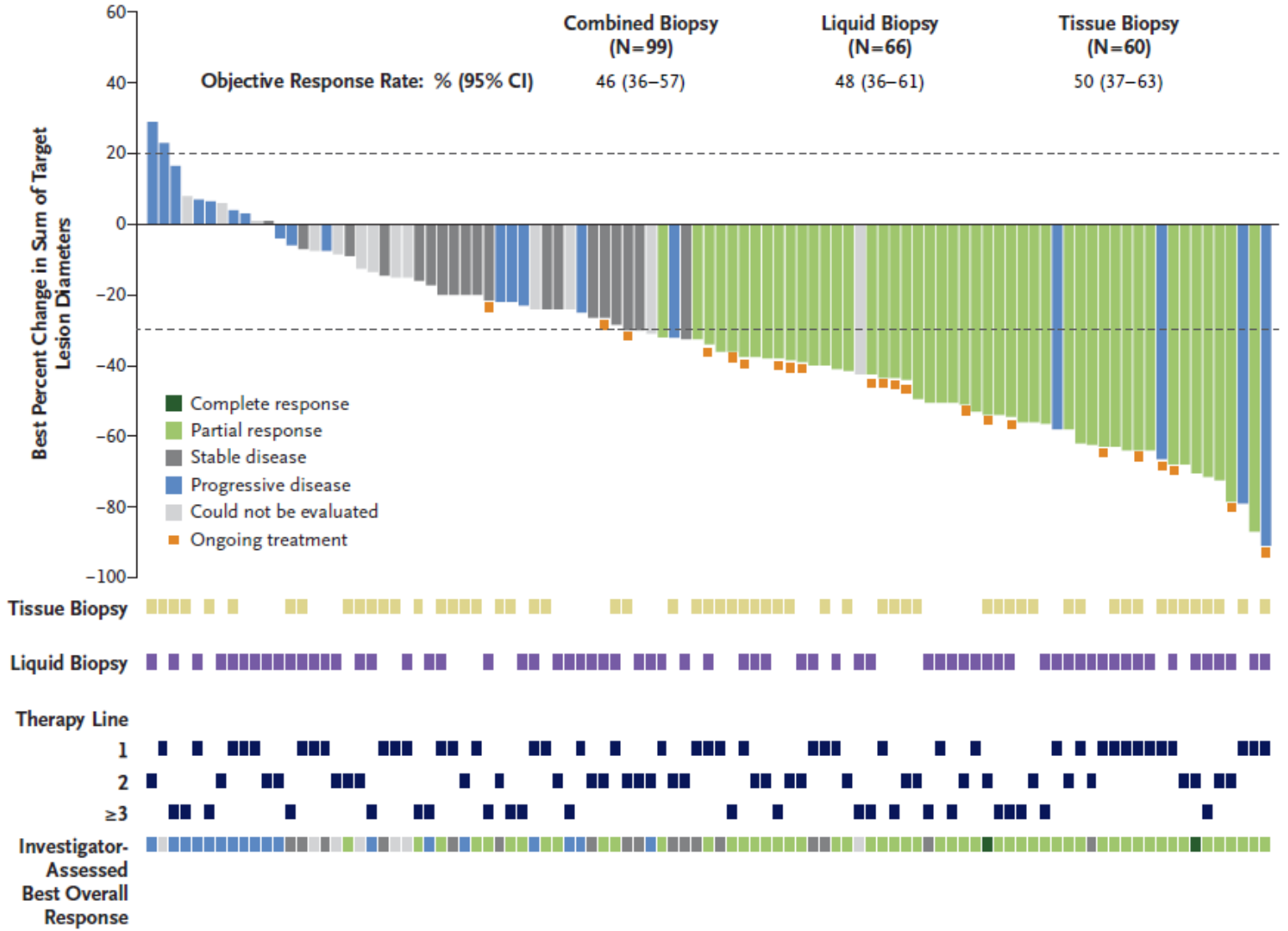
Capmatinib demonstrated limited activity in patients with MET-amplified NSCLC and tumor tissue with a gene copy number of less than 10

Wolf NEJM. 2020

Courtesy of Joel W Neal, MD, PhD

Tepotinib in Met Exon 14 NSCLC

152 patients across all cohorts, 99 pts for efficacy analysis



46% ORR (independent)

PFS 8.5 months

55% (6/11) with intracranial response

	Tepotinib, all (n=146)	Tepotinib no plat (n=71)	Tepotinib, prior plat (n=72)
Response Rate*	45%	42%	50%
Median DOR*	11.1 mo	10.8 mo	12.4 mo
Median PFS*	8.9 mo	8.5 mo	11.0 mo

Paik. NEJM. 2020

Mazieres NACLC 2020 Oral abstract

Courtesy of Joel W Neal, MD, PhD

For a patient with metastatic nonsquamous NSCLC with a MET exon 14 skipping mutation and a PD-L1 TPS of 10%, in what line of therapy should targeted treatment (eg, capmatinib, tepotinib) be used?

1. First line
2. Second line
3. Third line
4. Fourth line and beyond

Agenda

Case Presentation: Dr Deutsch – 67-year-old man

Module 1: ROS1 Rearrangements

Module 2: EGFR Exon 19 Deletion; Exon 21 (L858R) Point Mutation

Module 3: EGFR Exon 20 Insertion

Module 4: HER2 Amplification/Mutation

Module 5: ALK Rearrangement

Module 6: NTRK Gene Fusion

Module 7: RET Fusions

Module 8: MET Exon 14 Skipping Mutations

Module 9: KRAS G12C Mutation

Module 9: KRAS G12C Mutation

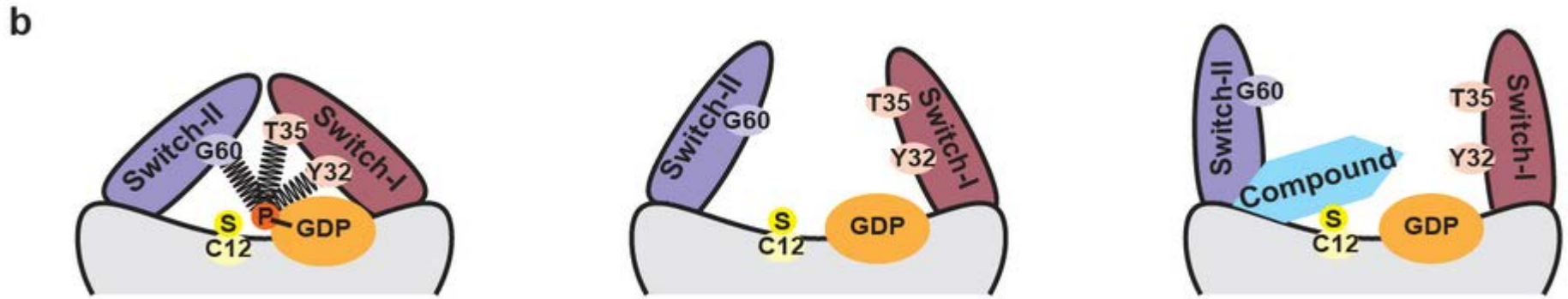
- **Key Relevant Data Set**
  - Sotorasib (AMG 510): Clinical benefit and biomarkers

How many patients with lung cancer and a KRAS G12C mutation are currently in your practice?

1. None
2. 1
3. 2
4. 3
5. 4
6. 5
7. More than 5

KRAS G12C allosteric inhibitors: how they work

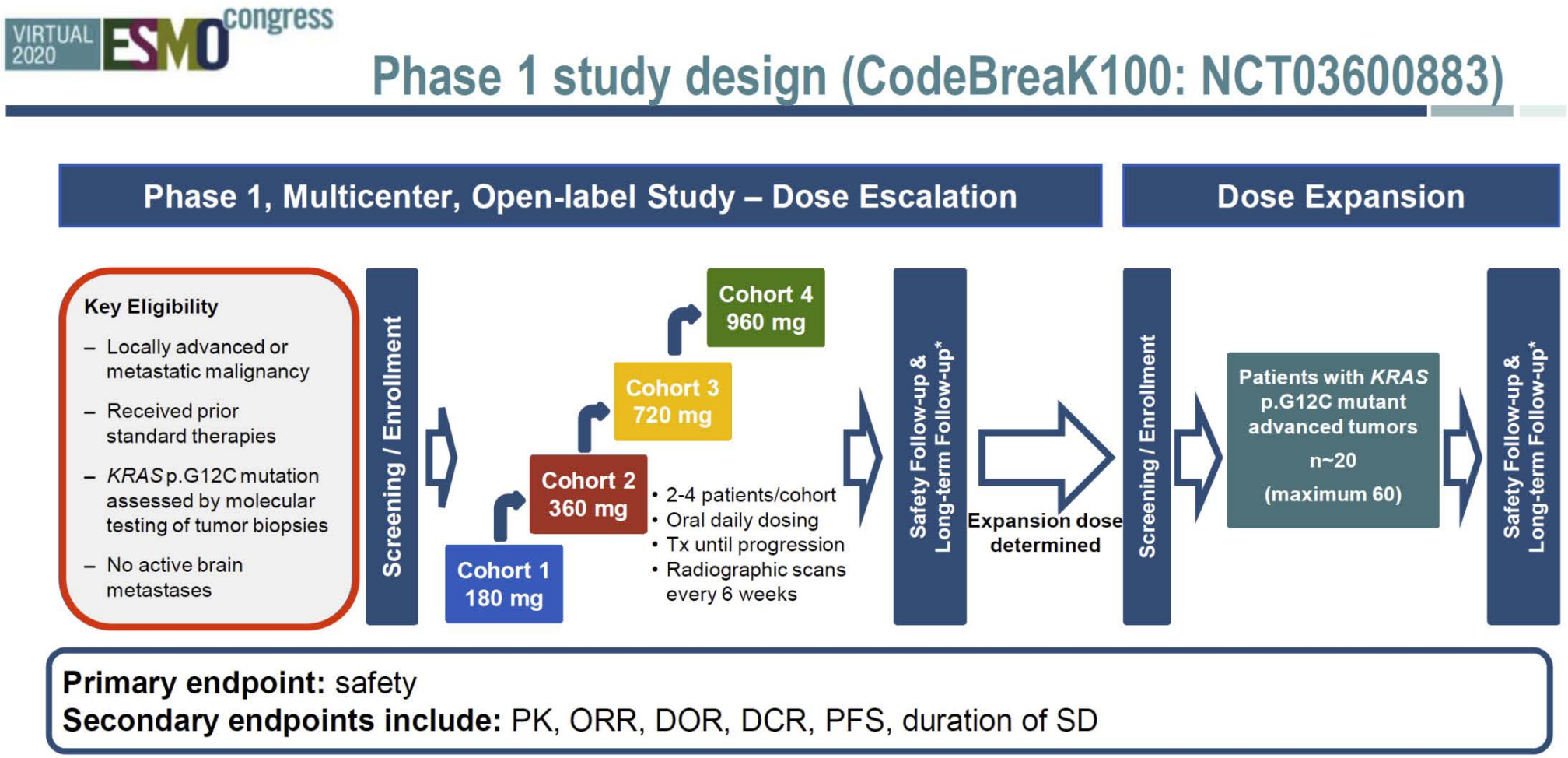
- RAS has picomolar affinity for GTP/GDP making competitive inhibition difficult
- RAS mutations impair GTP hydrolysis to GDP, causing constitutive activation
- Novel compound irreversibly binds GTP pocket through cysteine affinity at G12C
- Sos-mediated nucleotide exchange impairment leading to inhibition of KRAS



Courtesy of Paul K Paik, MD

Ostrem Nature 2013

AMG510 (sotorasib): CodeBreaK100

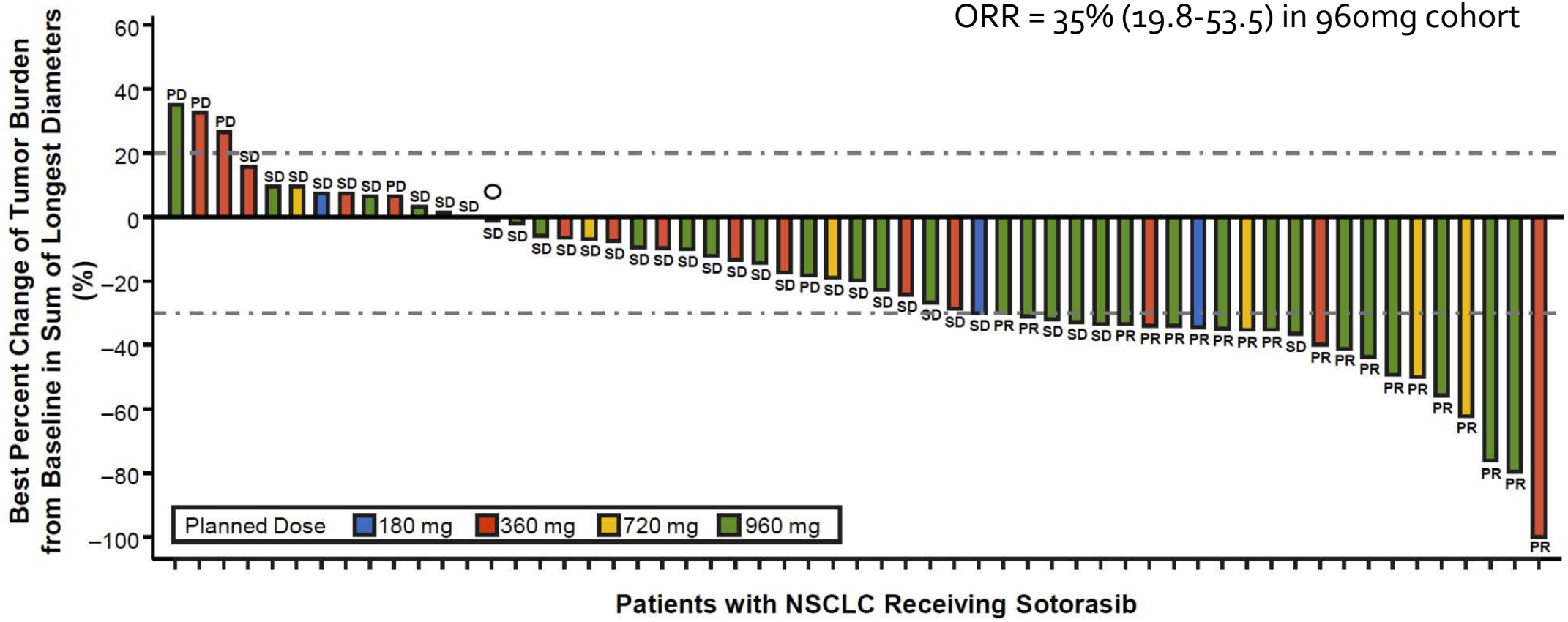


Courtesy of Paul K Paik, MD

Hong et al. ESMO 2020

AMG510 (sotorasib) efficacy

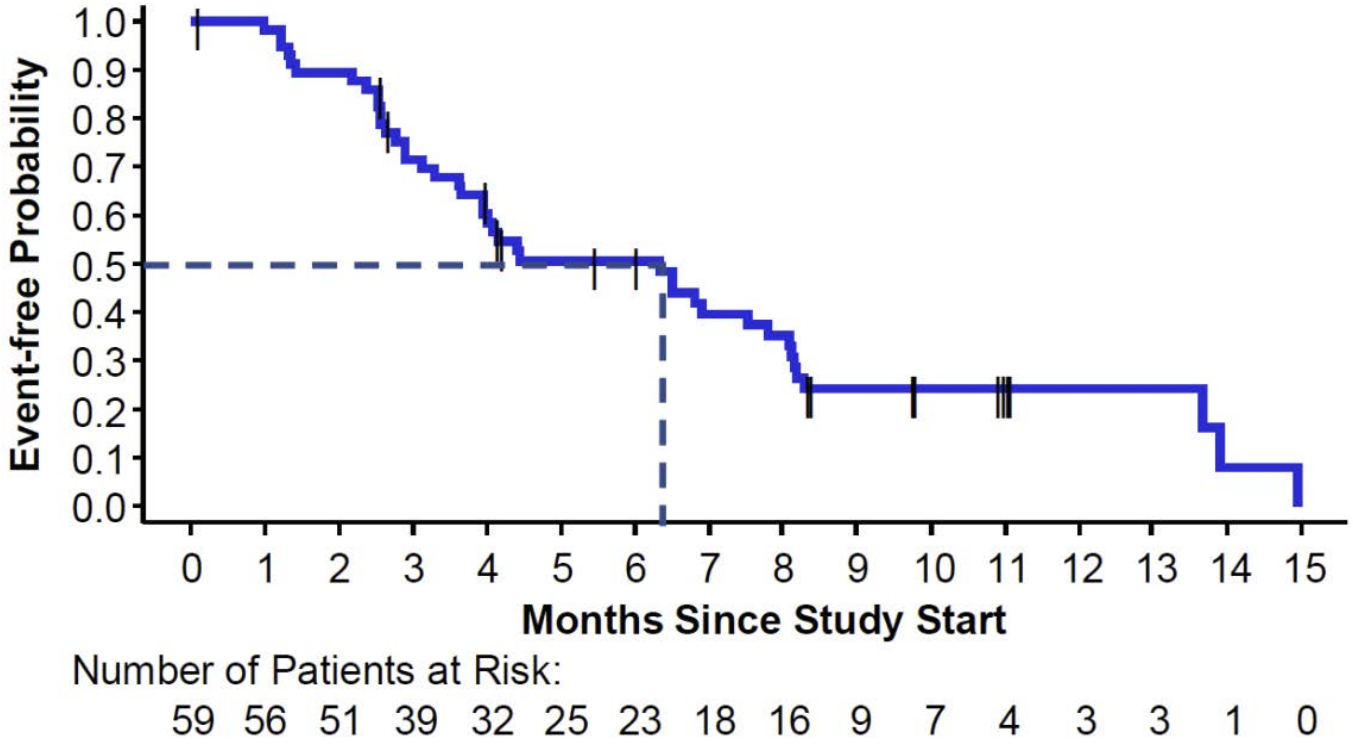
ORR = 35% (19.8-53.5) in 960mg cohort



Courtesy of Paul K Paik, MD

Hong et al. ESMO 2020

AMG510 (sotorasib) efficacy



Median PFS: 6.3 (range 0.0+ to 14.9) months

Courtesy of Paul K Paik, MD

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AMG510 (sotorasib) adverse events

Treatment-related Adverse Events	All Patients (N = 59) n (%)		
	Any Grade	Grade ≥3	Grade ≥4
Any	39 (66.1)	11 (18.6)	1 (1.7)
Diarrhea	15 (25.4)	3 (5.1)	0 (0.0)
ALT increased	12 (20.3)	6 (10.2)	1 (1.7)*
AST increased	12 (20.3)	3 (5.1)	0 (0.0)
Fatigue	6 (10.2)	0 (0.0)	0 (0.0)
Nausea	6 (10.2)	0 (0.0)	0 (0.0)
Alkaline phosphatase increased	5 (8.5)	2 (3.4)	0 (0.0)
Decreased appetite	4 (6.8)	0 (0.0)	0 (0.0)

Treatment-related Adverse Events	All Patients (N = 59) n (%)		
	Any Grade	Grade ≥3	Grade ≥4
Vomiting	4 (6.8)	0 (0.0)	0 (0.0)
Abdominal distension	3 (5.1)	0 (0.0)	0 (0.0)
Abdominal pain	3 (5.1)	0 (0.0)	0 (0.0)
Anemia	2 (3.4)	2 (3.4)	0 (0.0)
Lymphocyte count decreased	2 (3.4)	1 (1.7)	0 (0.0)
GGT increased	1 (1.7)	1 (1.7)	0 (0.0)
Hepatitis	1 (1.7)	1 (1.7)	0 (0.0)
Hyponatremia	1 (1.7)	1 (1.7)	0 (0.0)

Courtesy of Paul K Paik, MD

Hong et al. ESMO 2020

Cases from the Community: Investigators Discuss Emerging Research and Actual Patients with Hepatocellular Carcinoma (Part 1 of a 3-Part Series)

Wednesday, January 27, 2021
5:00 PM – 6:30 PM ET

Faculty

Richard S Finn, MD
Tim Greten, MD
James J Harding, MD
Ahmed Omar Kaseb, MD, CMQ

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Thank you for joining us!

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

RTP Year in Review 2020