13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress

Colorectal and Gastroesophageal Cancers

Wednesday, April 21, 2021
4:45 PM – 5:45 PM ET

Medical Oncologists

Johanna Bendell, MD
Daniel Catenacci, MD

Oncology Nurse Practitioner

Jessica Mitchell, APRN, CNP, MPH

Moderator

Neil Love, MD

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Medical Oncologists

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Director, Drug Development Unit Nashville
Sarah Cannon Research Institute
Tennessee Oncology
Nashville, Tennessee

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Associate Professor, Department of Medicine
Section of Hematology and Oncology
Director, Interdisciplinary Gastrointestinal Oncology Program
Assistant Director, Translational Research
Comprehensive Cancer Center
The University of Chicago Medical Center and Biological Sciences
Chicago, Illinois

Oncology Nurse Practitioner

Jessica Mitchell, APRN, CNP, MPH
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Rochester, Minnesota

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Commercial Support

This activity is supported by educational grants from Lilly and Taiho Oncology Inc.

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Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, Adaptive Biotechnologies Corporation, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Eisai Inc, Epizyme Inc, Exact Sciences Inc, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, Genentech, a member of the Roche Group, Gilead Sciences Inc, GlaxoSmithKline, Grail Inc, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Novartis, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seagen Inc, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro, A GSK Company, Turning Point Therapeutics Inc and Verastem Inc.

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Dr Bendell — Disclosures

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Dr Catenacci — Disclosures

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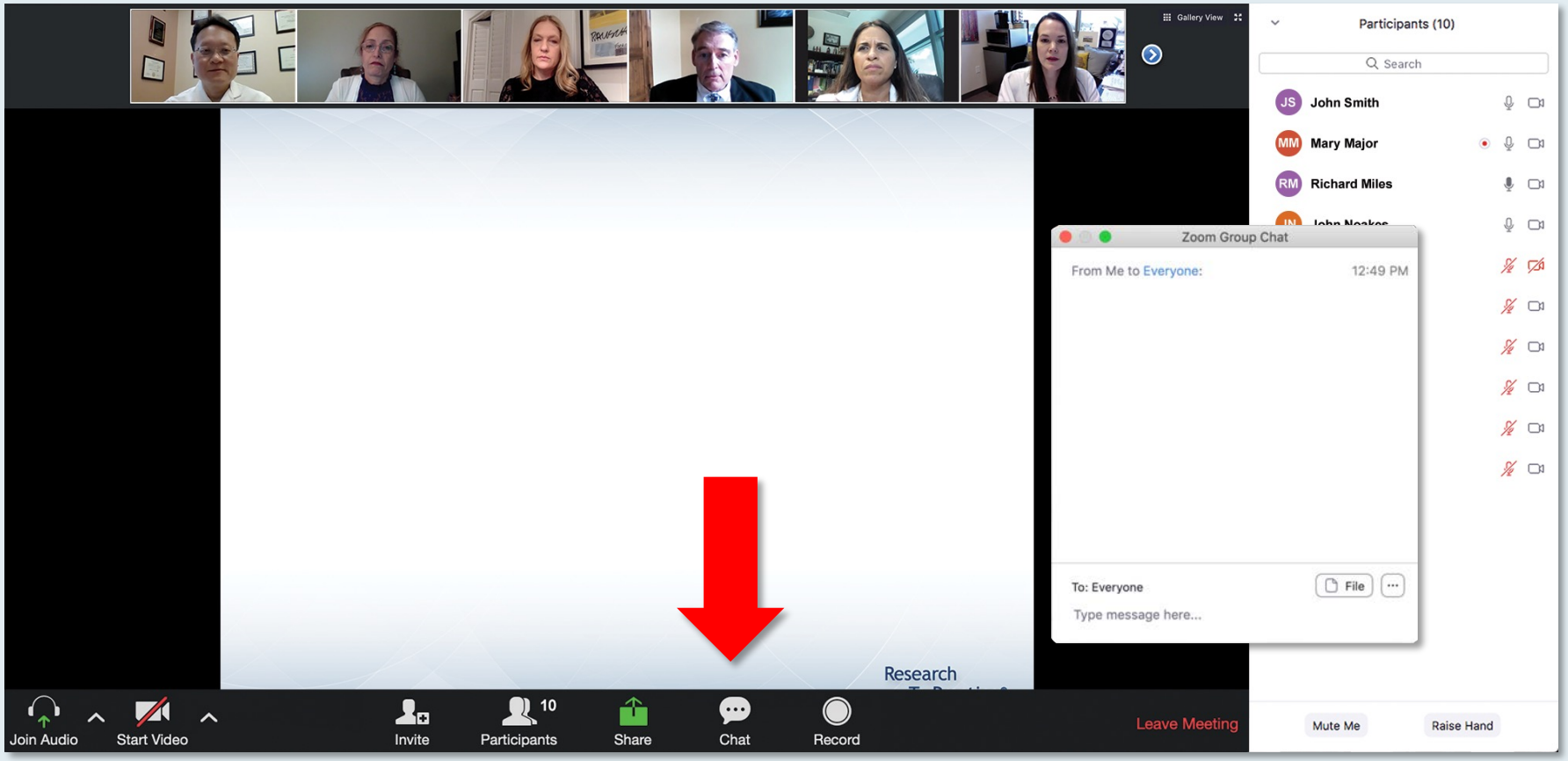
Speakers Bureau	Genentech, a member of the Roche Group, Guardant Health, Lilly, Merck, Tempus

Ms Mitchell — Disclosures

No relevant conflicts of interest to disclose.

We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

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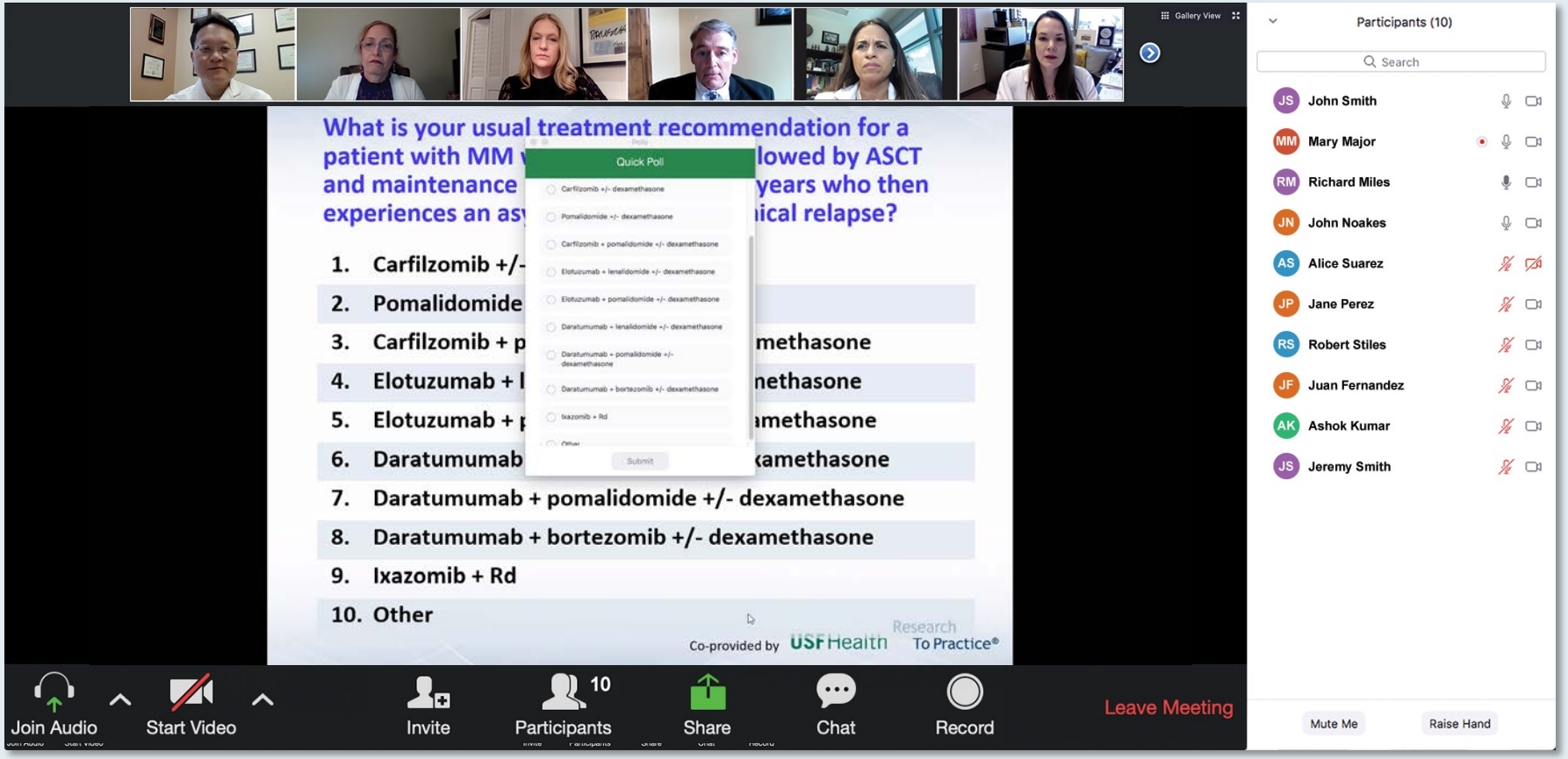
Familiarizing Yourself with the Zoom Interface

How to answer poll questions



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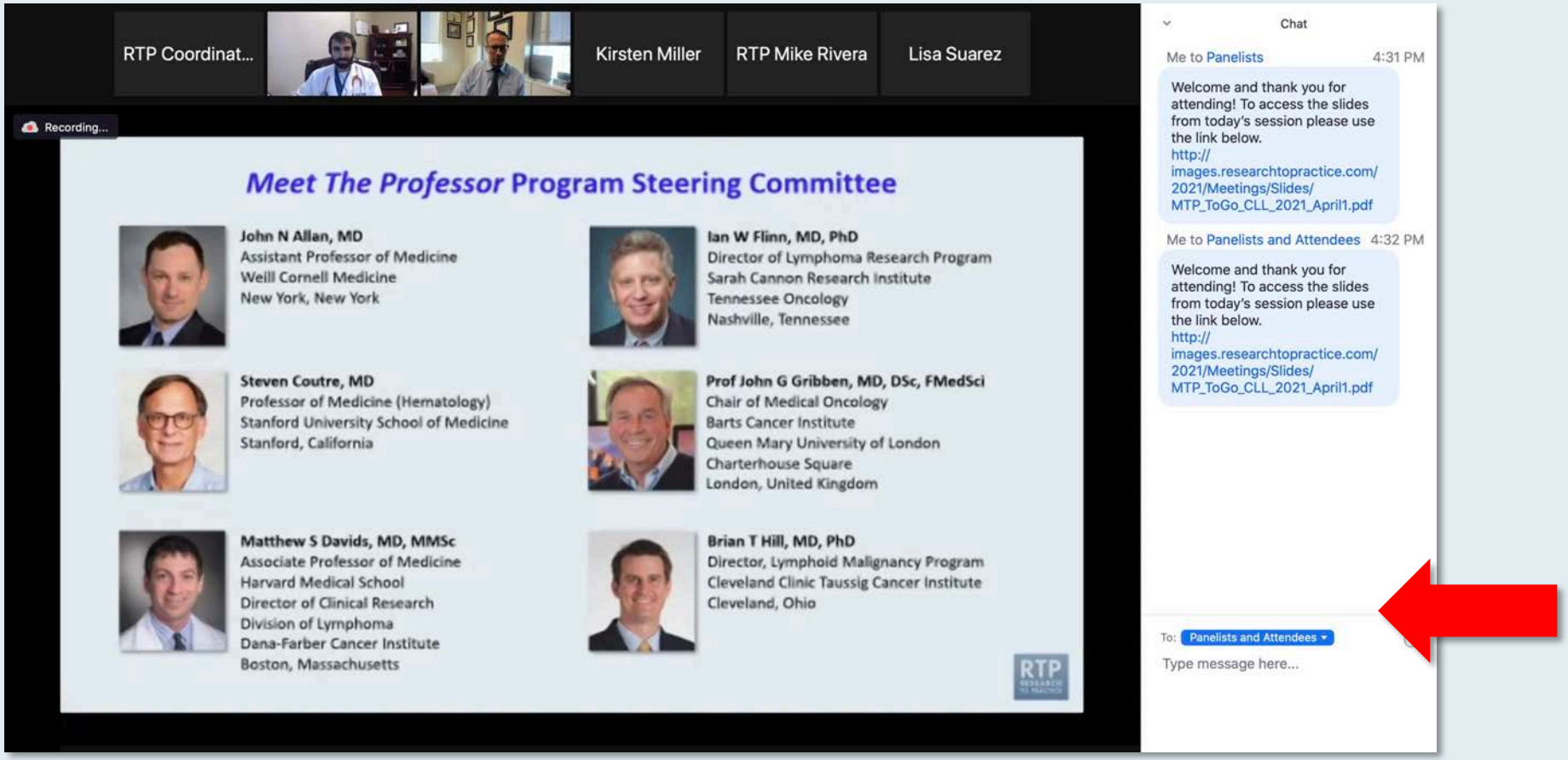
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



Drag the white line above the submission box up to create more space for your message.

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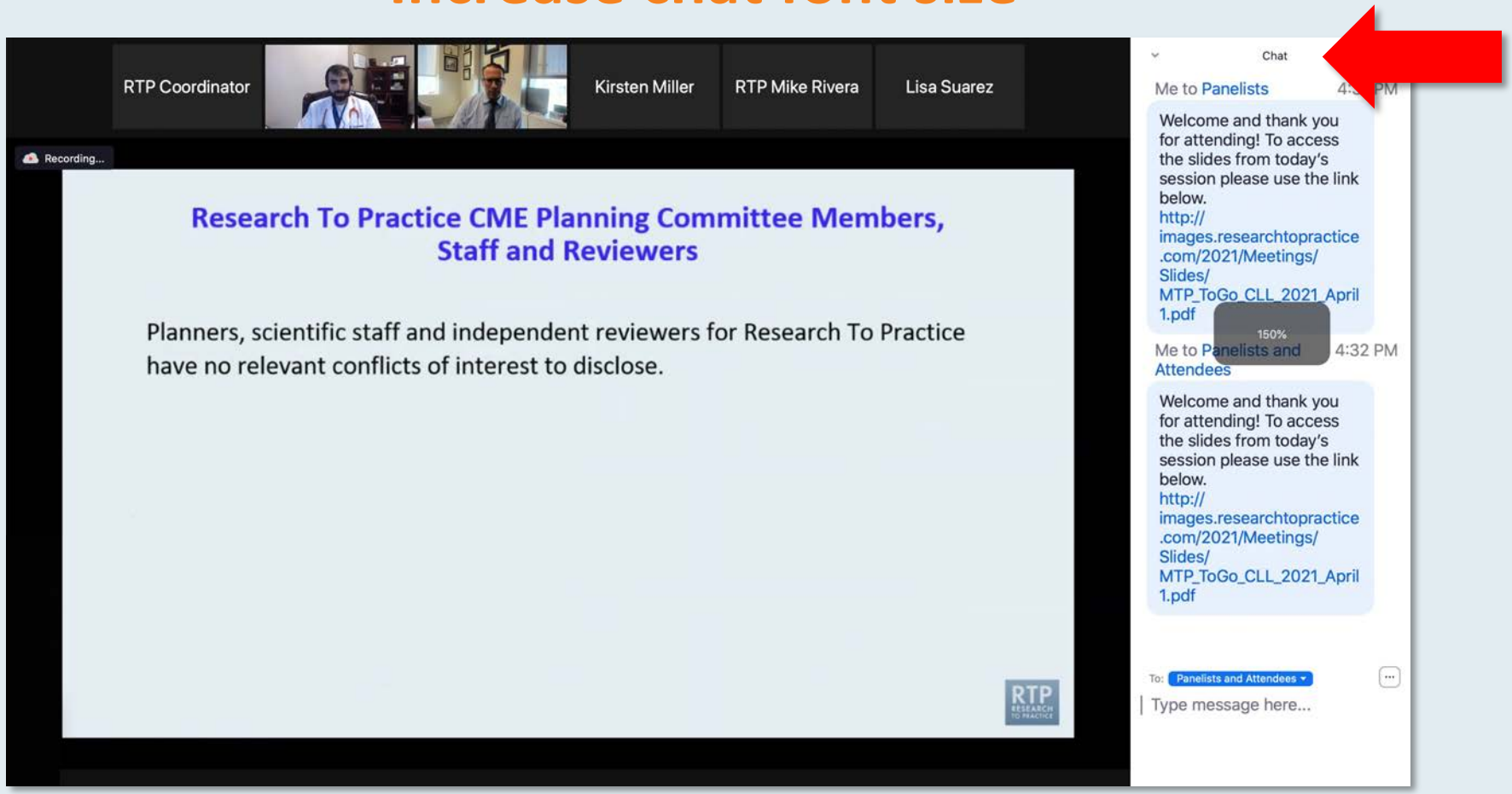
Familiarizing Yourself with the Zoom Interface

Increase chat font size



Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

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WITH DR NEIL LOVE

Key Recent Data Sets in Gastrointestinal Cancers

DR PHILIP A PHILIP

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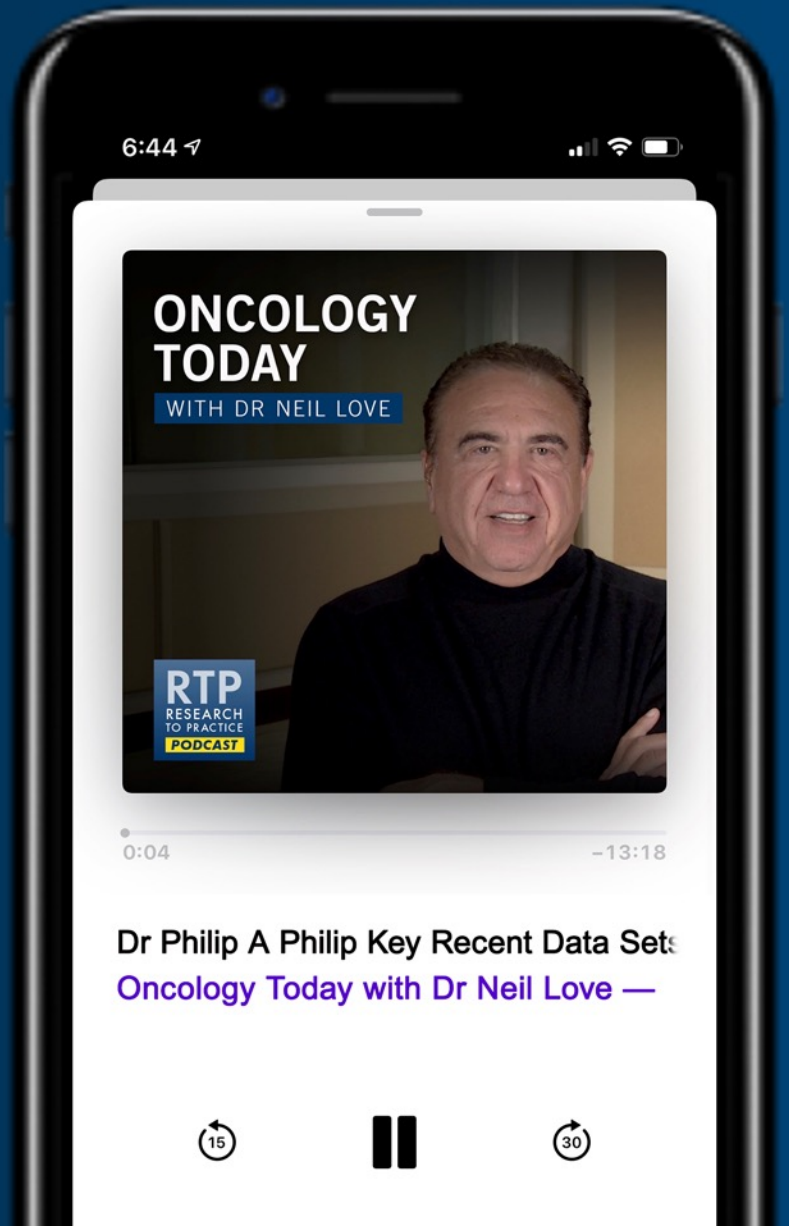

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Breast Cancer
Tuesday, April 20, 2021
8:30 AM – 10:00 AM ET

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5:00 PM – 6:30 PM ET

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Thursday, April 22, 2021
8:30 AM – 10:00 AM ET

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Multiple Myeloma
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Gynecologic Cancers
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Chimeric Antigen Receptor T-Cell Therapy
Thursday, April 29, 2021
5:00 PM – 6:30 PM ET

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Ask the Expert: Clinical Investigators Provide Perspectives on the Management of Renal Cell Carcinoma

In Partnership with Project Echo® and Florida Cancer Specialists

Tuesday, May 4, 2021
5:00 PM – 6:00 PM ET

Faculty

Chung-Han Lee, MD, PhD

Moderator

Neil Love, MD

Current Concepts and Recent Advances in Oncology

A Daylong Clinical Summit Hosted in Partnership with Medical Oncology Association of Southern California (MOASC)

Saturday, May 15, 2021
10:30 AM – 6:30 PM ET

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Saturday, May 15, 2021

10:30 AM — Breast Cancer
Ruth O'Regan, Tiffany A Traina

11:30 AM — Multiple Myeloma
Kenneth Anderson, Noopur Raje

12:50 PM — Chronic Lymphocytic Leukemia and Lymphomas
Craig Moskowitz, Jeff Sharman

1:50 PM — Genitourinary Cancers
Joaquim Bellmunt, Sumanta Kumar Pal

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Saturday, May 15, 2021

3:15 PM — Gastrointestinal Cancers
Wells A Messersmith, Eileen M O'Reilly

4:15 PM — Acute Myeloid Leukemia and Myelodysplastic Syndromes
Harry Paul Erba, Rami Komrokji

5:35 PM — Lung Cancer
D Ross Camidge, Benjamin Levy

Up for Debate: Oncology Investigators Provide Their Take on Current Controversies in Patient Care

A Daylong Multitumor Educational Webinar
in Partnership with Florida Cancer Specialists

Saturday, May 22, 2021
10:15 AM – 4:15 PM ET

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Saturday, May 22, 2021

10:15 AM — Lung Cancer
John V Heymach, Stephen V Liu

11:30 AM — Genitourinary Cancers
Maha Hussain, Elizabeth R Plimack

12:45 PM — Chronic Lymphocytic Leukemia and Lymphomas
Jonathan W Friedberg, Laurie H Sehn

2:00 PM — Multiple Myeloma
Irene M Ghobrial, Sagar Lonial

3:15 PM — Breast Cancer
Virginia Kaklamani, Nancy U Lin

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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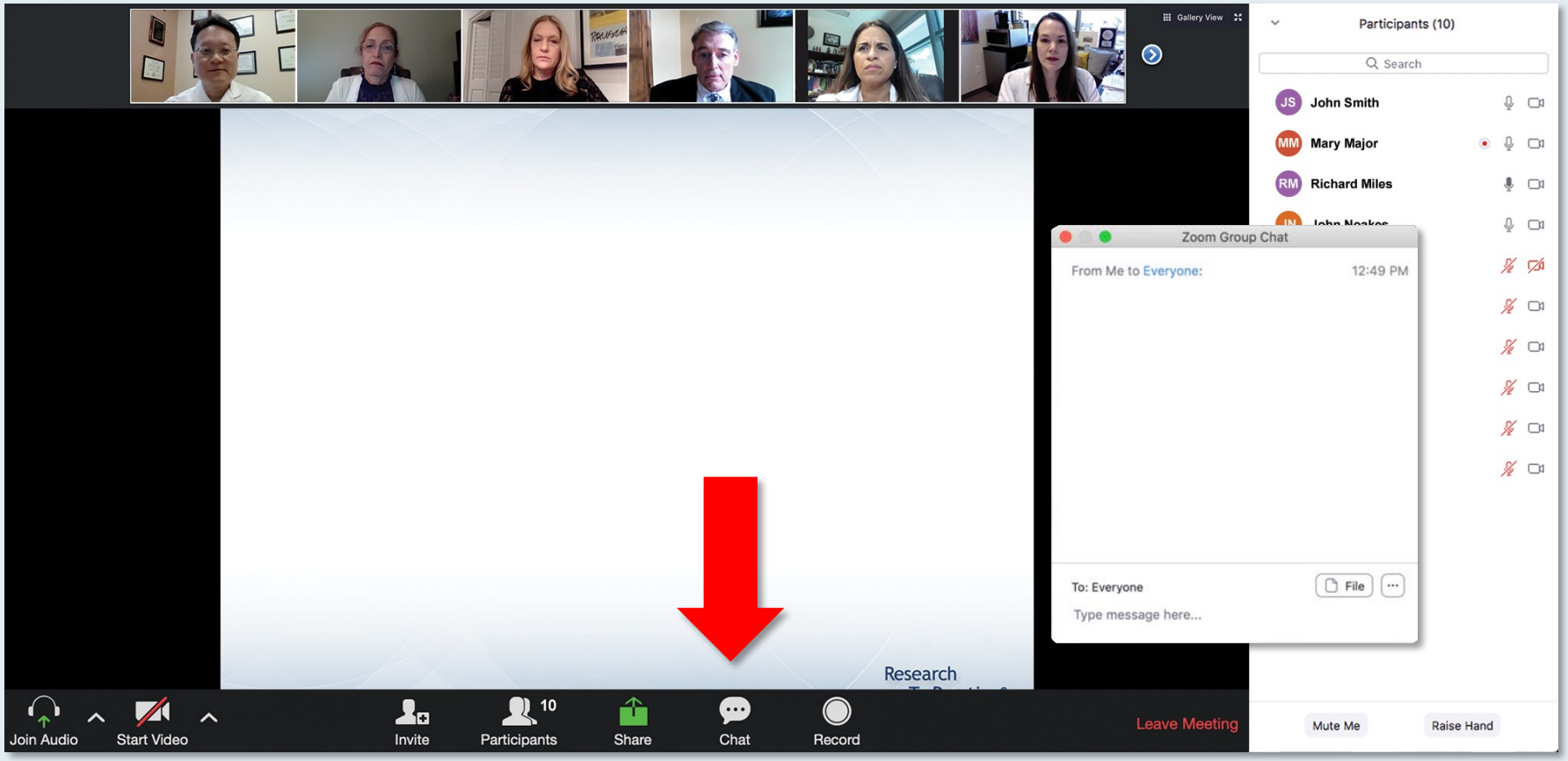

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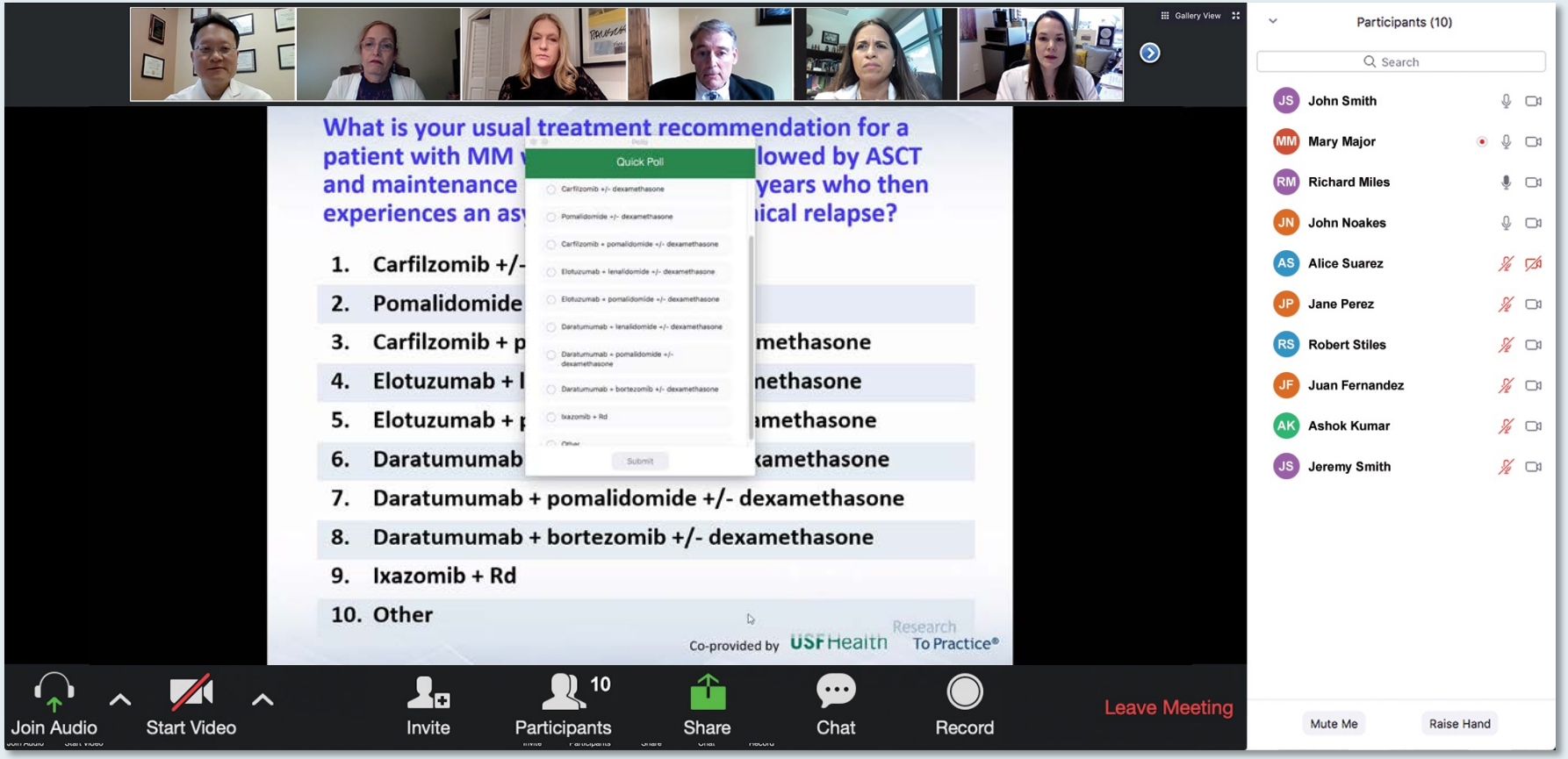

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Medical Oncologists

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Professor of Oncology and Medicine
Hartmann Endowed Chair for Prostate Cancer Research
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Director of Breast Immunotherapy Clinical Research
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Associate Professor of Medicine
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Oncology Nurse Practitioners

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Alli McClanahan, MSN, APRN, ANP-BC
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The James Cancer Hospital and Solove
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Victoria Sherry, DNP, CRNP, AOCNP
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Perelman Center for Advanced Medicine
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RYDER TRAUMA CENTER
Jackson Memorial Hospital

Oncology Grand Rounds Nursing Webinar Series

Monday	Tuesday	Wednesday	Thursday	Friday
19	20 Breast Ca 8:30 AM --- Lung Ca 5:00 PM	21 AML 12:00 PM --- CRC and GE Ca 4:45 PM	22 Prostate Ca 8:30 AM --- Lymphomas 5:00 PM	23
26	27 Multiple Myeloma 8:30 AM --- GYN 5:00 PM	28 Bladder Ca 12:00 PM	29 CLL 8:30 AM --- CAR-T 5:00 PM	30

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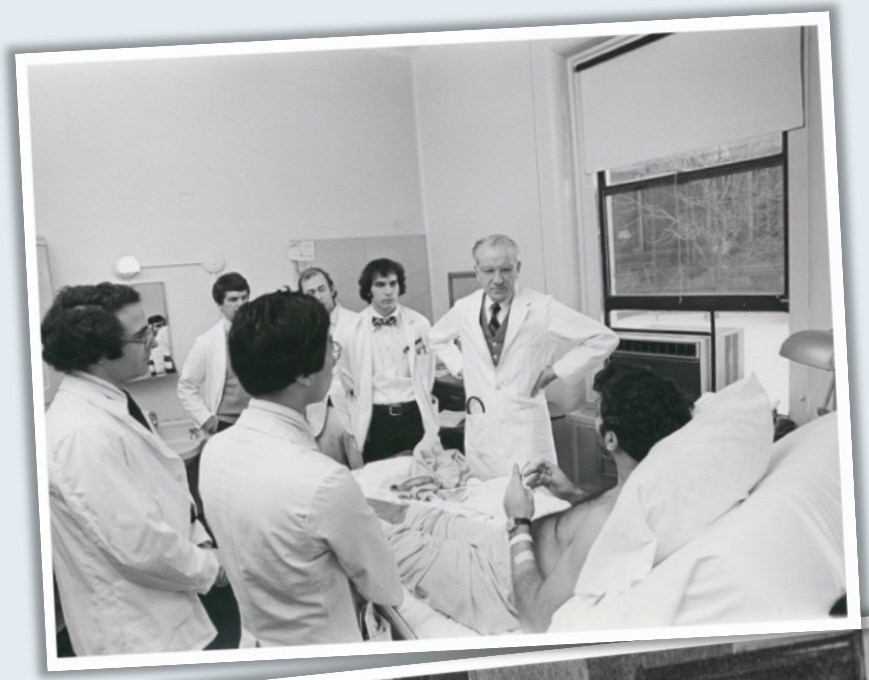

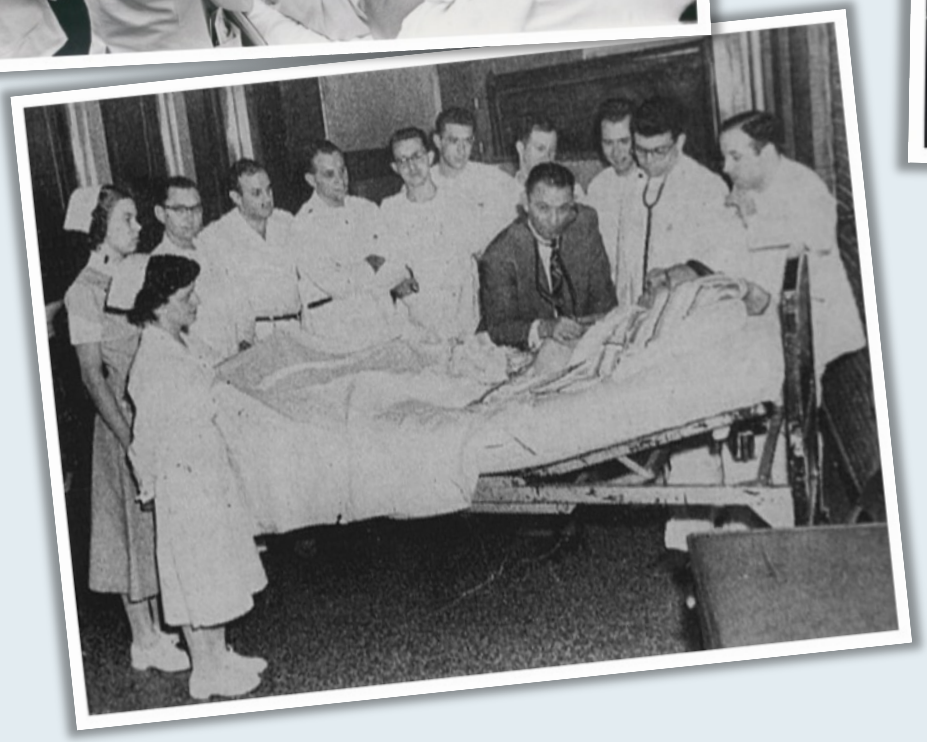


The Birmingham News

13th Annual Oncology Grand Rounds

Oncology Nurse Practitioners

Case Presentations

- Key patient-education issues
- Biopsychosocial considerations:
  - Family/loved ones
  - The bond that heals

Clinical Investigators

Oncology Strategy

- New agents and regimens
- Predictive biomarkers
- Ongoing research and implications

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13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress

Colorectal and Gastroesophageal Cancers

Wednesday, April 21, 2021
4:45 PM – 5:45 PM ET

Medical Oncologists

Johanna Bendell, MD
Daniel Catenacci, MD

Oncology Nurse Practitioner

Jessica Mitchell, APRN, CNP, MPH

Moderator

Neil Love, MD

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Jessica L Mitchell, APRN, CNP

Agenda

Cases from the Practice of Ms Mitchell

Case 1: A 79-year-old man with metastatic KRAS-mutant, microsatellite-stable (MSS) colorectal cancer

Case 2: A 79-year-old woman with metastatic left-sided MSS colorectal cancer with a BRAF V600E mutation

Case 3: A 65-year-old man with newly diagnosed metastatic esophageal cancer and a PD-L1 CPS of 10

Case 4: A 57-year-old man with metastatic HER2-positive GEJ cancer who received FOLFOX/trastuzumab, ramucirumab/paclitaxel and now has disease progression

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Case Presentation – A 79-year-old man with metastatic KRAS-mutant, MSS colorectal cancer (Part 1)

Ms Mitchell

- Widower whose wife recently died of pancreatic cancer presents to ER with excruciating pain in chest and is found to have a chest wall mass and metastatic disease

- Treated with radiation therapy followed by FOLFOX-bev and is now progressing on FOLFIRI bev

Patients with metastatic colorectal cancer and KRAS tumor mutations do not derive benefit from…

1. EGFR antibodies
2. Bevacizumab
3. Both
4. Neither

Case Presentation – A 79-year-old man with metastatic KRAS-mutant, MSS colorectal cancer (Part 2)

Ms Mitchell

- Widower whose wife recently died of pancreatic cancer presents to ER with excruciating pain in chest and is found to have a chest wall mass and metastatic disease
- Treated with radiation therapy followed by FOLFOX-bev and is now progressing on FOLFIRI bev
- ***Treated with TAS-102 plus bevacizumab***

Patients with metastatic colorectal cancer who experience neutropenia while receiving TAS-102…

1. Have a better clinical response rate than those who do not experience neutropenia
2. Have the same clinical response rate as those who do not not experience neutropenia
3. Have a worse clinical response rate than those who do not experience neutropenia
4. I don’t know
5. I am not familiar with this agent

Case Presentation – A 79-year-old man with metastatic KRAS-mutant, MSS colorectal cancer (Part 3)

Ms Mitchell

- Widower whose wife recently died of pancreatic cancer presents to ER with excruciating pain in chest and is found to have a chest wall mass and metastatic disease
- Treated with radiation therapy followed by FOLFOX-bev and is now progressing on FOLFIRI bev
- Treated with TAS-102 plus bevacizumab
- ***Patient education on dosing/schedule of TAS-102***

Trifluridine/Tipiracil (TAS-102)

Mechanism of action

- **Combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor**

Indication

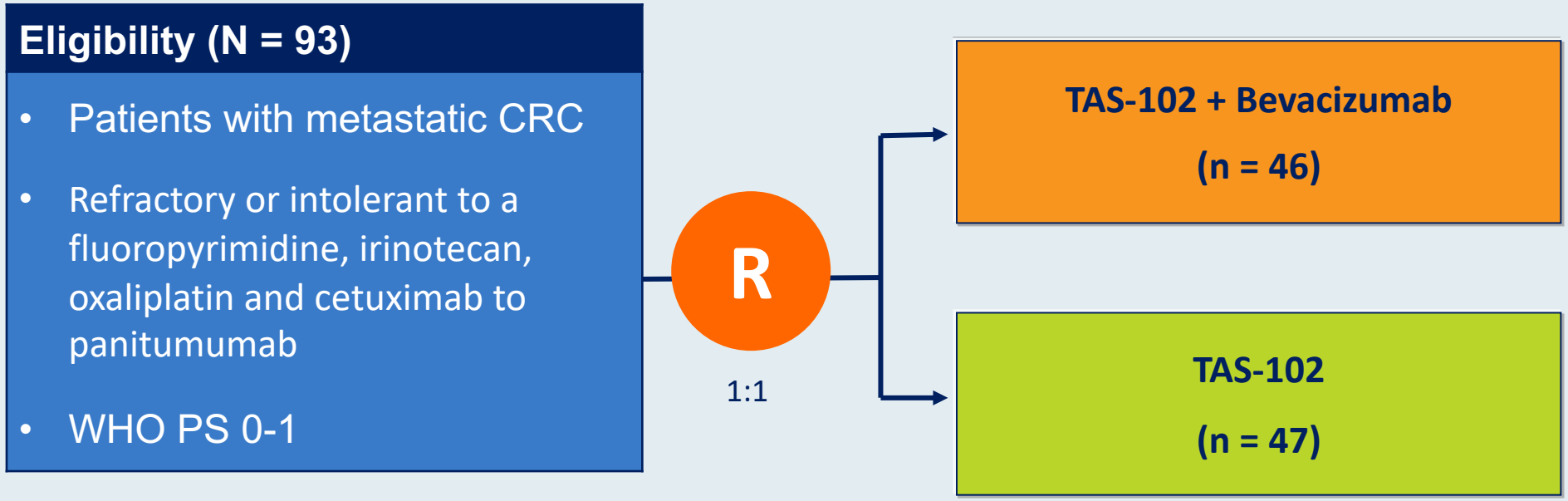
- **For patients with mCRC who have previously received fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biologic product and an anti-EGFR therapy, if RAS wild type**

Recommended dose

- **35 mg/m^2 per dose PO twice daily on days 1 through 5 and days 8 through 12 of each 28-day cycle**

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm463743.htm
TAS-102 package insert

A Phase II Trial of TAS-102 and Bevacizumab



Primary endpoint: Investigator-assessed progression-free survival

Key secondary endpoints include: Overall survival, response rate, toxicity and tumor markers

Pfeiffer P et al. *Lancet Oncol* 2020;21(3):412-20.

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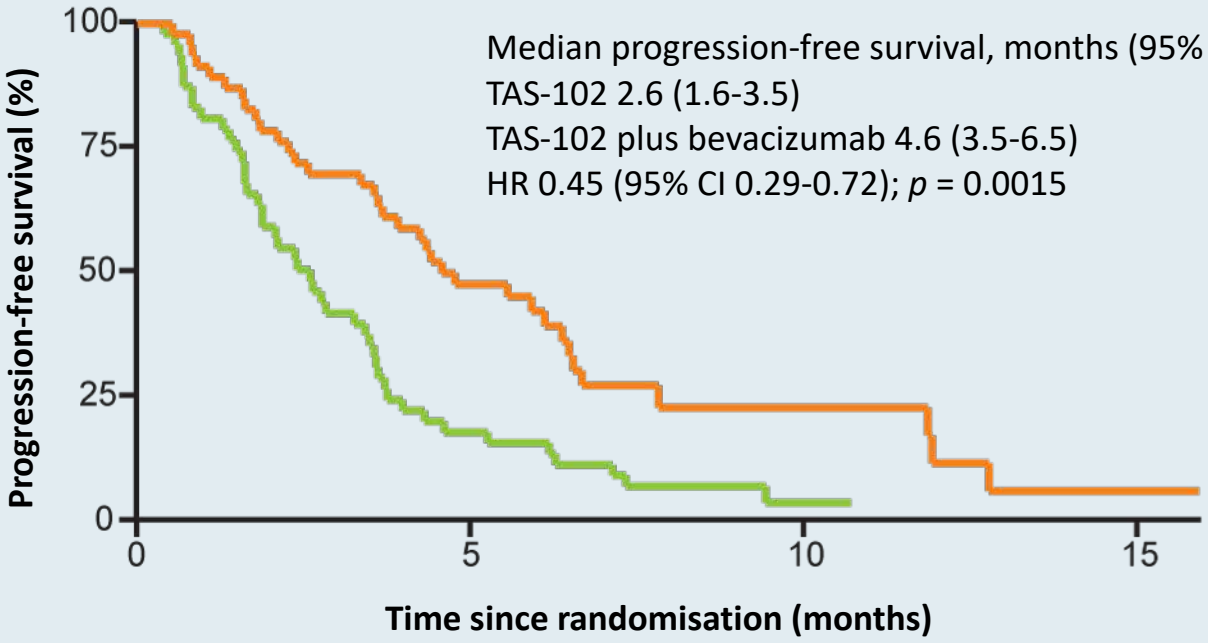
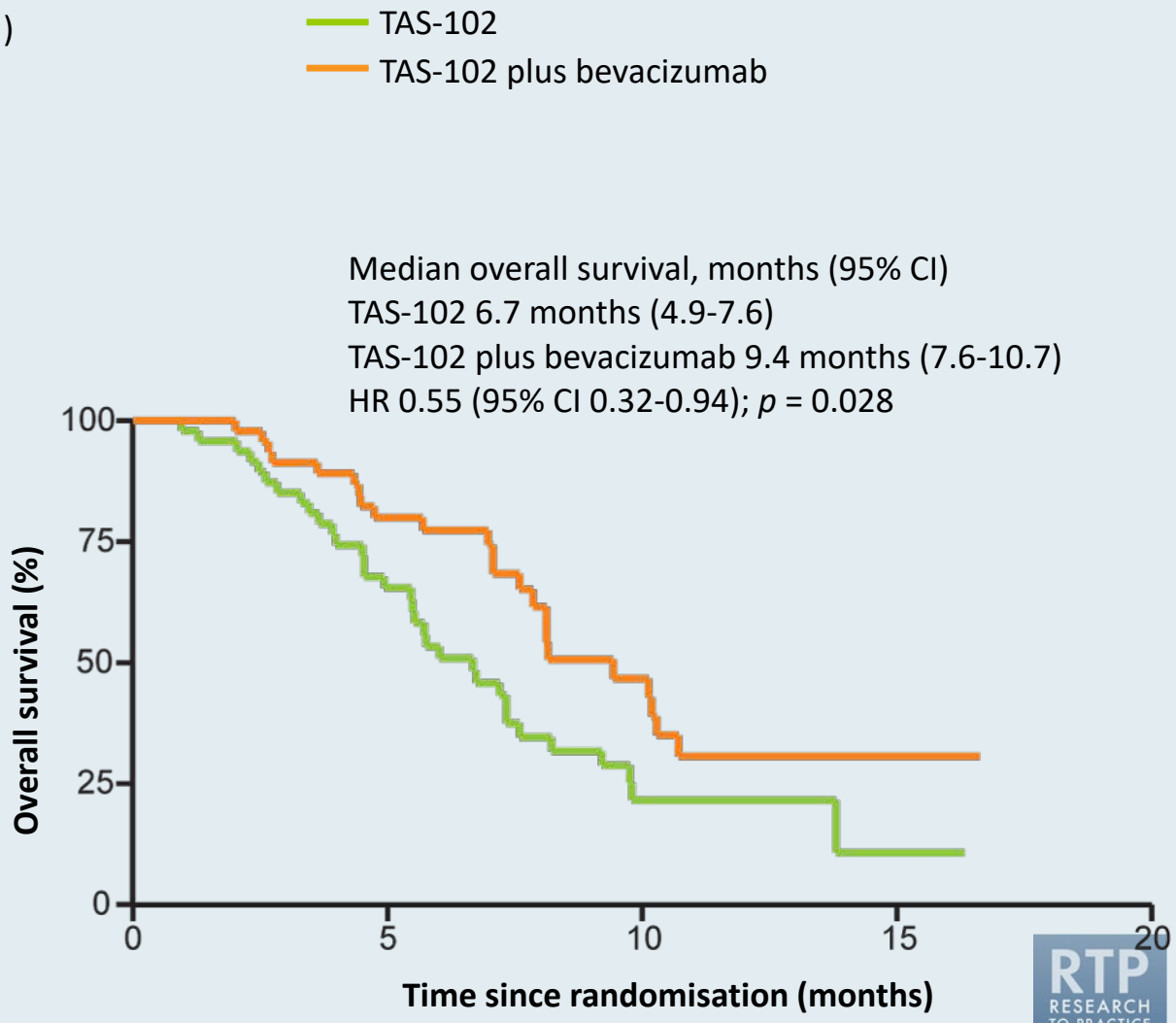
TAS-102 with or without Bevacizumab: Efficacy Results



Disease control rate:

- TAS-102/Bev = 67%
- TAS-102 = 51%



Pfeiffer P et al. *Lancet Oncol* 2020;21(3):412-20.

TAS-102 with or without Bevacizumab: Select Adverse Events

Adverse event, n (%)	TAS-102 (n = 47)		TAS-102 + bev (n = 46)	
	Grade 1-2	Grade 3-5	Grade 1-2	Grade 3-5
Fatigue	74%	11%	78%	7%
Nausea	64%	6%	57%	2%
Anemia	55%	17%	63%	4%
Diarrhea	32%	0	28%	9%
Neutropenia	28%	38%	17%	67%
Thrombocytopenia	17%	0	37%	2%
Febrile neutropenia	—	2%	—	6%

Pfeiffer P et al. *Lancet Oncol* 2020;21(3):412-20.

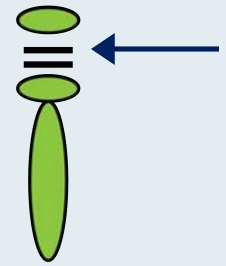
Patients with MSI-high metastatic colorectal cancer respond very well to…

1. Anti-PD-1/PD-L1 antibody monotherapy
2. Chemotherapy
3. PARP inhibitors
4. EGFR antibodies
5. I don’t know

What Is Microsatellite Instability (MSI)?

Microsatellites:

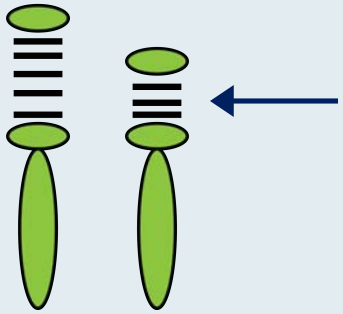
- **Repetitive segments of DNA**
- **The same number of repeats are present in every cell**



Normal microsatellite with 2 repeats

Microsatellite instability:

- **The number of microsatellite repeats differs between normal cells/tissue and tumor cells/tissue**
- ***Most MSI tumors are sporadic***
- ***Virtually all Lynch tumors are MSI high***



Tumor tissue with MSI variable repeat size 5 & 3

http://www.slideshare.net/Pammy98/hereditary-colorectal-cancer-powerpoint-educational-module

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The most common type of targeted therapy used to treat metastatic colorectal cancer with a BRAF mutation is…

1. Dabrafenib/trametinib
2. Vemurafenib/cobimetinib
3. Encorafenib/cetuximab
4. Encorafenib/binimetinib/cetuximab
5. I don’t know

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The most common type of toxicity associated with BRAF-targeted treatment is…

1. Renal
2. Dermatologic
3. Pulmonary
4. Gastrointestinal
5. I don’t know

Case Presentation – A 79-year-old woman with metastatic left-sided MSS colorectal cancer with a BRAF V600E mutation (Part 1)

Ms Mitchell

- Received multiple systemic regimens and surgeries but now stable on encorafenib and panitumumab

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Case Presentation – A 79-year-old woman with metastatic left-sided MSS colorectal cancer with a BRAF V600E mutation (Part 2)

Ms Mitchell

- Received multiple systemic regimens and surgeries but now stable on encorafenib and panitumumab

- ***Divorced artist experiencing anxiety and depression***

Case Presentation – A 79-year-old woman with metastatic left-sided MSS colorectal cancer with a BRAF V600E mutation (Part 3)

Ms Mitchell

- Received multiple systemic regimens and surgeries but now stable on encorafenib and panitumumab
- Divorced artist experiencing anxiety and depression
- ***Patient education on "smarter" targeted treatment of cancer***

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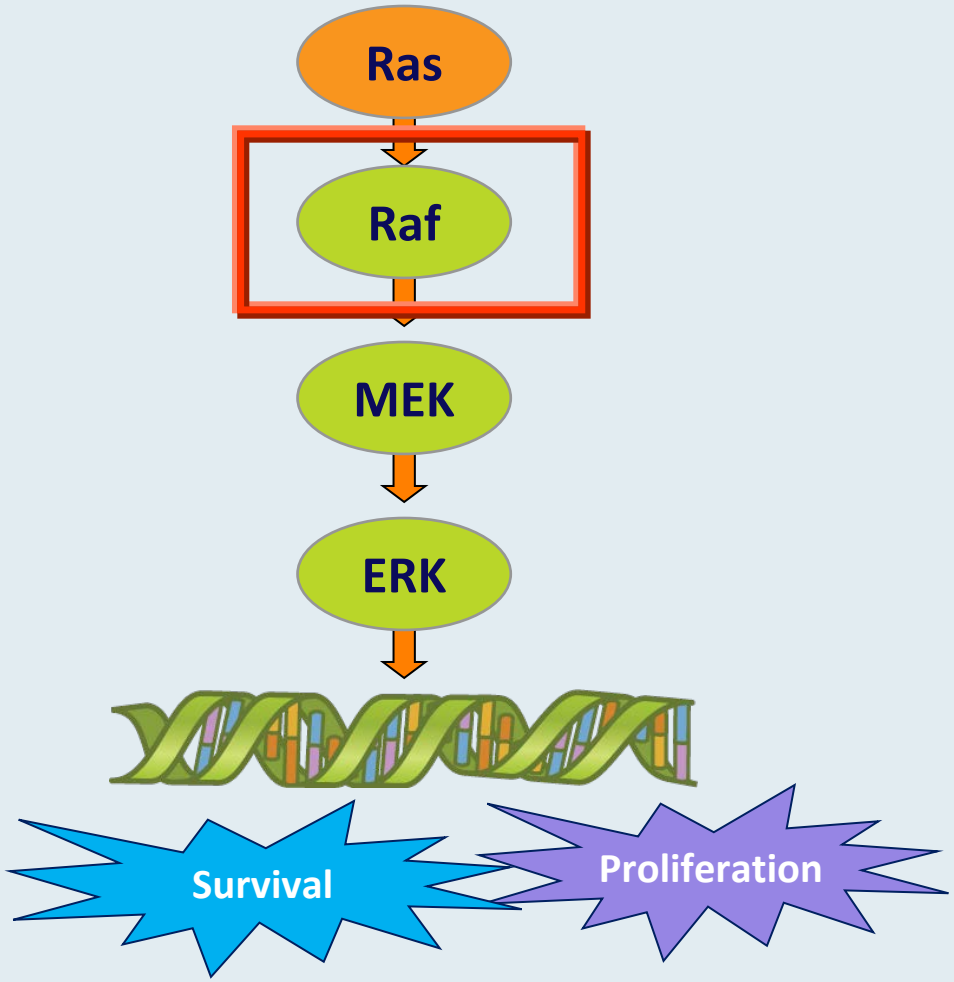
BRAF Mutations in Colorectal Cancer



- BRAF mutated in 10%-20% of CRC
- Leads to constitutive activation & cell proliferation
- Nonoverlapping pattern with KRAS mutation
- Confers inferior prognosis
- Poor response to single-agent BRAF inhibitors

Courtesy of Charles S Fuchs, MD.

Encorafenib and Cetuximab

Mechanism of action

- **Encorafenib – oral RAF kinase inhibitor**
- **Cetuximab – anti-EGFR monoclonal antibody**

Indication

- **Encorafenib in combination with cetuximab: For patients with mCRC and a BRAF V600E mutation**

Recommended dose

- **300 mg orally once daily in combination with cetuximab**
- **400 mg/m^2 initial dose → 250 mg/m^2 weekly**

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210496s006lbl.pdf

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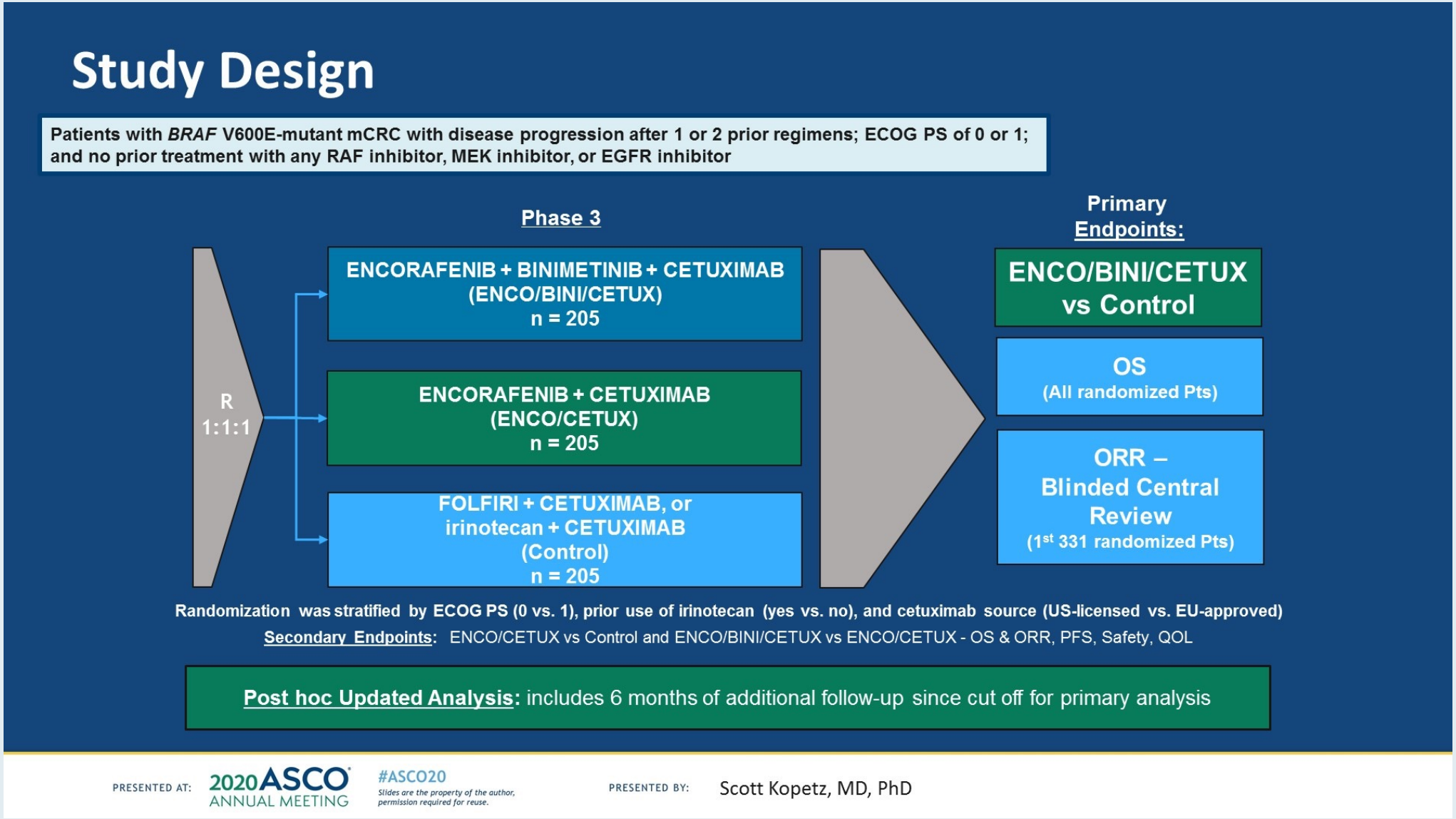
Phase III BEACON CRC Trial



Courtesy of Kristen K Ciombor, MD, MSCI

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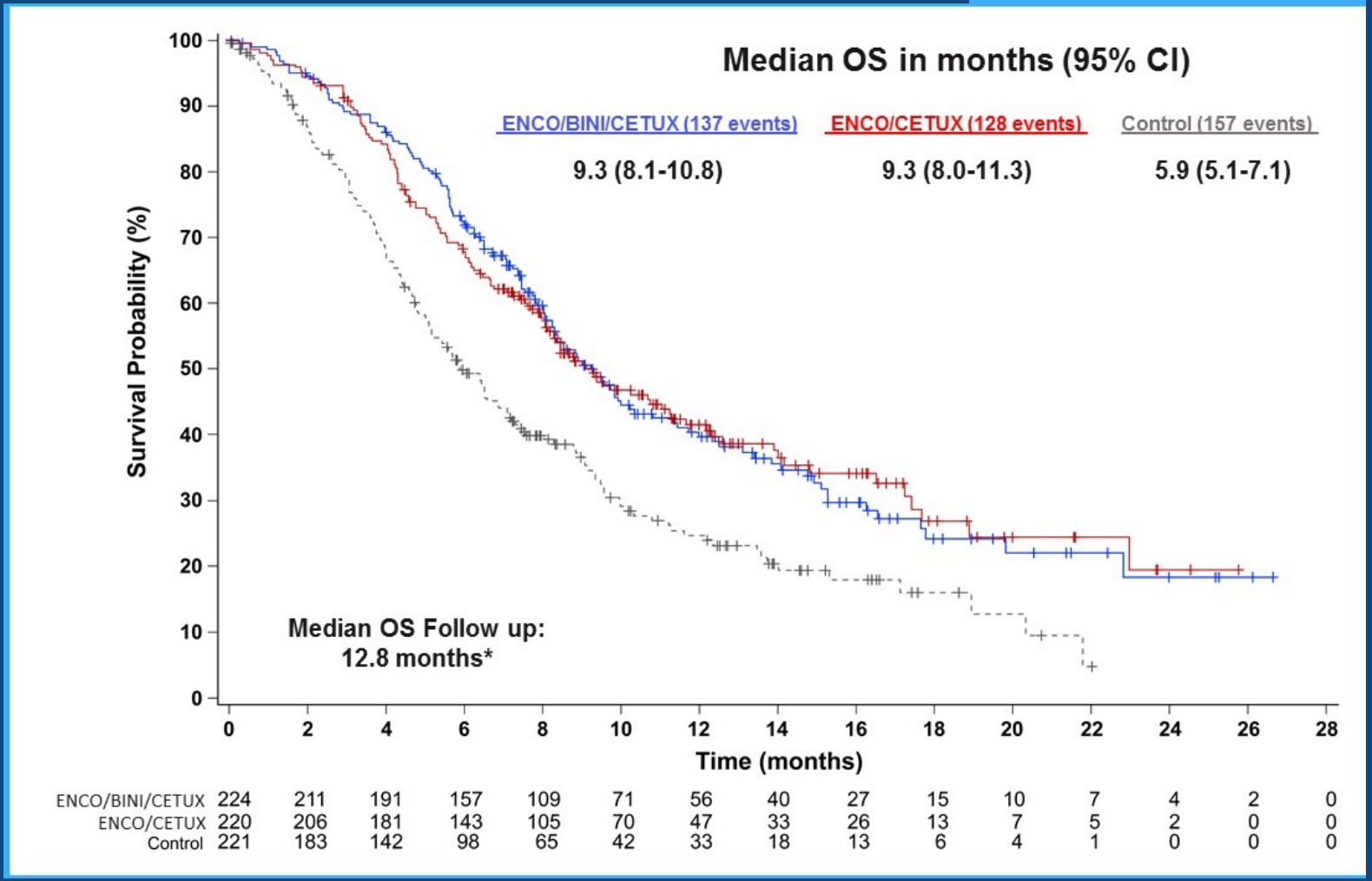
BEACON CRC

Updated Overall Survival: ENCO/BINI/CETUX vs ENCO/CETUX vs Control



Courtesy of Kristen K Ciombor, MD, MSCI

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Case Presentation – A 65-year-old man with newly diagnosed metastatic esophageal cancer and a PD-L1 combined positive score (CPS) of 10 (Part 1)

Ms Mitchell

- High-level CEO presented with dysphagia and is diagnosed with metastatic esophageal cancer
- Treated with first-line FOLFOX/pembrolizumab for 1 year
- Developed acute kidney failure requiring hospitalization
- Currently treated with ramucirumab/paclitaxel and doing well
- Coping with physical and lifestyle changes due to chemotherapy

Case Presentation – A 65-year-old man with newly diagnosed metastatic esophageal cancer and a PD-L1 CPS of 10 (Part 2)

Ms Mitchell

- High-level CEO presented with dysphagia and is diagnosed with metastatic esophageal cancer
- Treated with first-line FOLFOX/pembrolizumab for 1 year
- Developed acute kidney failure requiring hospitalization
- Currently treated with ramucirumab/paclitaxel and doing well
- Coping with physical and lifestyle changes due to chemotherapy
- ***Patient education on mechanism of action and tolerability of ramucirumab***

FDA Approves Pembrolizumab in Combination with Chemotherapy for Esophageal or GEJ Carcinoma

Press Release – March 22, 2021

"On March 22, 2021, the Food and Drug Administration approved pembrolizumab in combination with platinum and fluoropyrimidine-based chemotherapy for patients with metastatic or locally advanced esophageal or gastroesophageal (GEJ) (tumors with epicenter 1 to 5 centimeters above the gastroesophageal junction) carcinoma who are not candidates for surgical resection or definitive chemoradiation.

Efficacy was evaluated in KEYNOTE-590 (NCT03189719), a multicenter, randomized, placebo-controlled trial that enrolled 749 patients with metastatic or locally advanced esophageal or gastroesophageal junction carcinoma who were not candidates for surgical resection or definitive chemoradiation.

The recommended pembrolizumab dose for esophageal cancer is 200 mg every 3 weeks or 400 mg every 6 weeks."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-esophageal-or-gej-carcinoma?utm_medium=email&utm_source=govdelivery

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Pembrolizumab plus Chemotherapy versus Chemotherapy as First-Line Therapy in Patients with Advanced Esophageal Cancer: The Phase 3 KEYNOTE-590 Study

Kato K et al.

ESMO 2020;Abstract LBA8_PR.

FDA Approves Nivolumab with Chemotherapy for Front-Line Advanced Gastric Cancer

Press Release – April 16, 2021

"The FDA approved nivolumab in combination with certain types of chemotherapy for the frontline treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma, making it the first approved immunotherapy for this patient population.

The agency based the approval on data from the randomized, multicenter, open-label phase 3 CheckMate-649 trial, designed to evaluate nivolumab – a monoclonal antibody that inhibits tumor growth by enhancing T-cell function – plus chemotherapy in 1,581 patients with previously untreated advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma. Of the 789 patients treated in the nivolumab arm, median overall survival was 13.8 months, compared with 11.6 months for patients who received chemotherapy alone."

https://www.cancernetwork.com/view/fda-approves-nivolumab-plus-chemo-for-frontline-advanced-gastric-cancer?utm_source=sfmc&utm_medium=email&utm_campaign=4.16.21_CN_Breaking&eKey=Z2tlbGx5QHJlc2VhcmNodG9wcmFjdGljZS5jb20=

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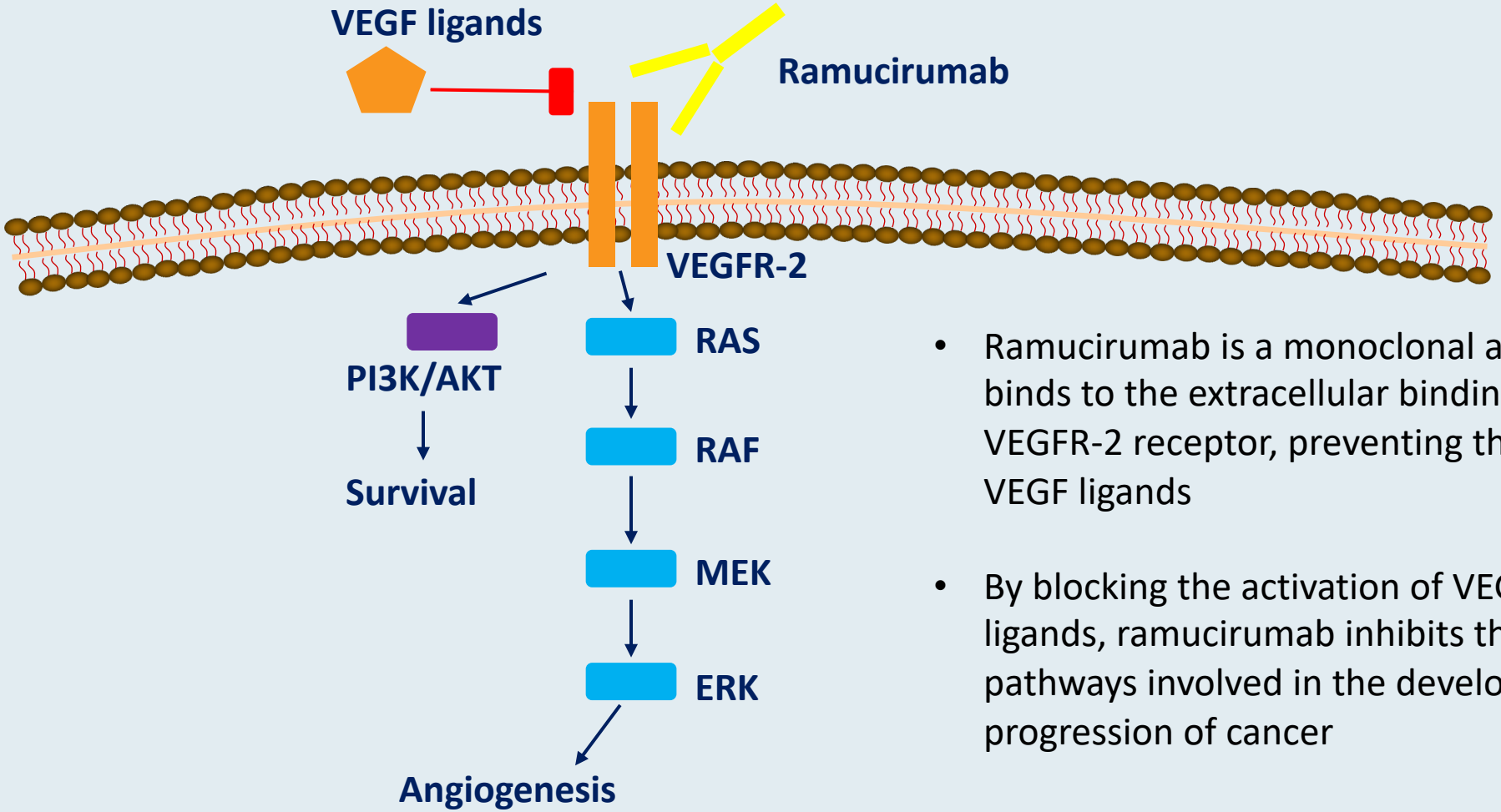
Mechanism of Action of Ramucirumab



- Ramucirumab is a monoclonal antibody that binds to the extracellular binding domain of the VEGFR-2 receptor, preventing the binding of VEGF ligands
- By blocking the activation of VEGFR-2 by VEGF ligands, ramucirumab inhibits the angiogenesis pathways involved in the development and progression of cancer

Ramucirumab

Mechanism of action

- Anti-VEGFR2 monoclonal antibody

Indication

- Single agent or in combination with paclitaxel for the treatment of advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy

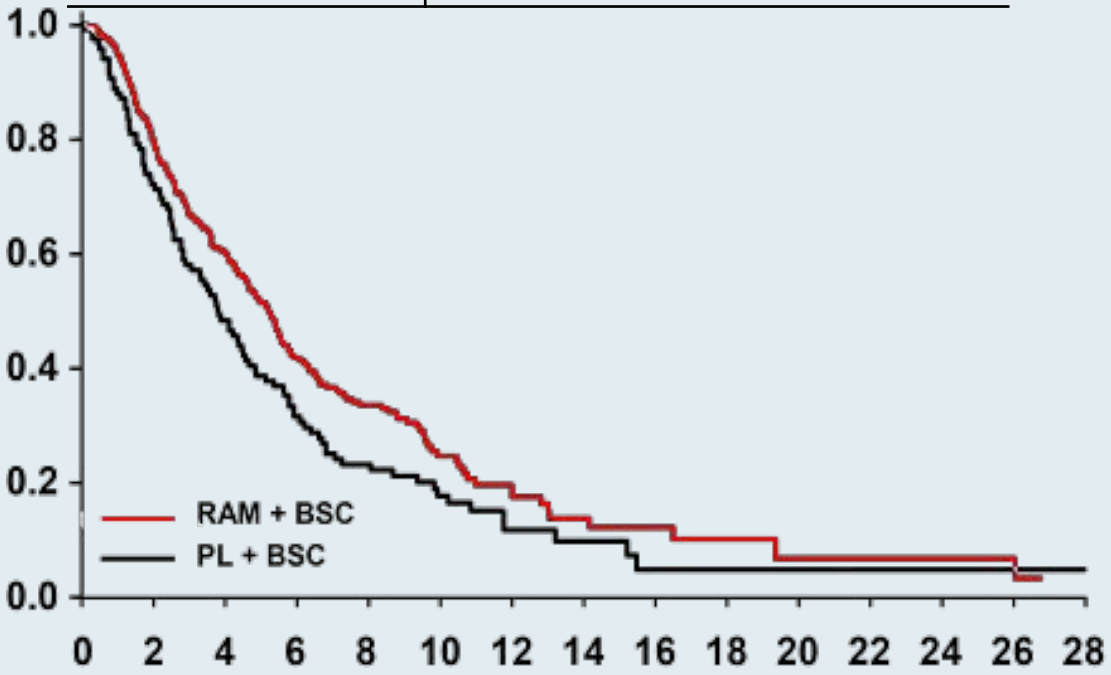
Dose/schedule

- 8 mg/kg every 2 weeks

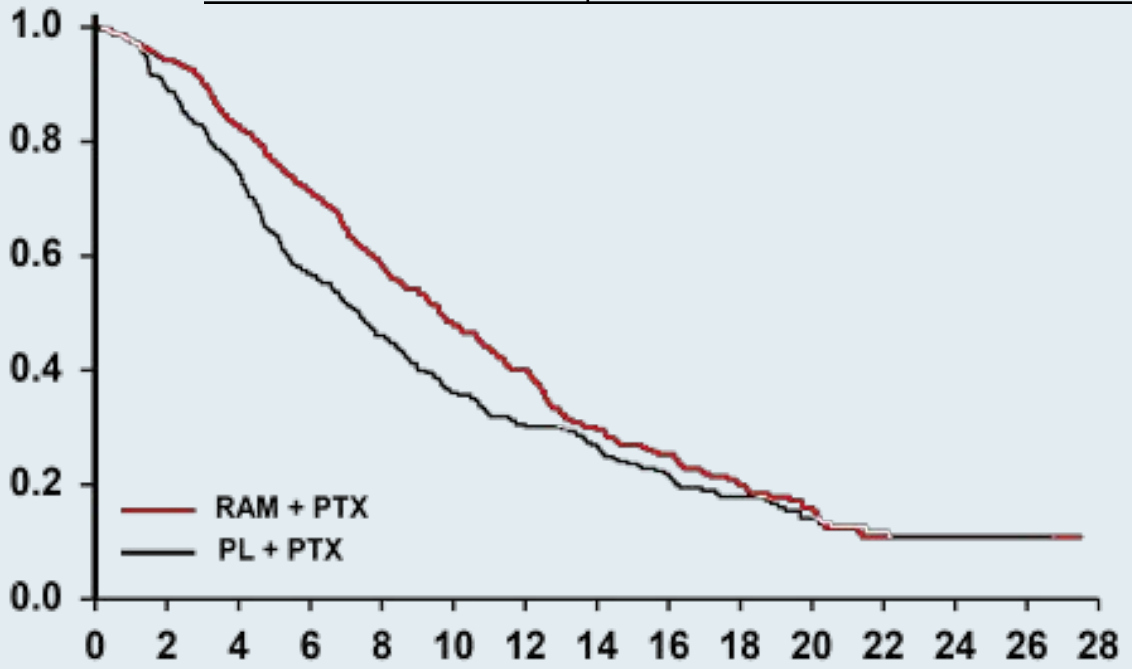
https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125477s034lbl.pdf; Ramucirumab package insert.

Overall Survival Results from 2 Phase III Trials of Ramucirumab as Second-Line Treatment for Advanced Gastric or GEJ Adenocarcinoma REGARD and RAINBOW

REGARD[1] OS	RAM	Placebo	*p*-value
Median (mo)	**5.2**	**3.8**	**0.047**
HR (95% CI)	**0.776 (0.603-0.998)**		



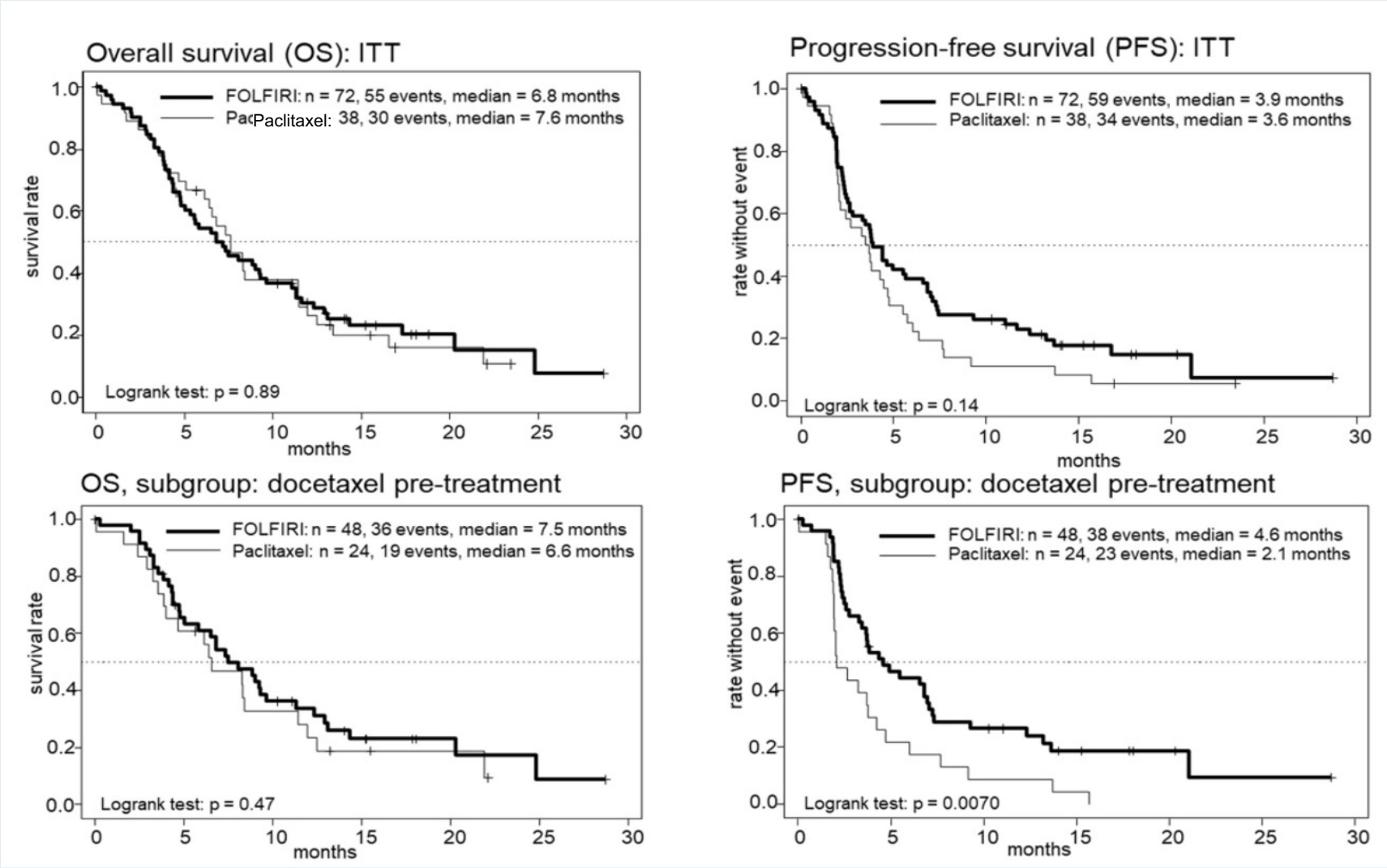
RAINBOW[2] OS	RAM	Placebo	*p*-value
Median (mo)	**9.6**	**7.4**	**0.017**
HR (95% CI)	**0.807 (0.678-0.962)**		



Abbreviations: BSC = best supportive care; PL = placebo; PTX = paclitaxel; RAM = ramucirumab

Muro K et al. Gastrointestinal Cancers Symposium 2017;Abstract 03 (Plots); [1] Fuchs CS et al. *Lancet* 2014;383(9911):31-9; [2] Wilke H et al. *Lancet Oncol* 2014;15(11):1224-35.

Phase II RAMIRIS Trial of Second-Line Ramucirumab with FOLFIRI: Patients with Advanced or Metastatic Gastroesophageal Adenocarcinoma with or without Prior Docetaxel



Lorenzen S et al. ASCO 2020;Abstract 4514.

Results of a Phase II Trial of Ramucirumab plus Irinotecan as Second-Line Treatment for Patients with Advanced Gastric Cancer (HGCSG 1603)

Kawamoto Y et al.

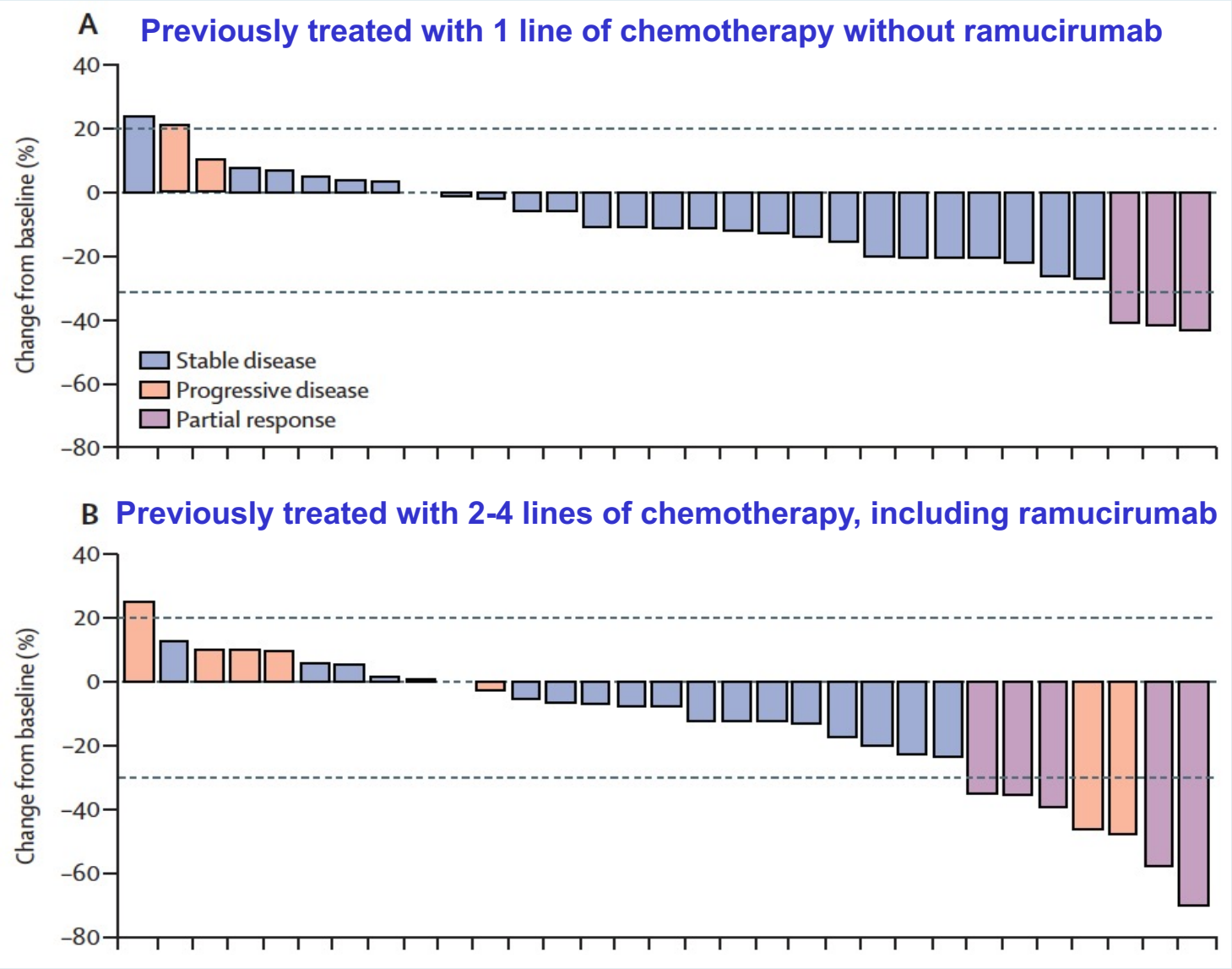
Gastrointestinal Cancers Symposium 2021;Abstract 217.

Safety and activity of trifluridine/tipiracil and ramucirumab in previously treated advanced gastric cancer: an open-label, single-arm, phase 2 trial

Akihito Kawazoe, Takayuki Ando, Hisashi Hosaka, Junya Fujita, Keisuke Koeda, Kazuhiro Nishikawa, Kenji Amagai, Kazumasa Fujitani, Kazuhiro Ogata, Keita Watanabe, Yuji Yamamoto, Kohei Shitara

***Lancet Gastroenterol Hepatol* 2021;6:209-17.**

TAS-102 with Ramucirumab in Previously Treated Advanced Gastric Cancer: Change in Tumor Size from Baseline



Kawazoe A et al. *Lancet Gastroenterol Hepatol* 2021;6:209-17.

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A Phase Ib Multicenter Study of Trifluridine/Tipiracil (FTD/TPI) in Combination with Irinotecan (IRI) in Patients with Advanced Recurrent or Unresectable Gastric and Gastroesophageal Adenocarcinoma (aGEC) After at Least One Line of Treatment with a Fluoropyrimidine and Platinum Containing Regimen

Dayyani F et al.

Gastrointestinal Cancers Symposium 2021;Abstract TPS251.

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Case Presentation – A 57-year-old man with metastatic HER2-positive GEJ cancer who received FOLFOX/ trastuzumab, ramucirumab/paclitaxel and now has disease progression (Part 1)

Ms Mitchell

- Construction worker treated with multiple lines of HER2-targeted therapy

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Case Presentation – A 57-year-old man with metastatic HER2-positive GEJ cancer who received FOLFOX/ trastuzumab, ramucirumab/paclitaxel and now has disease progression (Part 2)

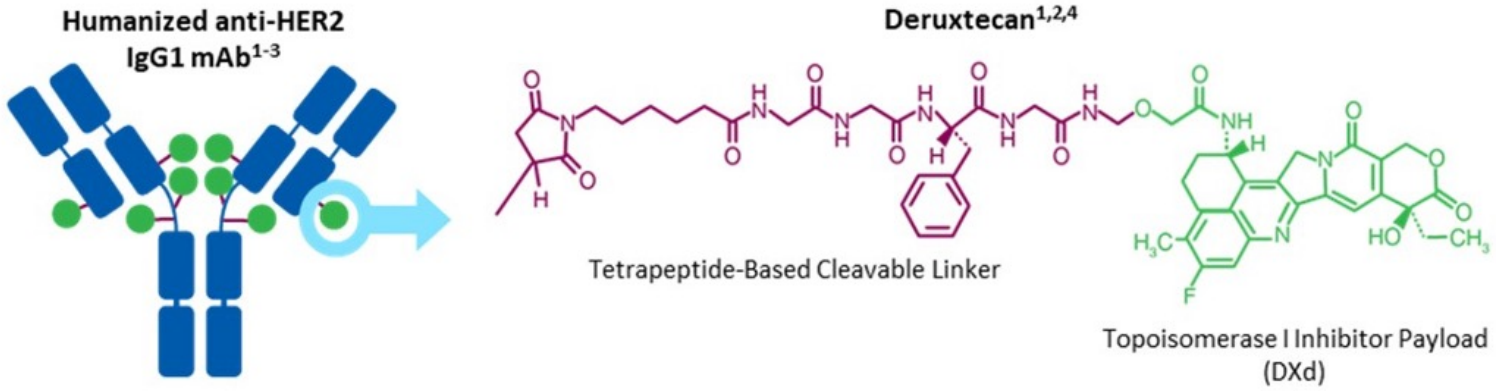
Ms Mitchell

- Construction worker treated with multiple lines of HER2-targeted therapy
- ***Helping patients with cancer and substance abuse issues***

Trastuzumab Deruxtecan (T-DXd) Is a Novel Antibody-Drug Conjugate Designed to Deliver an Antitumor Effect

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



- T-DXd is being clinically evaluated across a number of HER2-expressing or mutated cancers, including breast cancer, CRC, non-small cell lung cancer, and others

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

Siena S et al. ASCO 2020;Abstract 4000.

FDA Approves Trastuzumab Deruxtecan for HER2-Positive Gastric Adenocarcinoma

Press Release – January 15, 2021

"On January 15, 2021, the Food and Drug Administration approved fam-trastuzumab deruxtecan-nxki for adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.

Efficacy was evaluated in a multicenter, open-label, randomized trial (DESTINY-Gastric01, NCT03329690) in patients with HER2-positive locally advanced or metastatic gastric or GEJ adenocarcinoma who had progressed on at least two prior regimens, including trastuzumab, a fluoropyrimidine- and a platinum-containing chemotherapy. A total of 188 patients were randomized (2:1) to receive fam-trastuzumab deruxtecan-nxki 6.4 mg/kg intravenously every 3 weeks or physician's choice of either irinotecan or paclitaxel monotherapy."

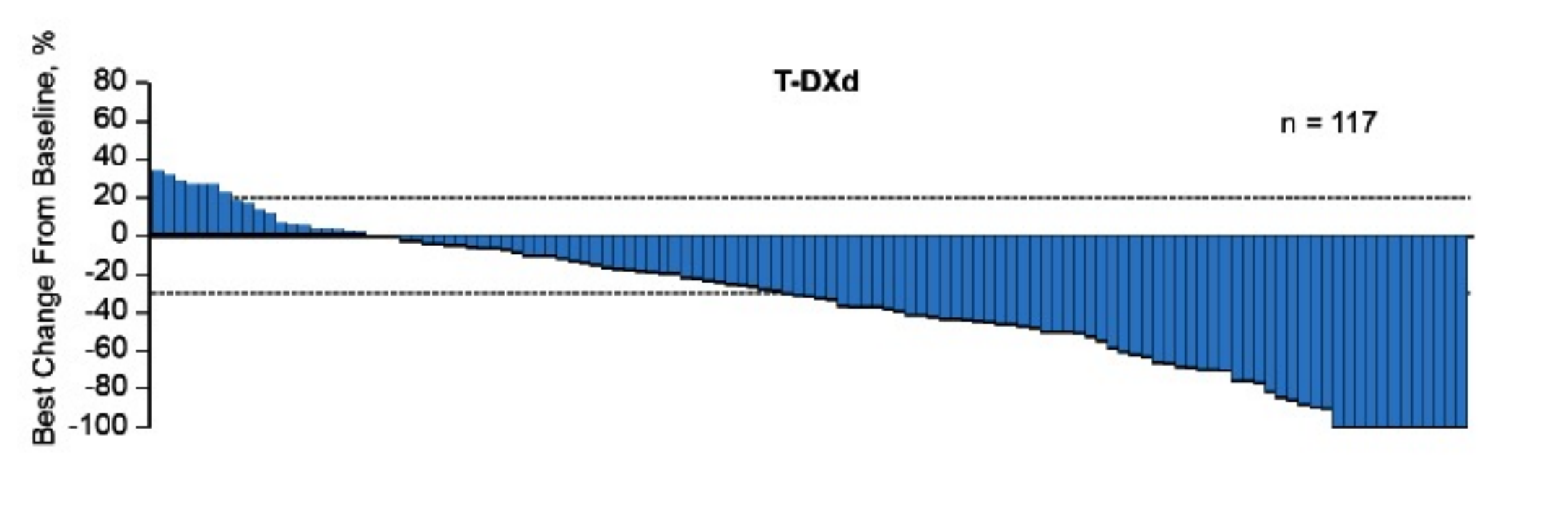
https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-fam-trastuzumab-deruxtecan-nxki-her2-positive-gastric-adenocarcinomas

Trastuzumab Deruxtecan (T-DXd; DS-8201) in Patients (pts) with HER2-Positive Advanced Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma: A Randomized, Phase 2, Multicenter, Open-Label Study (DESTINY-Gastric01)

Yamaguchi K et al.

ESMO World GI Congress 2020;Abstract O-11.

DESTINY-Gastric01: Best Change from Baseline in Tumor Size



Yamaguchi K et al. ESMO World GI Congress 2020;Abstract O-11.

DESTINY-Gastric01: AEs of Special Interest – Interstitial Lung Disease

	T-DXd (n = 125)					
Preferred Term, n	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade/ Total, n (%)
Interstitial Lung Disease	3	6	2	1	0	12 (9.6)

- Drug-related ILD/pneumonitis as determined by an independent adjudication committee was only observed in patients receiving T-DXd
- Among the 12 total events, the median time to investigator-reported first onset was 84.5 days (range, 36-638 days)

Recommendations: It is important to monitor for symptoms. Hold T-DXd and start steroids as soon as ILD is confirmed.

Yamaguchi K et al. ESMO World GI Congress 2020;Abstract O-11.

Ms Mitchell: The importance of hope for patients with cancer

13th Annual Oncology Grand Rounds

A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress

Prostate Cancer

Thursday, April 22, 2021
8:30 AM – 10:00 AM ET

Medical Oncologists

Charles J Ryan, MD
A Oliver Sartor, MD
Mary-Ellen Taplin, MD

Oncology Nurse Practitioners

Kathy D Burns, RN, MSN, AGACNP-BC, OCN
Brenda Martone, MSN, NP-BC, AOCNP
Ronald Stein, JD, MSN, NP-C, AOCNP

Moderator

Neil Love, MD

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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