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

Virtual Molecular Tumor Board: Identification of New and Emerging Genomic Alterations in Metastatic Non-Small Cell Lung Cancer

Friday, August 7, 2020

9:00 AM – 10:00 AM ET

Faculty

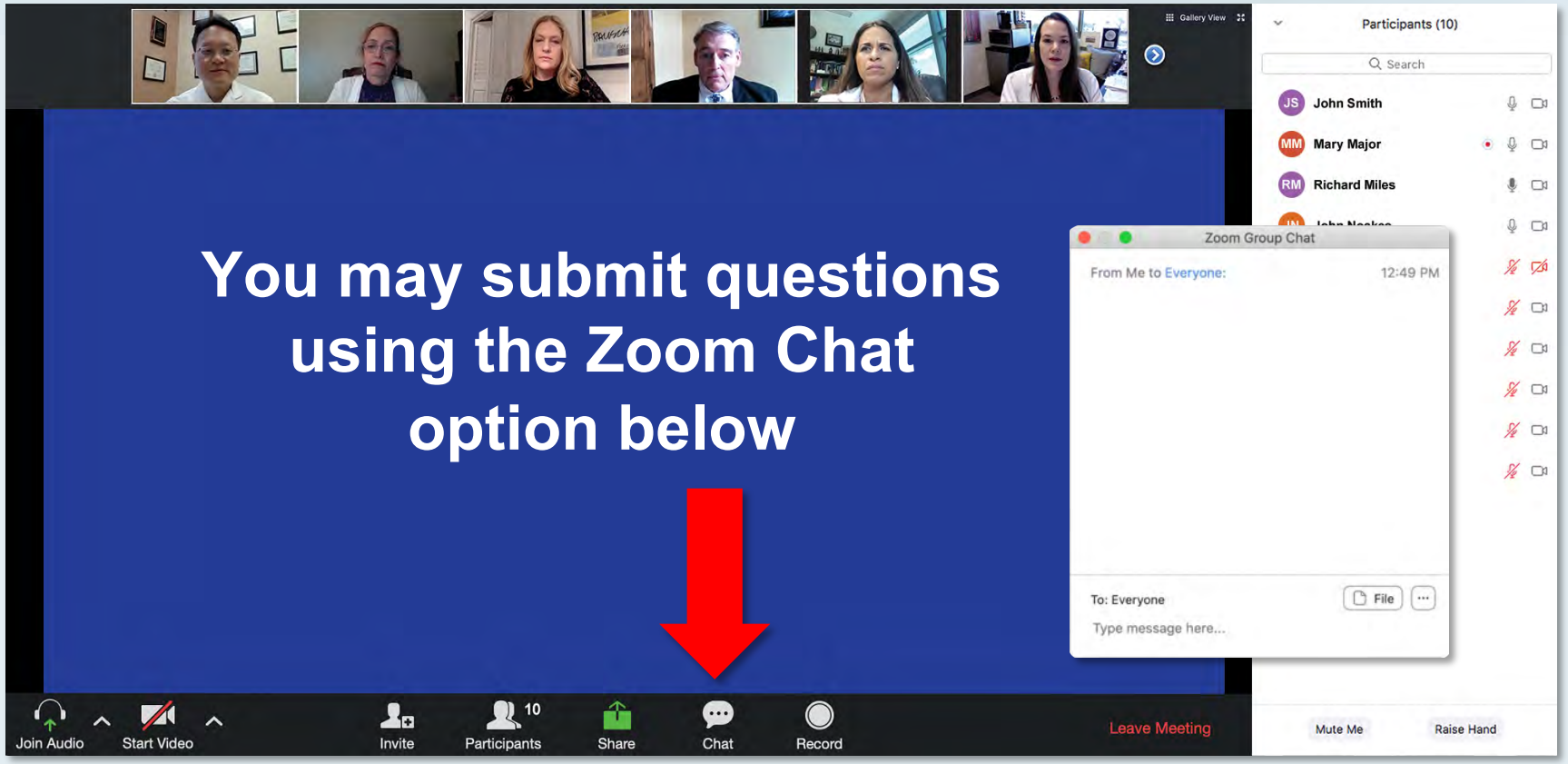
Alexander E Drilon, MD
Andrew McKenzie, PhD
Milan Radovich, PhD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Dr Love and Faculty Encourage You to Ask Questions



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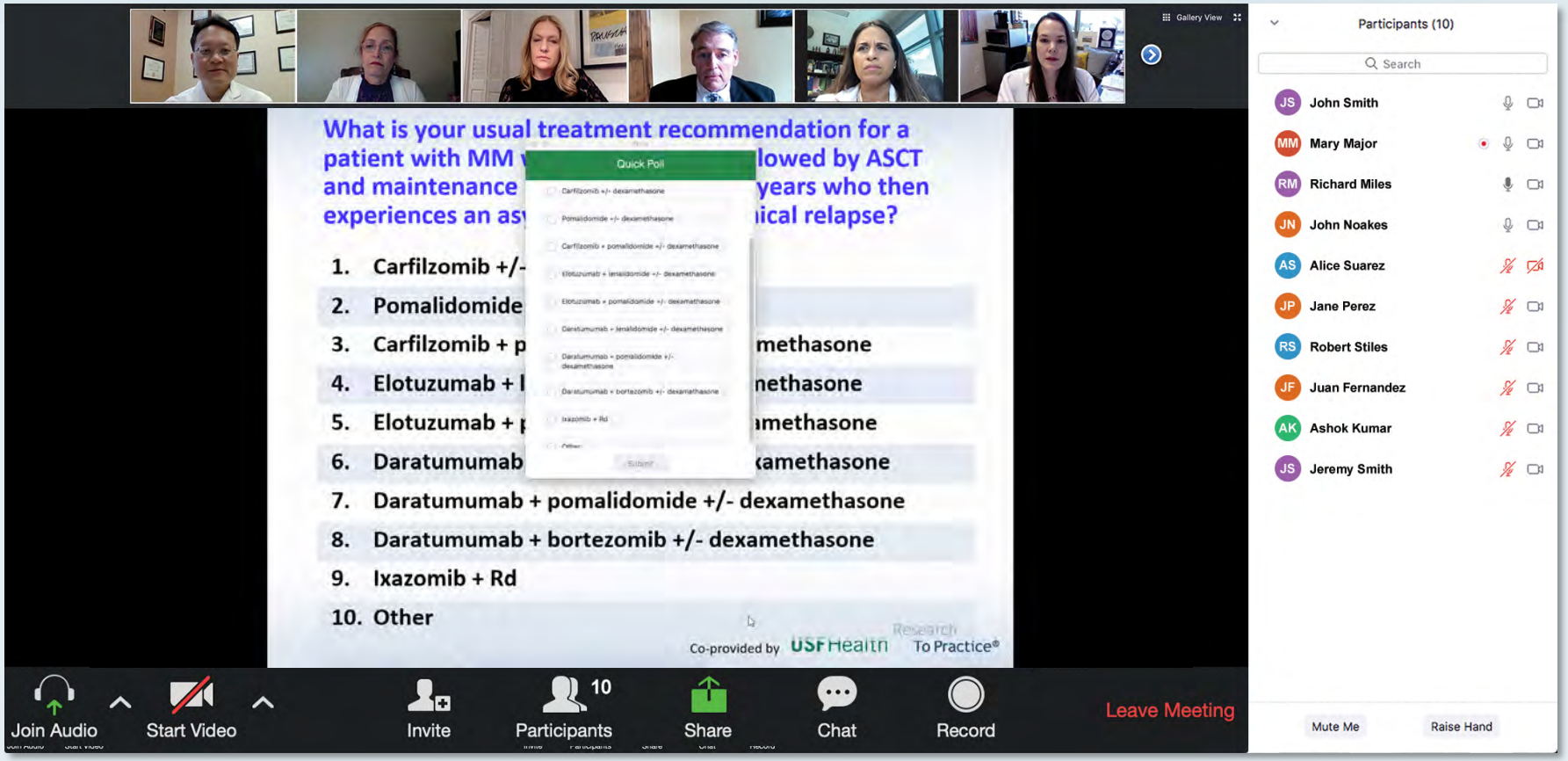
Familiarizing yourself with the Zoom interface
How to answer poll questions



When a poll question pops up, click your answer choice from the available options. Results will be shown after everyone has answered.

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Dr Radovich — Disclosures

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Upcoming Live Webinars

Monday, August 10, 2020
5:00 PM – 6:00 PM ET

Recent Advances in Medical Oncology: Hodgkin and Non-Hodgkin Lymphomas

Faculty
Jeremy Abramson, MD
Christopher R Flowers, MD, MS

Moderator
Neil Love, MD

Tuesday, August 11, 2020
5:00 PM – 6:00 PM ET

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

Faculty
Robert Z Orlowski, MD, PhD

Moderator
Neil Love, MD

Upcoming Live Webinars

Wednesday, August 12, 2020
1:00 PM – 2:00 PM ET

Meet The Professors Clinical Investigators Discuss Existing and Emerging Treatment Strategies for Patients with Ovarian, Cervical and Endometrial Cancer

Faculty
Stephanie Lheureux, MD, PhD
Professor Ignace Vergote

Moderator
Neil Love, MD

Wednesday, August 12, 2020
5:00 PM – 6:30 PM ET

Recent Advances in Medical Oncology: Hepatocellular Carcinoma and Pancreatic Cancer

Faculty
Tanios Bekaii-Saab, MD
Eileen M O'Reilly, MD
Philip A Philip, MD, PhD, FRCP
Alan P Venook, MD

Moderator
Neil Love, MD

Upcoming Live Webinars

Friday, August 14, 2020
9:00 AM – 10:00 AM ET

Virtual Molecular Tumor Board: Recognition and Management of Targetable Tumor Mutations in Less Common Cancer Types

Faculty
Marcia S Brose, MD, PhD
Milan Radovich, PhD

Additional faculty to be announced

Moderator
Neil Love, MD

Monday, August 17, 2020
5:00 PM – 6:00 PM ET

Recent Advances in Medical Oncology: ER-Positive Breast Cancer

Faculty
Virginia Kaklamani, MD, DSc
Sara M Tolaney, MD, MPH

Moderator
Neil Love, MD

Virtual Molecular Tumor Board: Optimizing Biomarker-Based Decision-Making for Patients with Solid Tumors

Recognition and Management of Targetable Tumor Mutations in Less Common Cancer Types

Friday, August 14, 2020
9:00 AM – 10:00 AM ET

Marcia S Brose, MD, PhD

Session moderated by Neil Love, MD and featuring Bryan Schneider, MD and Milan Radovich, PhD of the Indiana University Health Precision Genomics Program

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RTP RESEARCH TO PRACTICE

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Chief, Early Drug Development Service
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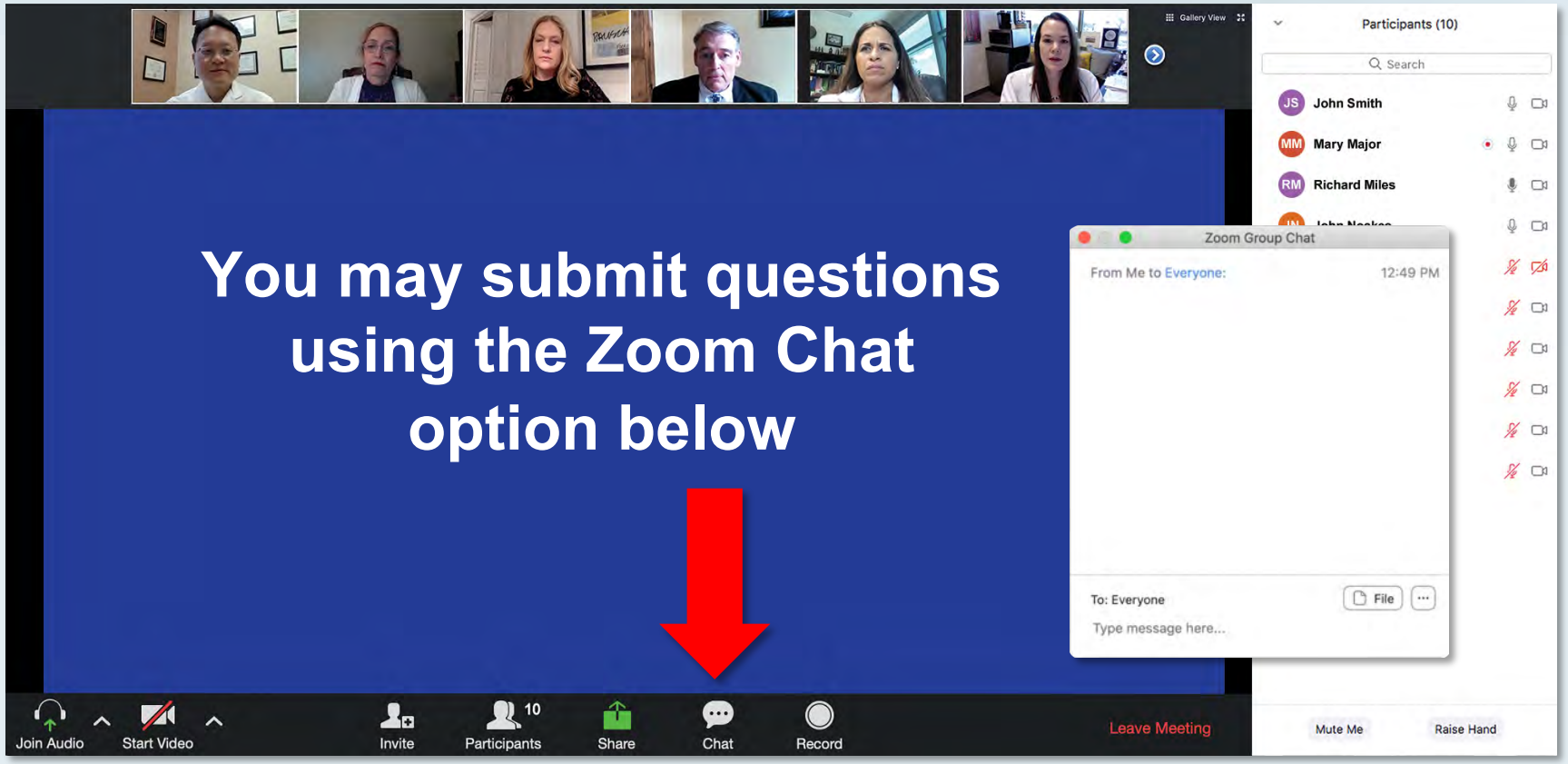
Associate Professor
IU Health Vice President for Oncology Genomics
Indiana University Melvin and
Bren Simon Comprehensive Cancer Center
Indianapolis, Indiana

Andrew McKenzie, PhD
Director, Personalized Medicine
Sarah Cannon Research Institute
Nashville, Tennessee

Dr Love and Faculty Encourage You to Ask Questions



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WITH DR NEIL LOVE

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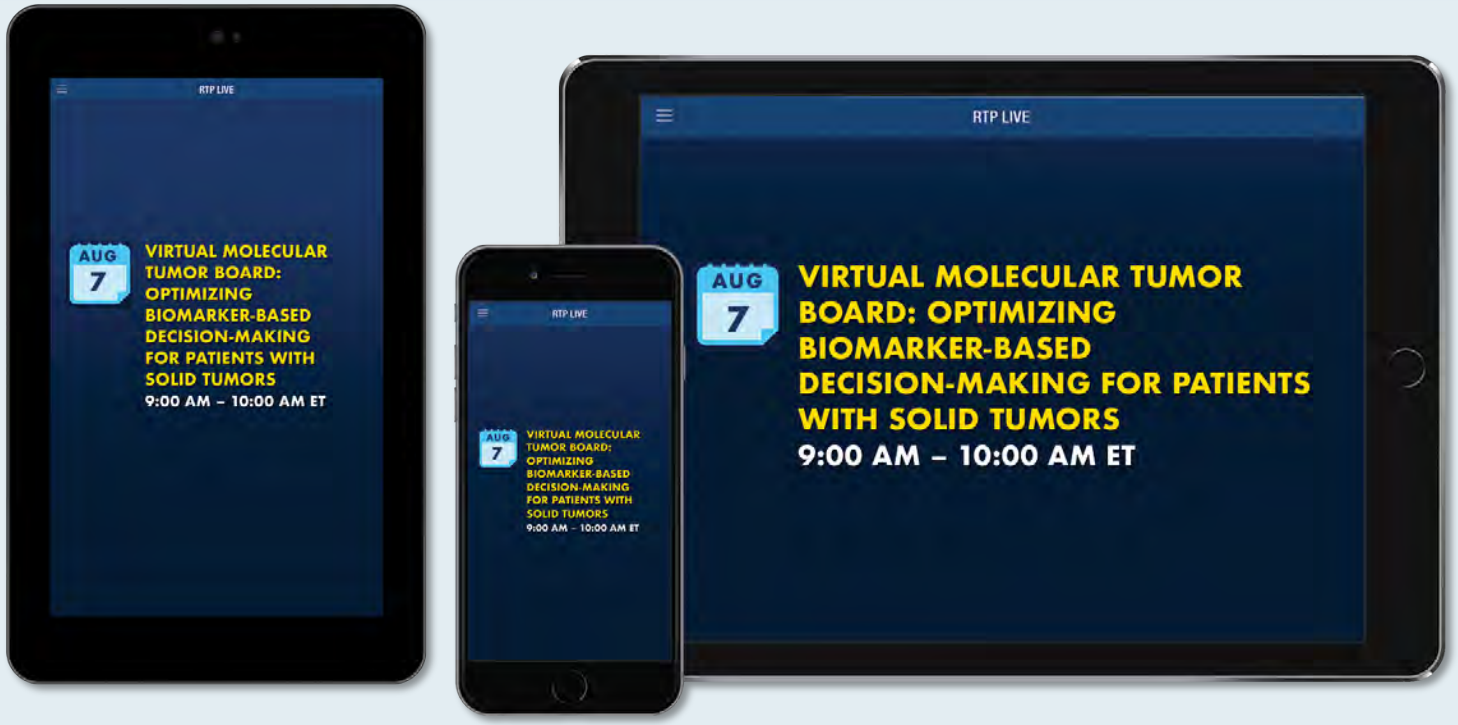

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RTP RESEARCH TO PRACTICE

Agenda

Part 1: Case Presentations

- Case 1 – Dr Radovich: A 71-year-old woman with metastatic adenocarcinoma of the lung (ERBB2, PALB2)
- Case 2 – Dr McKenzie: A 74-year-old man with metastatic adenocarcinoma of the lung (BRAF V600E)
- Case 3 – Dr Ibrahim: A 74-year-old woman with metastatic NSCLC (EGFR exon 19 insertion)
- Case 4 – Dr Radovich: A 66-year-old man with recurrent SCCHN (TMB 215 Muts/Mb)
- Case 5 – Dr Ibrahim: A 61-year-old man with metastatic adenocarcinoma of the lung (STK11, BRCA)
- Case 6 – Dr Drilon: A 33-year-old woman with metastatic adenocarcinoma of the lung (EML4-RET fusion)

Part 2: Beyond EGFR, BRAF and ALK — Actionable Biomarkers in NSCLC

Agenda

Part 3: Case Presentations

- Case 7 – Dr McKenzie: A 66-year-old woman with metastatic adenocarcinoma of the lung (RET fusion)
- Case 8 – Dr Ibrahim: A 59-year-old man with metastatic adenocarcinoma of the lung (RET fusion)
- Case 9 – Dr Radovich: A 68-year-old man with metastatic pancreatic cancer (ERC1/RET fusion)
- Case 10 – Dr Drilon: A 76-year-old woman with metastatic adenocarcinoma of the lung (EPS15-NTRK1)
- Case 11 – Dr McKenzie: An 82-year-old man with metastatic adenocarcinoma of the lung (MET exon 14)
- Case 12 – Dr Ibrahim: An 84-year-old with Stage IIIB NSCLC (MET exon 14 skipping mutation)
- Case 13 – Dr Radovich: A 72-year-old man with metastatic NSCLC (MET exon 14 splice site mutation)
- Case 14 – Dr Drilon: A 58-year-old woman with metastatic adenocarcinoma of the lung (KRAS G12C)
- Case 15 – Dr Ibrahim: A 68-year-old woman with metastatic adenocarcinoma of the lung (EGFR, ALK)

Agenda

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Part 2: Beyond EGFR, BRAF and ALK — Actionable Biomarkers in NSCLC

Case Presentation – Dr Radovich: A 71-year-old woman with metastatic adenocarcinoma of the lung

- **HISTORY OF PRESENT ILLNESS:** 71-year-old woman with a history of metastatic adenocarcinoma of the lung. The patient was diagnosed with a left upper lobe cancer in 2016. She underwent a VATS left upper lobe lobectomy and was found to have a T2 N2 M0 adenocarcinoma of the lung, PD-L1 negative. She received 4 cycles of pemetrexed with carboplatin followed by 60 Gy of radiation therapy. She did well until 2018 when she was found to have evidence of progression with increasing mediastinal adenopathy and pulmonary metastases. She received 4 cycles of carboplatin, pemetrexed, and pembrolizumab with progression after 4 cycles. She subsequently began nivolumab and was found to have slow progression.
- **PAST MEDICAL HISTORY:** Diabetes, Hypertension, COPD
- **FHx:** Maternal aunt breast cancer (60) & sister breast cancer (56)

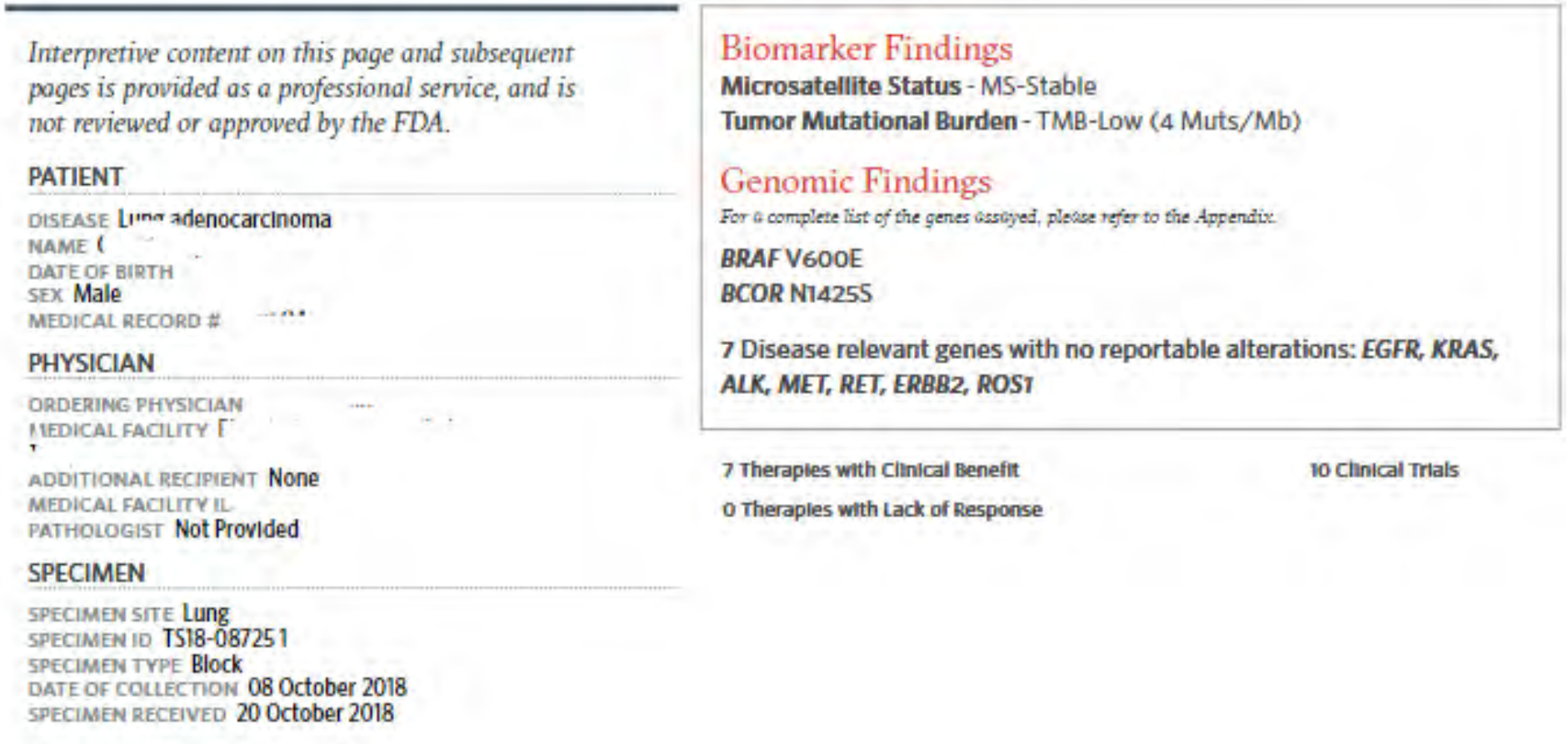
Case Presentation – Dr Radovich: A 71-year-old woman with metastatic adenocarcinoma of the lung (cont)

GENOMIC FINDINGS	MAF %	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
ERBB2 - A775_G776insYVMA	1.4%	Afatinib	Ado-trastuzumab emtansine
			⚠ Lapatinib[1]
			Neratinib
			Pertuzumab
			Trastuzumab
			Trastuzumab-anns
			Trastuzumab-dkst
			Trastuzumab-dttb
			Trastuzumab-pkrb
			Trastuzumab-qyyp
10 Trials see p. 14			
PALB2 - L253fs*3	47.6%	None	Niraparib
			Olaparib
			Rucaparib
			Talazoparib
10 Trials see p. 16			

Case Presentation - Dr McKenzie: A 74-year-old man with metastatic NSCLC and a BRAF V600E mutation

- 74yr Male
- Diagnosed 2018 with Stage IV NSCLC adenocarcinoma (former smoker)
- Tissue-based testing prior to front-line treatment revealed BRAF V600E mutation
- Dabrafenib + Trametinib initiated December 2018 and continues treatment today
  - “No adverse events. No SAEs. No hospitalizations. No nausea vomiting diarrhea. No infections. No new lumps bumps or headaches. QOL stable. Doing usual activities.”

Case Presentation - Dr McKenzie: A 74-year-old man with metastatic NSCLC and a BRAF V600E mutation (cont)



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PATIENT

DISEASE Lung adenocarcinoma
NAME
DATE OF BIRTH
SEX Male
MEDICAL RECORD #

PHYSICIAN

ORDERING PHYSICIAN
MEDICAL FACILITY
ADDITIONAL RECIPIENT None
MEDICAL FACILITY IL
PATHOLOGIST Not Provided

SPECIMEN

SPECIMEN SITE Lung
SPECIMEN ID TS18-087251
SPECIMEN TYPE Block
DATE OF COLLECTION 08 October 2018
SPECIMEN RECEIVED 20 October 2018

Biomarker Findings

Microsatellite Status - MS-Stable
Tumor Mutational Burden - TMB-Low (4 Muts/Mb)

Genomic Findings

For a complete list of the genes assayed, please refer to the Appendix.

BRAF V600E
BCOR N1425S

7 Disease relevant genes with no reportable alterations: ***EGFR, KRAS, ALK, MET, RET, ERBB2, ROS1***

7 Therapies with Clinical Benefit
0 Therapies with Lack of Response
10 Clinical Trials

Case Presentation – Dr Ibrahim: A 74-year-old woman with metastatic NSCLC and an exon 19 insertion mutation

Sulfi Ibrahim, MD

74-year-old African American never smoker who presents with increasing cough and dyspnea that does not respond to antibiotics. Eventually bronchoscopy reveals lung adenocarcinoma metastatic to the contralateral lung. NGS shows the exon 19 insertion. Started on osimertinib with a great response and she is off ambulatory oxygen within a month of starting therapy with no toxicity.

Questions

- Is Osimertinib the best agent to treat exon 19 insertion mutation?
- Is this seen more classically in African American never smoking women?
- Do patients who have the RB1 and P53 mutation have a shorter PFS with Osimertinib and higher risk of transformation to small cell cancer?
- Because of a higher risk to small cell transformation, should a tissue biopsy be done at the time of disease progression?

Case Presentation – Dr Ibrahim: 74-year-old woman
NGS report

Biomarker Findings

Microsatellite status - MS-Stable
Tumor Mutational Burden - 0 Muts/Mb

Genomic Findings

For a complete list of the genes assayed, please refer to the Appendix.

EGFR K745_E746insIPVAIK
BRCA1 rearrangement intron 16
CTNNB1 S45P
MCL1 amplification - equivocal†
RB1 loss exons 18-27
TP53 M1K

7 Disease relevant genes with no reportable alterations: ***ALK, BRAF, ERBB2, KRAS, MET, RET, ROS1***

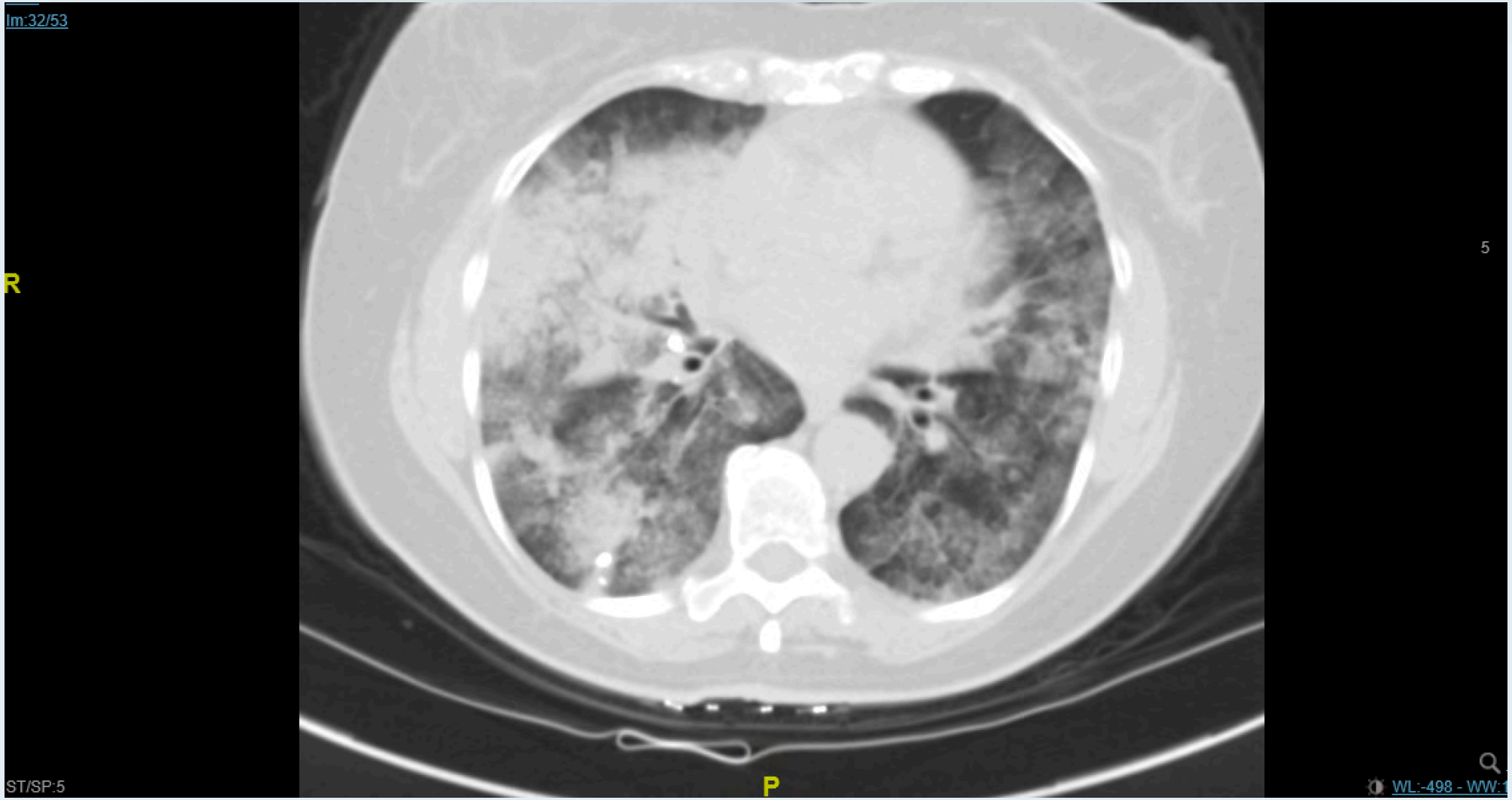
---

† See About the Test in appendix for details.

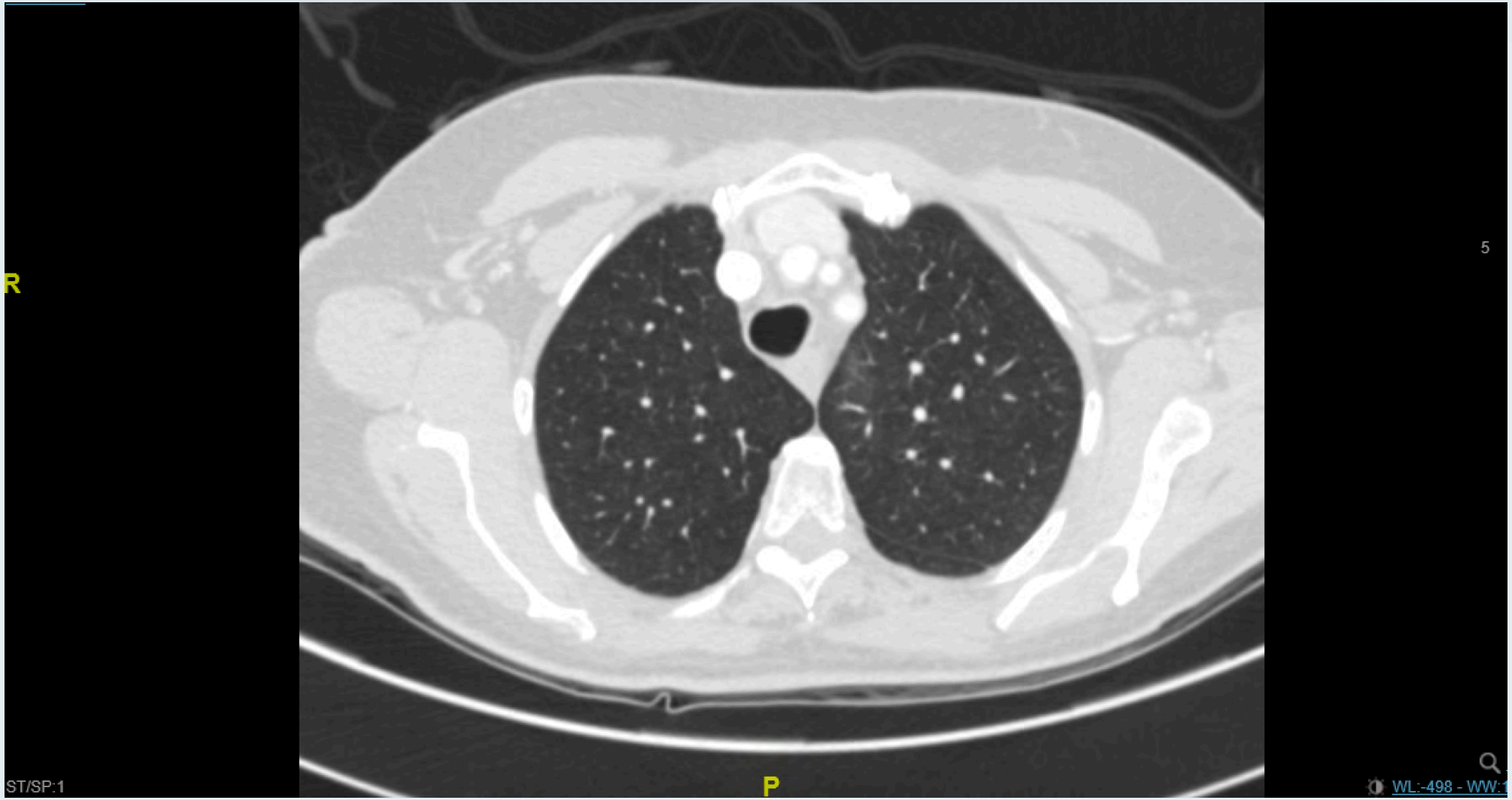
9 Therapies with Clinical Benefit
0 Therapies with Lack of Response

28 Clinical Trials

Case Presentation – Dr Ibrahim: 74-year-old woman
Before treatment



Case Presentation – Dr Ibrahim: 74-year-old woman
Complete response in 2 months



Case Presentation – Dr Radovich: A 66-year-old man with recurrent squamous cell carcinoma of the head and neck

- **HISTORY OF PRESENT ILLNESS:** Patient is a 66-year-old man who was diagnosed to have recurrent squamous cell carcinoma of the skin in the head and neck region. The patient was noted to have a progression of the squamous cell carcinoma, along with metastatic disease with a single large liver metastasis, along with a left axillary node as well in February 2016. The patient underwent a biopsy of this liver lesion, along with the left axillary lymph node biopsy as well. This was consistent with the poorly differentiated squamous cell carcinoma. Patient was initiated on chemotherapy with cisplatin along with cetuximab in March of 2016. He received his 5th cycle of cisplatin on 07/06/2016. The patient was noted to have decreased hearing, and it was decided that his disease has been stable without any changes; hence, the cisplatin dose was held and he was continued on cetuximab alone. Patient was noted to have progression of disease in 09/2016 while genomics was pending. It was decided to add cisplatin again. Hence, patient received cisplatin on 10/13/2016. Genomics identified a massive tumor mutation burden at 215 mutations per megabase and was recommended to receive nivolumab.

  He is on systemic treatment with nivolumab since 12/8/2016 due to high mutational burden and remains on nivolumab to date (August 2020).

Case Presentation – Dr Radovich: A 66-year-old man with recurrent squamous cell carcinoma of the head and neck (cont)

PATIENT RESULTS

- 19 genomic findings
- 5 therapies associated with potential clinical benefit
- 0 therapies associated with lack of response
- 16 clinical trials

TUMOR TYPE: SKIN SQUAMOUS CELL CARCINOMA (SCC)

Genomic Alterations Identified†

BRCA2 E350*
KDR R1032Q
CTNNB1 S33C
ARID2 Q490*
BAP1 S460*
BCORL1 V1059fs*25
CHD2 S450*
CTNNA1 Q531*
LRP1B H3856Y
MAGI2 splice site 3424-1G>A
MLL2 E2844*
NOTCH1 E663*
NOTCH2 P1052fs*22
PIK3R1 Q606*
TP53 E258K, P34L, R248Q, V272M

Additional Findings†

Tumor Mutation Burden TMB-High; 215 Muts/Mb

† For a complete list of the genes assayed and performance specifications, please refer to the Appendix

Case Presentation – Dr Ibrahim: A 61-year-old man with metastatic NSCLC

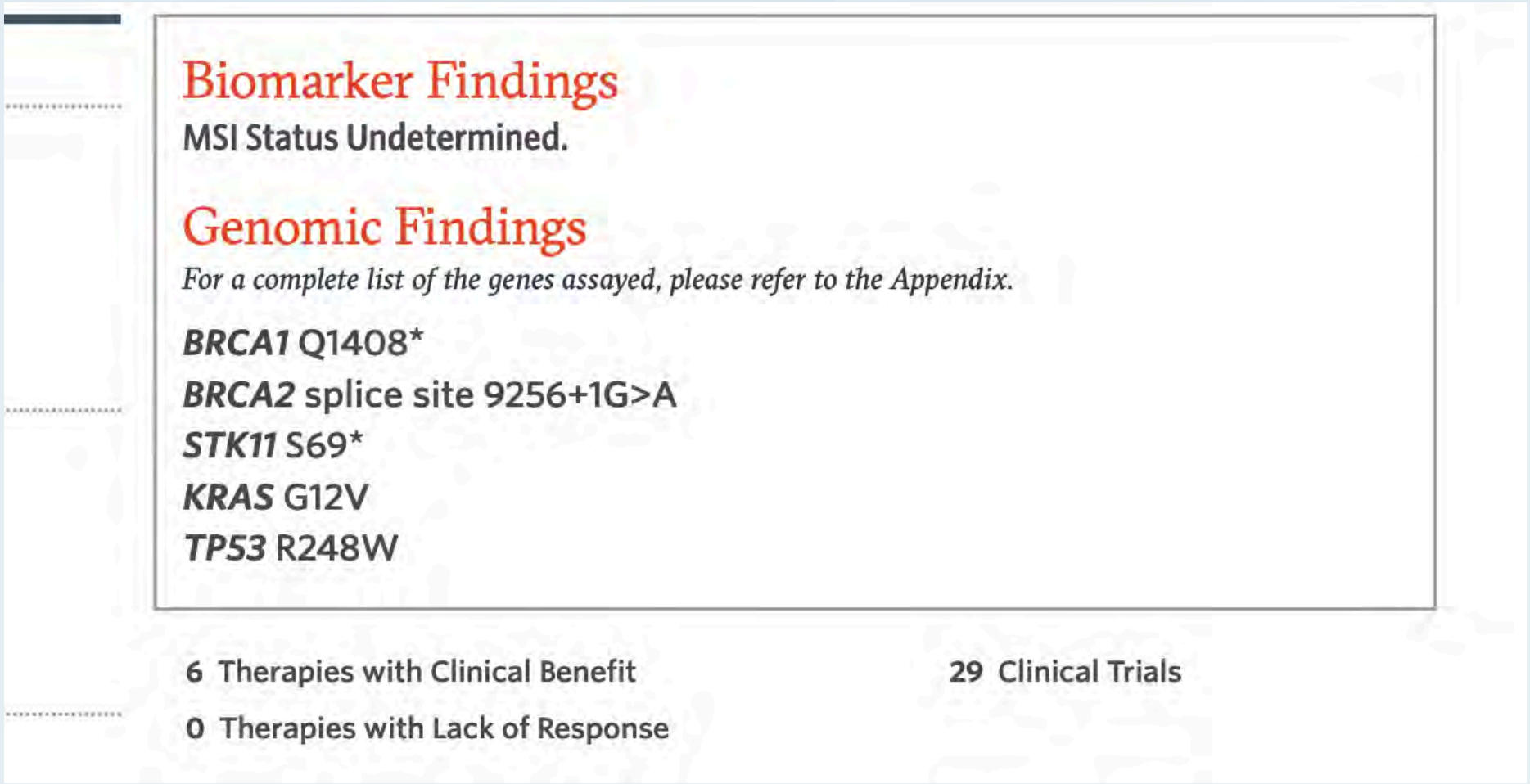
Sulfi Ibrahim, MD

61-year-old man who presented with a worsening cough and pleuritic chest pain. Work up revealed lung metastatic adenocarcinoma of the adrenal gland and peritoneum. Patient has a 35-pack-year history of smoking and is a current smoker. Initial bronchoscopy performed is insufficient for NGS. Given his smoking history I suggested the CHECKMATE 189 regimen of chemo-immunotherapy. This was denied by insurance because I could not show testing for EGFR/ALK — they were willing to cover the chemotherapy but not the immunotherapy. Started with Carboplatin and Pemetrexed and got plasma based NGS. When this came back the insurance approved the pembrolizumab. Disease progression on this regimen and subsequent progression on docetaxel and ramucirumab.

Questions

- Should EGFR and ALK always be determined prior to starting immunotherapy even in a patient with a long history of smoking?
- In patients who need to start therapy quickly, what is the optimal strategy for obtaining molecular testing quickly?
- In patients who have the STK11 mutation, should immunotherapy be entirely avoided?
- Any significance of BRCA mutations in patients with non small cell lung cancer?

Case Presentation – Dr Ibrahim: 61-year-old man
NGS report



Biomarker Findings

MSI Status Undetermined.

Genomic Findings

For a complete list of the genes assayed, please refer to the Appendix.

BRCA1 Q1408*

BRCA2 splice site 9256+1G>A

STK11 S69*

KRAS G12V

TP53 R248W

6 Therapies with Clinical Benefit

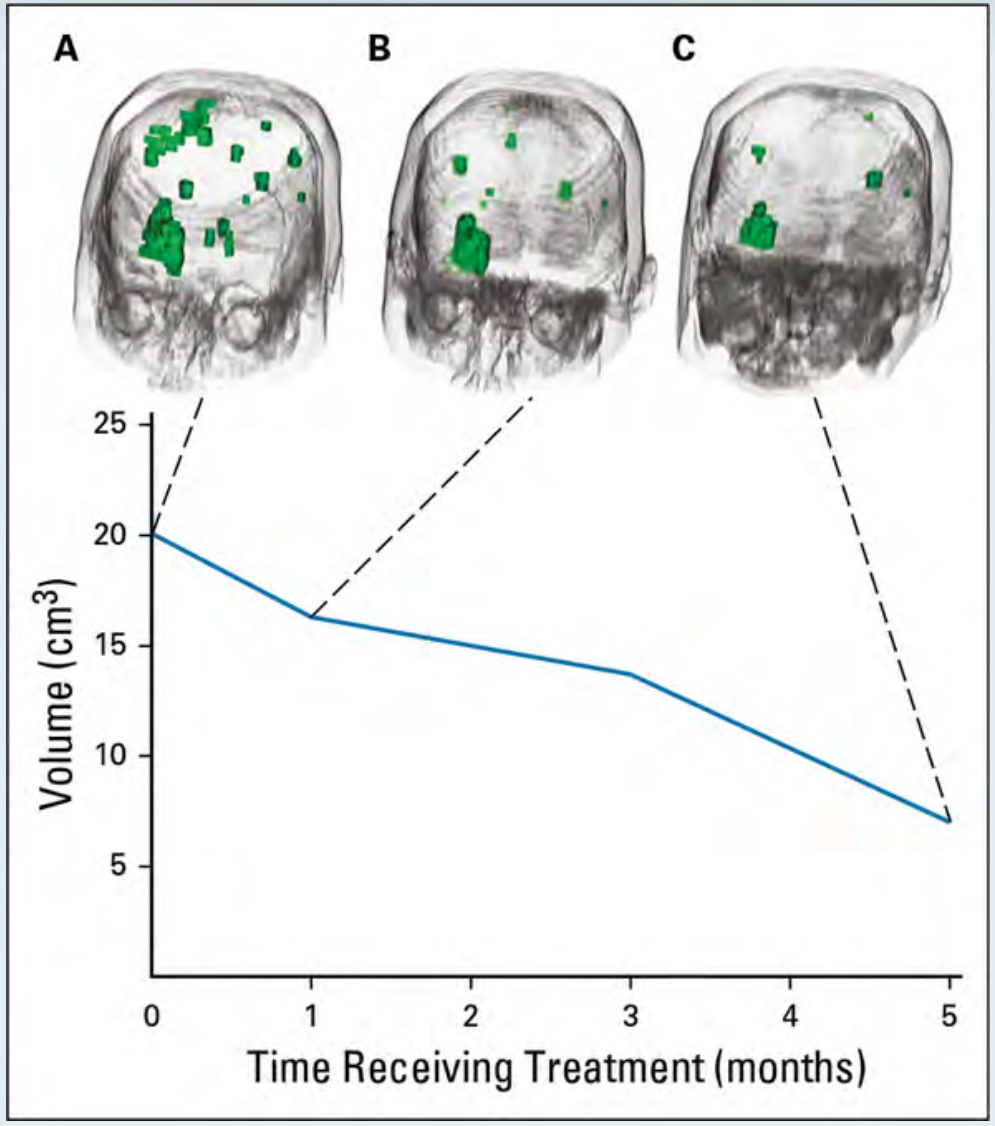
0 Therapies with Lack of Response

29 Clinical Trials

Case Presentation – Dr Drilon: A 33-year-old woman with NSCLC and a RET fusion

- Presented with shortness of breath and cough
- **Imaging:** 4.8-cm RLL mass, bilateral thoracic adenopathy, osseous metastases, multiple brain metastases
- **Biopsy** (endobronchial R4): Adenocarcinoma with signet ring features, TTF1+, p40-
- **NGS:** *EML4-RET* fusion, TP53 mutation; negative for other drivers, PD-L1 20%
- **Treatment**
  - Multikinase inhibitor of RET (RXDX-105 on trial): Confirmed PR → later required SRS to 5 lesions initially (1 year after starting), then 7 lesions later (7 months later) → 4 months later developed symptomatic CNS progression and new leptomeningeal disease, left facial/tongue/upper extremity tingling and neck pain deemed to be secondary to lepto predominantly in the R parietal lobe; LP recommended but declined
  - Was ineligible for LIBRETTO-001 trial of selpercatinib
  - We got a single patient use protocol of selpercatinib → clinical response to therapy in the first week with resolution of neurologic symptoms → complete resolution of leptomeningeal enhancement and overall confirmed PR (volume of intracranial disease by volumetric analysis shown in graph) → remains on at 2.5 years later

Case Presentation – Dr Drilon: A 33-year-old woman with NSCLC and a RET fusion (cont)



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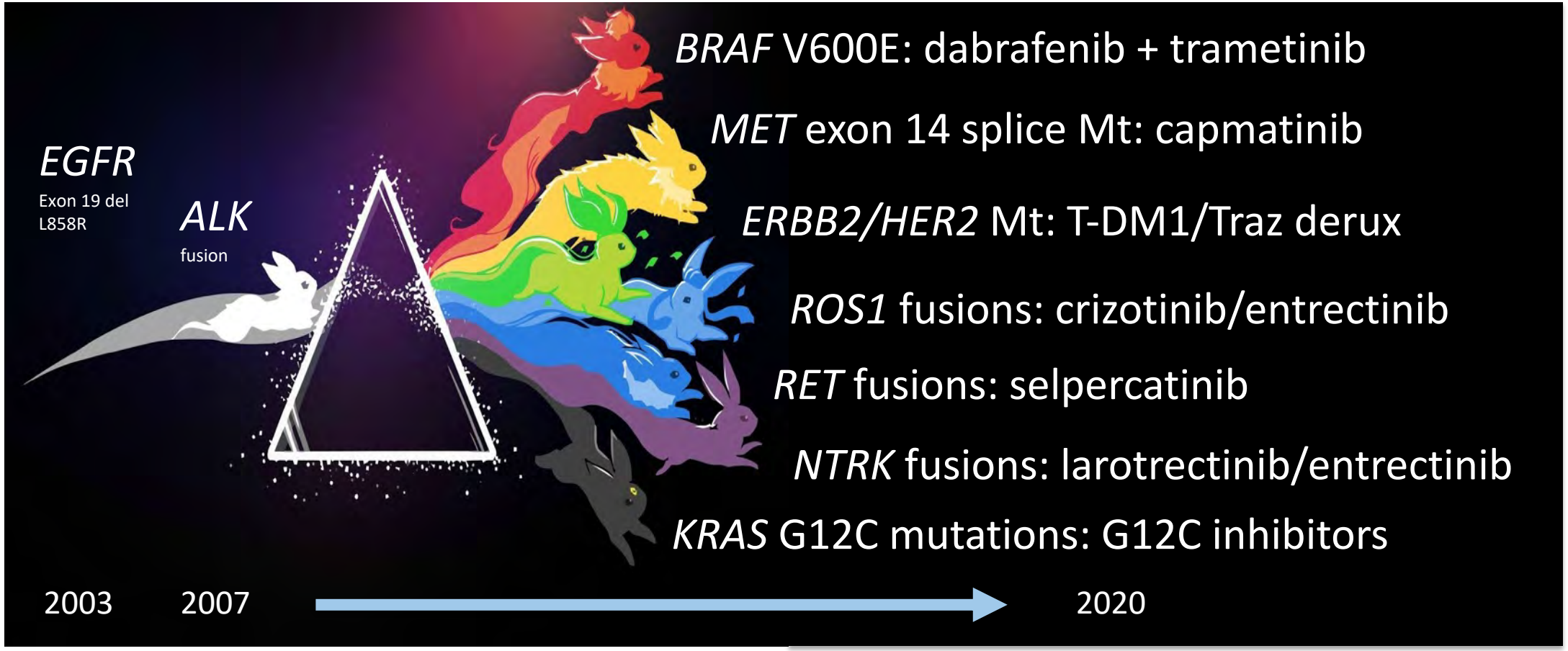
Memorial Sloan Kettering
Cancer Center

Beyond *EGFR, BRAF* and *ALK*:
Actionable Biomarkers in NSCLC

Alexander Drilon, MD
Chief, Early Drug Development Service
Associate Attending Physician, Thoracic Oncology Service
Memorial Sloan Kettering Cancer Center

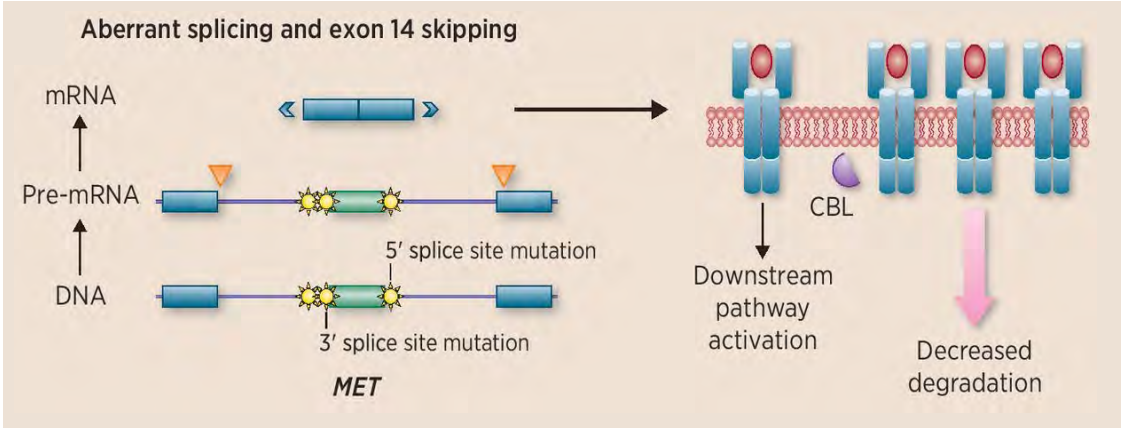
Various targeted therapies are active in oncogene-driven lung cancers



MET exon 14-altered lung cancers

MET exon 14 alterations: ~4% of NSCLCs

- older patients with a more substantial smoking history
- mutations are highly heterogeneous – need a comprehensive test!
- adenocarcinomas & sarcomatoid CAs

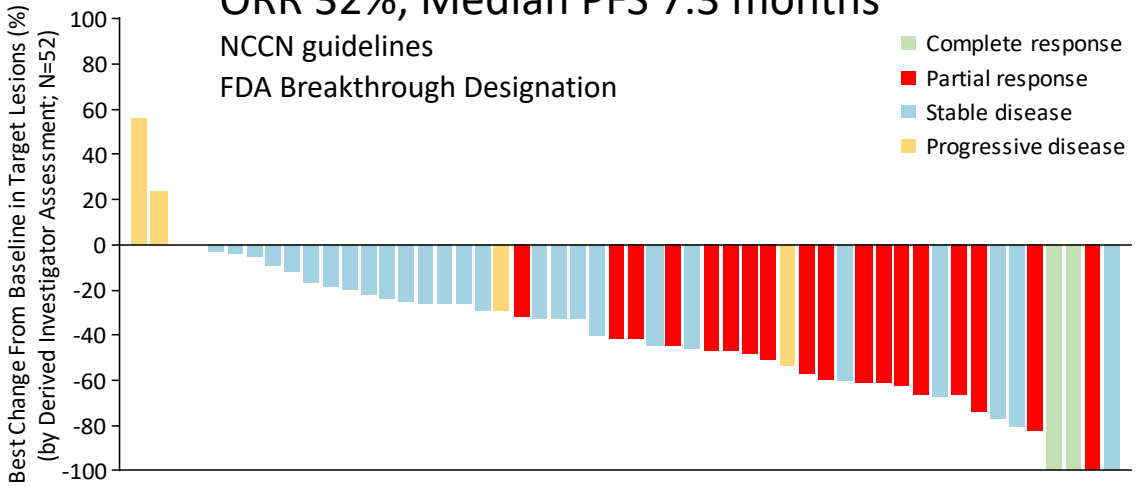


Crizotinib

ORR 32%, Median PFS 7.3 months

NCCN guidelines

FDA Breakthrough Designation



Drilon et al, Nature Med 2020; Felip et al ASCO 2018; Wolf et al, ESMO 2018, Drilon CCR 2017

Activity of selective MET inhibitors

	Capmatinib (GEOMETRY)	Tepotinib (VISION)
ORR		
Overall	(not reported)	46% (36-57, n=99)
Treatment naïve	67% (48-84, n=28)	44% (29-60, n=43)
Second line	48% (30-67, n=31)	48% (30-66, n=33)
Median PFS		
Overall	(not reported)	8.6 months
Treatment naïve	9.7 months	(not reported)
Second line	8.1 months	(not reported)
Adverse events		
Peripheral edema	84%	63%

Groen et al ASCO 2020 (second-line), Wolf et al ASCO 2019 (treatment-naïve), Paik et al NEJM 2020

HER2-mutant lung cancers

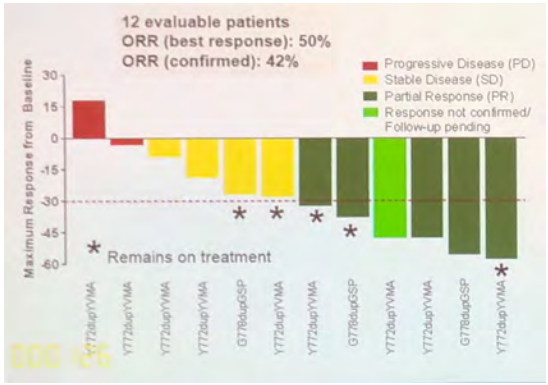
***HER2* mutations: ~2% of NSCLCs**

- younger, never smoker, slight female predominance
- mostly adenocarcinomas

HER2 TKIs

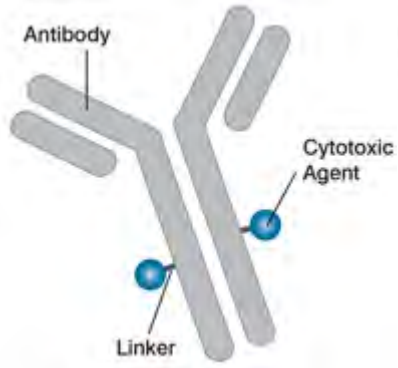
Afatinib, Neratinib, Dacomitinib, Lapatinib: ORR 0-13%

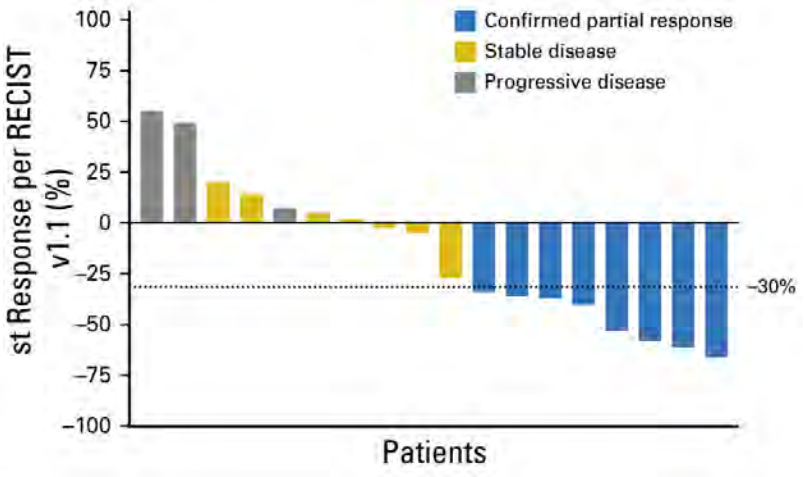
Poziotinib: ORR 42%
median PFS 5 mo



HER2 ADCs

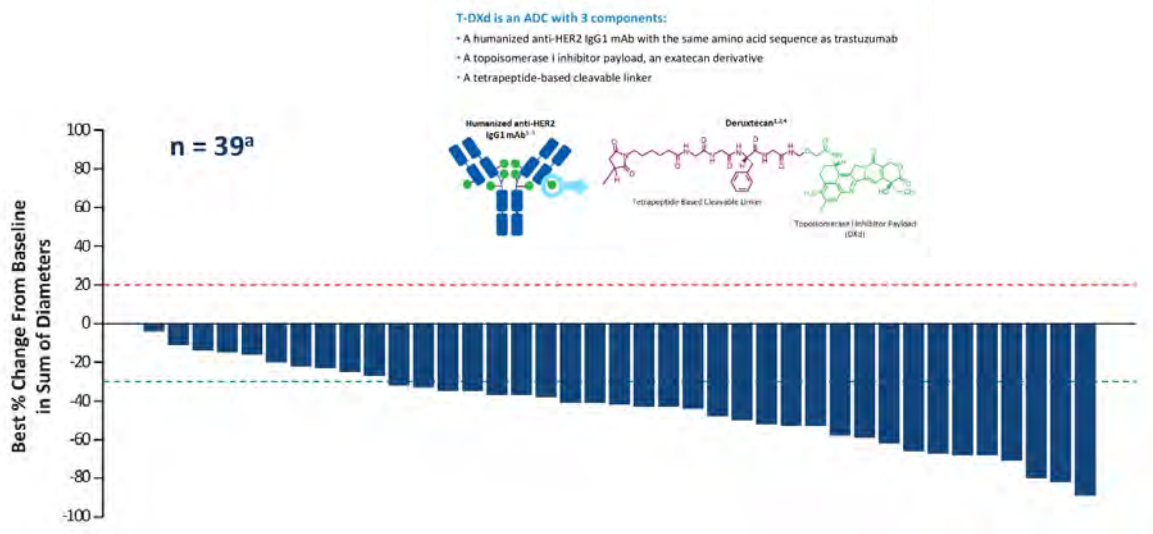
T-DM1
ORR 44%
median PFS 5 mo
NCCN guidelines



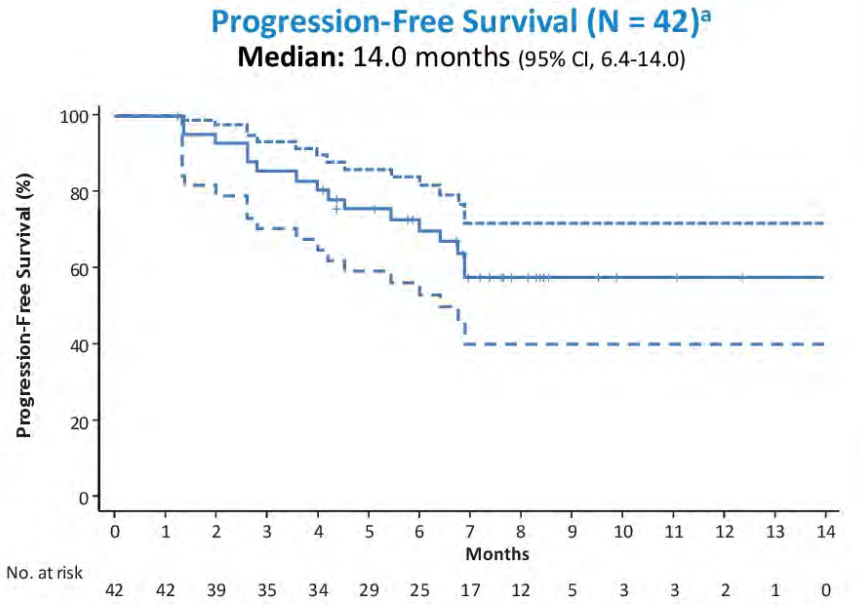


Li et al, JCO 2018; Tsurutani et al, WCLC 2018; Heymach et al, WCLC 2018

Trastuzumab deruxtecan is active in *HER2*-mutant NSCLCs



	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)



Most common AEs: nausea (>70%), alopecia/anemia/neutropenia (>40%)

	All Patients (N = 42)					
n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade/ Total
Interstitial lung disease	0[1]	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 et al, ASCO 2020

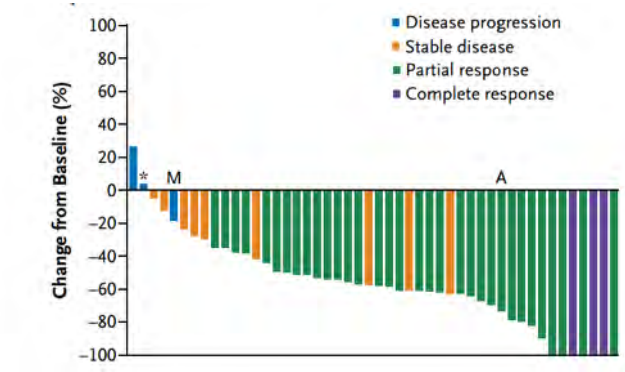
ROS1 TKIs are active in *ROS1* fusion-positive lung cancers

ROS1 fusions: 1-2% of NSCLCs

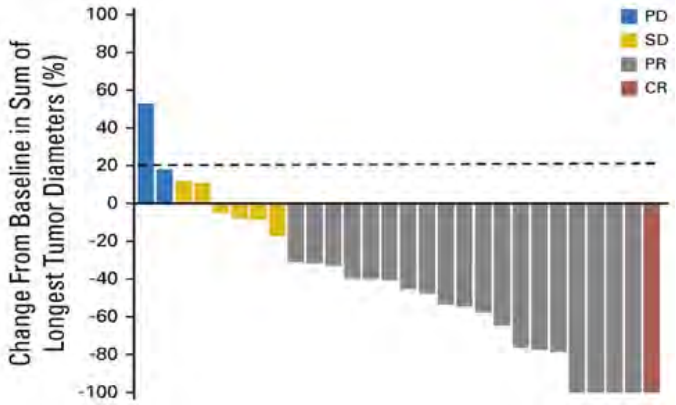
- younger, never smoker
- mostly adenocarcinomas

Early-gen TKIs

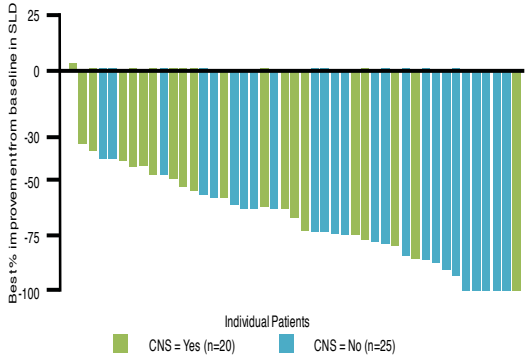
Crizotinib
ORR 72%
median PFS 19 mos



Ceritinib
ORR 62%
median PFS 19 mos
(intracranial ORR 25%)



Entrectinib
ORR 77%
median PFS 19 mos
(intracranial ORR 55%)



Drilon et al, ASCO 2018, Shaw et al, NEJM 2014; Wu et al JCO 2017; Lim et al, JCO 2017; Doebele et al WCLC 2018, Wu et al JCO 2017; WCLC 2018; Ou et al, WCLC 2018, Drilon et al Cancer discovery 2018

Next-gen ROS1 TKIs are active in *ROS1* fusion-positive NSCLCs

TKI-naive

Lorlatinib (NCCN)
ORR 62%
median PFS 21 mos

Repotrectinib (Fast Track Designation)
ORR 91%
median 24.6 mos

TKI-resistant

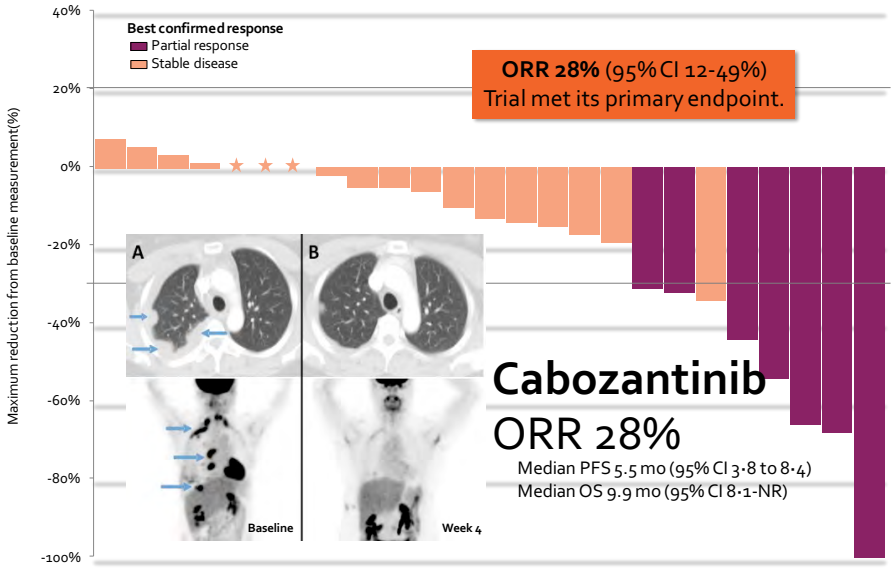
Lorlatinib
ORR 35%
median PFS 8.5 mos

Repotrectinib
ORR 39%
median PFS not reported

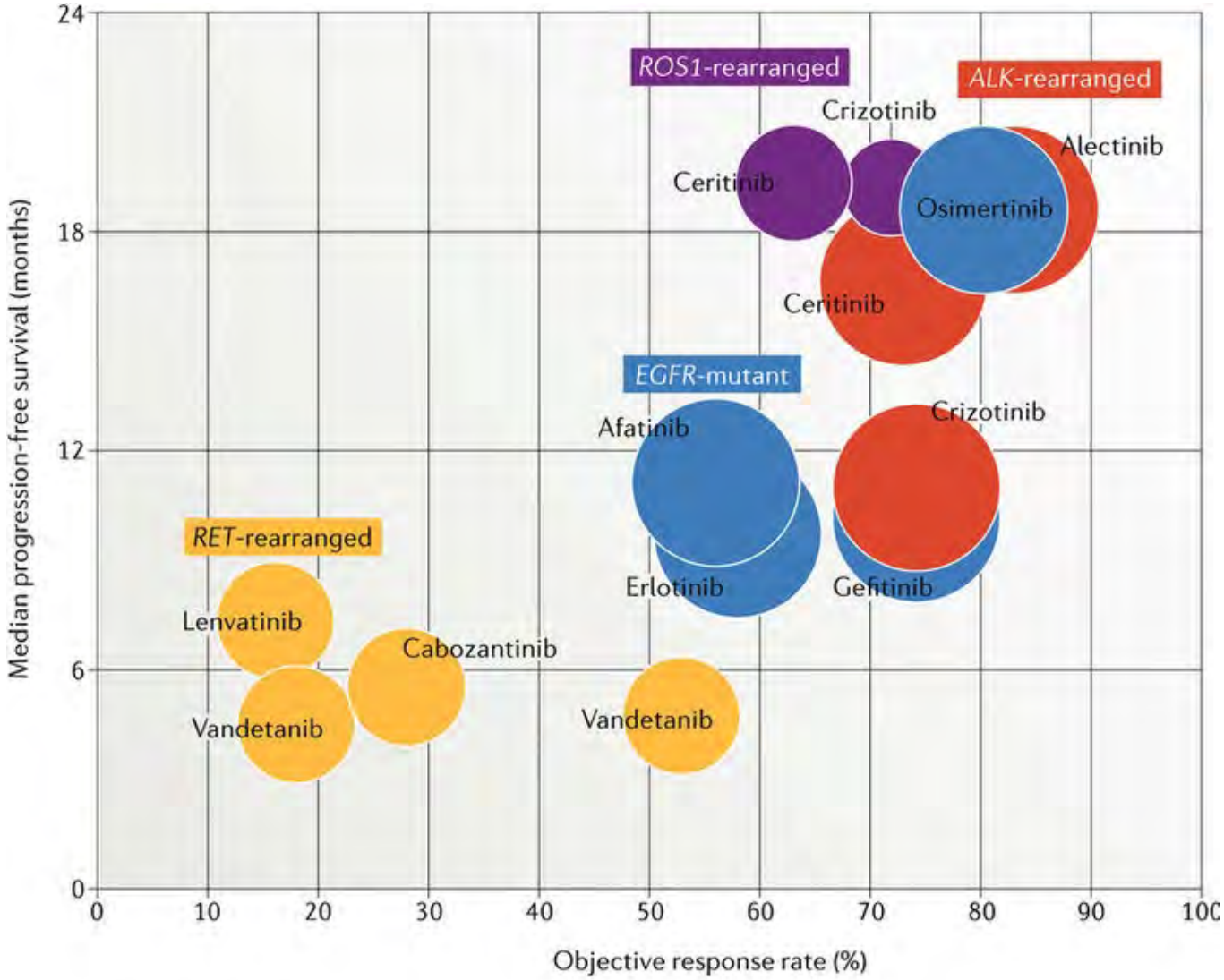
Older RET inhibitors were multikinase agents with modest activity and substantial toxicity

RET fusions: 1-2% of NSCLCs

- younger, never smoker
- mostly adenocarcinomas

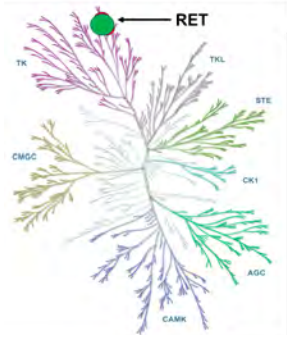


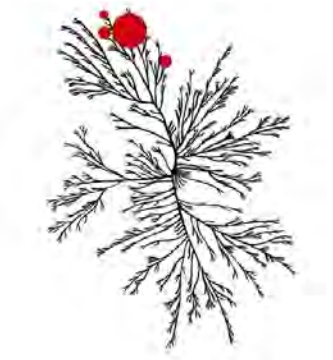
* Cabozantinib and Vandetanib: NCCN guidelines



Drilon et al, Lancet Oncol 2016; Drilon et al, Nat Rev Clin Oncol 2017

Selective RET inhibitors are active in *RET* fusion-positive NSCLC





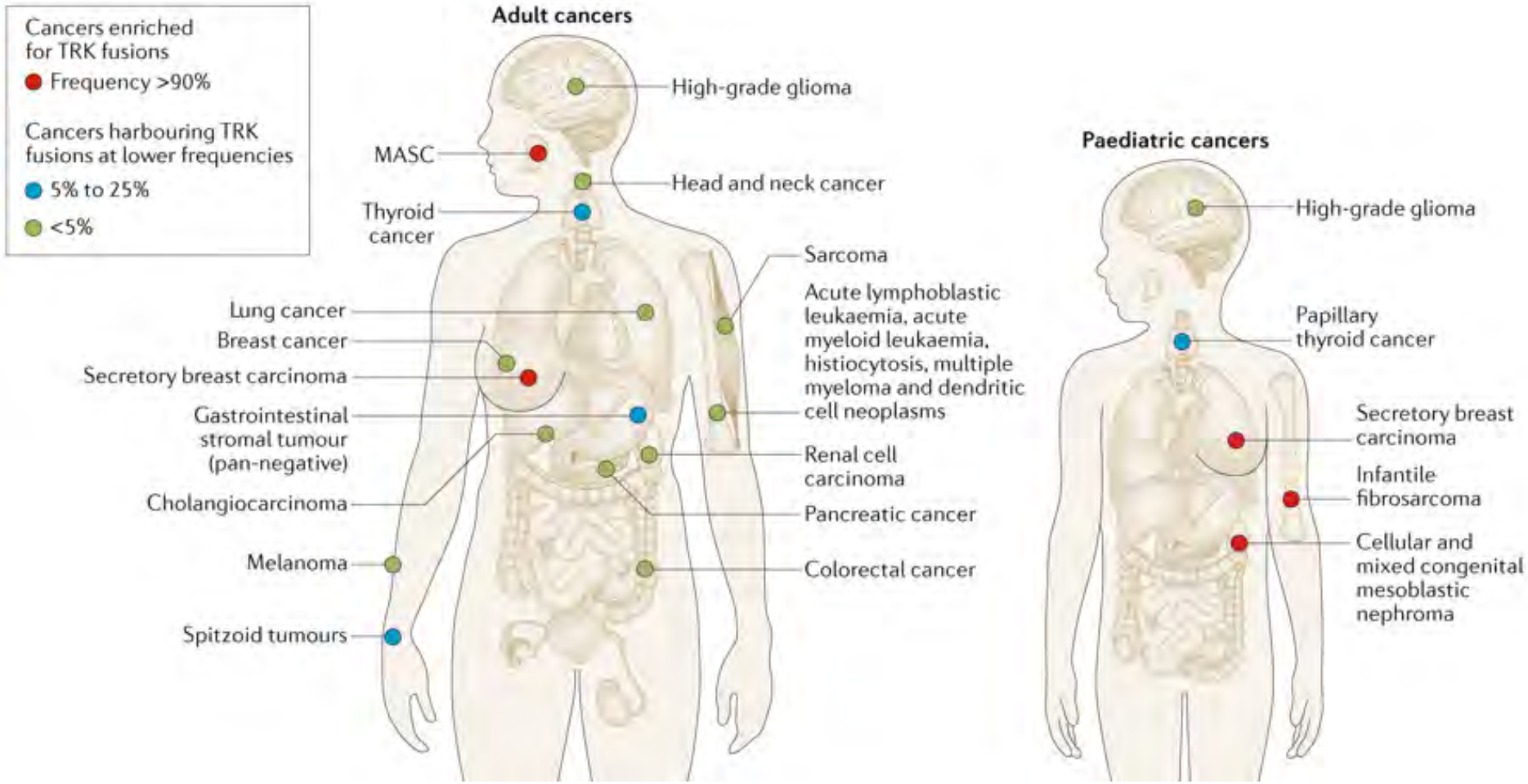
	Selpercatinib (LIBRETTO-001)	Pralsetinib (ARROW)
ORR		
Treatment naïve	85% (70-94, n=39)	66% (46-82, n=29)
Platinum pretreated	64% (54-73, n=105)	55% (45-66, n=92)
-Intracranial ORR	91% (59-100, n=11)	(not reported)
Median PFS		
Treatment naïve	not reached (14-NE)	17 months (14-NE)
Platinum pretreated	(not reported)	(not reported)

*both by independent review and in intent-to-treat population; NE – not evaluable

Goto et al, ASCO 2020; Gainor et al, ASCO 2020

NTRK fusions are found across a diverse array of cancers

NTRK fusions: 0.2% of NSCLCs



Cocco et al, Nat Rev Clin Oncol 2018

TRK inhibitors are active in TRK fusion-positive cancers

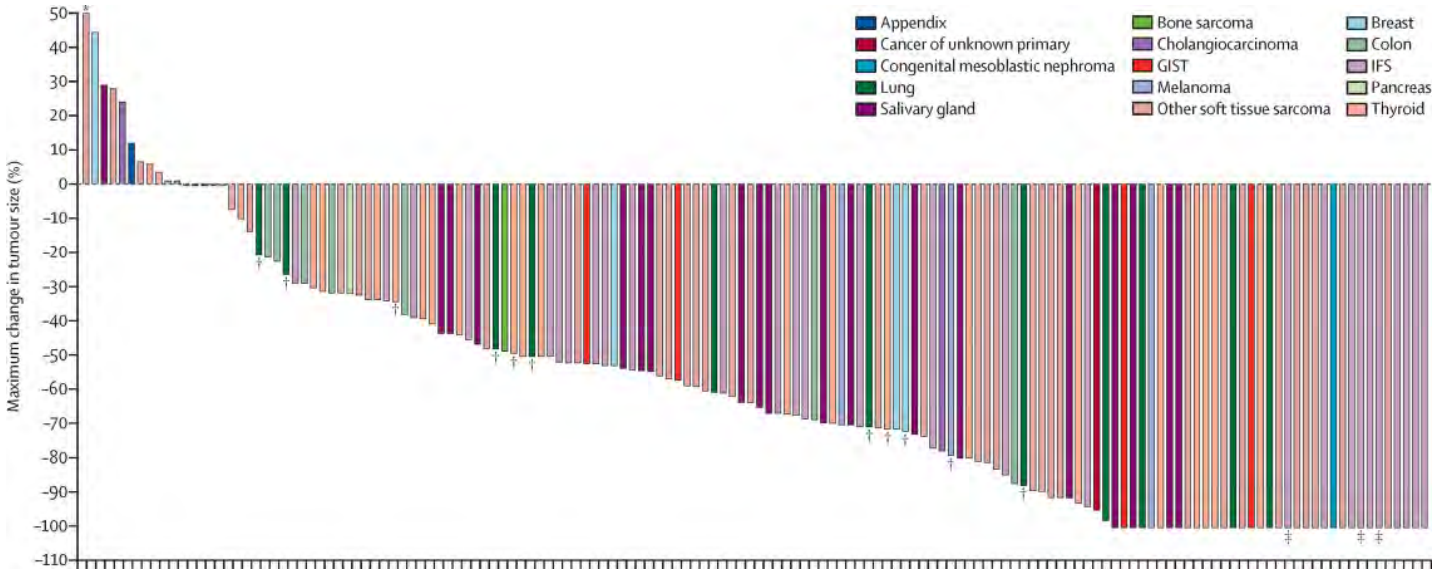
Larotrectinib

ORR 79%

(95% CI 72-85%, n=159)

Median DoR 35.2 months

Median PFS 28.3 months



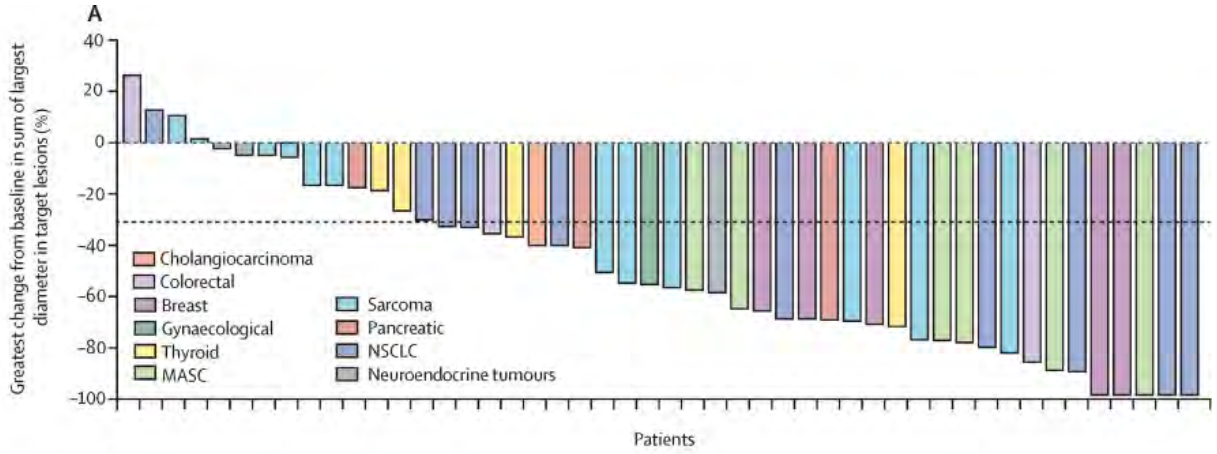
Entrectinib

ORR 57%

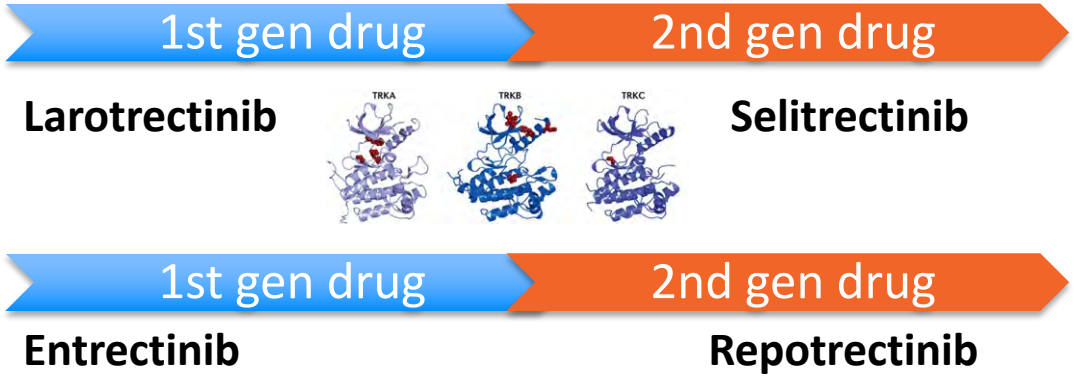
(95% CI 43-71%, n=54)

Median DoR 10 months

Median PFS 11 months



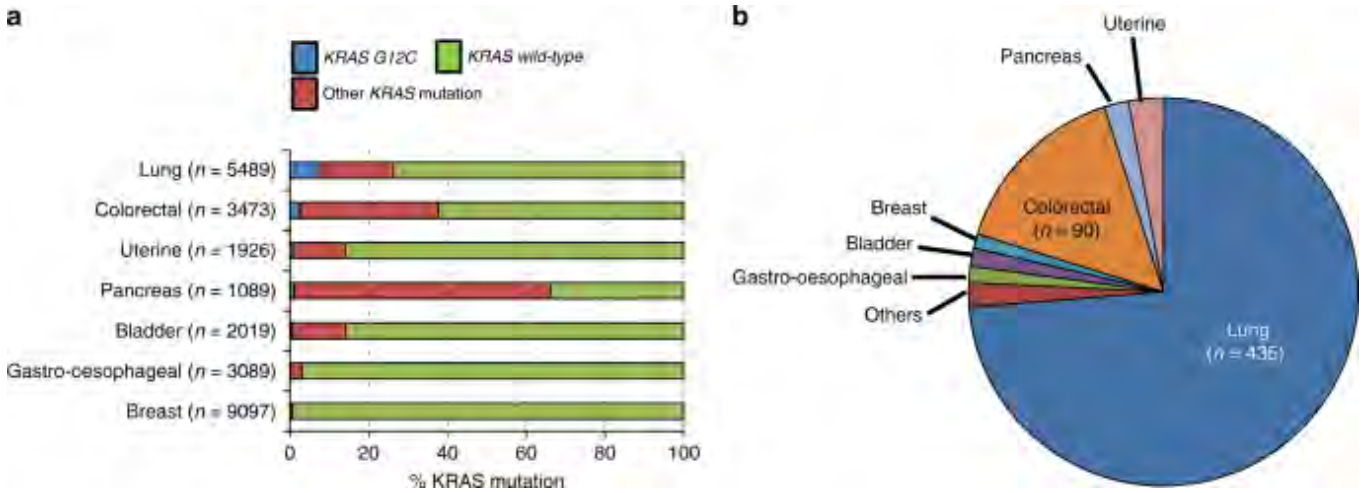
Second-generation TRK inhibitors can address on-target resistance

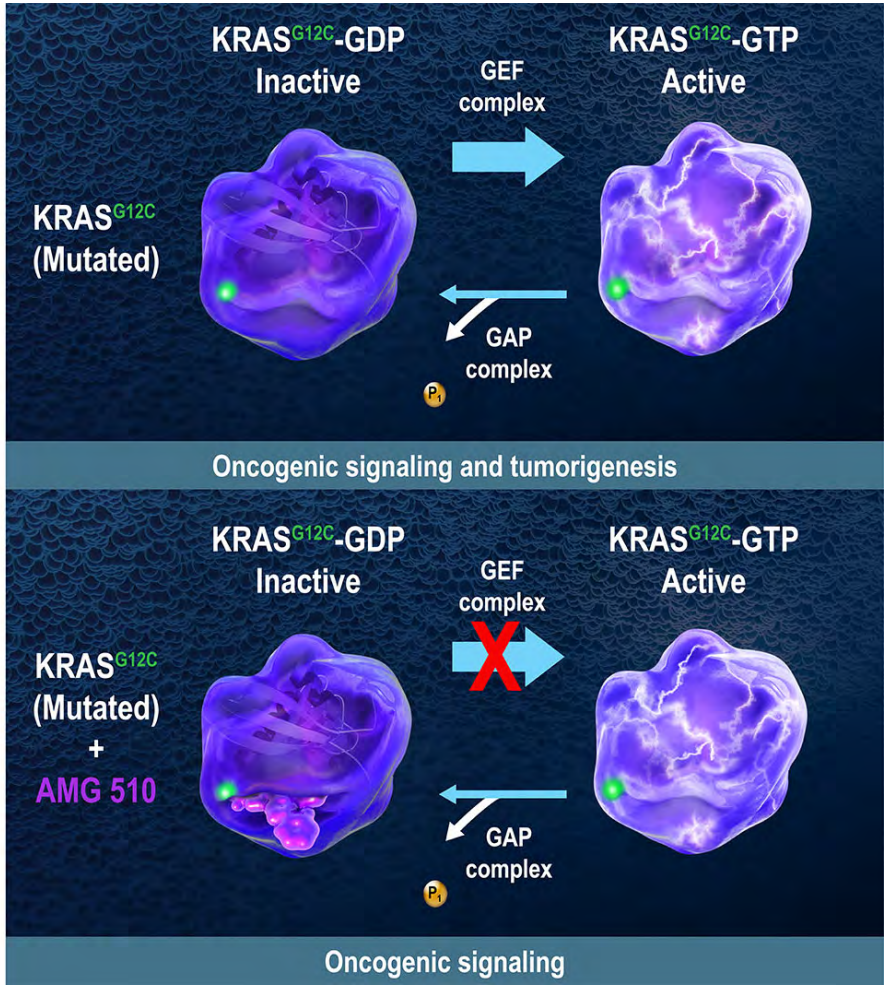


Drilon et al, Cancer Discov 2017; Drilon et al, Cancer Discov 2018

Mutant-selective direct inhibitors: *KRAS* G12C-mutant NSCLC

***KRAS* G12C: 10-12% of NSCLCs**





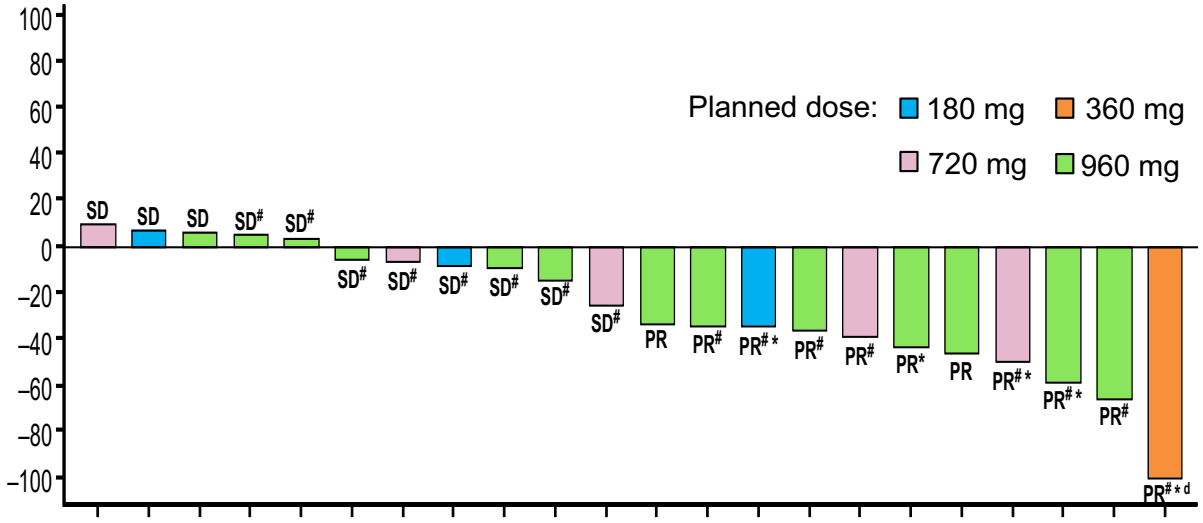
Li et al, IASLC N Am Conf Lung CA 2019

Mutant-selective direct inhibitors: *KRAS* G12C-mutant NSCLC

Sotorasib
(AMG-510, n=23)

ORR 48%

PR 48%
SD 48%
PD 4%

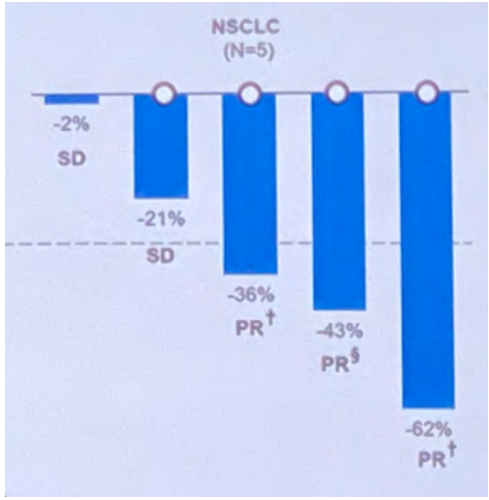


No DLTs or AEs leading
to Tx discontinuation

MRTX849

3/5 PRs

(n=5)



Li et al, IASLC N Am Conf Lung CA 2019; Janne et al, EORTC-AACR-NCI 2019

Agenda

Part 3: Case Presentations

- Case 7 – Dr McKenzie: A 66-year-old woman with metastatic adenocarcinoma of the lung (RET fusion)
- Case 8 – Dr Ibrahim: A 59-year-old man with metastatic adenocarcinoma of the lung (RET fusion)
- Case 9 – Dr Radovich: A 68-year-old man with metastatic pancreatic cancer (ERC1/RET fusion)
- Case 10 – Dr Drilon: A 76-year-old woman with metastatic adenocarcinoma of the lung (EPS15-NTRK1)
- Case 11 – Dr McKenzie: An 82-year-old man with metastatic adenocarcinoma of the lung (MET exon 14)
- Case 12 – Dr Ibrahim: An 84-year-old with Stage IIIB NSCLC (MET exon 14 skipping mutation)
- Case 13 – Dr Radovich: A 72-year-old man with metastatic NSCLC (MET exon 14 splice site mutation)
- Case 14 – Dr Drilon: A 58-year-old woman with metastatic adenocarcinoma of the lung (KRAS G12C)
- Case 15 – Dr Ibrahim: A 68-year-old woman with metastatic adenocarcinoma of the lung (EGFR, ALK)

Case Presentation - Dr McKenzie: A 66-year-old woman with metastatic NSCLC and a RET fusion

- 66yr Female – never smoker
- Diagnosed 2019 with Stage IV NSCLC adenocarcinoma
  - PDL1 = 0%
  - Primary right lung mass, with innumerable right pulmonary nodules, pleural effusion, bony metastatic disease in the sacrum and L5 vertebra, as well as right cerebellar and left frontal lesions.
  - She completed whole brain radiation therapy in August 2019
- Liquid biopsy NGS and tissue-based NGS performed in August 2019
  - Liquid Biopsy revealed KIF5B-RET fusion, MYC amplification, APC mutation, and FGFR3 VUS
  - Tissue based NGS confirmed KIF5B-RET fusion and MYC amp but also detected MDM2 amp and HSD3B1 mutation
- Received investigational RET inhibitor until progression in July 2020 (no obvious resistance mechanism)
- Currently in screening for additional clinical trials targeting RET

Case Presentation - Dr McKenzie: A 66-year-old woman with metastatic NSCLC and a RET fusion (cont)

Alteration	% cfDNA or Amp	Alteration Trend
KIF5B-RET Fusion	0.6%	
FGFR3 V306I	0.2%	Variant of Uncertain Significance§
MYC Amplification Amplifications not graphed above	ND	Plasma copy number
APC R382T	ND	

comprehensive companion diagnostic for all solid tumors.

Interpretive content on this page and subsequent pages is provided as a professional service, and is not reviewed or approved by the FDA.

PATIENT

DISEASE Lung adenocarcinoma
NAME
DATE O BIRTH
SEX Female
MEDICAL RECORD #

PHYSICIAN

ORDERING PHYSICIAN
MEDICAL FACILITY
ADDITIONAL RECIPIENT None
MEDICAL FACILITY ID
PATHOLOGIST Provided, Not

SPECIMEN

SPECIMEN SITE Lymph Node
SPECIMEN ID SN-19-0001185-A1
SPECIMEN TYPE Block
DATE OF COLLECTION 25 July 2019
SPECIMEN RECEIVED 17 August 2019

Biomarker Findings

Microsatellite status - MS-Stable
Tumor Mutational Burden - TMB-Low (5 Muts/Mb)

Genomic Findings

For a complete list of the genes assayed, please refer to the Appendix

RET **KIF5B-RET fusion**
MDM2 **amplification**
MYC **amplification**
HSD3B1 **T353M**

7 Disease relevant genes with no reportable alterations: *EGFR, KRAS, ALK, BRAF, MET, ERBB2, ROS1*

6 Therapies with Clinical Benefit
0 Therapies with Lack of Response
19 Clinical Trials

SARAH CANNON

Case Presentation – Dr Ibrahim: A 59-year-old man with metastatic NSCLC and a RET fusion mutation

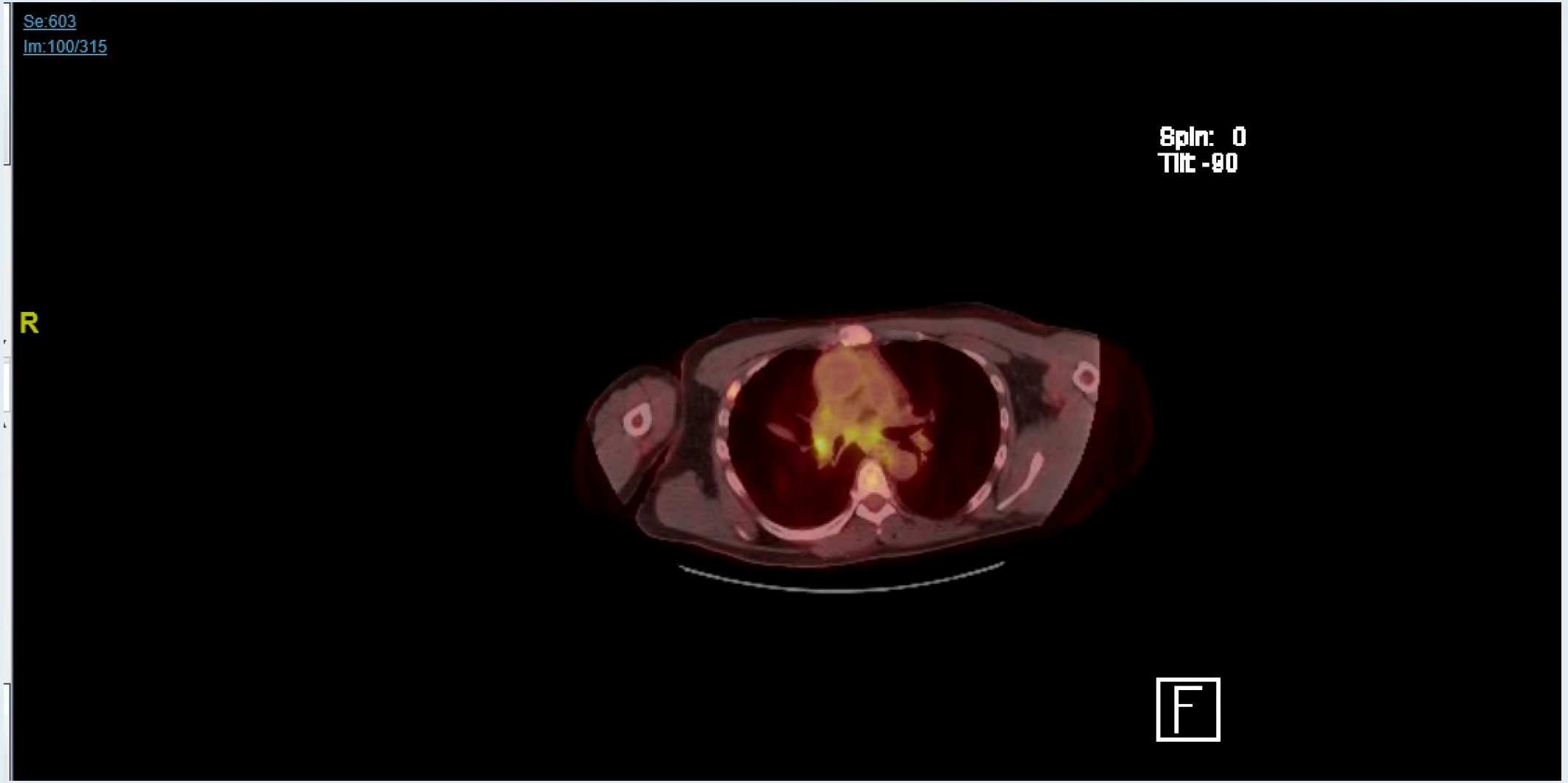
Sulfi Ibrahim, MD

59-year-old who presented with a worsening cough. Workup revealed metastatic adenocarcinoma. NGS reveals a high PD-L1 level but also a RET fusion

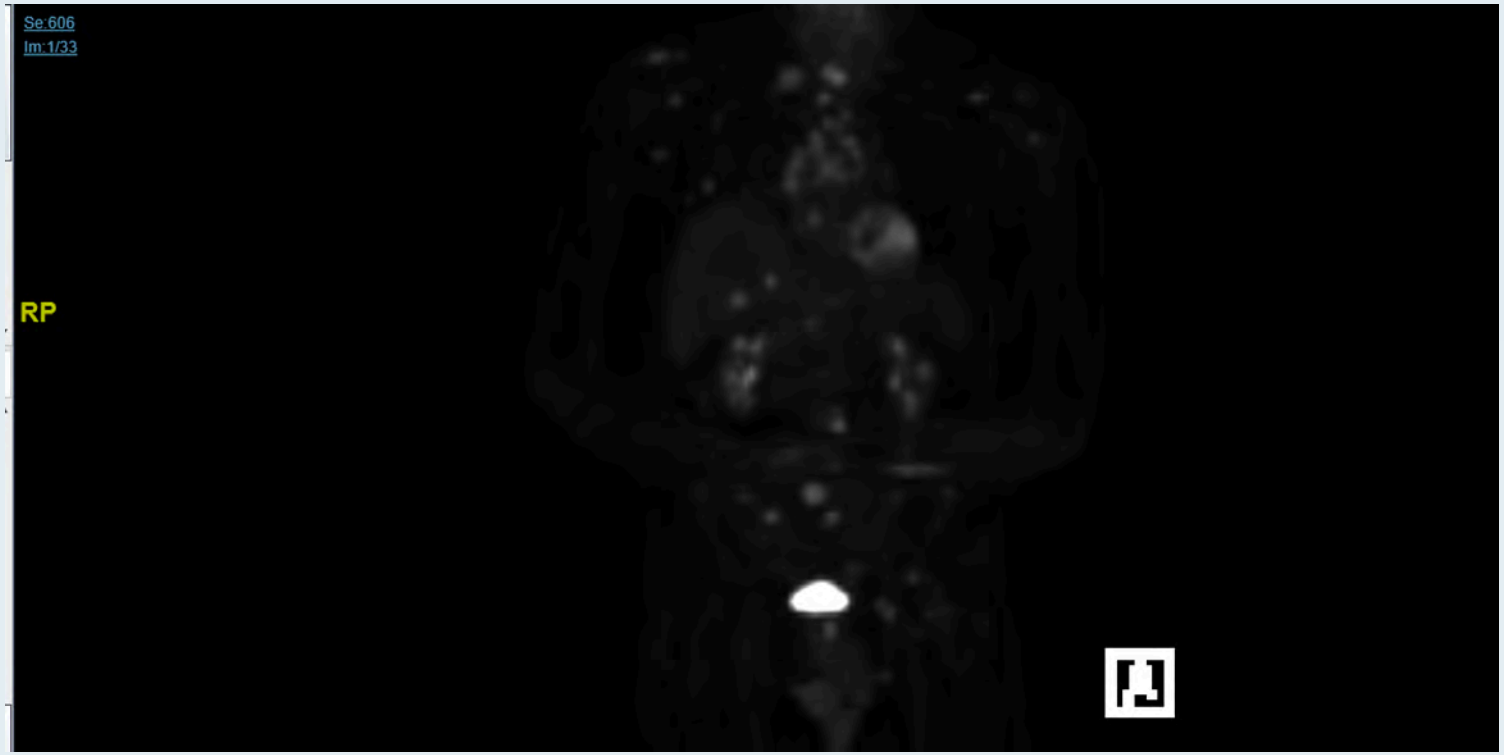
Questions:

- Would you treat him with single agent pembrolizumab, combination chemo-immunotherapy or RET directed therapy with selpercatinib?
- Should RNA based assays be used to identify RET fusions? How does a general medical oncologist determine which RET mutations are actionable?
- Are PD-L1 levels indicative of response in patients with driver mutations, or are they not indicative of response to immunotherapy in this population?

Case Presentation – Dr Ibrahim: 59-year-old man
Right lung mass and adenopathy



Case Presentation – Dr Ibrahim: 59-year-old man
Diffuse metastatic disease in liver and bone



Case Presentation – Dr Ibrahim: 59-year-old man
PD-L1 expression

ASK AN EXPERT

Our Medical Affairs team is available to help you understand the results of this assay

PD-L1 IMMUNOHISTOCHEMISTRY (IHC) ANALYSIS

Tumor Proportion Score (TPS) (%) 99

Electronically signed by: [redacted] Date: [redacted]

RESULTS CRITERA	
Non-Small Cell Lung Cancer (NSCLC)	• The specimen should be considered to have PD-L1 expression if TPS ≥ 1% and high PD-L1 expression if TPS ≥ 50%. • PD-L1 IHC is indicated as an aid identifying NSCLC patients for treatment with pembrolizumab. See the pembrolizumab product label for expression

Case Presentation – Dr Ibrahim: 59-year-old man
NGS report

OTHER ALTERATIONS & BIOMARKERS IDENTIFIED

Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product. See *professional services* section for additional information.

Microsatellite status MS-Stable §

Tumor Mutational Burden 3 Muts/Mb §

CDKN2A loss §

CDKN2B loss §

RET KIF5B(NM_004521)-RET(NM_020630) fusion (K15; R12) §

§ Refer to appendix for limitation statements related to detection of any copy number alterations, gene rearrangements, LOH, MSI or TMB result in this section.

Please refer to appendix for Explanation of Clinical Significance Classification and for variants of unknown significance (VUS).

Case Presentation – Dr Radovich: A 68-year-old man with metastatic pancreatic cancer

- **HISTORY OF PRESENT ILLNESS:** 68-year-old man with metastatic pancreatic cancer. The patient's pertinent history dates to 10/2018 when he presented with abdominal pain and imaging showed a pancreatic head mass. Patient had a Whipple procedure followed by adjuvant chemotherapy with gemcitabine and *nab* paclitaxel followed by chemoradiation with capecitabine completing in 09/2019. In 05/2020 on surveillance was found to have metastatic disease and started on FOLFIRINOX.
- **PAST MEDICAL HISTORY:** Diabetes
- **FHx:** Mother with breast cancer (50s) & father with prostate cancer (50s)

Case Presentation – Dr Radovich: 68-year-old man with metastatic pancreatic cancer (cont)

Diagnosis: **Pancreatic Cancer**

TUMOR GENOMIC ALTERATIONS[1]

ARID1A ATM ERC1/RET

GENOMIC TARGETS	FDA-APPROVED DRUGS -for patient's cancer	FDA-APPROVED DRUGS -for another cancer	DRUGS PREDICTED NON-BENEFICIAL	POTENTIAL CLINICAL TRIALS
3	0	13	0	Yes
ARID1A (Y222*)				Yes
ATM (E2676*)		niraparib, olaparib, rucaparib, talazoparib		Yes
ERC1/RET (Fusion)		alectinib, cabozantinib, lenvatinib, ponatinib, regorafenib, selpercatinib, sorafenib, sunitinib, vandetanib		Yes

TUMOR MUTATION BURDEN (TMB)

LOW (2 mut/Mb)		No

MICROSATELLITE STATUS (MSI)

STABLE		No

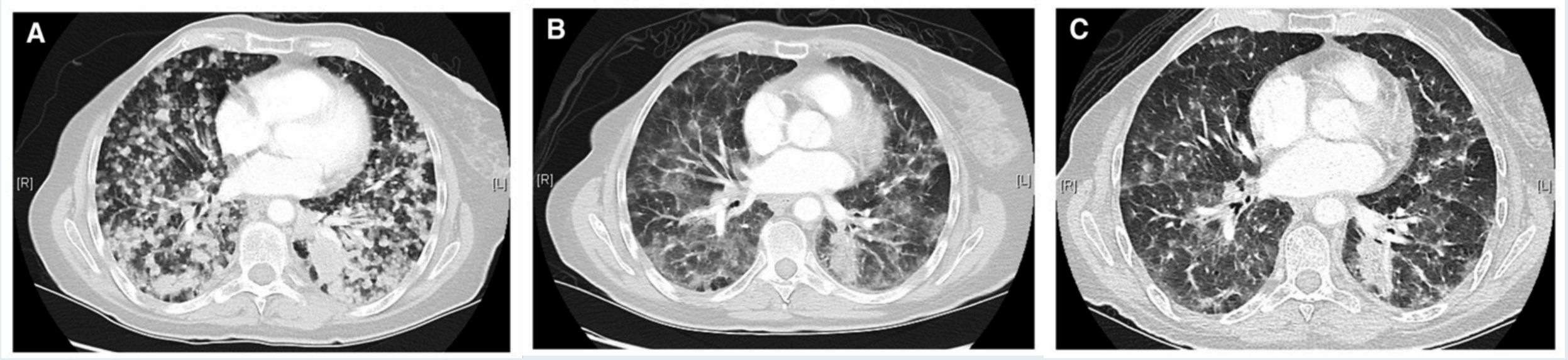
ADDITIONAL SIGNIFICANT ALTERATIONS

RET_TBC1D22A (Structural Translocation)		No
SMAD4 (R361H)		No

Case Presentation – Dr Drilon: A 76-year-old woman with NSCLC and an NTRK fusion

- Presented with a persistent cough and increasing copious oral secretions
- **Imaging**: Innumerable pulmonary nodules, widespread thoracic adenopathy, hepatic, adrenal, and osseous metastases; more than 10 subcentimeter brain metastases
- **Biopsy** (mediastinal, endobronchial LN): Adenocarcinoma consistent with a lung primary (TTF1+, p40-), PD-L1 0%
- **NGS**: *EPS15-NTRK1*, no other drivers
- **Treatment**
  - Larotrectinib on NAVIGATE study → PR achieved in 4 weeks, confirmed 8 weeks later; had regression at all disease sites and near resolution of all brain metastases; decrease in oral secretions (see photo for response)
  - Progression after 1 year and 9 months (increase in oral secretions)
  - Switched to commercial larotrectinib (in 2020, drug was already approved by the US FDA) and carbo/pem started → PR with symptomatic improvement

Case Presentation – Dr Drilon: A 76-year-old woman with NSCLC and an NTRK fusion (cont)

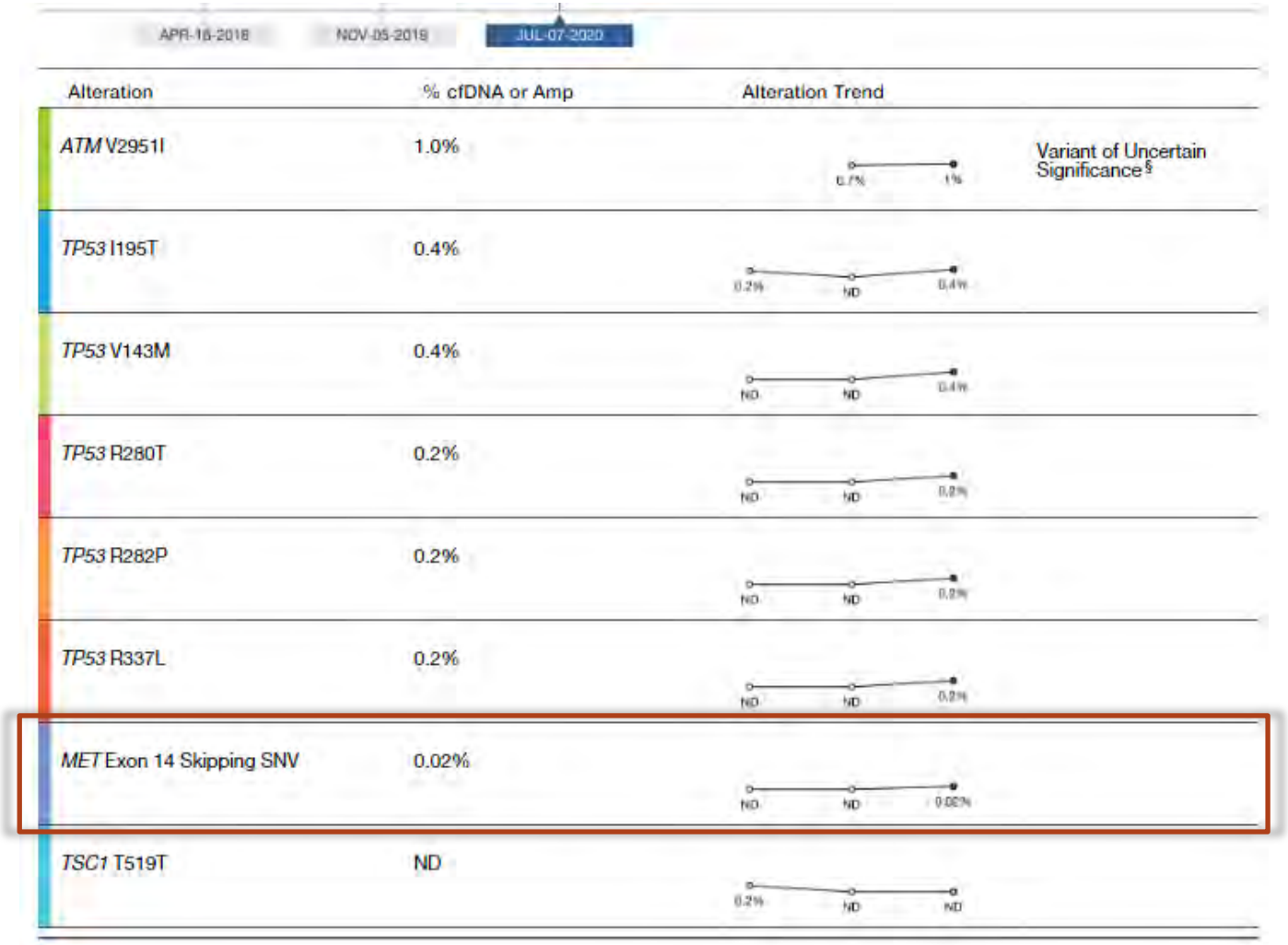


Case Presentation - Dr McKenzie: An 82-year-old man with metastatic NSCLC and a MET exon 14 skipping mutation

- 82yr Male
- Diagnosed 2015 with Stage Ia NSCLC
  - Primary XRT 7-8/2015; Thoracentesis (Tx) 2/2016; erlotinib 7-8/2016 (DC'd for grade III dermatotoxicity and constitutional decline early into Tx)
- Metastatic disease diagnosed 2017
  - Nivolumab 2/2017 – 11/2019 (PR → SD → POD)
  - Carboplatin/Gemcitabine11/2019 – 7/2020 (PR → POD)
  - Carboplatin/Paclitaxel 7/2020 – present
  - Planning capmatinib due to Met exon14 skipping

Case Presentation - Dr McKenzie: An 82-year-old man with metastatic NSCLC and a MET exon 14 skipping mutation (cont)

No Driver mutations detected on first two tests in 2016 or 2019. Third test revealed Met exon14 skipping



SARAH CANNON

Case Presentation – Dr Ibrahim: An 84-year-old with Stage IIIB lung cancer and a MET exon 14 skipping mutation

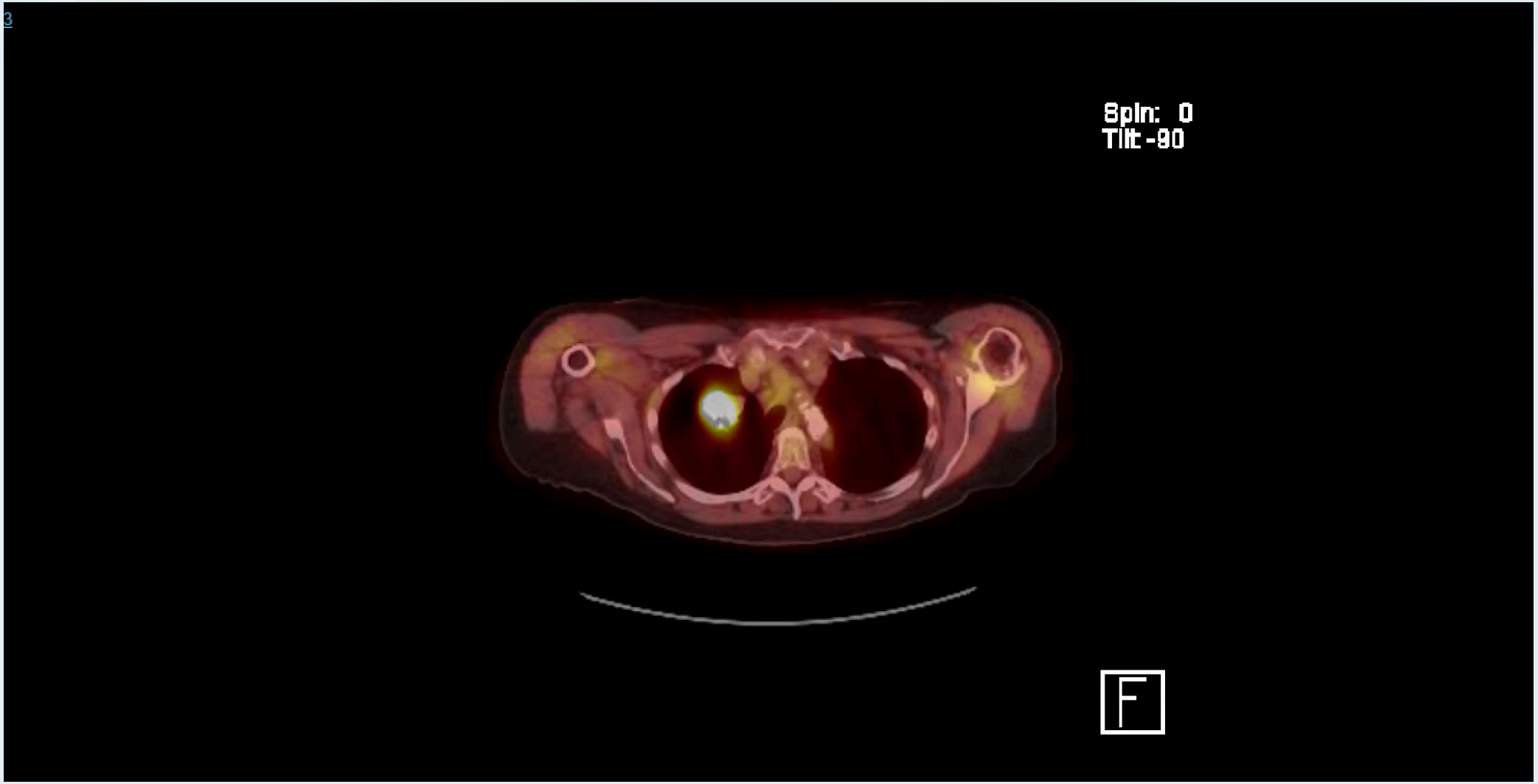
Sulfi Ibrahim, MD

84-year-old with stage IIIB adenocarcinoma of the right lung with a complete response. Started on consolidation durvalumab based on the PACIFIC study, has some evidence of radiation fibrosis after treatment. Started on durvalumab and develops dyspnea. Does not need to be hospitalized but dyspnea improves with steroids. Patient did not tolerate steroids well and after discussion decides to stop durvalumab

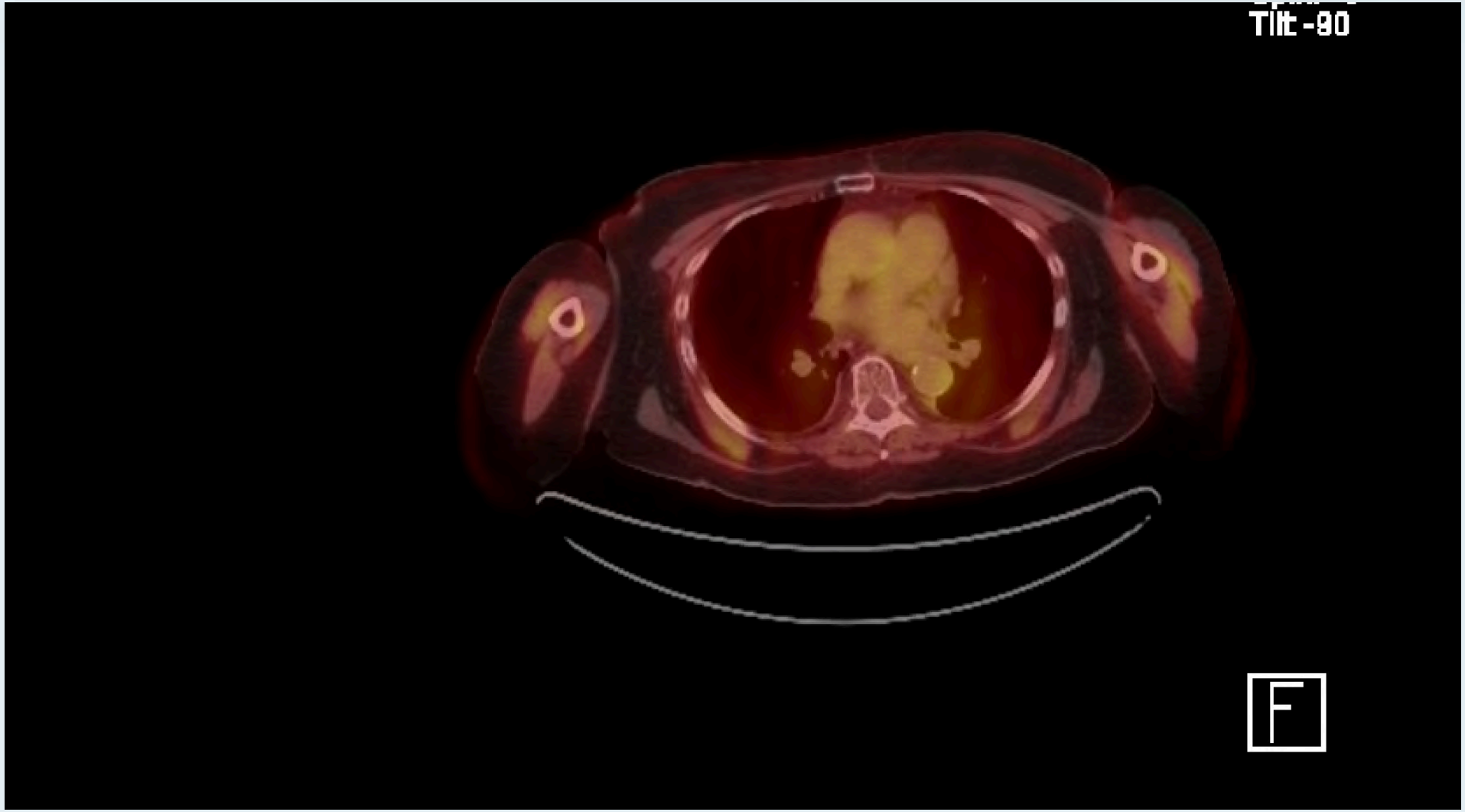
Question:

- This patient has a high PD-L1 level but also has the MET exon 14 skipping mutation. Is there data showing that immunotherapy does not have a high degree of activity in patients with the MET exon 14 skipping mutation? Is the PD-L1 level meaningful in this population?
- If this patient were to develop metastatic disease, would you use capmatinib as first line therapy?
- Any difference in the activity of capmatinib and tepotinib?

Case Presentation – Dr Ibrahim: 84-year-old
Right lung mass



Case Presentation – Dr Ibrahim: 84-year-old
Complete response to treatment



Case Presentation – Dr Ibrahim: 84-year-old
PD-L1 expression

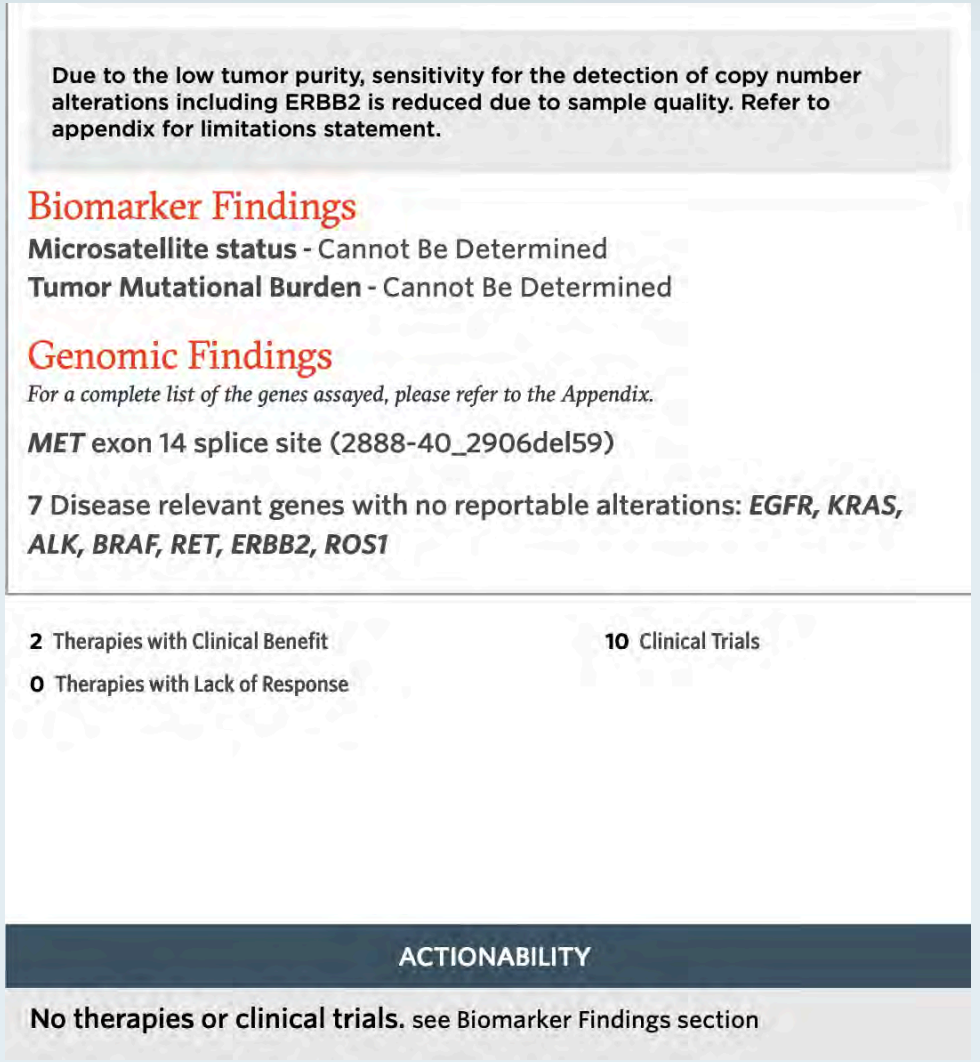
PD-L1 IMMUNOHISTOCHEMISTRY (IHC) ANALYSIS

Tumor Proportion Score (TPS) (%) 90

Electronically signed by: [redacted] Date: [redacted]

RESULTS CRITERA	
Non-Small Cell Lung Cancer (NSCLC)	• The specimen should be considered to have PD-L1 expression if TPS ≥ 1% and high PD-L1 expression if TPS ≥ 50%. • PD-L1 IHC is indicated as an aid identifying NSCLC patients for treatment with pembrolizumab. See the pembrolizumab product label for expression cutoff values guiding therapy in specific clinical circumstances.

Case Presentation – Dr Ibrahim: 84-year-old
NGS report



Due to the low tumor purity, sensitivity for the detection of copy number alterations including ERBB2 is reduced due to sample quality. Refer to appendix for limitations statement.

Biomarker Findings

Microsatellite status - Cannot Be Determined

Tumor Mutational Burden - Cannot Be Determined

Genomic Findings

For a complete list of the genes assayed, please refer to the Appendix.

MET exon 14 splice site (2888-40_2906del59)

7 Disease relevant genes with no reportable alterations: ***EGFR, KRAS, ALK, BRAF, RET, ERBB2, ROS1***

2 Therapies with Clinical Benefit

0 Therapies with Lack of Response

10 Clinical Trials

ACTIONABILITY

No therapies or clinical trials. see Biomarker Findings section

Case Presentation – Dr Radovich: A 72-year-old man with metastatic NSCLC and a MET exon 14 splice mutation

- **HISTORY OF PRESENT ILLNESS:** 72-year-old male with history of NSCLC, Stage I, s/p resection, now with liver metastases and enlarged mediastinal and supraclavicular lymph nodes. Due to prior liver transplant, immunotherapy was contraindicated. Patient had 6 cycles of carboplatin and pemetrexed and unfortunately had progression in 01/2020. Genomic sequencing identified a MET exon 14 splice site mutation. Patient was started on crizotinib, for which he continues to date.

Case Presentation – Dr Radovich: A 72-year-old man with metastatic NSCLC and a MET exon 14 splice mutation

BIOMARKER FINDINGS	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
Tumor Mutational Burden - TMB-Intermediate (6 Muts/Mb)	Atezolizumab	Avelumab
	Durvalumab	Cemiplimab-rwlc
	Nivolumab	
10 Trials *see p. 16*	Pembrolizumab	
Microsatellite status - MS-Stable	**No therapies or clinical trials.** see Biomarker Findings section	

GENOMIC FINDINGS	THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE)	THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE)
MET - exon 14 splice site (2888-16_2898del27)	Crizotinib	Cabozantinib
10 Trials *see p. 19*		
NF1 - Y235*	Trametinib	Binimetinib
		Cobimetinib
10 Trials *see p. 21*		

Case Presentation – Dr Drilon: A 58-year-old woman with NSCLC and a KRAS G12C mutation

- Presented with 40-lb weight loss and cough
- **Imaging:** 5-cm LLL mass, bilateral pulmonary nodules, bilateral thoracic adenopathy, pleural thickening, adrenal metastases
- **Biopsy** (mediastinal, endobronchial L4 biopsy): Adenocarcinoma consistent with a lung primary (TTF1+, p40-), PD-L1 30%
- **NGS:** *KRAS* G12C, no other drivers
- **Treatment**
  - Carbo/pem/pembro then pem/pembro maintenance → stable disease for 1 year, minor shrinkage in the primary mass
  - Presented with worsening cough → CT showed increase in pulmonary nodules and thoracic adenopathy, several new thoracic and lumbar metastases
  - Went onto a trial of a KRAS G12C-selective direct inhibitor on a clinical trial → minor shrinkage of pulmonary nodules, some attenuation of the cough at 2 months → progression of disease at 6 months with worsening intrathoracic disease
  - Started on another KRAS-directed clinical trial (MEK + FGFR inhibitor) with progression of disease
  - Later declined rapidly, DNR, hospice, passed away

Case Presentation – Dr Ibrahim: A 68-year-old woman with metastatic NSCLC

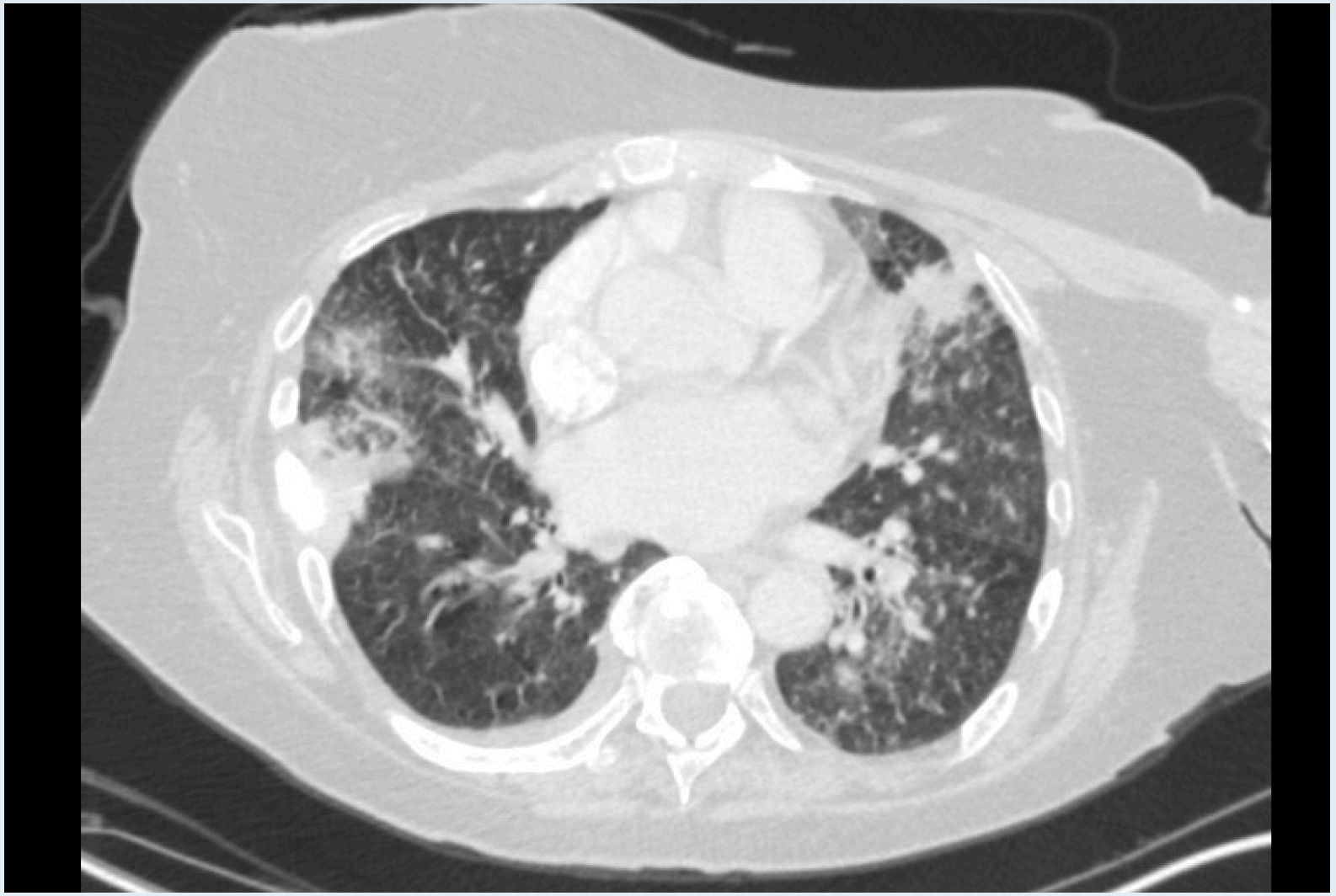
Sulfi Ibrahim, MD

68-year-old who was diagnosed with metastatic lung adenocarcinoma to the bone about 3 years ago. Was found to have the EGFR exon 19 mutation, was started on afatinib which she tolerated well with a dose reduction at 30mg daily. Now with symptomatic progression in the lung and bone. Biopsy done at the site of progression in the lung shows the ALK translocation

Questions:

- Is this actionable and if so what EGFR and ALK agents should be used?
- Are RNA based assays required to reliably pick up ALK translocations?
- What kind of biopsy should be done at the time of disease progression — Tissue, Liquid or both?

Case Presentation – Dr Ibrahim: 68-year-old woman
Worsening lung infiltrates



Case Presentation – Dr Ibrahim: 68-year-old woman
PD-L1 expression

PD-L1 IMMUNOHISTOCHEMISTRY (IHC) ANALYSIS

Tumor Proportion Score (TPS) (%) 50

Electronically signed by: [redacted] Date: [redacted]

Case Presentation – Dr Ibrahim: 68-year-old woman
NGS report

Companion Diagnostic (CDx) Associated Findings

GENOMIC FINDINGS DETECTED		FDA-APPROVED THERAPEUTIC OPTIONS
ALK	EML4-ALK fusion (Variant 5a/b)	Alectinib Crizotinib Ceritinib
EGFR	exon 19 deletion (L747_T751>P)	Afatinib Gefitinib Osimertinib Erlotinib

For Microsatellite Instability (MSI) results, confirmatory testing using a validated orthogonal method should be performed.

OTHER ALTERATIONS & BIOMARKERS IDENTIFIED

Recent Advances in Medical Oncology: Hodgkin and Non-Hodgkin Lymphomas

Monday, August 10, 2020

5:00 PM – 6:00 PM ET

Faculty

Jeremy Abramson, MD
Christopher R Flowers, MD, MS

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 days.