Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with Advanced Gastrointestinal Cancers

Kristen K Ciombor, MD, MSCI
Assistant Professor of Medicine
Division of Hematology/Oncology
Vanderbilt-Ingram Cancer Center
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Commercial Support

This activity is supported by an educational grant from Lilly.

Dr Love — Disclosures

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Consulting Agreements	Merck, Natera Inc
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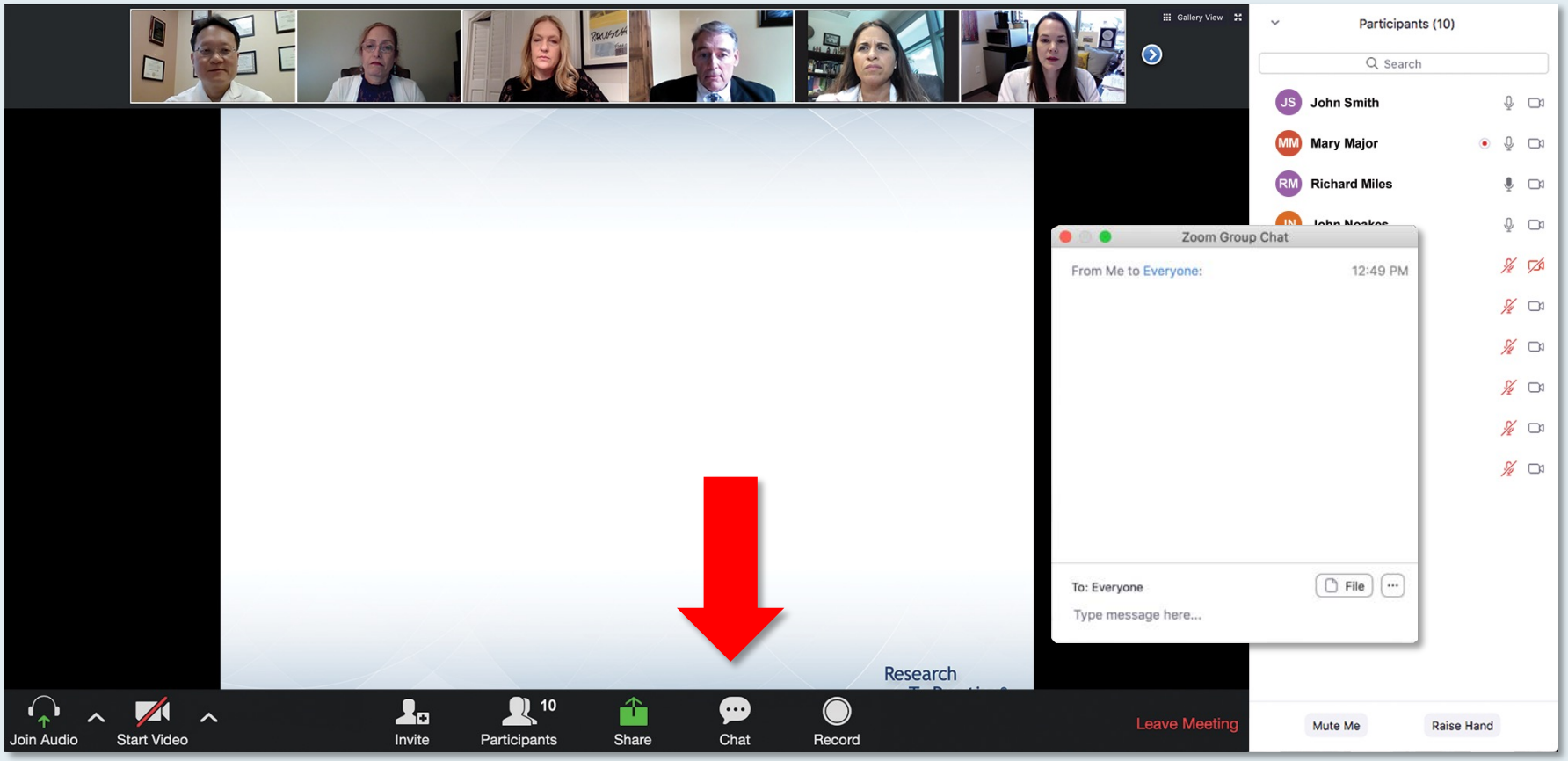

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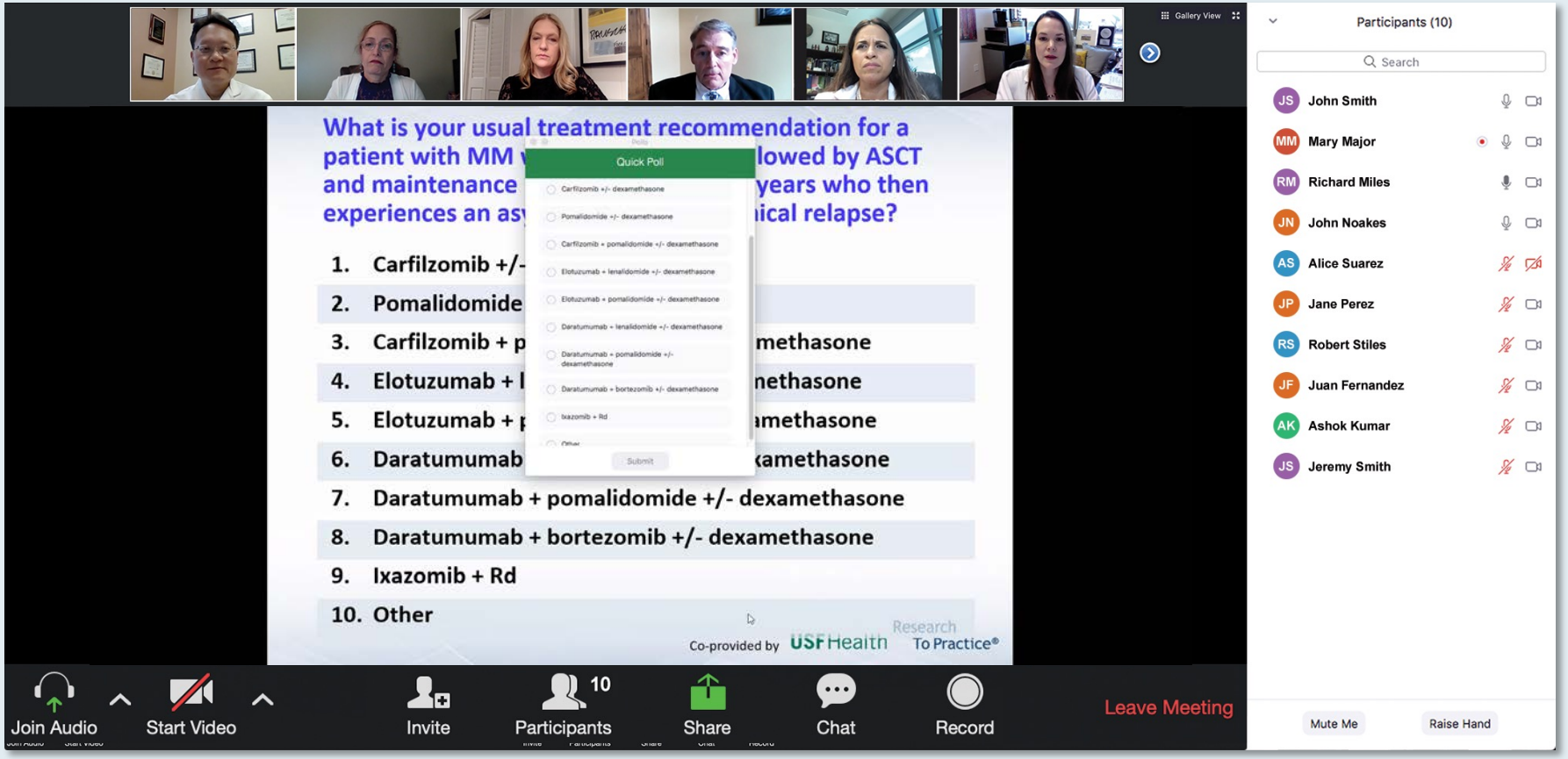
How to answer poll questions



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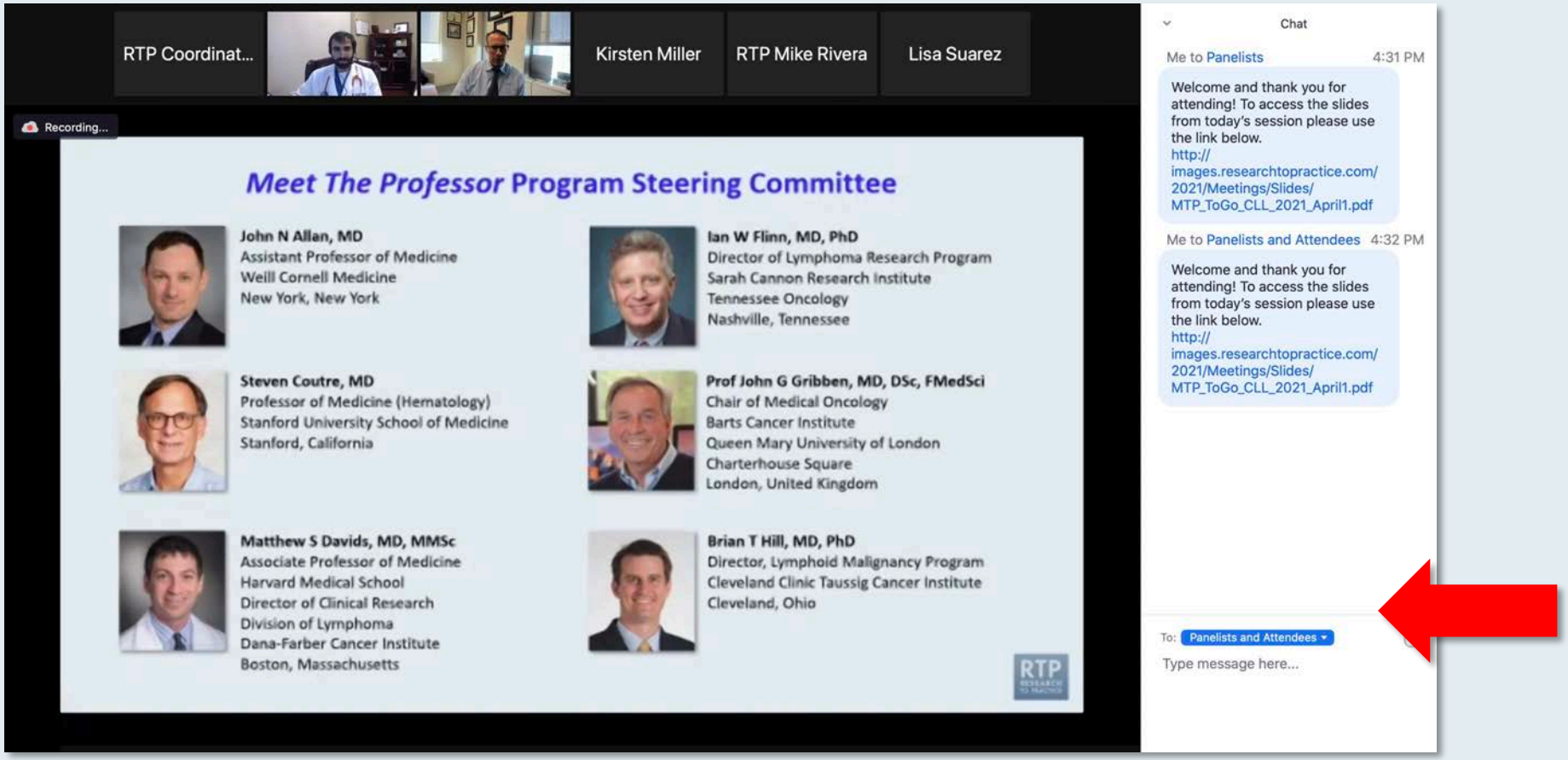
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



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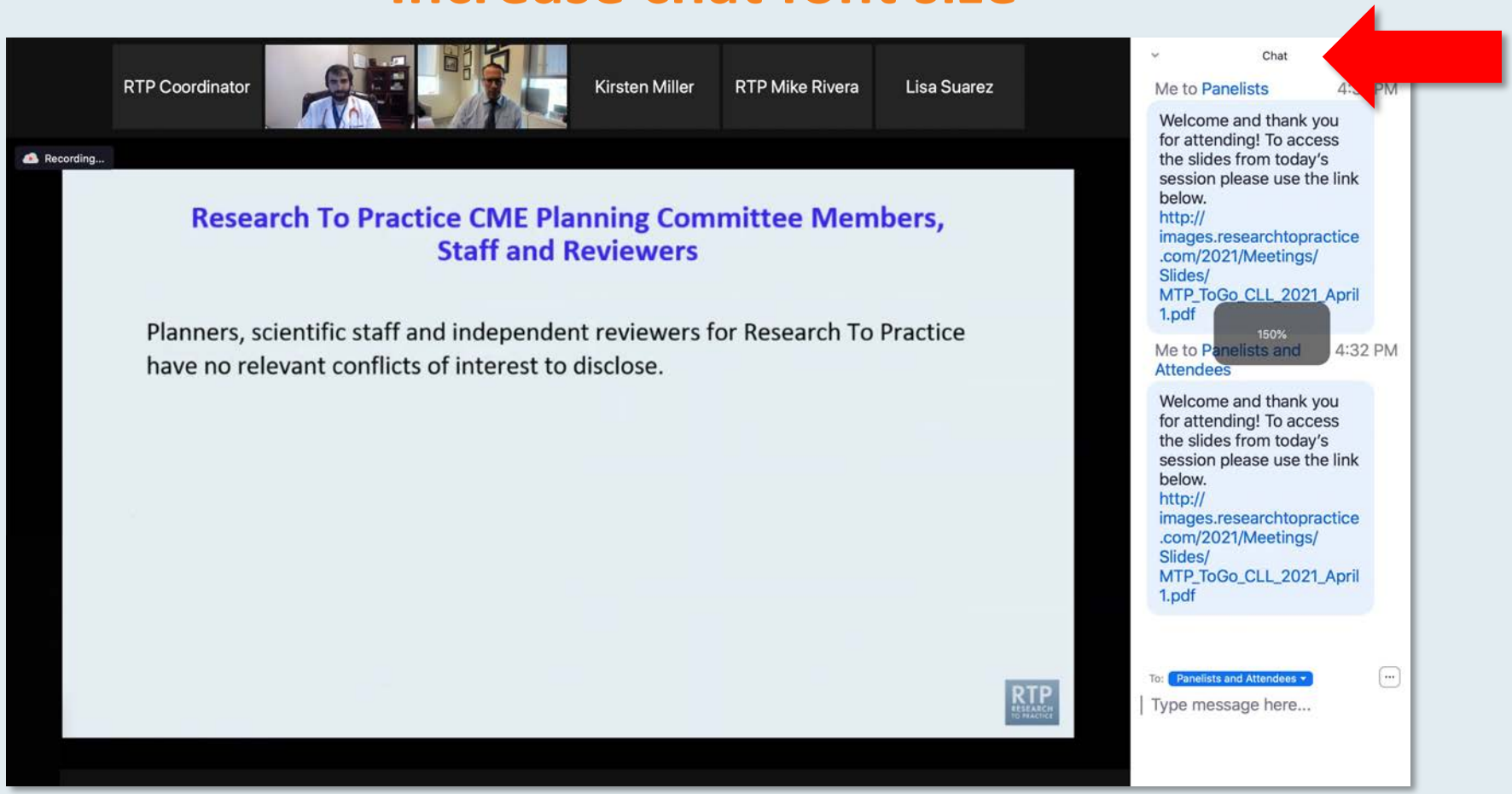
Increase chat font size



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

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Meet The Professor
Management of Ovarian Cancer

Tuesday, June 15, 2021
4:00 PM – 5:00 PM ET

Faculty
Susana Banerjee, MBBS, MA, PhD

Moderator
Neil Love, MD

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ASCO Highlights and More: Investigators Review Recent Data Sets and Provide Perspectives on Current Oncology Care

A Daylong Multitumor Educational Webinar in Partnership with the Texas Society of Clinical Oncology (TxSCO)

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Ovarian Cancer
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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, July 6, 2021
5:00 PM – 6:00 PM ET

Faculty

David I Quinn, MBBS, PhD

Moderator

Neil Love, MD

Thank you for joining us!

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

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Meet The Professor Program Participating Faculty

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Director, Interdisciplinary Gastrointestinal Oncology Program
Assistant Director, Translational Research
Comprehensive Cancer Center
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Attending Physician, Member
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Leader, GI and Neuroendocrine Oncology
Vice President of Medical Affairs
Karmanos Cancer Institute
Wayne State University
Detroit, Michigan

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Meet The Professor Program Participating Faculty

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Shorenstein Associate Director
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Jonsson Comprehensive Cancer Center
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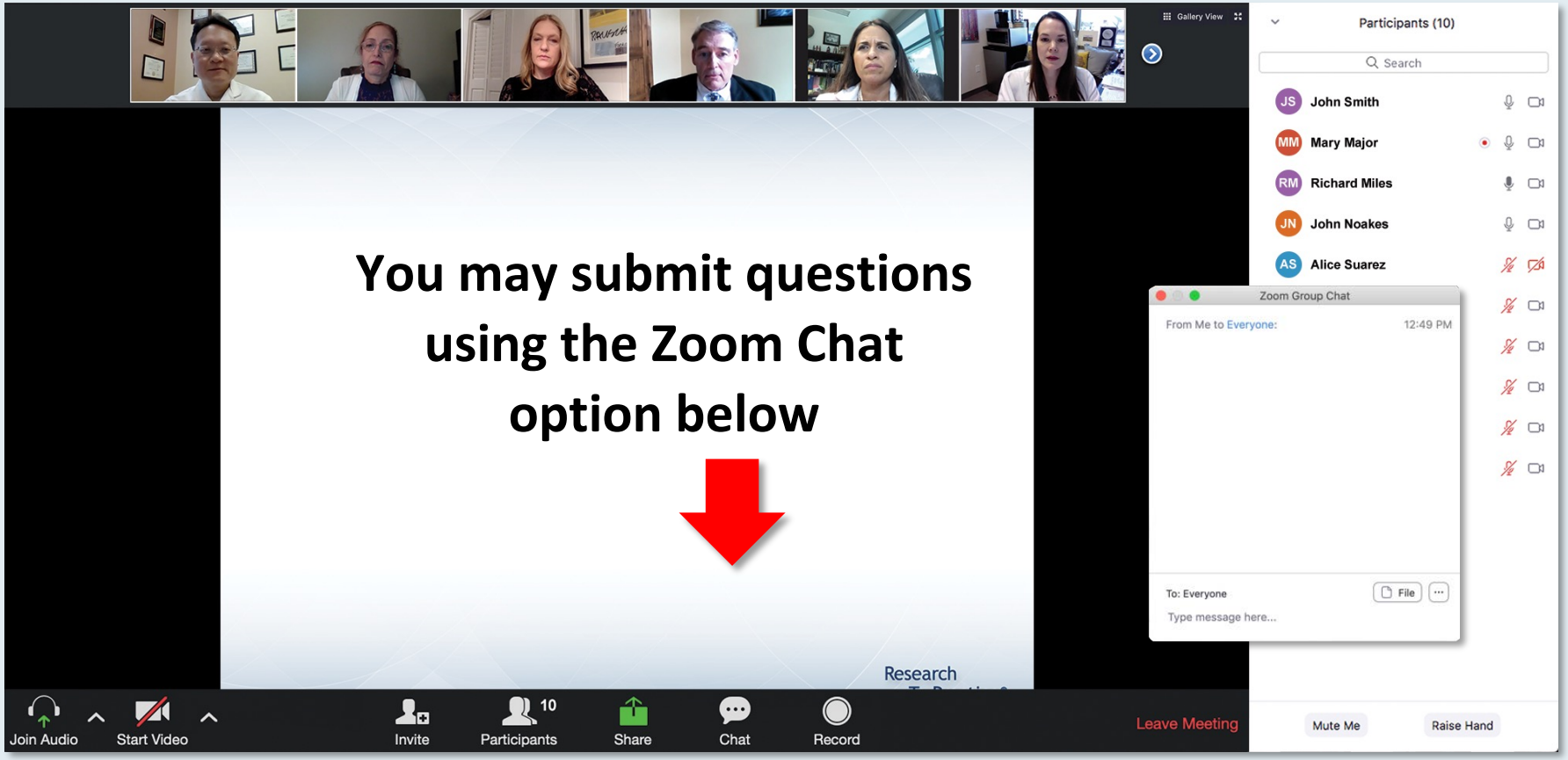

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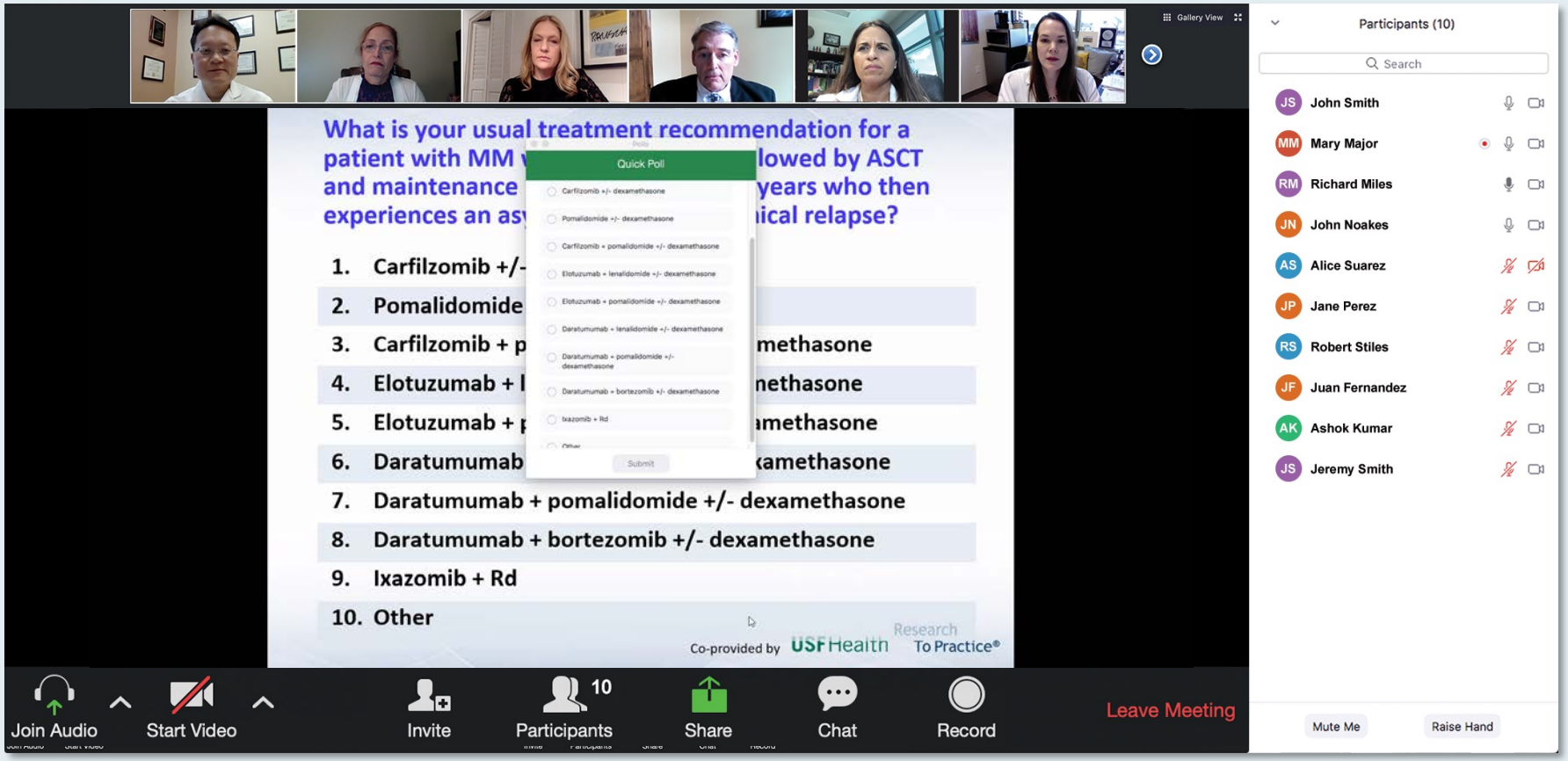

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Florida Cancer Specialists and
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Laurie Matt-Amaral, MD, MPH
Attending Physician
Cleveland Clinic Akron General
Medical Center
Akron, Ohio

Farshid Dayyani, MD, PhD
Professor of Clinical Medicine
Division of Hematology/Oncology
Department of Medicine
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Orange, California

Erik J Rupard, MD
Chief, Division of Hematology-Oncology
Tower Health – McGlinn Cancer Institute
West Reading, Pennsylvania

Rahul Gosain, MD
Division of Hematology and Oncology
Guthrie Corning Cancer Center
Corning, New York

John Yang, MD
Chief of Hematology/Oncology
Steward/St Anne's Hospital
Westwood, Massachusetts

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Meet The Professor with Dr Ciombor

MODULE 1: Cases from Drs Gosain and Yang

- Dr Gosain: A 59-year-old man with metastatic colon cancer – RAS and BRAF wild type, MSS
- Dr Yang: A 66-year-old woman with metastatic colon cancer – BRAF V600E mutation, high MSI

MODULE 2: Beyond the Guidelines; Key Data – Colorectal Cancer

MODULE 3: Cases from Drs Matt-Amaral and Rupard

- Dr Matt-Amaral: A 72-year-old man with metastatic HER2-positive GEJ adenocarcinoma – Microsatellite stable (MSS), PD-L1 CPS 1
- Dr Rupard: A 43-year-old woman with metastatic gastroesophageal adenocarcinoma and a history of ALL and melanoma

MODULE 4: Beyond the Guidelines; Key Data – Gastroesophageal Cancers

MODULE 5: Case from Drs Dayyani and Choksi

- Dr Dayyani: An 81-year-old man with recurrent, unresectable Child-Pugh A hepatocellular carcinoma (HCC)
- Dr Choksi: A 63-year-old woman with recurrent Child-Pugh B HCC with liver cirrhosis and elevated AFP

MODULE 6: Beyond the Guidelines; Key Data – Hepatocellular Carcinoma

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Case Presentation – Dr Gosain: A 59-year-old man with metastatic colon cancer – RAS and BRAF wild type, microsatellite stable (MSS)

Dr Rahul Gosain

- 2011: Diagnosed with Stage IIIC colon cancer; resection → FOLFOX x 12 cycles
- 2015-2018: Multiple local recurrences treated by resections with or without adjuvant FOLFOX
- 2019: Surveillance imaging reveals several subcentimeter lung nodules (not amenable to biopsy); CEA is rising
- FOLFIRI/bevacizumab with poor tolerability (fatigue and nausea)

Questions

- Would you have considered FOLFIRI and an anti-EGFR antibody, like cetuximab or panitumumab, instead of bevacizumab? Would that be a better choice?
- How important is it to know which side the tumor was in second or third line when you're considering anti-EGFR therapy for these patients?

Case Presentation – Dr Gosain: A 59-year-old man with metastatic colon cancer – RAS and BRAF wild type, MSS (continued)

Dr Rahul Gosain

- 2011: Diagnosed with Stage IIIC colon cancer; resection → FOLFOX x 12 cycles
- 2015-2018: Multiple local recurrences treated by resections with or without adjuvant FOLFOX
- 2019: Surveillance imaging reveals several subcentimeter lung nodules (not amenable to biopsy); CEA is rising
- FOLFIRI/bevacizumab with poor tolerability (fatigue and nausea)
- ***Irinotecan/panitumumab initiated and patient is tolerating therapy well, except for Grade 2/3 facial rash that is being managed with doxycycline***

Questions

- ***How would you manage the Grade 2/3 facial rash? Do you have a preference between cetuximab and panitumumab? Do you consider one or the other depending on your geographical area?***

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Case Presentation – Dr Gosain: A 59-year-old man with metastatic colon cancer – RAS and BRAF wild type, MSS (continued)

Dr Rahul Gosain

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- Irinotecan/panitumumab initiated and patient is tolerating therapy well, except for Grade 2/3 facial rash that is being managed with doxycycline

Questions

- How would you manage the Grade 2/3 facial rash? Do you have a preference between cetuximab and panitumumab? Do you consider one or the other depending on your geographical area?
- ***I was considering regorafenib or TAS-102 as next-line therapy for this patient if he progresses. Would you recommend something different? How do you dose regorafenib? What are your thoughts on the TAS-102/bevacizumab regimen?***

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Case Presentation – Dr Yang: A 66-year-old woman with metastatic colon cancer – BRAF V600E mutation, high microsatellite instability (MSI)

Dr John Yang

- S/p resection of Stage III MSI-high colon cancer, 2/20 positive nodes
- Mesenteric nodule positive for cancer was also resected

Questions

- What is the clinical significance of a positive mesenteric nodule? Does it impact prognosis? Is this considered to be an indicator of a more aggressive cancer?
- In the adjuvant setting, when you're seeing someone with Stage III colon cancer who is MSI-high, how do you approach adjuvant chemotherapy? Would you be tempted to consider immunotherapy?

Case Presentation – Dr Yang: A 66-year-old woman with metastatic colon cancer – BRAF V600E mutation, high MSI (continued)

Dr John Yang

- S/p resection of Stage III MSI-high colon cancer, 2/20 positive nodes
- Mesenteric nodule positive for cancer was also resected
- ***Adjuvant FOLFOX x 8 cycles → PD with widespread liver and pelvic metastases, CEA and LFTs elevated***
- ***Pembrolizumab → CEA normalized, and patient symptoms alleviated after 4 cycles***
- ***Results of re-staging imaging are pending***

Questions

- How long should I continue immunotherapy for her? What would you recommend as her next therapy if she has disease progression?
- Where does encorafenib fit into the treatment algorithm? How would you sequence her lines of therapy?

Meet The Professor with Dr Ciombor

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MODULE 6: Beyond the Guidelines; Key Data – Hepatocellular Carcinoma

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What is your usual first-line treatment recommendation for a clinically stable 60-year-old patient with left-sided, MSS, pan-RAS wild-type, BRAF wild-type metastatic colorectal cancer (mCRC)?

1. Chemotherapy
2. Chemotherapy + anti-VEGF antibody
3. Chemotherapy + anti-EGFR antibody
4. Chemotherapy + immunotherapy
5. Other

What is your usual first-line treatment recommendation for a clinically stable 60-year-old patient with left-sided, MSS, pan-RAS wild-type, BRAF wild-type metastatic colorectal cancer (mCRC)?

 Prof Arnold	FOLFOX + cetuximab	 Dr Ciombor	FOLFOX/CAPOX + bevacizumab
 Dr Bekaii-Saab	FOLFOXIRI + bevacizumab	 Dr O'Reilly	FOLFOX/CAPOX + bevacizumab
 Dr Bendell	FOLFOXIRI + bevacizumab	 Dr Venook	FOLFOXIRI + bevacizumab
 Dr Catenacci	FOLFIRI + bevacizumab	 Dr Wainberg	FOLFOX/CAPOX + bevacizumab

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What is your usual first-line treatment recommendation for a clinically stable 60-year-old patient with left-sided, pan-RAS wild-type, BRAF wild-type, MSI-high mCRC?

1. Pembrolizumab
2. Nivolumab
3. Nivolumab/ipilimumab
4. Chemotherapy
5. Chemotherapy + anti-VEGF antibody
6. Chemotherapy + anti-EGFR antibody
7. Chemotherapy + immunotherapy
8. Other

What is your usual first-line treatment recommendation for a clinically stable 60-year-old patient with left-sided, pan-RAS wild-type, BRAF wild-type, MSI-high mCRC?

 Prof Arnold	Pembrolizumab	 Dr Ciombor	Pembrolizumab
 Dr Bekaii-Saab	Pembrolizumab	 Dr O'Reilly	Pembrolizumab
 Dr Bendell	Pembrolizumab	 Dr Venook	Pembrolizumab
 Dr Catenacci	Pembrolizumab	 Dr Wainberg	Pembrolizumab

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Regulatory and reimbursement issues aside, for a patient with pan-RAS wild-type mCRC with a BRAF V600E mutation, in what line of therapy would you generally administer BRAF-targeted therapy?

 Prof Arnold	Second line	 Dr Ciombor	Second line
 Dr Bekaii-Saab	Second line	 Dr O'Reilly	Second line
 Dr Bendell	Second line	 Dr Venook	Second line
 Dr Catenacci	Second line	 Dr Wainberg	Second line

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For a patient with mCRC with a BRAF V600E mutation to whom you would administer BRAF-targeted therapy, what would be your preferred treatment?

1. Irinotecan + vemurafenib + EGFR antibody
2. Dabrafenib + trametinib + EGFR antibody
3. Encorafenib + binimetinib + EGFR antibody
4. Encorafenib + EGFR antibody
5. Other

For a patient with mCRC with a BRAF V600E mutation to whom you would administer BRAF-targeted therapy, what would be your preferred treatment?

 Prof Arnold	Encorafenib + cetuximab	 Dr Ciombor	Encorafenib + panitumumab
 Dr Bekaii-Saab	Encorafenib + panitumumab	 Dr O'Reilly	Encorafenib + cetuximab
 Dr Bendell	Encorafenib + panitumumab	 Dr Venook	Encorafenib + panitumumab
 Dr Catenacci	Encorafenib + cetuximab	 Dr Wainberg	Encorafenib + binimetinib + cetuximab

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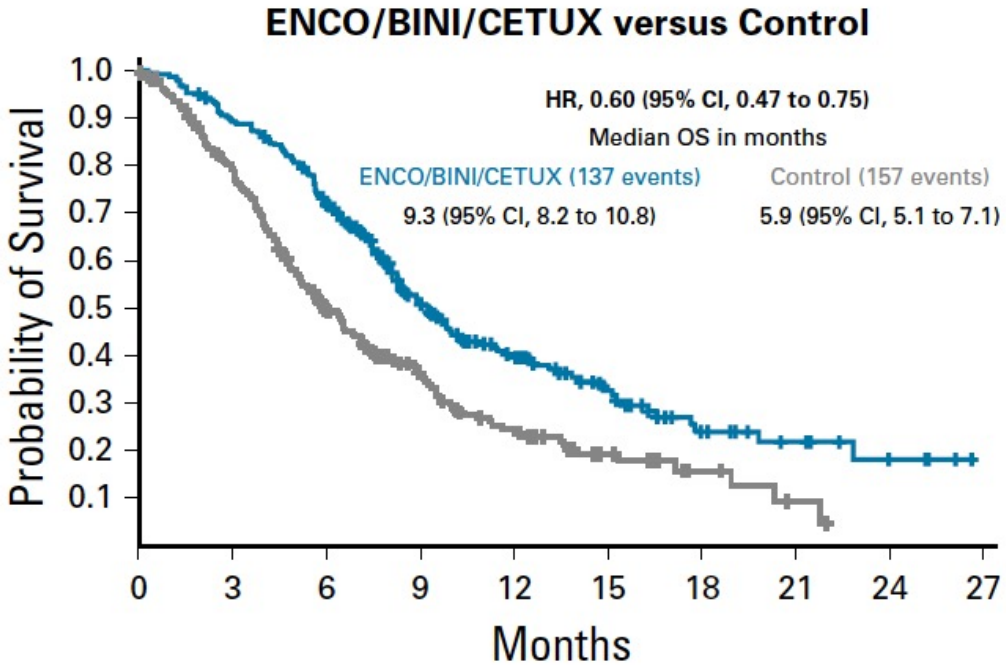
rapid communications

Encorafenib Plus Cetuximab as a New Standard of Care for Previously Treated *BRAF* V600E–Mutant Metastatic Colorectal Cancer: Updated Survival Results and Subgroup Analyses from the BEACON Study

Josep Tabernero, MD, PhD[1]; Axel Grothey, MD[2]; Eric Van Cutsem, MD, PhD[3]; Rona Yaeger, MD[4]; Harpreet Wasan, MD[5]; Takayuki Yoshino, MD, PhD[6]; Jayesh Desai, MBBS[7]; Fortunato Ciardiello, MD, PhD[8]; Fotios Loupakis, MD, PhD[9]; Yong Sang Hong, MD, PhD[10]; Neeltje Steeghs, MD, PhD[11]; Tormod Kyrre Guren, MD, PhD[12]; Hendrik-Tobias Arkenau, MD, PhD[13]; Pilar Garcia-Alfonso, MD[14]; Elena Elez, MD, PhD[1]; Ashwin Gollerkeri, MD[15]; Kati Maharry, PhD[15]; Janna Christy-Bittel, MSN[15]; and Scott Kopetz, MD, PhD[16]

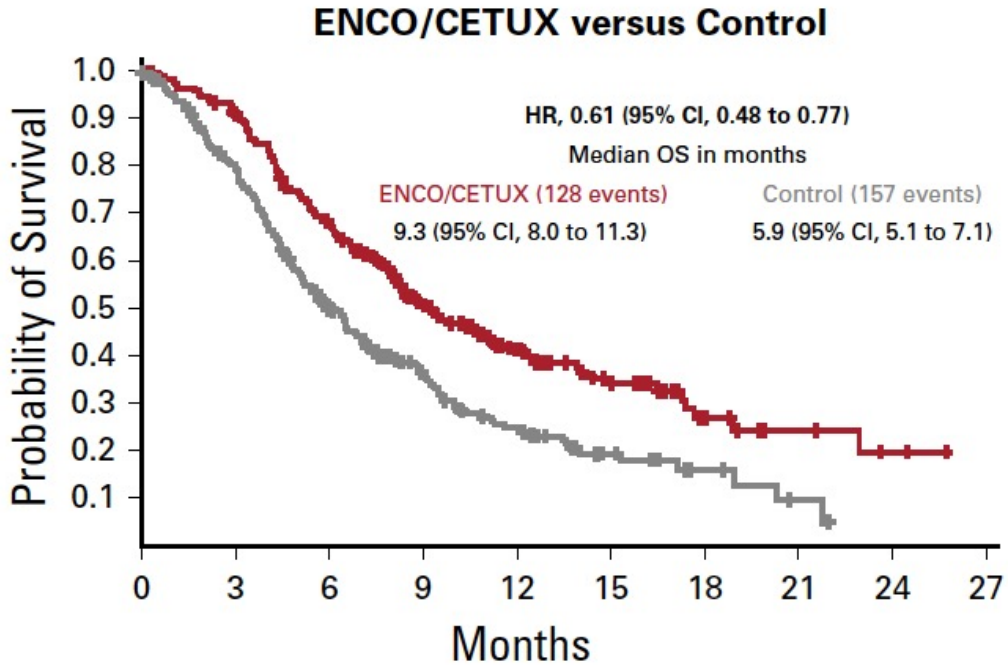
J Clin Oncol 2021;39(4):273-84.

BEACON: Overall Survival Results



Number of patients at risk

ENCO/BINI/CETUX	224	198	157	89	56	33	15	9	4	0
Control	221	166	98	54	33	15	6	2	0	0



Number of patients at risk

ENCO/CETUX	220	197	143	83	47	28	13	7	2	0
Control	221	166	98	54	33	15	6	2	0	0

Tabanero J et al. *J Clin Oncol* 2021;39(4):273-84.

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FDA Approves New Dosing Regimen for Cetuximab

Press Release – April 6, 2021

"On April 6, 2021, the Food and Drug Administration approved a new dosage regimen of 500 mg/m^2 as a 120-minute intravenous infusion every two weeks (Q2W) for cetuximab for patients with K-Ras wild-type, EGFR-expressing colorectal cancer (mCRC) or squamous cell carcinoma of the head and neck (SCCHN).

The approval was based on population pharmacokinetic (PK) modeling analyses that compared the predicted exposures of cetuximab 500 mg Q2W to observed cetuximab exposures in patients who received cetuximab 250 mg weekly. The application was also supported by pooled analyses of overall response rates, progression-free survival, and overall survival (OS) from published literature in patients with CRC and SCCHN, and OS analyses using real-world data in patients with mCRC who received either the weekly cetuximab or Q2W regimens. In these exploratory analyses, the observed efficacy results were consistent across dosage regimens and supported the results of the population PK modeling analyses.

The most common adverse reactions (incidence ≥25%) to cetuximab are cutaneous adverse reactions (including rash, pruritus, and nail changes), headache, diarrhea, and infection."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-new-dosing-regimen-cetuximab

The Randomized Phase II Study of FOLFOXIRI plus Cetuximab versus FOLFOXIRI plus Bevacizumab as the First-line Treatment in Metastatic Colorectal Cancer with RAS Wild-type Tumors: The DEEPER Trial (JACCRO CC-13)

Tsuji A et al.
ASCO 2021;Abstract 3501.

Monday, June 7, 1:15 PM - 4:15 PM EDT

Randomized Study to Investigate FOLFOXIRI plus Either Bevacizumab or Cetuximab as First-line Treatment of BRAF V600E-mutant mCRC: The Phase-II FIRE-4.5 Study (AIO KRK-0116)

Stintzing S et al.
ASCO 2021;Abstract 3502.

Monday, June 7, 1:15 PM - 4:15 PM EDT

Oral Maintenance Capecitabine versus Active Monitoring for Patients with Metastatic Colorectal Cancer (mCRC) Who are Stable or Responding After 16 Weeks of First-line Treatment: Results from the Randomized FOCUS4-N Trial

Adams R et al.

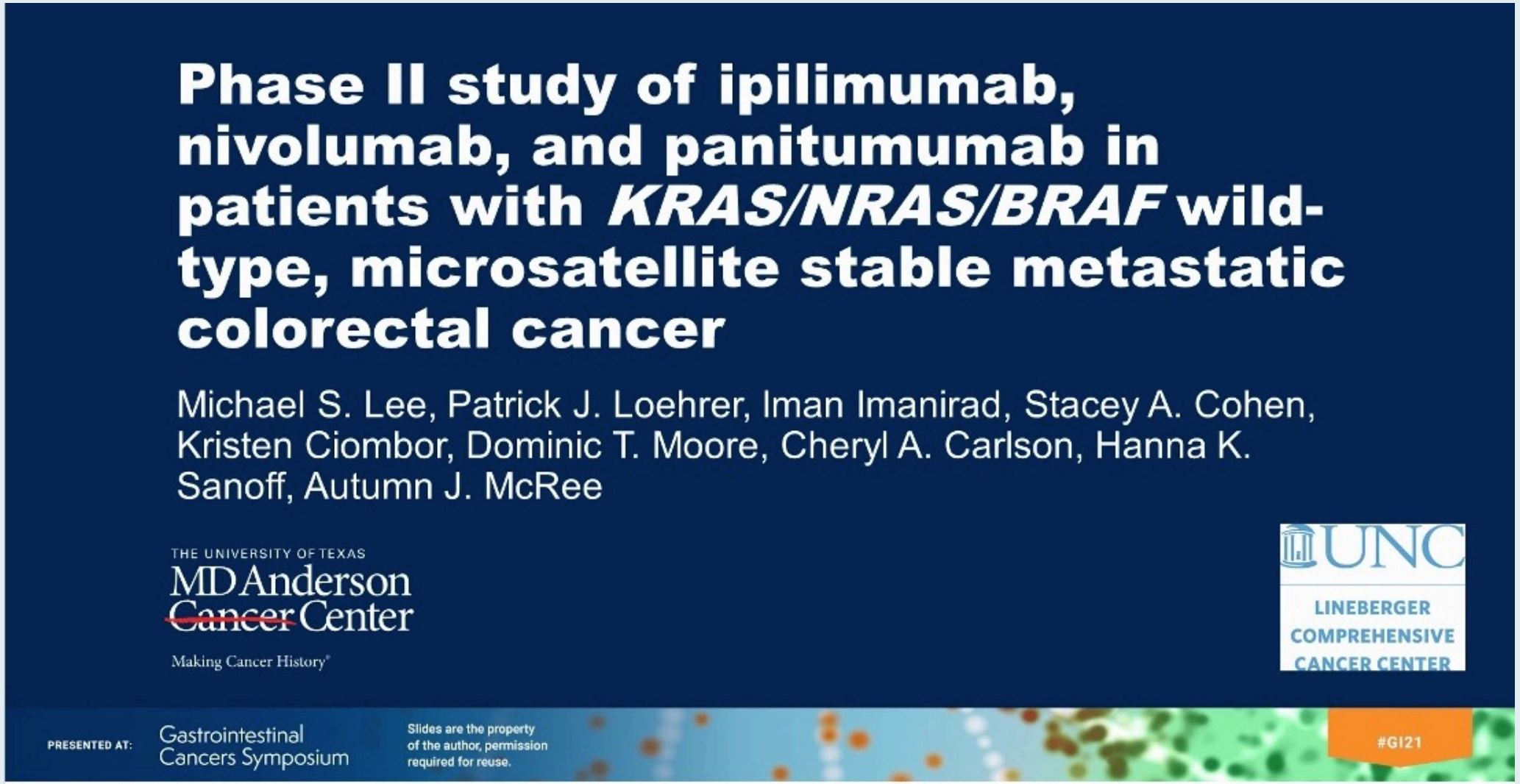
ASCO 2021;Abstract 3504.

Monday, June 7, 1:15 PM - 4:15 PM EDT

Phase II Study of Anti-EGFR Rechallenge Therapy with Panitumumab Driven by Circulating Tumor DNA Molecular Selection in Metastatic Colorectal Cancer: The CHRONOS Trial

Sartore-Bianchi A et al.
ASCO 2021;Abstract 3506.

Monday, June 7, 1:15 PM - 4:15 PM EDT



Abstract 7

Presented By Michael Lee at 2021 Gastrointestinal Cancers Symposium

Oncologist 2021;[Online ahead of print].

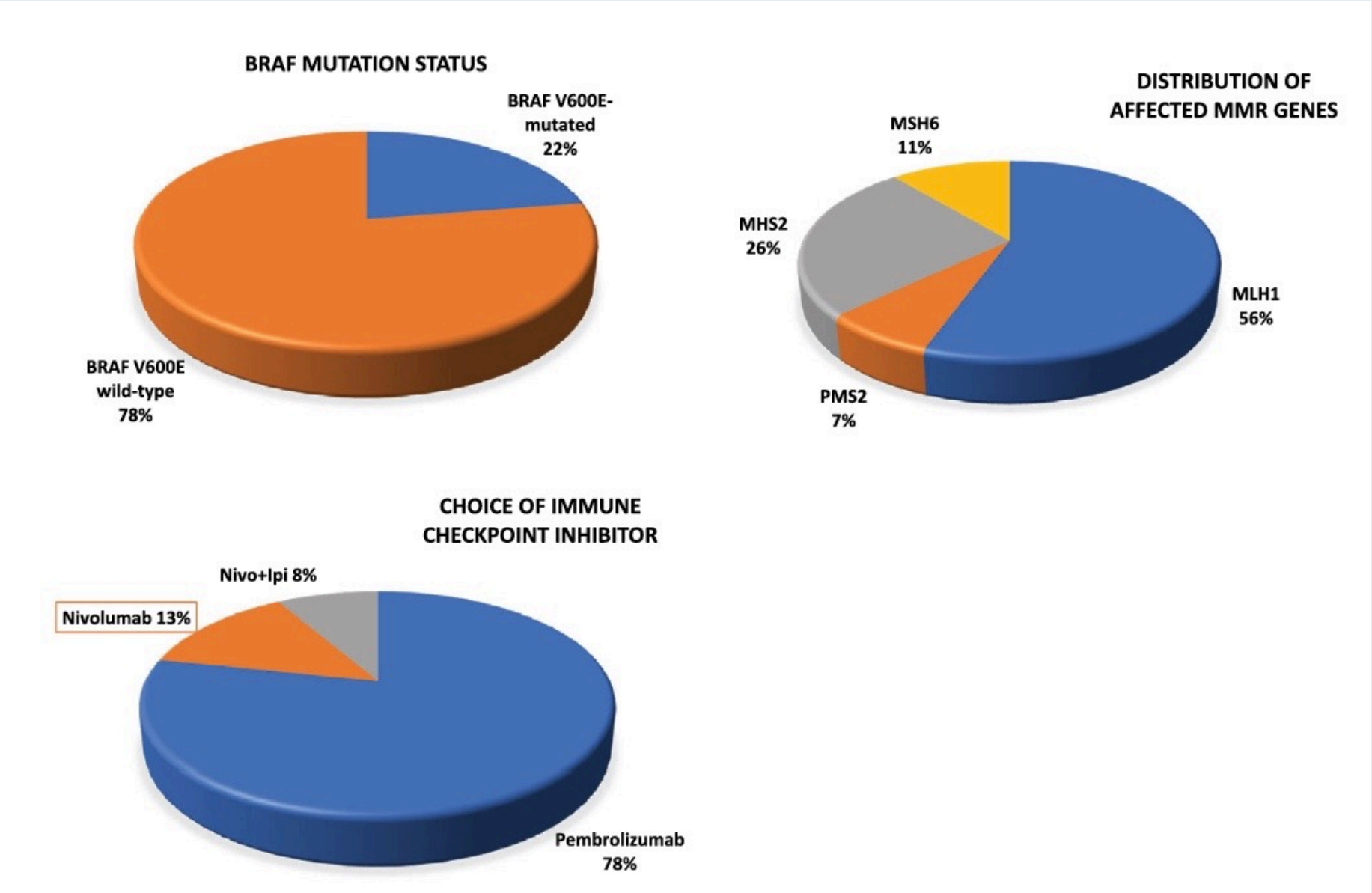
The Oncologist®

Gastrointestinal Cancer

Mismatch Repair (MMR) Gene Alteration and BRAF V600E Mutation Are Potential Predictive Biomarkers of Immune Checkpoint Inhibitors in MMR-Deficient Colorectal Cancer

Ibrahim Halil Sahin[a], Subir Goyal[b], Yoanna Pumpalova[c], Mohamad B. Sonbol[d], Satya Das[e], Sigurdis Haraldsdottir[f], Daniel Ahn[d], Kristen K. Ciombor[e], Zhengjia Chen[b], Amber Draper[b], Jordan Berlin[e], Tanios Bekaii-Saab[d], Gregory B. Lesinski[b], Bassel F. El-Rayes[b], Christina Wu[b]

Distribution of Clinical and Molecular Variables in the Cohort of Interest



Sahin IH et al. *Oncologist* 2021;[Online ahead of print].

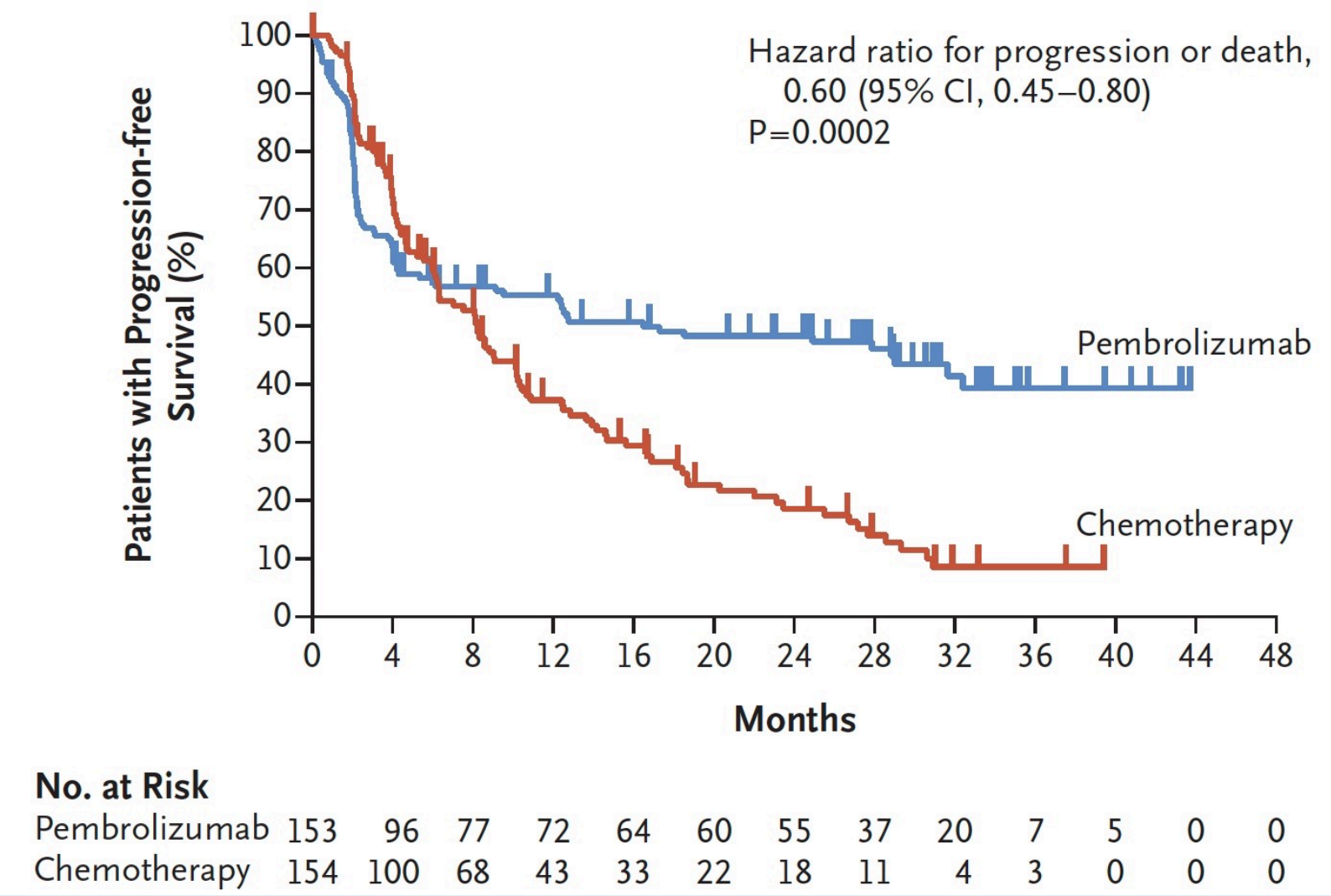
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 3, 2020 VOL. 383 NO. 23

Pembrolizumab in Microsatellite-Instability–High Advanced Colorectal Cancer

T. André, K.-K. Shiu, T.W. Kim, B.V. Jensen, L.H. Jensen, C. Punt, D. Smith, R. Garcia-Carbonero, M. Benavides, P. Gibbs, C. de la Fouchardiere, F. Rivera, E. Elez, J. Bendell, D.T. Le, T. Yoshino, E. Van Cutsem, P. Yang, M.Z.H. Farooqui, P. Marinello, and L.A. Diaz, Jr., for the KEYNOTE-177 Investigators*

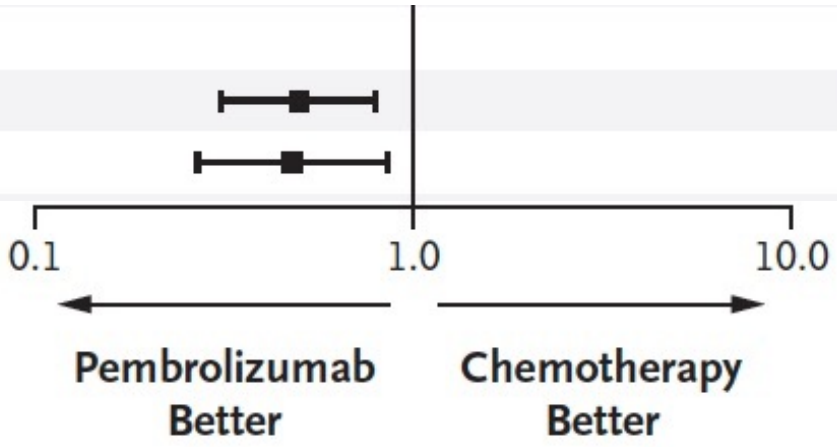
Progression-Free Survival for Patients with MSI-H/dMMR Metastatic Colorectal Cancer



André T et al. *N Engl J Med* 2020;383(23):2207-18.

Progression-Free Survival in Key Subgroups of Patients with MSI-H/dMMR Metastatic Colorectal Cancer

Subgroup	No. of Events/No. of Patients	Hazard Ratio (95% CI)
BRAF		
BRAF wild type	78/131	0.50 (0.31–0.80)
BRAF^{V600E}	51/77	0.48 (0.27–0.86)



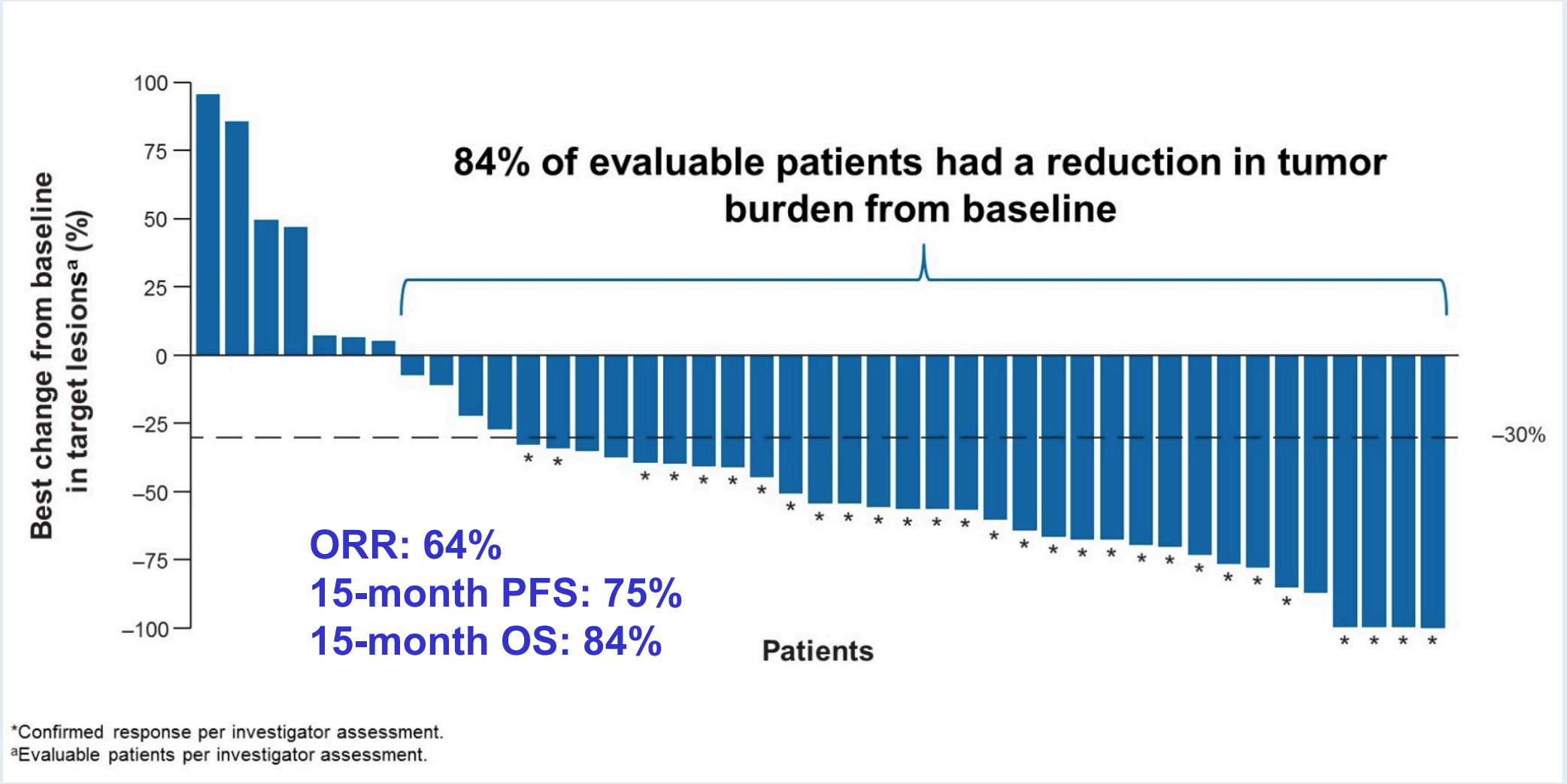
André T et al. *N Engl J Med* 2020;383(23):2207-18.

Nivolumab plus Low-Dose Ipilimumab as First-Line Therapy in Microsatellite Instability-High/DNA Mismatch Repair Deficient mCRC: Clinical Update

Lenz H-J et al.

Gastrointestinal Cancers Symposium 2020;Abstract 11.

CheckMate 142: Nivolumab/Ipilimumab as First-Line Therapy in MSI-H/dMMR mCRC



*Confirmed response per investigator assessment.
[a]Evaluable patients per investigator assessment.

Lenz H-J et al. Gastrointestinal Cancers Symposium 2020;Abstract 11.

RTP RESEARCH TO PRACTICE

Trastuzumab Deruxtecan (T-DXd; DS-8201) in Patients (pts) with HER2-Expressing Metastatic Colorectal Cancer (mCRC): Final Results from a Phase 2, Multicenter, Open-Label Study (DESTINY-CRC01)

Yoshino T et al.
ASCO 2021;Abstract 3505.

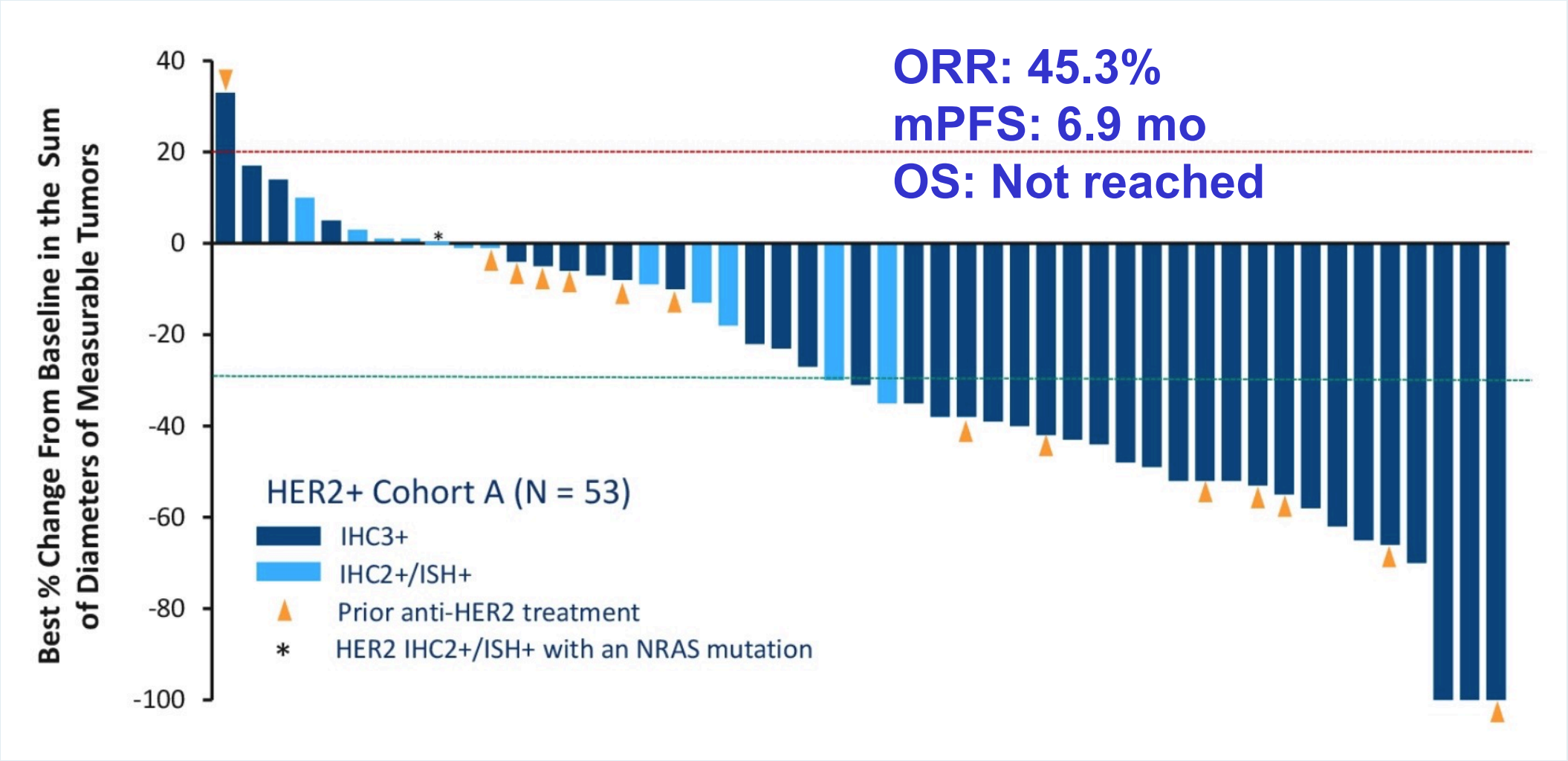
Monday, June 7, 1:15 PM - 4:15 PM EDT

A Phase II, Multicenter, Open-Label Study of Trastuzumab Deruxtecan (T-DXd; DS-8201) in Patients (pts) with HER2-Expressing Metastatic Colorectal Cancer (mCRC): DESTINY-CRC01

Siena S et al.

ASCO 2020;Abstract 4000.

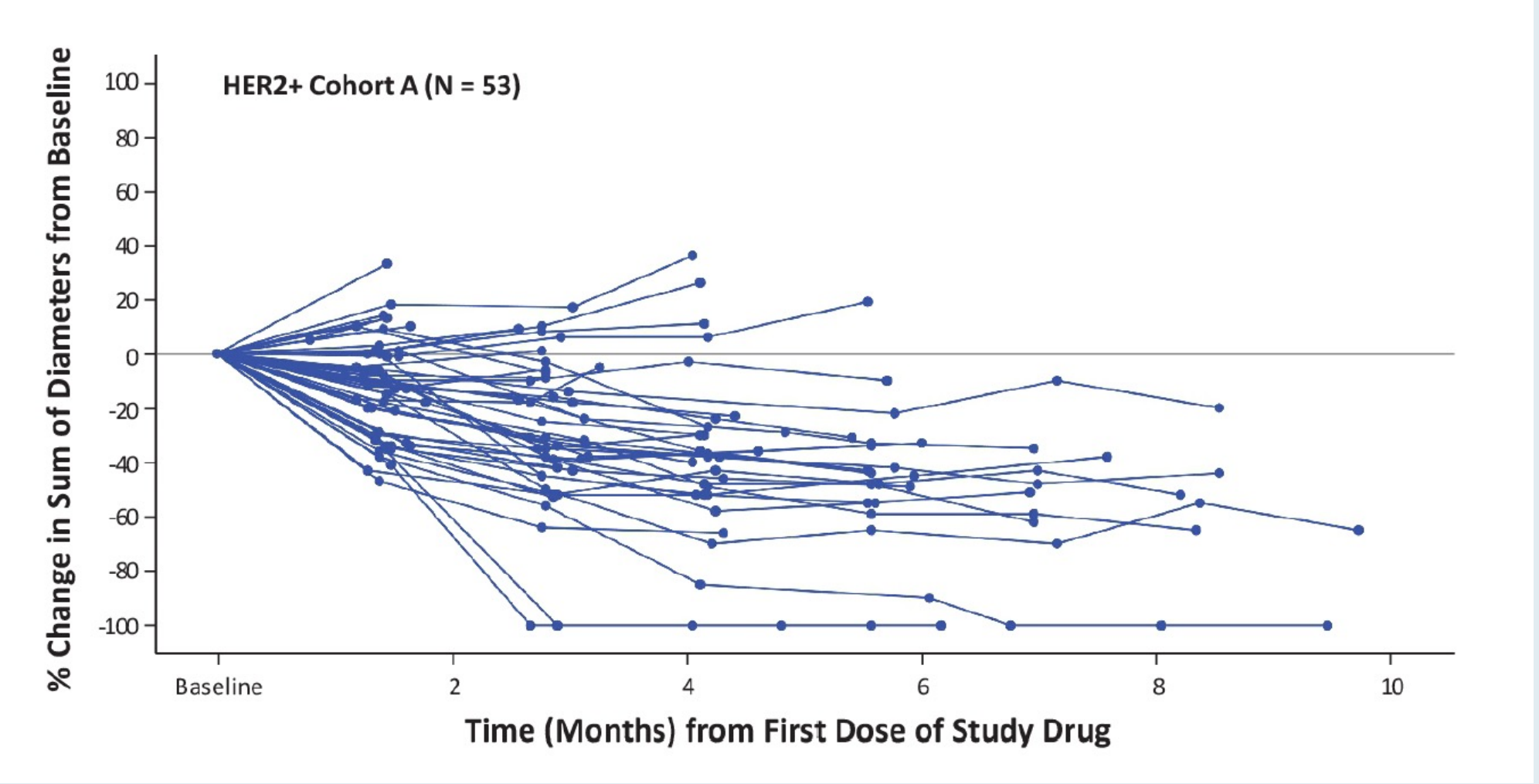
DESTINY-CRC01: Best Change in Tumor Size Over Time



Siena S et al. ASCO 2020;Abstract 4000.

RTP RESEARCH TO PRACTICE

DESTINY-CRC01: Tumor Shrinkage Over Time



Siena S et al. ASCO 2020;Abstract 4000.

DESTINY-CRC01: AEs of Special Interest

	All Patients (N = 78)					
Preferred Term, n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any Grade/ Total
Interstitial Lung Disease	0	2 (2.6)	1 (1.3)	0	2 (2.6)	5 (6.4)

Among the 5 total events:

- Median time to investigator-reported onset was 80 days (range, 22-132)
- 5 of 5 patients with grade ≥ 2 ILD received corticosteroids
- 2 patients recovered, 1 did not recover (later died due to disease progression), and 2 died
- In the 2 fatal cases, onset was from 40-126 days, both received steroids as part of treatment, and death occurred 6-18 days after diagnosis

Protocol recommendations: Monitor for symptoms. Hold T-DXd and start steroids as soon as ILD is suspected

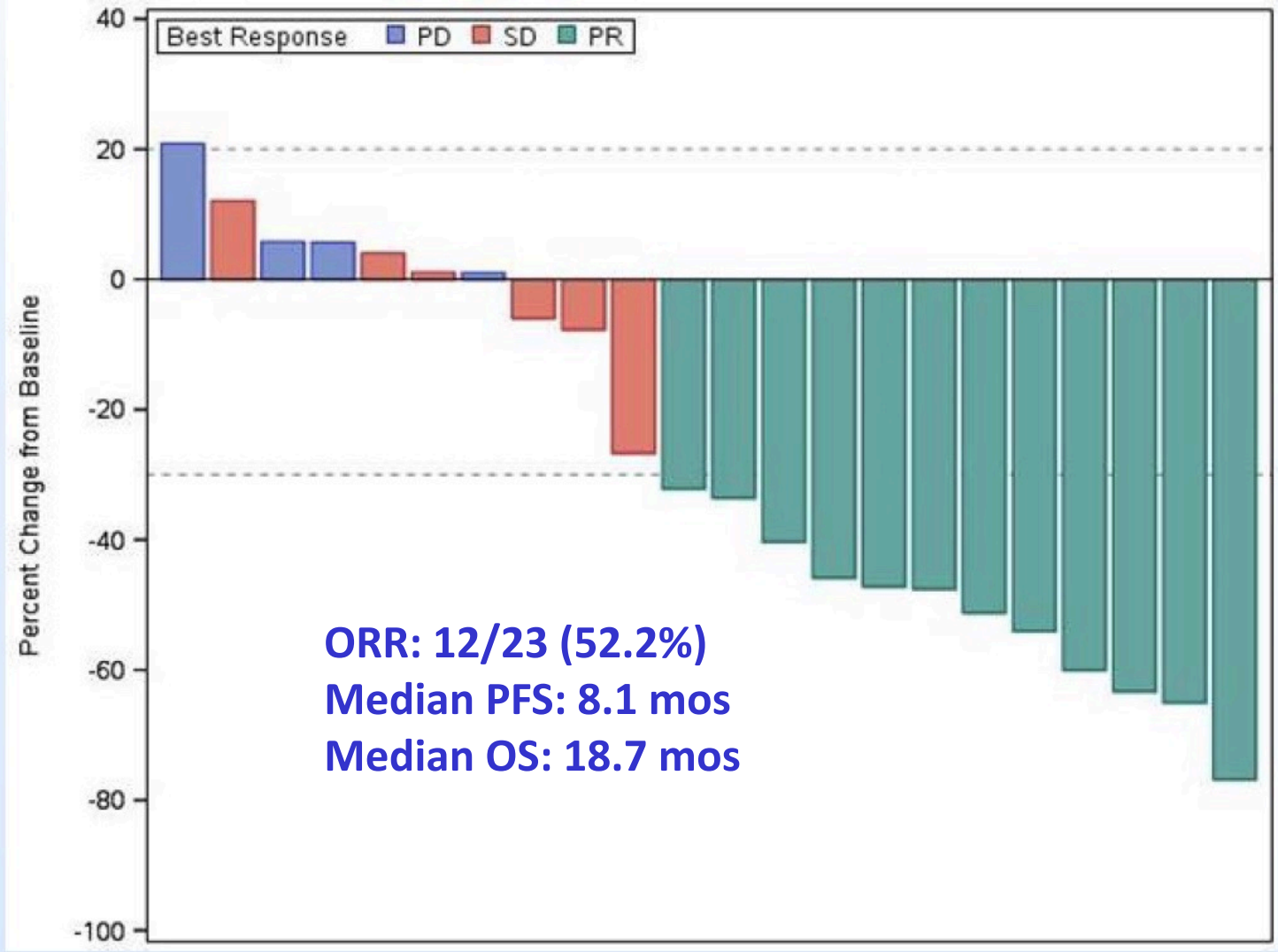
Siena S et al. ASCO 2020;Abstract 4000.

Trastuzumab and Tucatinib for the Treatment of HER2 Amplified Metastatic Colorectal Cancer: Initial Results from the MOUNTAINEER Trial

Strickler JH et al.

ESMO 2019;Abstract 527PD.

MOUNTAINEER: Response and Survival



Strickler JH et al. ESMO 2019;Abstract 527PD.

Oncologist 2021;[Online ahead of print].

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Symptom Management and Supportive Care

Preemptive Versus Reactive Topical Clobetasol for Regorafenib-Induced Hand-Foot Reactions: A Preplanned Analysis of the ReDOS Trial

Aminah Jatoi,[a] Fang-Shu Ou,[a] Daniel H. Ahn,[b] Tyler J. Zemla,[a] Jennifer G. Le-Rademacher,[a] Patrick Boland,[c] Kristen K. Ciombor,[d] Nisha L. Jacobs,[e] Boris Pasche,[f] James M. Cleary,[g] Jeannine S. McCune,[h] Katrina S. Pedersen,[i] Afsaneh Barzi,[h] E. Gabriela Chiorean,[j] Erica N. Heying,[a] Heinz-Josef Lenz,[k] Jeff A. Sloan,[a] Axel Grothey,[l] Mario E. Lacouture,[m] Tanios Bekaii-Saab[b]

The TRUSTY Study: A Randomized Phase 2/3 Study of Trifluridine/Tipiracil plus Bevacizumab versus Irinotecan and Fluoropyrimidine plus Bevacizumab as Second-Line Treatment in Patients with Metastatic Colorectal Cancer

Kuboki Y et al.
ASCO 2021;Abstract 3507.

Monday, June 7, 1:15 PM - 4:15 PM EDT

EXPERT OPINION ON DRUG SAFETY
https://doi.org/10.1080/14740338.2021.1915281

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Taylor & Francis Group

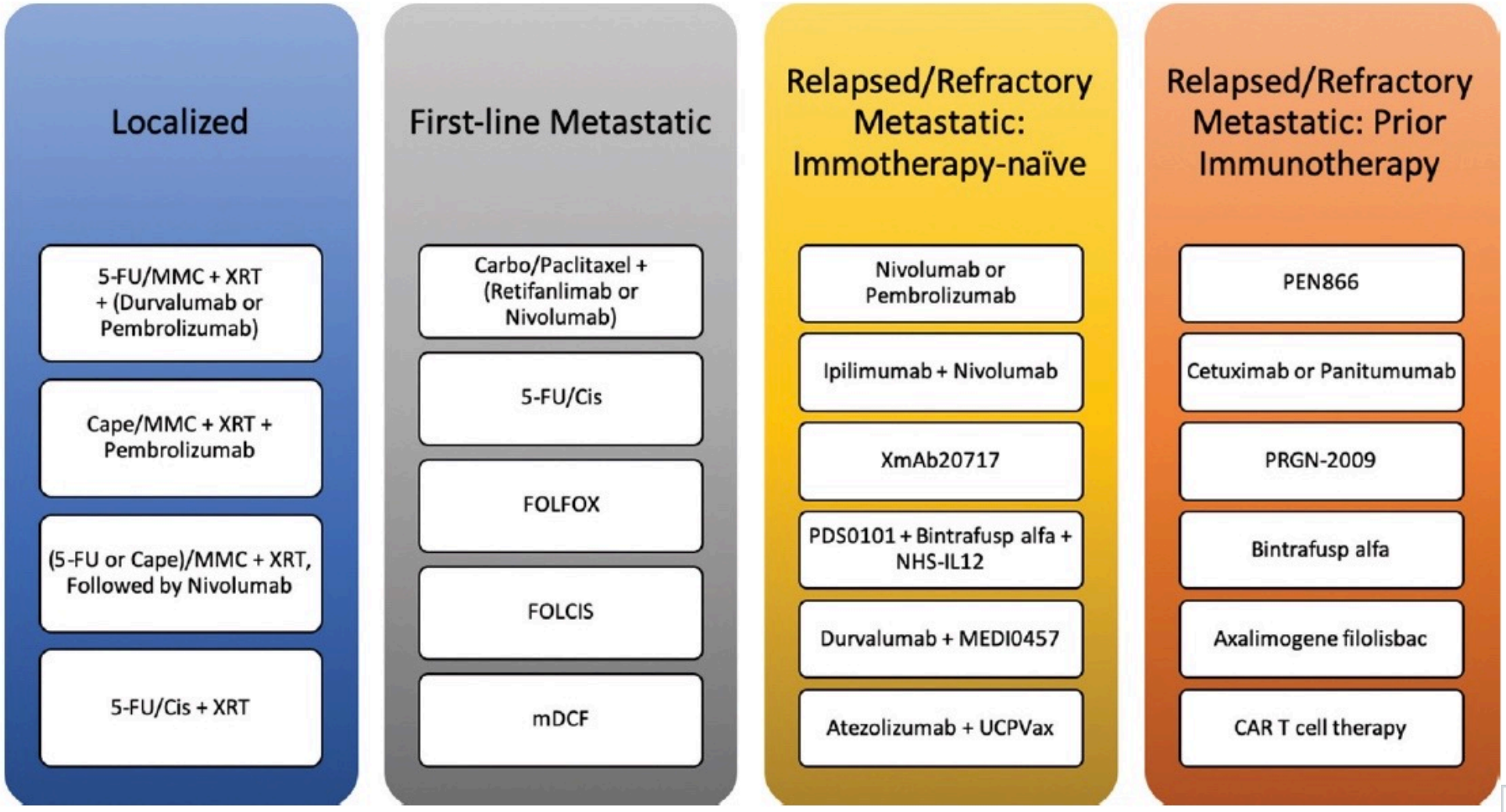
REVIEW

Safety considerations with new treatment regimens for anal cancer

Sarah K Cimino[a], Kristen K. Ciombor[b], A Bapsi Chakravarthy [c], Christina E. Bailey[d], M Benjamin Hopkins[e], Timothy M. Geiger[e], Alexander T. Hawkins[e] and Cathy Eng[b]

[a]Department of Pharmacy, Vanderbilt University Medical Center, Nashville, TN, USA; [b]Department of Medicine: Division of Hematology and Oncology, Vanderbilt University Medical Center, Nashville, TN, USA; [c]Department of Radiation Oncology, Vanderbilt University Medical Center, Nashville, TN, USA; [d]Department of Surgery: Division of Surgical Oncology and Endocrine Surgery, Vanderbilt University Medical Center, Nashville, TN, USA; [e]Department of Surgery: Division of Colon and Rectal Surgery, Vanderbilt University Medical Center, Nashville, TN, USA

Synopsis of Potential Treatment Guideline Changes Resulting from Ongoing Studies Examining New Treatment Regimens



Cimino SK et al. *Expert Opin Drug Saf* 2021;26:1-14.

A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naive Metastatic Anal Cancer Patients: A Trial of the ECOG-ACRIN Cancer Research Group (EA2176)

Roth MT et al.

ASCO 2021;Abstract TPS3614.

J Radiat Oncol 2020:1-3

REVIEW

Early detection of SARS-CoV-2 from staging PET-CT

Mohamed H. Khattab[1] · Alexander D. Sherry[2] · Aaron C. Jessop[3] · Kristen K. Ciombor[4] · Bapsi Chakravarthy[1]

Meet The Professor with Dr Ciombor

MODULE 1: Cases from Drs Gosain and Yang

- Dr Gosain: A 59-year-old man with metastatic colon cancer – RAS and BRAF wild type, MSS
- Dr Yang: A 66-year-old woman with metastatic colon cancer – BRAF V600E mutation, high MSI

MODULE 2: Beyond the Guidelines; Key Data – Colorectal Cancer

MODULE 3: Cases from Drs Matt-Amaral and Rupard

- Dr Matt-Amaral: A 72-year-old man with metastatic HER2-positive GEJ adenocarcinoma – Microsatellite stable (MSS), PD-L1 CPS 1
- Dr Rupard: A 43-year-old woman with metastatic gastroesophageal adenocarcinoma and a history of ALL and melanoma

MODULE 4: Beyond the Guidelines; Key Data – Gastroesophageal Cancers

MODULE 5: Case from Drs Dayyani and Choksi

- Dr Dayyani: An 81-year-old man with recurrent, unresectable Child-Pugh A hepatocellular carcinoma (HCC)
- Dr Choksi: A 63-year-old woman with recurrent Child-Pugh B HCC with liver cirrhosis and elevated AFP

MODULE 6: Beyond the Guidelines; Key Data – Hepatocellular Carcinoma

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Case Presentation – Dr Matt-Amaral: A 72-year-old man with metastatic HER2-positive gastroesophageal junction adenocarcinoma – MSS, PD-L1 CPS 1

Dr Laurie Matt-Amaral

- December 2019: Presents to ER with left leg pain and workup reveals DVT and metastatic GEJ adenocarcinoma, HER2-positive
- Molecular studies: MSS, PD-L1 CPS 1
- January 2020: CAPOX + trastuzumab initiated
  - Trastuzumab stopped after cycle 1 due to poor ejection fraction
- Completed CAPOX → maintenance 5-FU → PD

Questions

- What treatment would you recommend next for this patient? Do you think HER2-targeted therapy is still appropriate for this patient given his LVF decline with trastuzumab?

Case Presentation – Dr Rupard: A 43-year-old woman with metastatic gastroesophageal adenocarcinoma and a history of ALL and melanoma

Dr Erik Rupard

- PMH: ALL in 2013 at age 39
- 2018: Presents with difficulty swallowing and workup reveals metastatic GEJ adenocarcinoma, HER2-positive
  - Molecular studies: ATM mutation, MSS, PD-L1 CPS 5, TMB 17
  - FOLFOX/trastuzumab → CR
- Presents with difficulty swallowing again and workup reveals disease present in the distal esophagus only
- Repeat biopsy shows esophageal adenoma, now HER2-negative

Case Presentation – Dr Rupard: A 43-year-old woman with metastatic gastroesophageal adenocarcinoma and a history of ALL and melanoma (continued)

Dr Erik Rupard

- PMH: ALL in 2013 at age 39; melanoma
- 2018: Presents with difficulty swallowing and workup reveals metastatic GEJ adenocarcinoma, HER2-positive
  - Molecular studies: ATM mutation, MSS, PD-L1 CPS 5, TMB 17
  - FOLFOX/trastuzumab → CR
- Presents with difficulty swallowing again and workup reveals disease present in the distal esophagus only
- Repeat biopsy shows esophageal adenoma, now HER2-negative
- ***Nivolumab/paclitaxel/ramucirumab initiated after recommendation from second-opinion consult***
- ***Disease has relapsed again, and considering trastuzumab deruxtecan as potential next therapy***

Meet The Professor with Dr Ciombor

MODULE 1: Cases from Drs Gosain and Yang

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MODULE 6: Beyond the Guidelines; Key Data – Hepatocellular Carcinoma

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Regulatory and reimbursement issues aside, what would you currently recommend as second-line therapy for a patient with metastatic HER2-negative, MSS adenocarcinoma of the GEJ who has experienced disease progression on first-line FOLFOX?

 Prof Arnold	Ramucirumab/ paclitaxel	 Dr Ciombor	FOLFIRI/ramucirumab
 Dr Bekaii-Saab	Test for PD-L1 CPS and administer pembrolizumab if ≥10	 Dr O'Reilly	Ramucirumab/ paclitaxel
 Dr Bendell	Test for PD-L1 CPS and administer pembrolizumab if ≥10	 Dr Venook	Ramucirumab/ paclitaxel
 Dr Catenacci	FOLFIRI/ramucirumab	 Dr Wainberg	Ramucirumab/ paclitaxel

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, what would you currently recommend as second-line therapy for a patient with metastatic HER2-positive, MSS adenocarcinoma of the GEJ who has experienced disease progression on first-line FOLFOX/trastuzumab?

 Prof Arnold	Ramucirumab/ paclitaxel	 Dr Ciombor	FOLFIRI/ramucirumab
 Dr Bekaii-Saab	Trastuzumab deruxtecan	 Dr O'Reilly	Trastuzumab deruxtecan
 Dr Bendell	Test for PD-L1 CPS and administer pembrolizumab if ≥10%	 Dr Venook	Ramucirumab/ paclitaxel
 Dr Catenacci	Continue trastuzumab and switch chemotherapy	 Dr Wainberg	Trastuzumab deruxtecan

RTP RESEARCH TO PRACTICE

Regulatory and reimbursement issues aside, in which line of therapy would you generally recommend trastuzumab deruxtecan for a 65-year-old patient with metastatic HER2-positive, MSS adenocarcinoma of the GEJ?

 Prof Arnold	Third line	 Dr Ciombor	Third line
 Dr Bekaii-Saab	Second line	 Dr O'Reilly	Second line
 Dr Bendell	Second line	 Dr Venook	Second line
 Dr Catenacci	Third line	 Dr Wainberg	Second line

RTP RESEARCH TO PRACTICE

Checkpoint Inhibitor Approvals in Gastric, GEJ and Esophageal Cancers

Regimen	Location	Histology	Setting	PD-L1
Pembrolizumab 9/22/2017	Gastric, GEJ	Adenocarcinoma	• Recurrent locally advanced or metastatic • Progression on or after ≥2 prior lines of therapy, including fluoropyrimidine- and platinum-containing chemotherapy and, if appropriate, HER2/neu-targeted therapy	CPS ≥1
Pembrolizumab 7/30/2019	Esophageal, GEJ	Squamous	• Recurrent locally advanced or metastatic • Not amenable to surgical resection or definitive chemoradiation • After ≥1 prior lines of systemic therapy	CPS ≥10
Nivolumab 6/10/2020	Esophageal	Squamous	• Unresectable advanced, recurrent or metastatic • After prior fluoropyrimidine- and platinum-based chemotherapy	Not required
Pembrolizumab + cisplatin/5-FU 3/22/2021	Esophageal, GEJ	Adenocarcinoma and squamous	• Recurrent locally advanced or metastatic • Not amenable to surgical resection or definitive chemoradiation	Not required
Nivolumab + mFOLFOX6 or CAPOX 4/16/2021	Gastric, GEJ, esophageal	Adenocarcinoma	• Advanced or metastatic gastric, GEJ or esophageal adenocarcinoma	Not required

Selected Adjuvant and Neoadjuvant Studies of Immunotherapy in Gastric Cancers

Study/IO agents	Phase	Protocol summary
KEYNOTE-585 Pembrolizumab	3	Pembrolizumab (MK-3475) Plus Chemotherapy (XP or FP) Versus Placebo Plus Chemotherapy (XP or FP) as Neoadjuvant/Adjuvant Treatment for Gastric and Gastroesophageal Junction (GEJ) Adenocarcinoma
ONO-4538-38 Nivolumab	3	Adjuvant chemotherapy with Nivolumab in combination with S-1 therapy or capecitabine + oxaliplatin, in comparison with placebo in combination with S-1 therapy or CapeOX therapy, in Stage III gastric cancer (including esophagogastric junction cancer) after D2 or more extensive lymph node dissection
VESTIGE Nivolumab, ipilimumab	2	Adjuvant Immunotherapy in Patients With Resected Esophageal, Gastroesophageal Junction and Gastric Cancer Following Preoperative Chemotherapy With High Risk for Recurrence (N+ and/or R1)
NCT04745988 Pembrolizumab	2	Lenvatinib With Pembrolizumab in the Neoadjuvant/Adjuvant Treatment for Patients With Gastric Cancer
RESONANCE-III Nivolumab	2	Nivolumab, S-1 Combined With Oxaliplatin (Nivo+SOX) Versus Nivolumab (Nivo) as Neoadjuvant Therapy in Patients With Locally Advanced Gastric Adenocarcinoma

Adjuvant Nivolumab (NIVO) in Resected Esophageal or Gastroesophageal Junction Cancer (EC/GEJC) Following Neoadjuvant Chemoradiotherapy (CRT): Expanded Efficacy and Safety Analyses from CheckMate 577

Kelly RJ et al.
ASCO 2021;Abstract 4003.

Saturday, June 5, 1:45 PM - 4:45 PM EDT

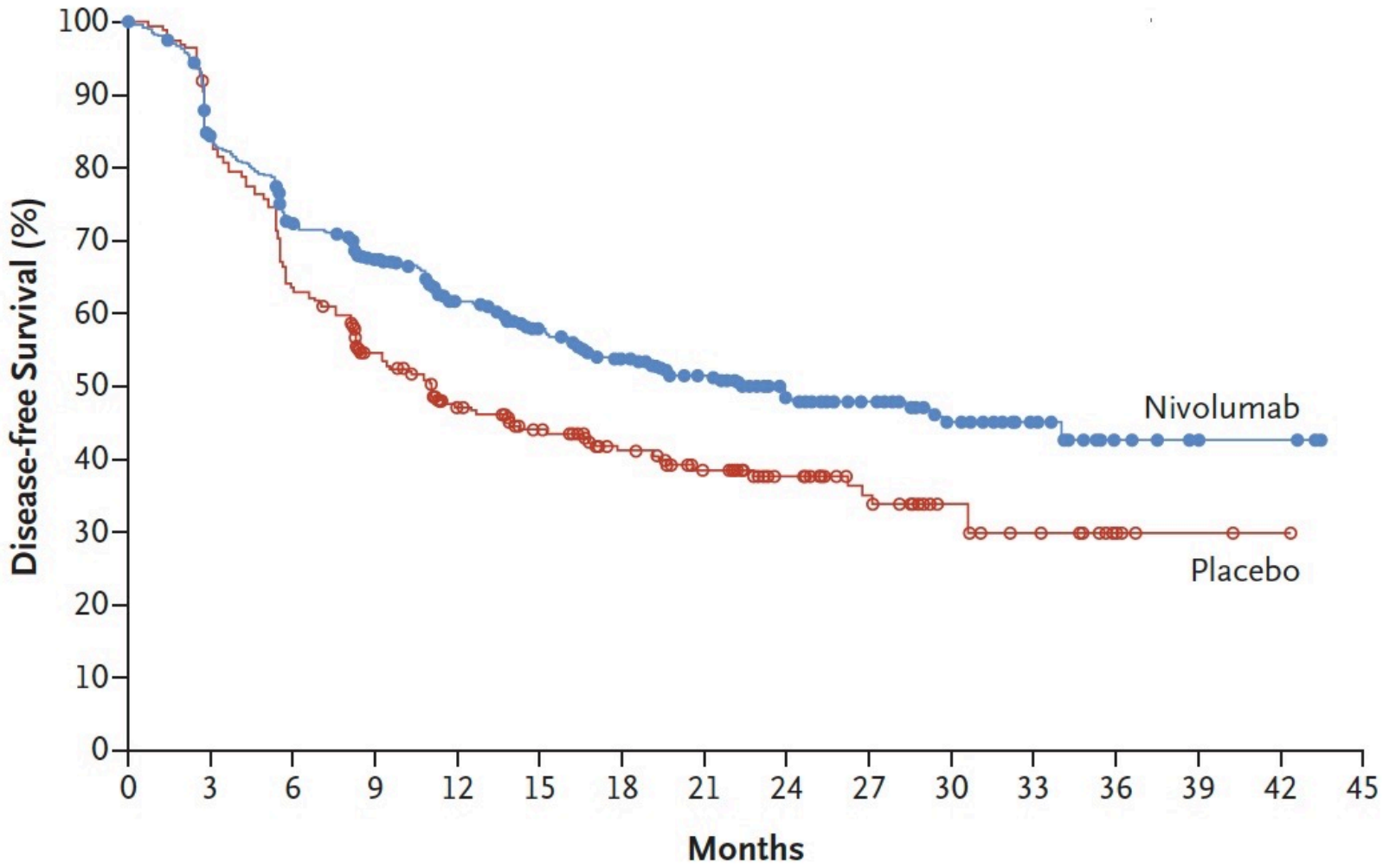
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 1, 2021 VOL. 384 NO. 13

Adjuvant Nivolumab in Resected Esophageal or Gastroesophageal Junction Cancer

R.J. Kelly, J.A. Ajani, J. Kuzdzal, T. Zander, E. Van Cutsem, G. Piessen, G. Mendez, J. Feliciano, S. Motoyama, A. Lièvre, H. Uronis, E. Elimova, C. Grootscholten, K. Geboes, S. Zafar, S. Snow, A.H. Ko, K. Feeney, M. Schenker, P. Kocon, J. Zhang, L. Zhu, M. Lei, P. Singh, K. Kondo, J.M. Cleary, and M. Moehler, for the CheckMate 577 Investigators*

Disease-Free Survival in the Overall Population



	No. of Patients	Median Disease-free Survival
		mo (95% CI)
Nivolumab	532	22.4 (16.6–34.0)
Placebo	262	11.0 (8.3–14.3)

Hazard ratio for disease recurrence or death, 0.69 (96.4% CI, 0.56–0.86)
P<0.001

Kelly RJ et al. *N Engl J Med* 2021;384(13):1191-203.

Multicenter, Randomized Phase II Study of Neoadjuvant Pembrolizumab plus Chemotherapy and Chemoradiotherapy in Esophageal Adenocarcinoma (EAC)

Shah MA et al.
ASCO 2021;Abstract 4005.

Saturday, June 5, 1:45 PM - 4:45 PM EDT

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Oncologist 2021;26(1):e186-8.

The Oncologist®

Brief Communications

All in the Levels—Programmed Death-Ligand 1 Expression as a Biomarker for Immune Checkpoint Inhibitor Response in Patients with Gastrointestinal Cancer

Satya Das,[a] Sarah Cimino,[b] Shemeka Davis,[a] Kristen Ciombor[a]

Departments of [a]Hematology and Oncology and [b]Pharmaceutical Services, Vanderbilt University Medical Center, Nashville, Tennessee, USA

Oncologist 2020;25(8):669-79.

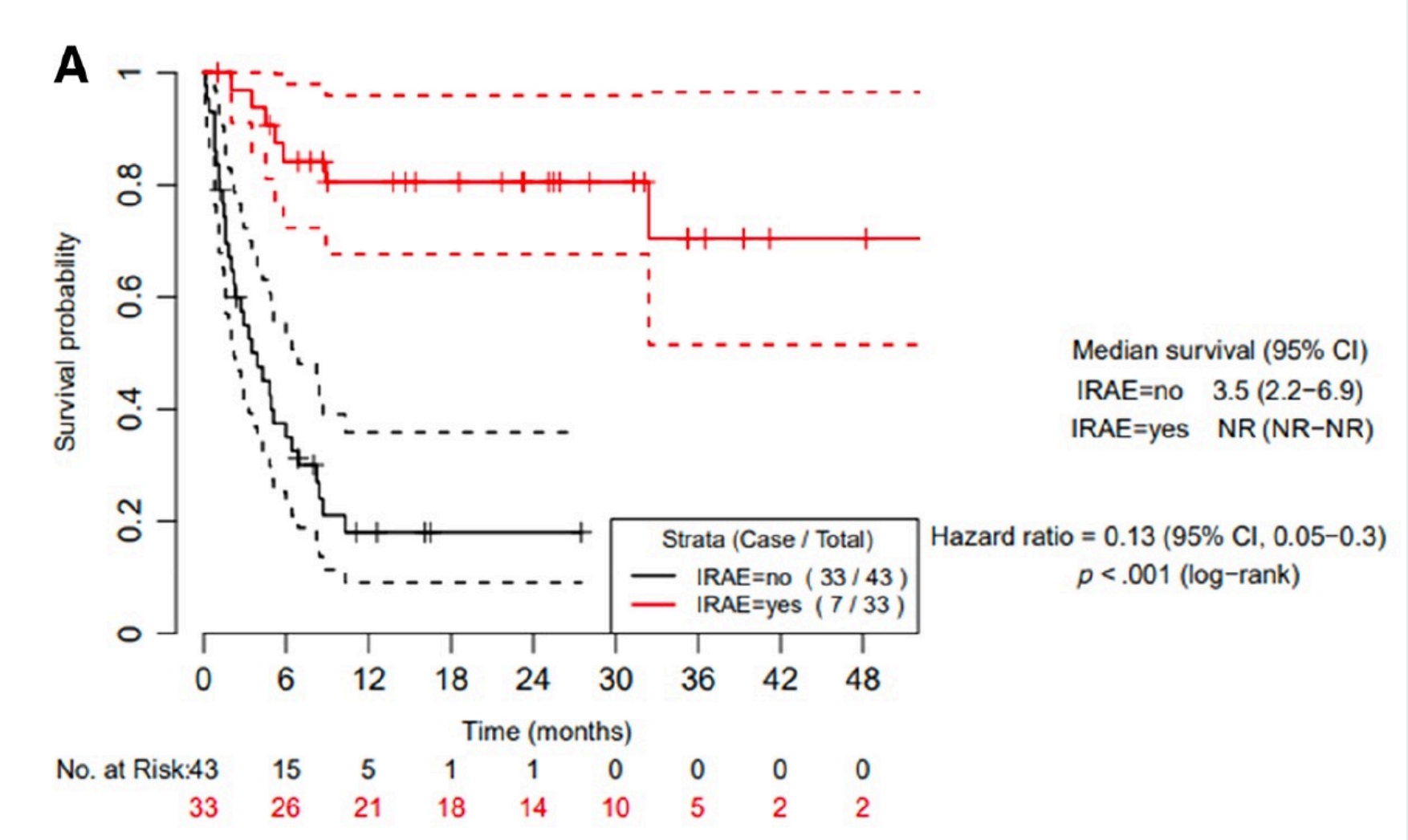
The Oncologist®

Gastrointestinal Cancer

Immune-Related Adverse Events and Immune Checkpoint Inhibitor Efficacy in Patients with Gastrointestinal Cancer with Food and Drug Administration-Approved Indications for Immunotherapy

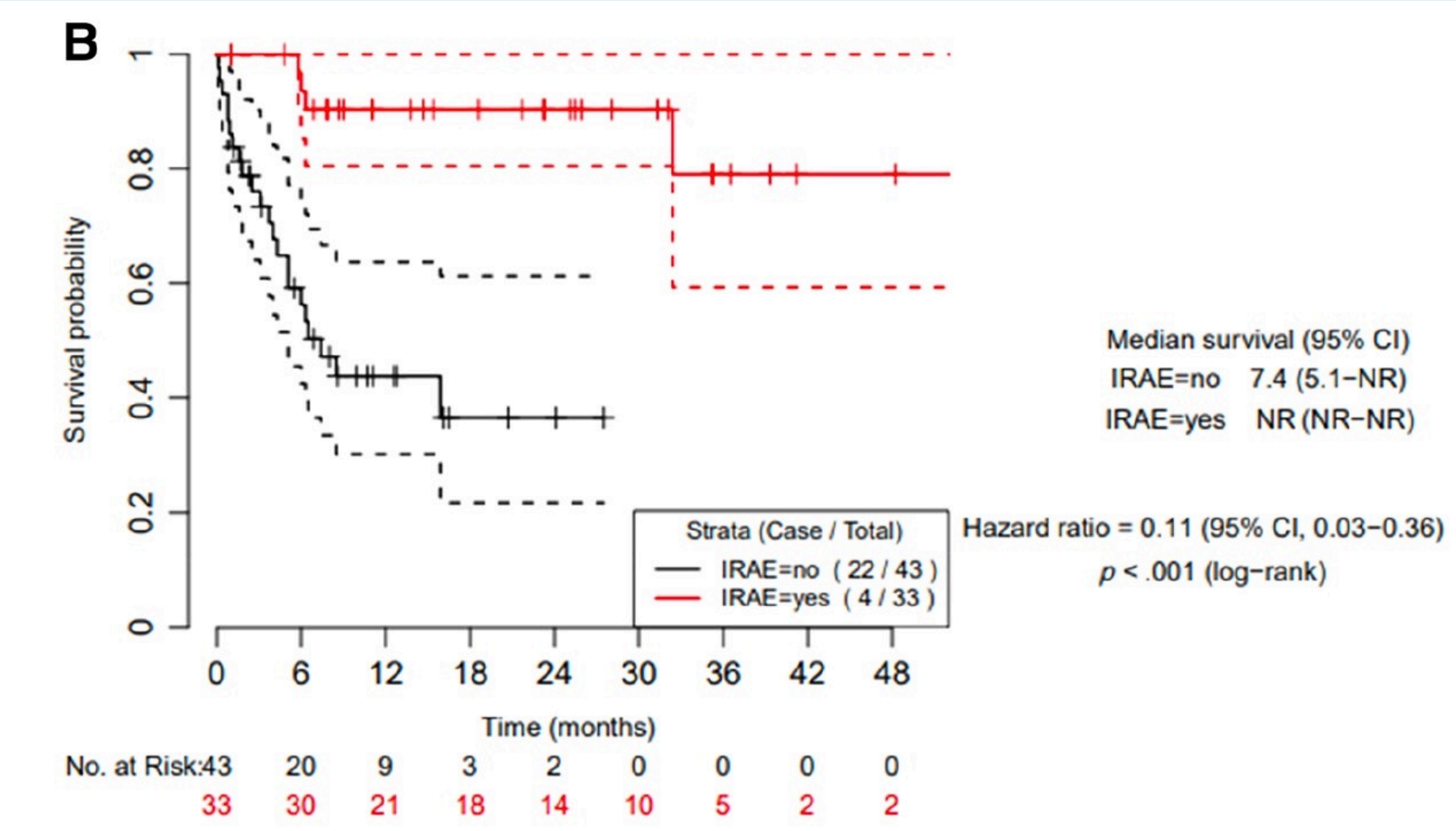
Satya Das,[a] Kristen K. Ciombor,[a] Sigurdis Haraldsdottir,[c] Yoanna Pumpalova,[d] Ibrahim H. Sahin,[e] G. Pineda,[c] Yu Shyr,[b] E.P. Lin,[b,f] Chih-Yuan Hsu,[b] Shih-Kai Chu,[b] Laura W. Goff,[a] Dana B. Cardin,[a] Mehmet A. Bilen,[e] George A. Fisher,[c] Christina Wu,[e] Jordan Berlin[a]

Progression-Free Survival for Patients Who Did and Did Not Experience IRAEs



Das S et al. *Oncologist* 2020;25(8):669-79.

Overall Survival for Patients Who Did and Did Not Experience IRAEs



Das S et al. *Oncologist* 2020;25(8):669-79.

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

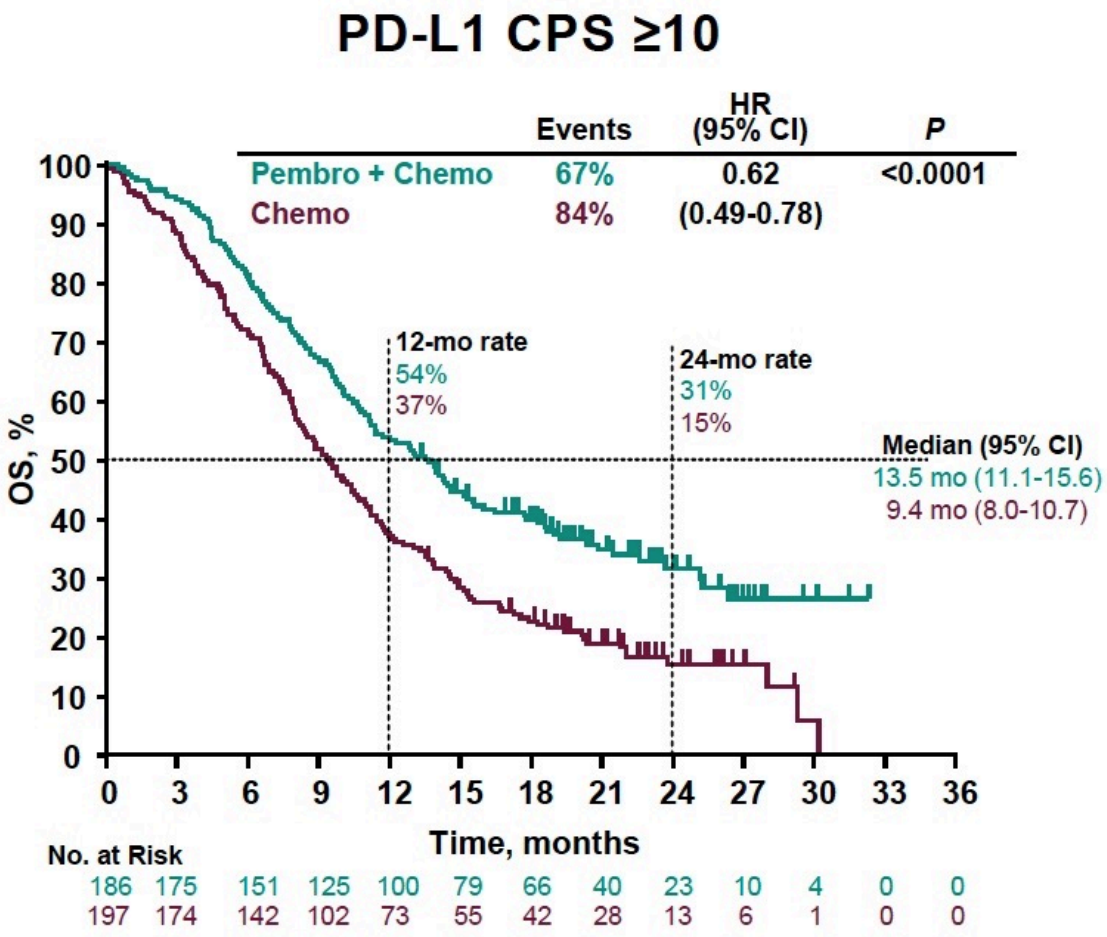
RTP RESEARCH TO PRACTICE

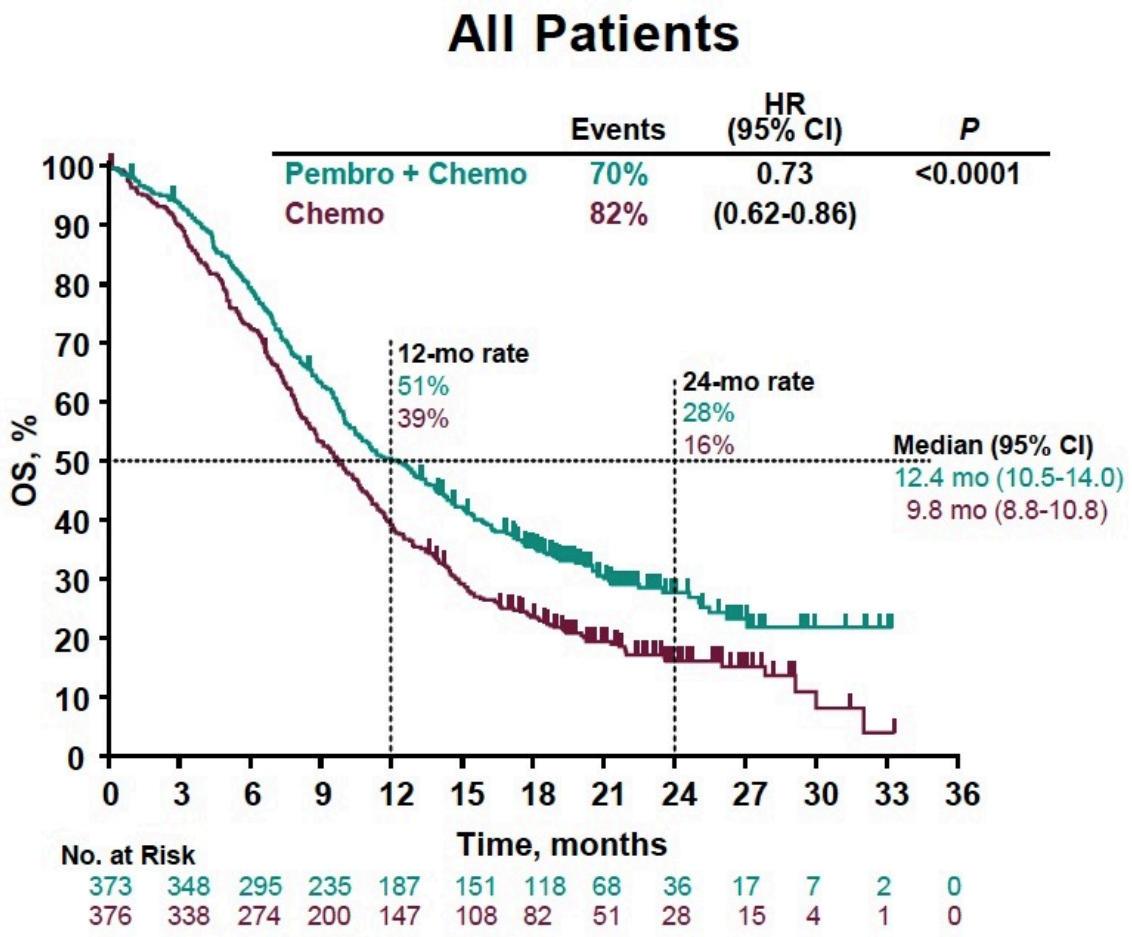
Pembrolizumab plus Chemotherapy versus Chemotherapy as First-Line Therapy in Patients with Advanced Esophageal Cancer: The Phase 3 KEYNOTE-590 Study

Kato K et al.

ESMO 2020;Abstract LBA8_PR.

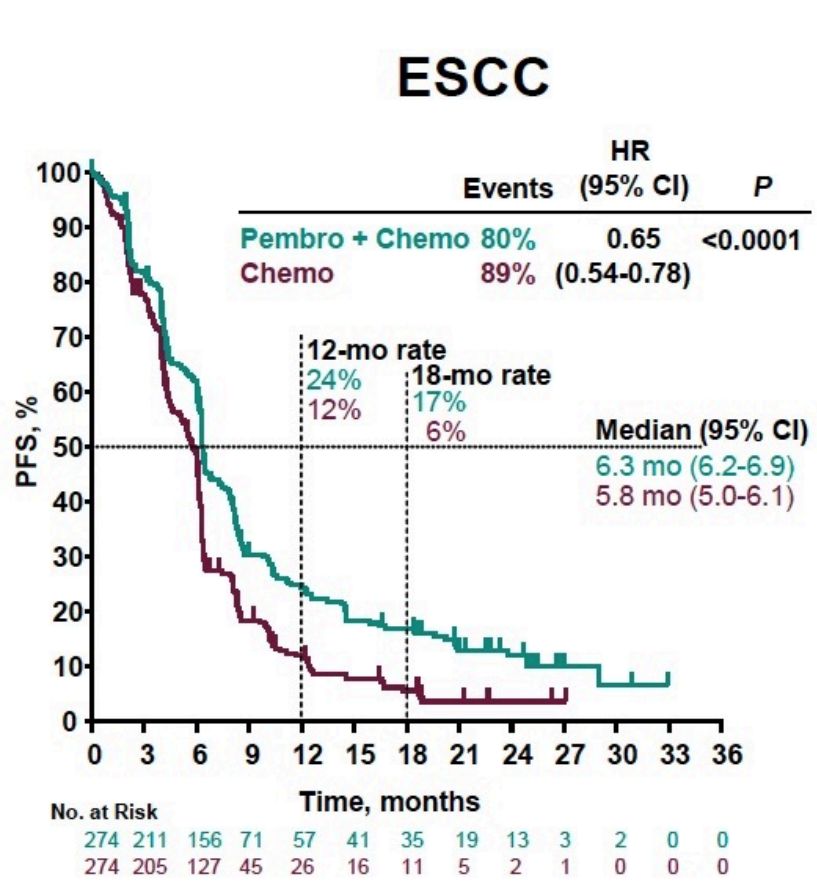
KEYNOTE-590: Overall Survival

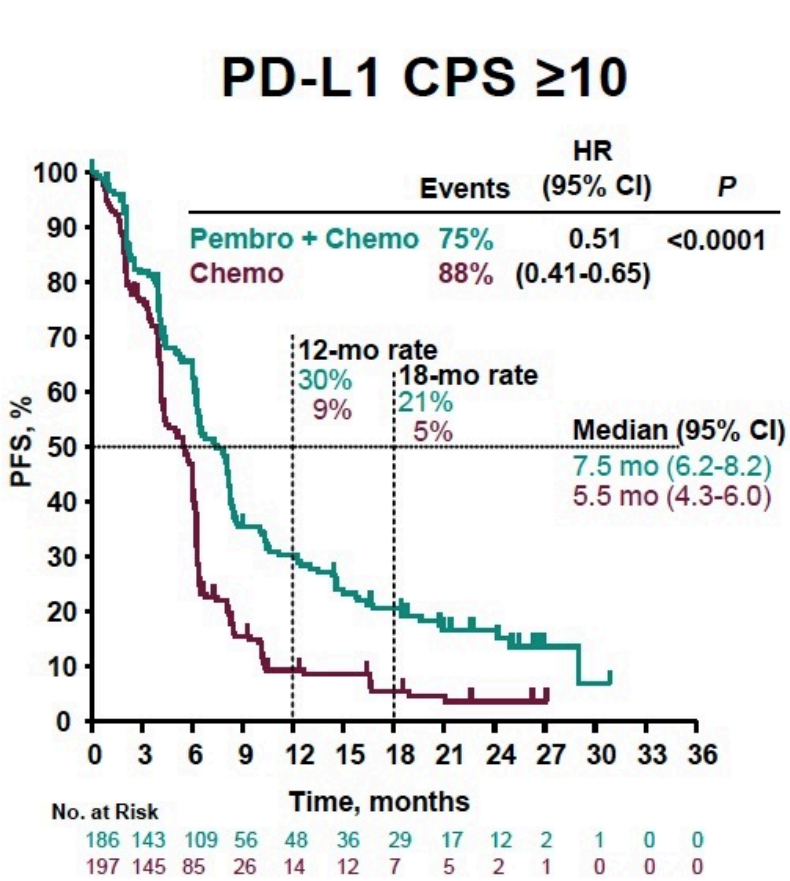


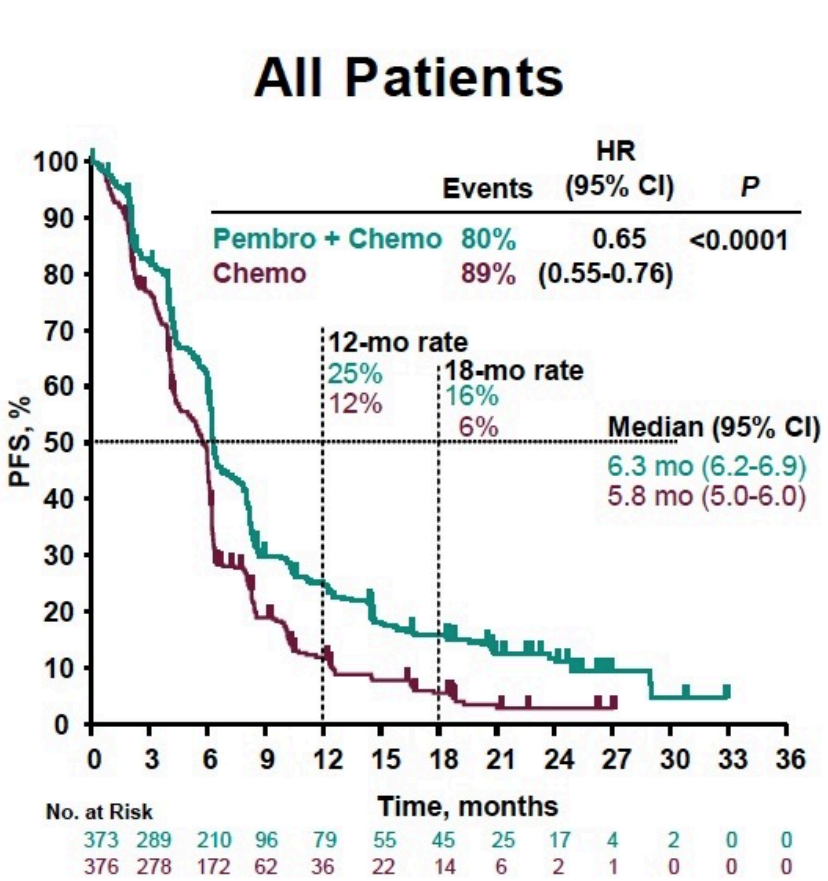


Kato K et al. ESMO 2020;Abstract LBA8_PR.

KEYNOTE-590: Progression-Free Survival







Kato K et al. ESMO 2020;Abstract LBA8_PR.

RTP RESEARCH TO PRACTICE

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=

RTP RESEARCH TO PRACTICE

First-Line (1L) Nivolumab (NIVO) plus Chemotherapy (Chemo) versus Chemo in Advanced Gastric Cancer/Gastroesophageal Junction Cancer/Esophageal Adenocarcinoma (GC/GEJC/EAC): Expanded Efficacy and Safety Data from CheckMate 649

Moehler MH et al.
ASCO 2021;Abstract 4002.

Saturday, June 5, 1:45 PM - 4:45 PM EDT

Nivolumab (NIVO) plus Ipilimumab (IPI) or NIVO plus Chemotherapy (Chemo) versus Chemo as First-Line (1L) Treatment for Advanced Esophageal Squamous Cell Carcinoma (ESCC): First Results of the CheckMate 648 Study

Chau I et al.
ASCO 2021;Abstract LBA4001.

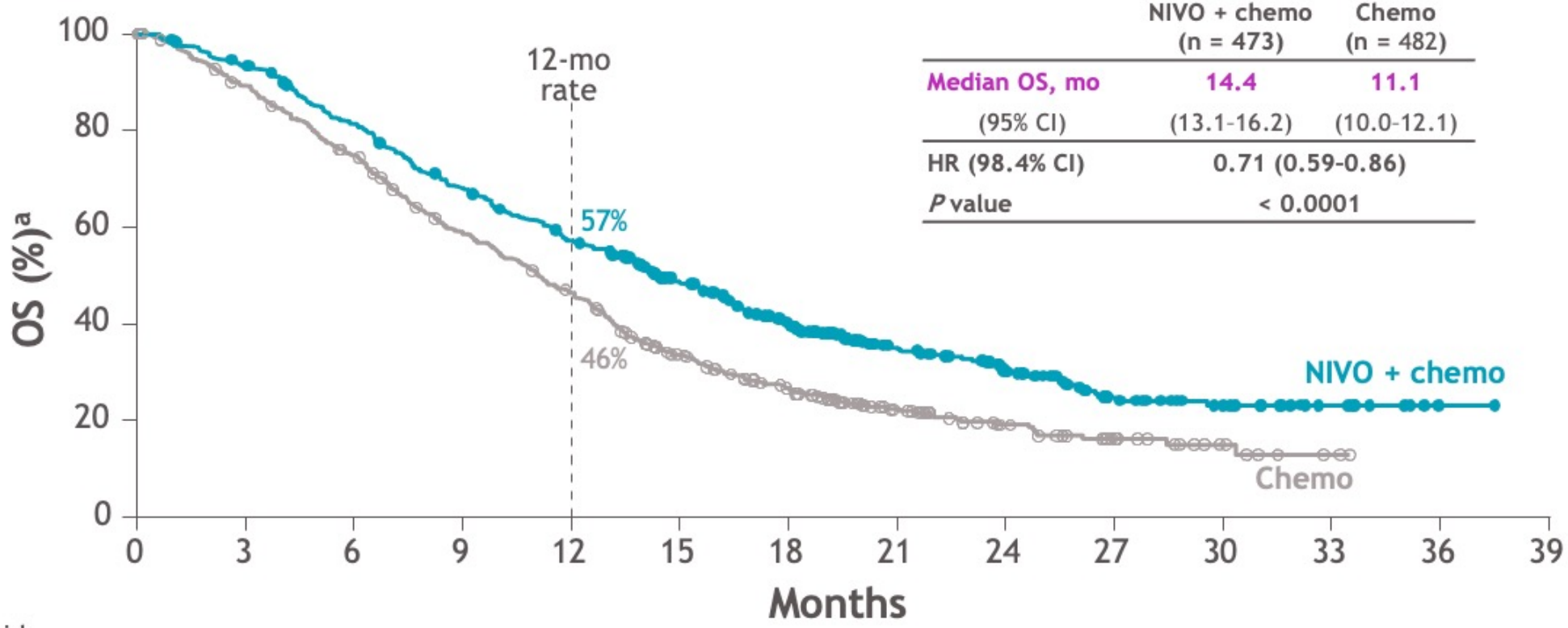
Saturday, June 5, 1:45 PM - 4:45 PM EDT

Nivolumab plus Chemotherapy versus Chemotherapy as First-Line Treatment for Advanced Gastric Cancer/Gastroesophageal Junction Cancer/Esophageal Adenocarcinoma: First Results of the CheckMate 649 Study

Moehler M et al.

ESMO 2020;Abstract LBA6.

CheckMate 649: Dual Primary Endpoint – OS (PD-L1 CPS ≥5)



	NIVO + chemo (n = 473)	Chemo (n = 482)
Median OS, mo	14.4	11.1
(95% CI)	(13.1-16.2)	(10.0-12.1)
HR (98.4% CI)	0.71 (0.59-0.86)	
P value	< 0.0001	

No. at risk														
NIVO + chemo	473	438	377	313	261	198	149	96	65	33	22	9	1	0
Chemo	482	421	350	271	211	138	98	56	34	19	8	2	0	0

- Superior OS, 29% reduction in the risk of death, and a 3.3-month improvement in median OS with NIVO + chemo versus chemo in patients whose tumors expressed PD-L1 CPS ≥ 5

[a]Minimum follow-up 12.1 months.

Moehler M et al. ESMO 2020;Abstract LBA6.

RTP RESEARCH TO PRACTICE

Cancers (Basel) 2020;12(10):2985.

cancers

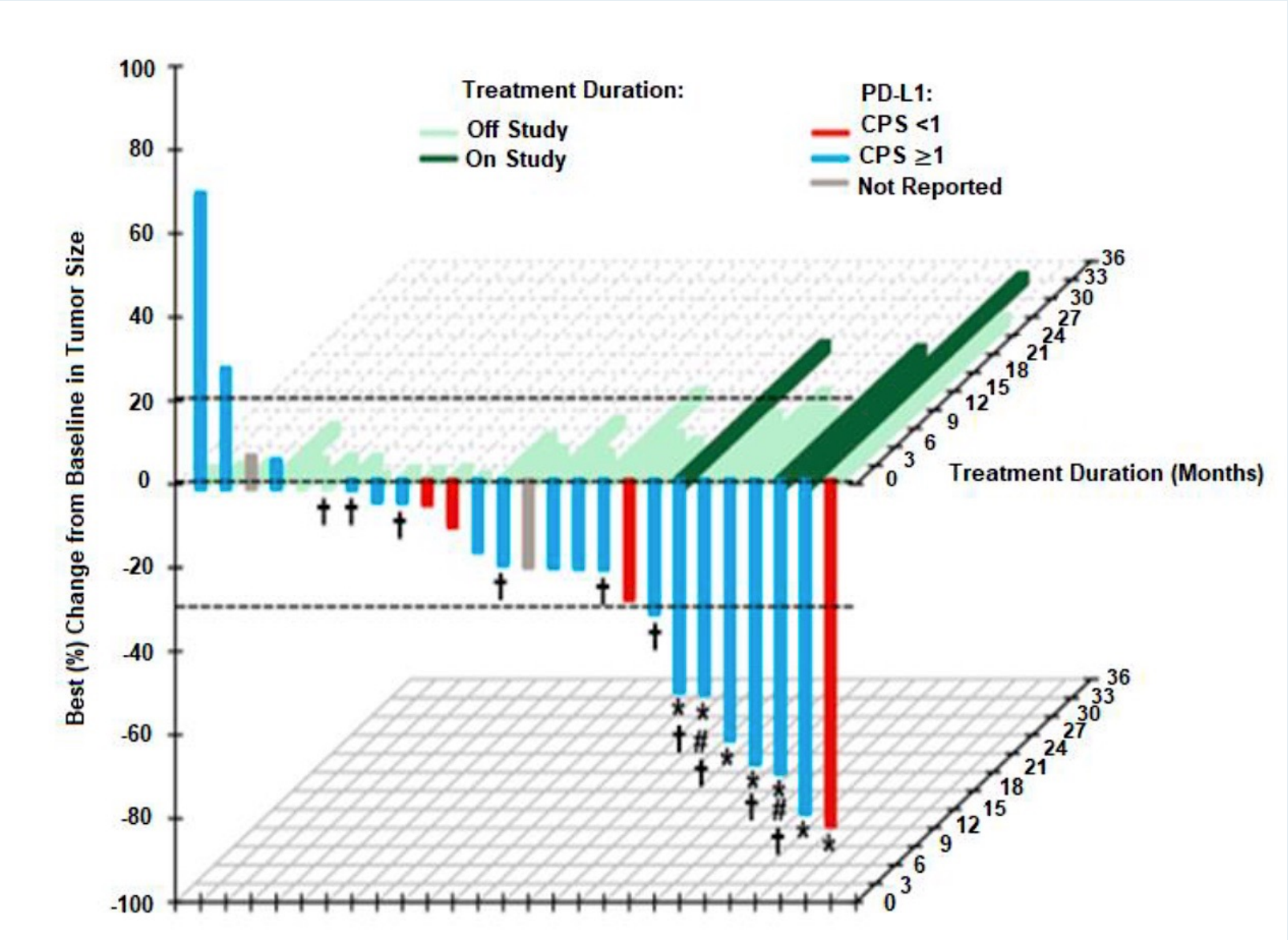
MDPI

Article

Ramucirumab in Combination with Pembrolizumab in Treatment-Naïve Advanced Gastric or GEJ Adenocarcinoma: Safety and Antitumor Activity from the Phase 1a/b JVDF Trial

Ian Chau [1,*], Nicolas Penel [2], Andres O. Soriano [3], Hendrik-Tobias Arkenau [4], Jennifer Cultrera [5], Rafael Santana-Davila [6], Emiliano Calvo [7], Christophe Le Tourneau [8], Lars Zender [9], Johanna C. Bendell [10], Gu Mi [11], Ling Gao [11], Samuel Clark McNeely [11], Joana M. Oliveira [12], David Ferry [12], Roy S. Herbst [13] and Charles S. Fuchs [13,14]

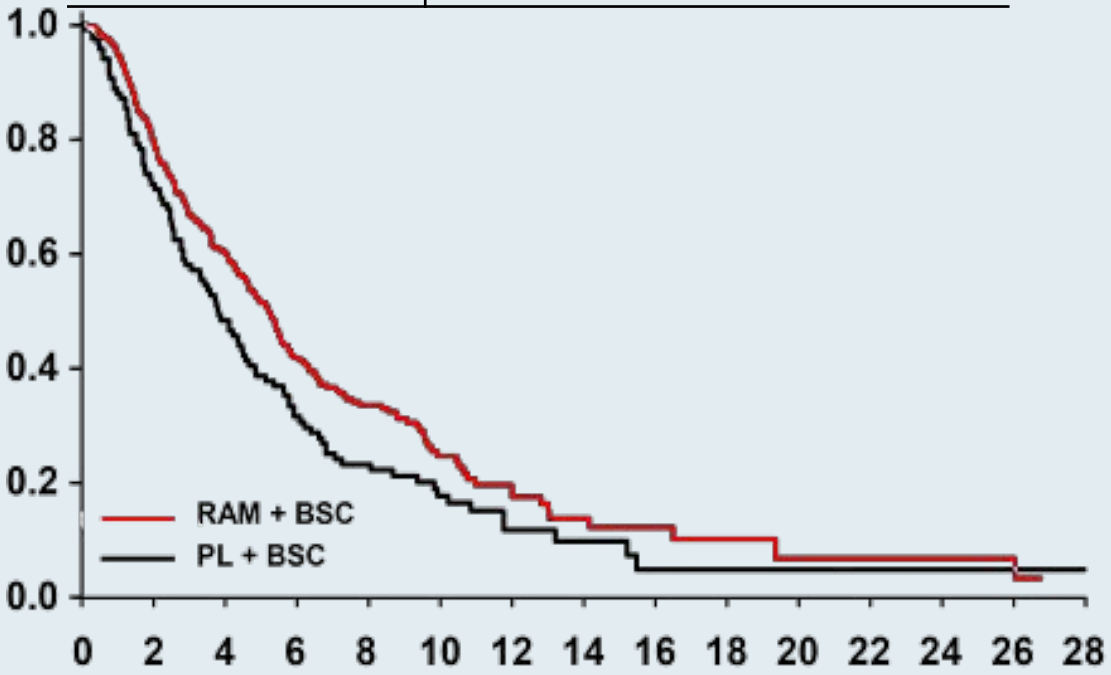
Best Percentage Change of Targeted Lesions from Baseline versus Treatment Duration



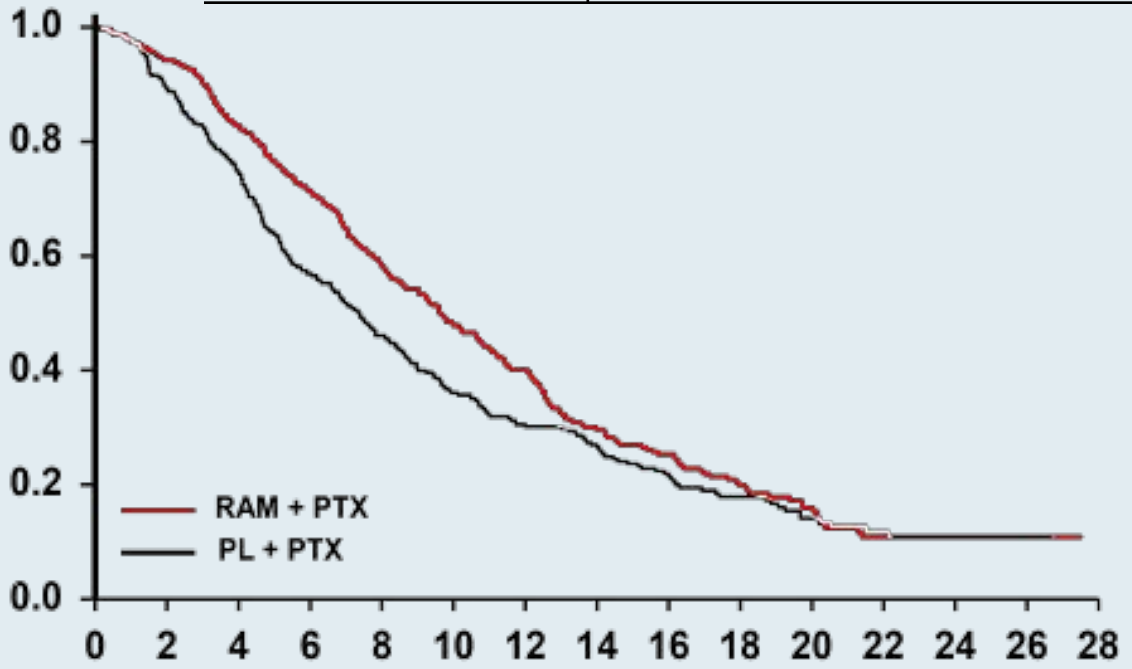
Chau I et al. *Cancers (Basel)* 2020;12(10):2985.

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)**		



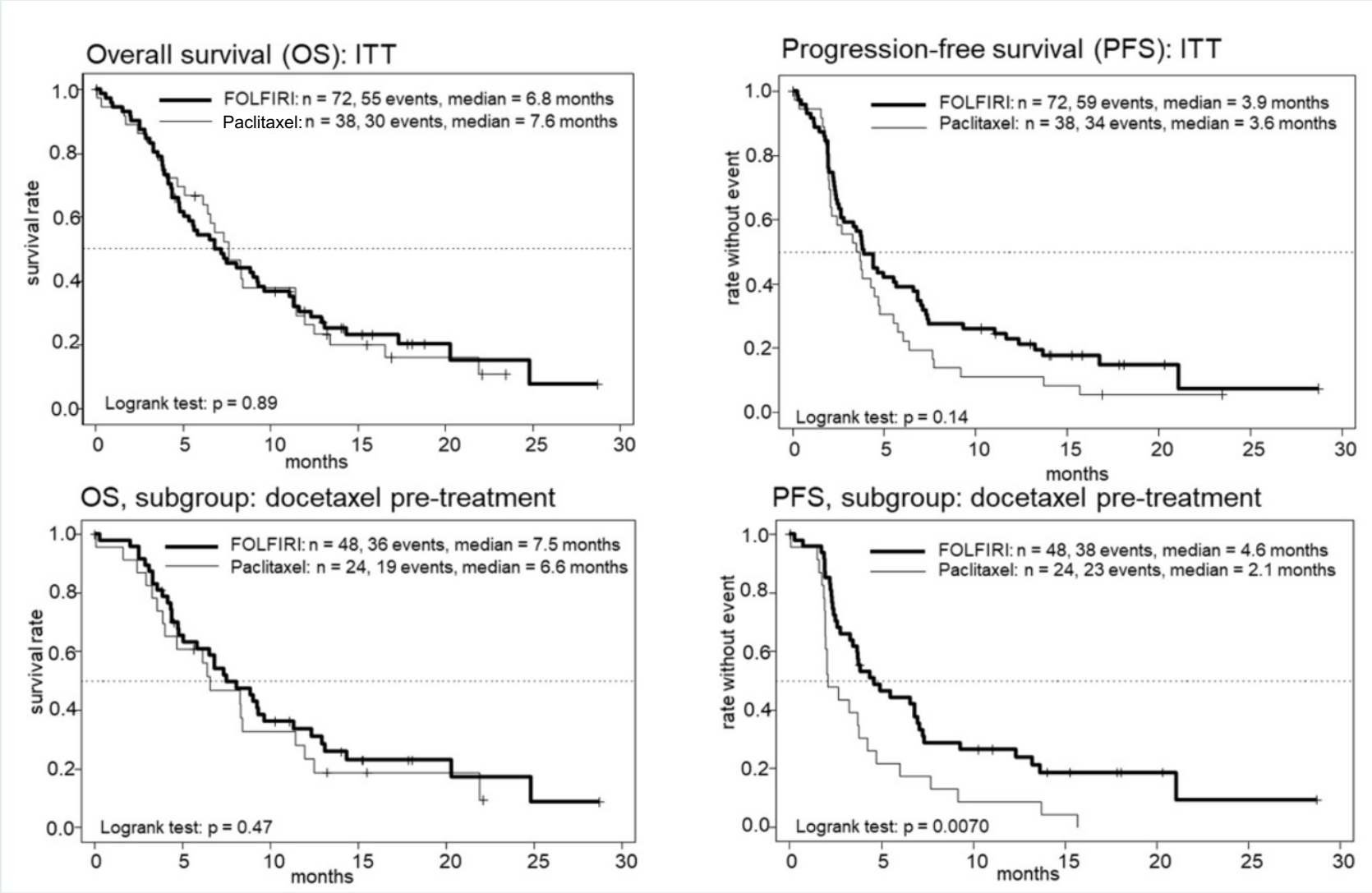
RAINBOW[2] OS	RAM	Placebo	*p*-value
Median (mo)	**9.6**	**7.4**	**0.017**
HR (95% CI)	**0.807 (0.678-0.962)**		



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 plus FOLFIRI – Patients with Advanced or Metastatic Gastroesophageal Adenocarcinoma with or without Prior Docetaxel



Lorenzen S et al. ASCO 2020;Abstract 4514.

FDA Approves Trastuzumab Deruxtecan for HER2-Positive Gastric Adenocarcinomas

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

The NEW ENGLAND JOURNAL of MEDICINE

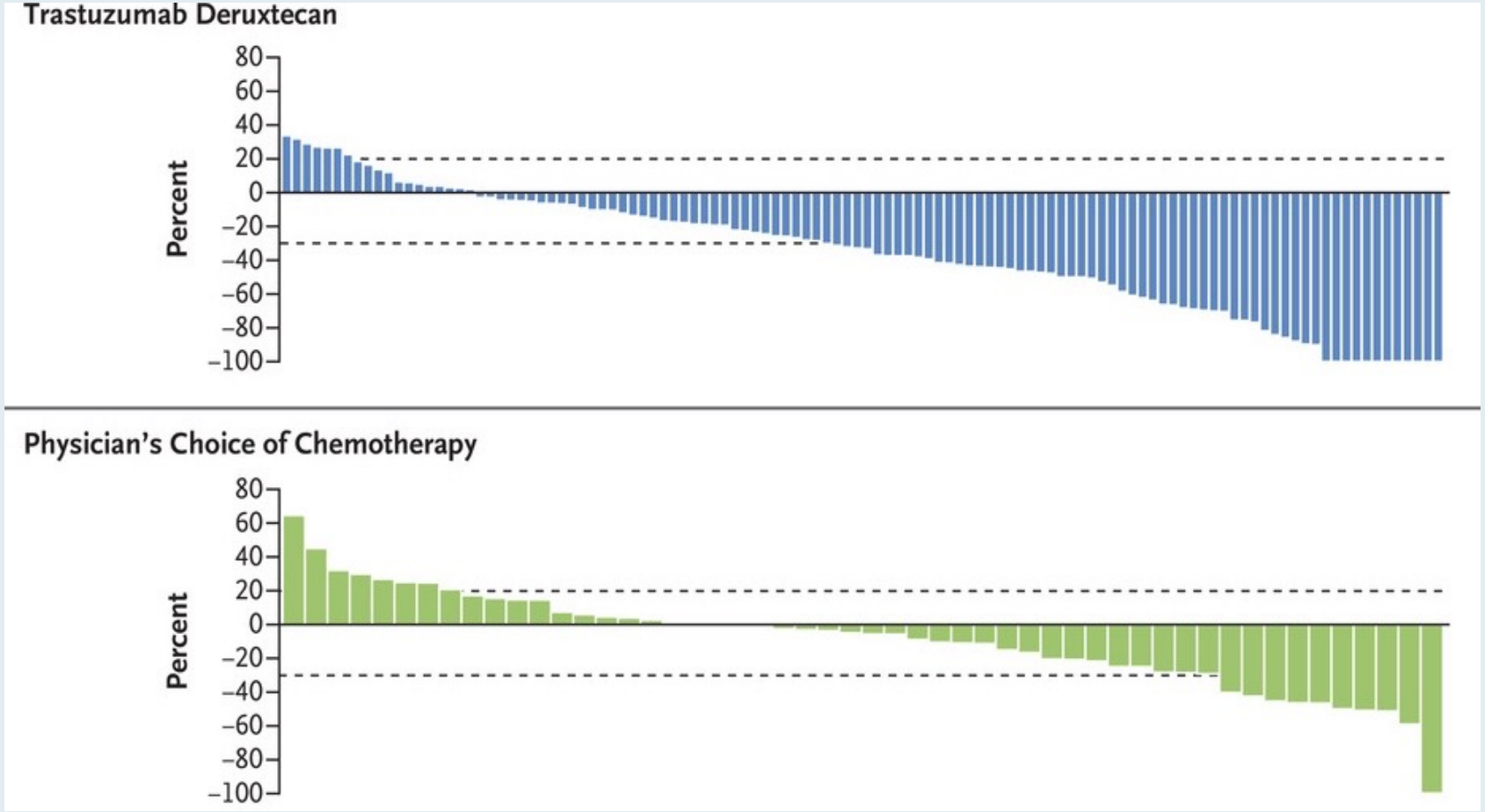
ORIGINAL ARTICLE

Trastuzumab Deruxtecan in Previously Treated HER2-Positive Gastric Cancer

K. Shitara, Y.-J. Bang, S. Iwasa, N. Sugimoto, M.-H. Ryu, D. Sakai, H.-C. Chung, H. Kawakami, H. Yabusaki, J. Lee, K. Saito, Y. Kawaguchi, T. Kamio, A. Kojima, M. Sugihara, and K. Yamaguchi, for the DESTINY-Gastric01 Investigators*

***N Engl J Med* 2020;382(25):2419-30.**

DESTINY-Gastric01:Trastuzumab Deruxtecan in Previously Treated HER2-Positive Gastric Cancer



	T-DXd (n = 119)	PC (n = 56)
ORR	**51%**	**14%**
Confirmed ORR	**43%**	**12%**
CR	8%	0%
PR	34%	12%

Shitara K et al. *N Engl J Med* 2020;382(25):2419-30.

RTP RESEARCH TO PRACTICE

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.

DESTINY-Gastric01: Select Adverse Events

Adverse event	Trastuzumab deruxtecan (n = 125)			Physician's choice of chemo (n = 62)		
	Any grade	Grade 3	Grade 4	Any grade	Grade 3	Grade 4
Neutrophil count decreased	63%	38%	13%	35%	16%	8%
Anemia	58%	38%	0	31%	21%	2%
Platelet count decreased	39%	10%	2%	6%	2%	2%
White cell count decreased	38%	21%	0	35%	8%	3%
Fatigue	22%	7%	0	24%	3%	0
Lymphocyte count decreased	22%	6%	5%	3%	0	2%

- A total of 12 patients (10%) in the trastuzumab deruxtecan group had drug-related interstitial lung disease or pneumonitis compared to 0 patients in the physician's choice group
- 1 drug-related death (pneumonia) occurred in the trastuzumab deruxtecan group

Shitara K et al. *N Engl J Med* 2020;382(25):2419-30.

FDA Grants Accelerated Approval to Pembrolizumab with Trastuzumab and Chemotherapy as First-Line Therapy for HER2-Positive Gastric Cancer

Press Release – May 5, 2021

"On May 5, 2021, the Food and Drug Administration granted accelerated approval to pembrolizumab in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.

Approval was based on the prespecified interim analysis of the first 264 patients of the ongoing KEYNOTE-811 (NCT03615326) trial, a multicenter, randomized, double-blind, placebo-controlled trial in patients with HER2-positive advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma who had not previously received systemic therapy for metastatic disease. Patients were randomized (1:1) to receive pembrolizumab 200 mg or placebo every 3 weeks, in combination with trastuzumab and either fluorouracil plus cisplatin or capecitabine plus oxaliplatin.

The main efficacy measure for this analysis was overall response rate (ORR) assessed by blinded independent review committee. The ORR was 74% in the pembrolizumab arm and 52% in the placebo arm (one-sided p-value < 0.0001, statistically significant). The median duration of response (DoR) was 10.6 months for patients treated with pembrolizumab and 9.5 months for those in the placebo arm."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-pembrolizumab-her2-positive-gastric-cancer

RTP RESEARCH TO PRACTICE

Meet The Professor with Dr Ciombor

MODULE 1: Cases from Drs Gosain and Yang

- Dr Gosain: A 59-year-old man with metastatic colon cancer – RAS and BRAF wild type, MSS
- Dr Yang: A 66-year-old woman with metastatic colon cancer – BRAF V600E mutation, high MSI

MODULE 2: Beyond the Guidelines; Key Data – Colorectal Cancer

MODULE 3: Cases from Drs Matt-Amaral and Rupard

- Dr Matt-Amaral: A 72-year-old man with metastatic HER2-positive GEJ adenocarcinoma – Microsatellite stable (MSS), PD-L1 CPS 1
- Dr Rupard: A 43-year-old woman with metastatic gastroesophageal adenocarcinoma and a history of ALL and melanoma

MODULE 4: Beyond the Guidelines; Key Data – Gastroesophageal Cancers

MODULE 5: Case from Drs Dayyani and Choksi

- Dr Dayyani: An 81-year-old man with recurrent, unresectable Child-Pugh A hepatocellular carcinoma (HCC)
- Dr Choksi: A 63-year-old woman with recurrent Child-Pugh B HCC with liver cirrhosis and elevated AFP

MODULE 6: Beyond the Guidelines; Key Data – Hepatocellular Carcinoma

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Case Presentation – Dr Dayyani: An 81-year-old man with recurrent, unresectable Child-Pugh A HCC

Dr Farshid Dayyani

- 2018: Resection of primary HCC
  - PMH: BPH, PAF, chronic left sciatica, gallstone pancreatitis – s/p cholecystectomy
- 2019: 3 recurrences followed by TACE after each recurrence
  - Imaging demonstrates at least 3 viable remaining lesions in the liver
- Enrolled in clinical trial of tivozanib with durvalumab → Stable disease for 1 year
  - Grade 1 diarrhea managed with loperamide
- PD in liver only – AFP is not elevated, no known varices

Question

- What would you recommend as second-line therapy for this patient?

Case Presentation – Dr Dayyani: An 81-year-old man with recurrent, unresectable Child-Pugh A HCC (continued)

Dr Farshid Dayyani

- 2018: Resection of primary HCC
  - PMH: BPH, PAF, chronic left sciatica, gallstone pancreatitis – s/p cholecystectomy
- 2019: 3 recurrences followed by TACE after each recurrence
  - Imaging demonstrates at least 3 viable remaining lesions in the liver
- Enrolled in clinical trial of tivozanib with durvalumab → Stable disease for 1 year
  - Grade 1 diarrhea managed with loperamide
- PD in liver only – AFP is not elevated, no known varices
- ***Atezolizumab/bevacizumab administered, patient tolerating well***

Case Presentation – Dr Choksi: A 63-year-old woman with recurrent Child-Pugh B HCC with liver cirrhosis and elevated AFP

Dr Mamta Choksi

- 2017: Initial diagnosis of HCC treated with radiofrequency ablation as her tumor was deemed unresectable due to liver cirrhosis and underlying hemochromatosis
- October 2020: Restaging workup reveals 2 liver lesions and elevated alpha-fetoprotein; radiofrequency ablation repeated
- Liver function tests, creatinine and renal panel showed worsened results post-procedure

Question

- What would you recommend next for this patient?

Meet The Professor with Dr Ciombor

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- Dr Choksi: A 63-year-old woman with recurrent Child-Pugh B HCC with liver cirrhosis and elevated AFP

MODULE 6: Beyond the Guidelines; Key Data – Hepatocellular Carcinoma

RTP RESEARCH TO PRACTICE

What would be your current preferred first-line systemic treatment for a 65-year-old patient with HCC, a Child-Pugh B7 score and PS 1?

1. Sorafenib
2. Lenvatinib
3. Atezolizumab/bevacizumab
4. Chemotherapy
5. Other

What would be your current preferred first-line systemic treatment for a 65-year-old patient with HCC, a Child-Pugh B7 score and a PS of 1?

 Prof Arnold	Atezolizumab/ bevacizumab	 Dr Ciombor	Sorafenib
 Dr Bekaii-Saab	Atezolizumab/ bevacizumab	 Dr O'Reilly	Lenvatinib
 Dr Bendell	Atezolizumab/ bevacizumab	 Dr Venook	Atezolizumab/ bevacizumab
 Dr Catenacci	Atezolizumab/ bevacizumab	 Dr Wainberg	Lenvatinib

RTP RESEARCH TO PRACTICE

What would be your most likely second-line systemic therapy for a 65-year-old patient with HCC, a Child-Pugh A score and a PS of 0 who received first-line atezolizumab/bevacizumab with minimal toxicity, had stable disease for 14 months and then experienced disease progression (alpha-fetoprotein, AFP, 2,500 ng/mL)?

 Prof Arnold	Cabozantinib	 Dr Ciombor	Sorafenib
 Dr Bekaii-Saab	Cabozantinib	 Dr O'Reilly	Lenvatinib
 Dr Bendell	Cabozantinib	 Dr Venook	Lenvatinib
 Dr Catenacci	Lenvatinib	 Dr Wainberg	Ramucirumab

RTP RESEARCH TO PRACTICE

What would be your most likely second-line systemic therapy for a 65-year-old patient with HCC, a Child-Pugh A score and a PS of 0 who received first-line standard-dose sorafenib with minimal toxicity, had stable disease for 14 months and then experienced disease progression (AFP 2,500 ng/mL)?

 Prof Arnold	Nivolumab	 Dr Ciombor	Atezolizumab/ bevacizumab
 Dr Bekaii-Saab	Atezolizumab/ bevacizumab	 Dr O'Reilly	Nivolumab/ ipilimumab
 Dr Bendell	Atezolizumab/ bevacizumab	 Dr Venook	Atezolizumab/ bevacizumab
 Dr Catenacci	Atezolizumab/ bevacizumab	 Dr Wainberg	Ramucirumab

RTP RESEARCH TO PRACTICE

What would be your most likely third-line systemic therapy recommendation for an otherwise healthy 65-year-old patient with HCC who experienced disease progression on first-line atezolizumab/bevacizumab and second-line lenvatinib (AFP 2,500 ng/mL)?

 Prof Arnold	Ramucirumab	 Dr Ciombor	Ramucirumab
 Dr Bekaii-Saab	Cabozantinib	 Dr O'Reilly	Nivolumab/ ipilimumab
 Dr Bendell	Cabozantinib	 Dr Venook	Cabozantinib
 Dr Catenacci	Ramucirumab	 Dr Wainberg	Ramucirumab

RTP RESEARCH TO PRACTICE

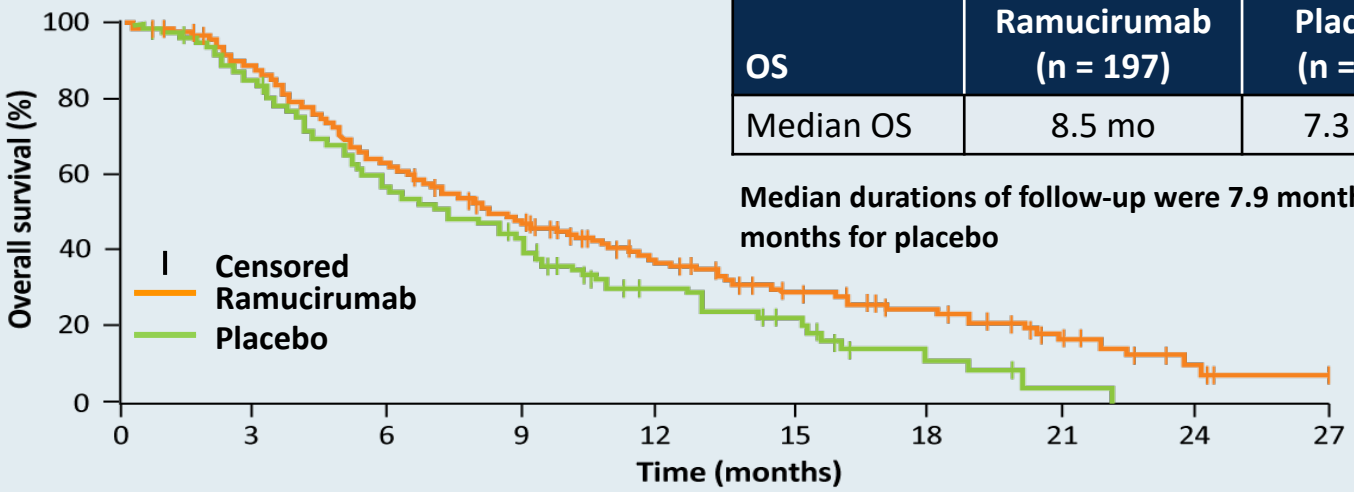
Articles

Ramucirumab after sorafenib in patients with advanced hepatocellular carcinoma and increased α-fetoprotein concentrations (REACH-2): a randomised, double-blind, placebo-controlled, phase 3 trial

*Andrew X Zhu, Yoon-Koo Kang, Chia-Jui Yen, Richard S Finn, Peter R Galle, Josep M Llovet, Eric Assenat, Giovanni Brandi, Marc Pracht, Ho Yeong Lim, Kun-Ming Rau, Kenta Motomura, Izumi Ohno, Philippe Merle, Bruno Daniele, Dong Bok Shin, Guido Gerken, Christophe Borg, Jean-Baptiste Hiriart, Takuji Okusaka, Manabu Morimoto, Yanzhi Hsu, Paolo B Abada, Masatoshi Kudo, for the REACH-2 study investigators**

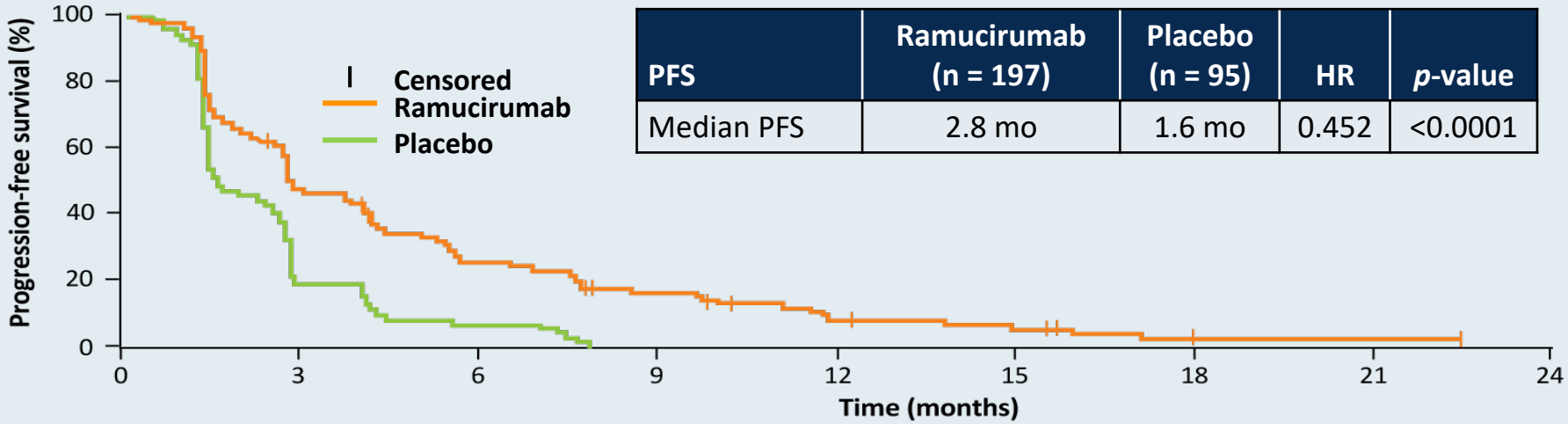
Lancet Oncol 2019;20(2):282-96.

REACH-2: A Phase III Trial of Ramucirumab After Sorafenib for Patients with Advanced HCC and Increased AFP



OS	Ramucirumab (n = 197)	Placebo (n = 95)	HR	*p*-value
Median OS	8.5 mo	7.3 mo	0.710	0.0199

Median durations of follow-up were 7.9 months for ramucirumab, 6.6 months for placebo



PFS	Ramucirumab (n = 197)	Placebo (n = 95)	HR	*p*-value
Median PFS	2.8 mo	1.6 mo	0.452	<0.0001

Grade ≥3 AEs associated with ramucirumab included hypertension and hyponatremia.

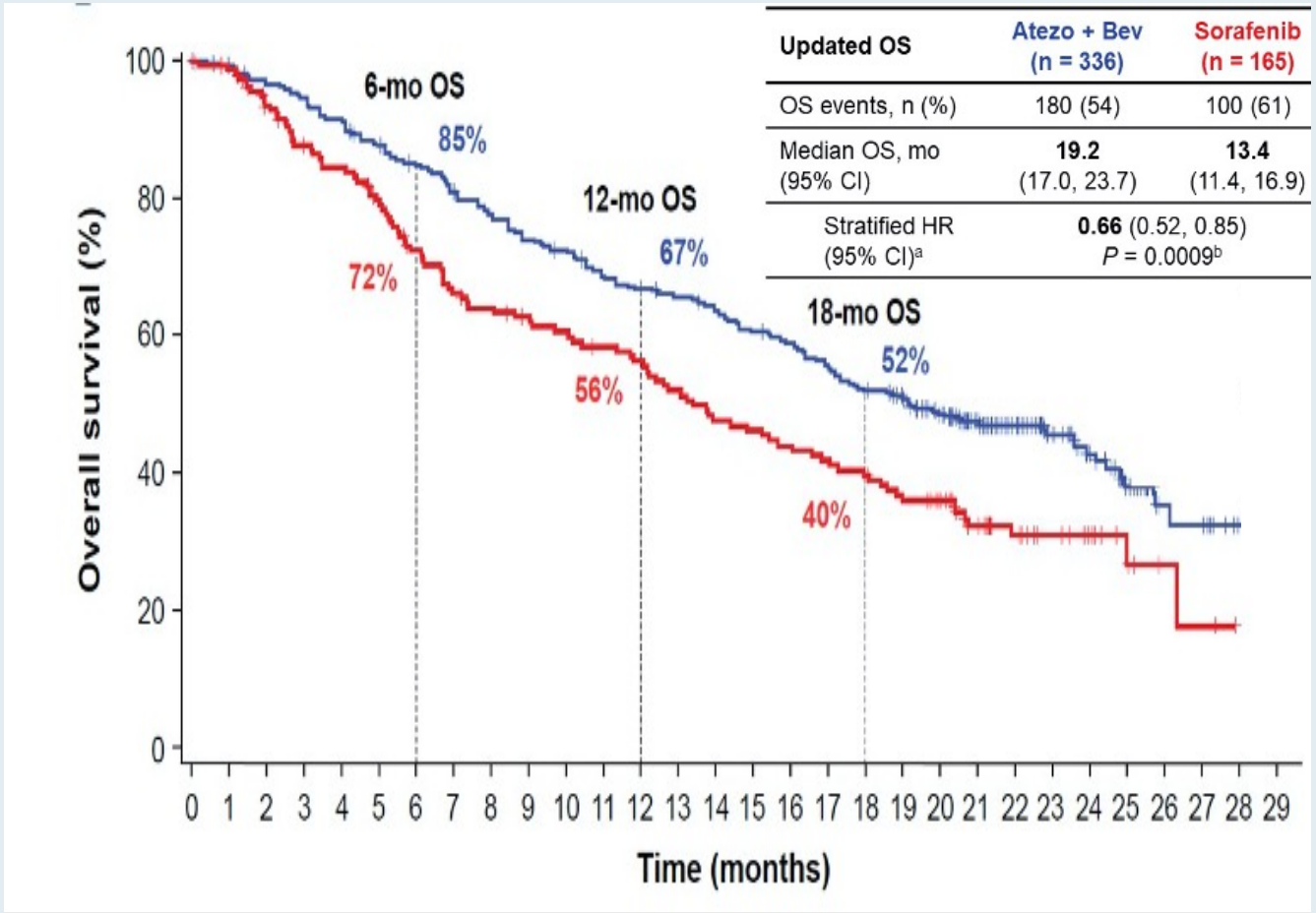
Zhu AX et al. ASCO 2018;Abstract 4003; *Lancet Oncol* 2019;20(2):282-96.

IMbrave150: Updated Overall Survival (OS) Data from a Global, Randomized, Open-Label Phase III Study of Atezolizumab (atezo) + Bevacizumab (bev) versus Sorafenib (sor) in Patients (pts) with Unresectable Hepatocellular Carcinoma (HCC)

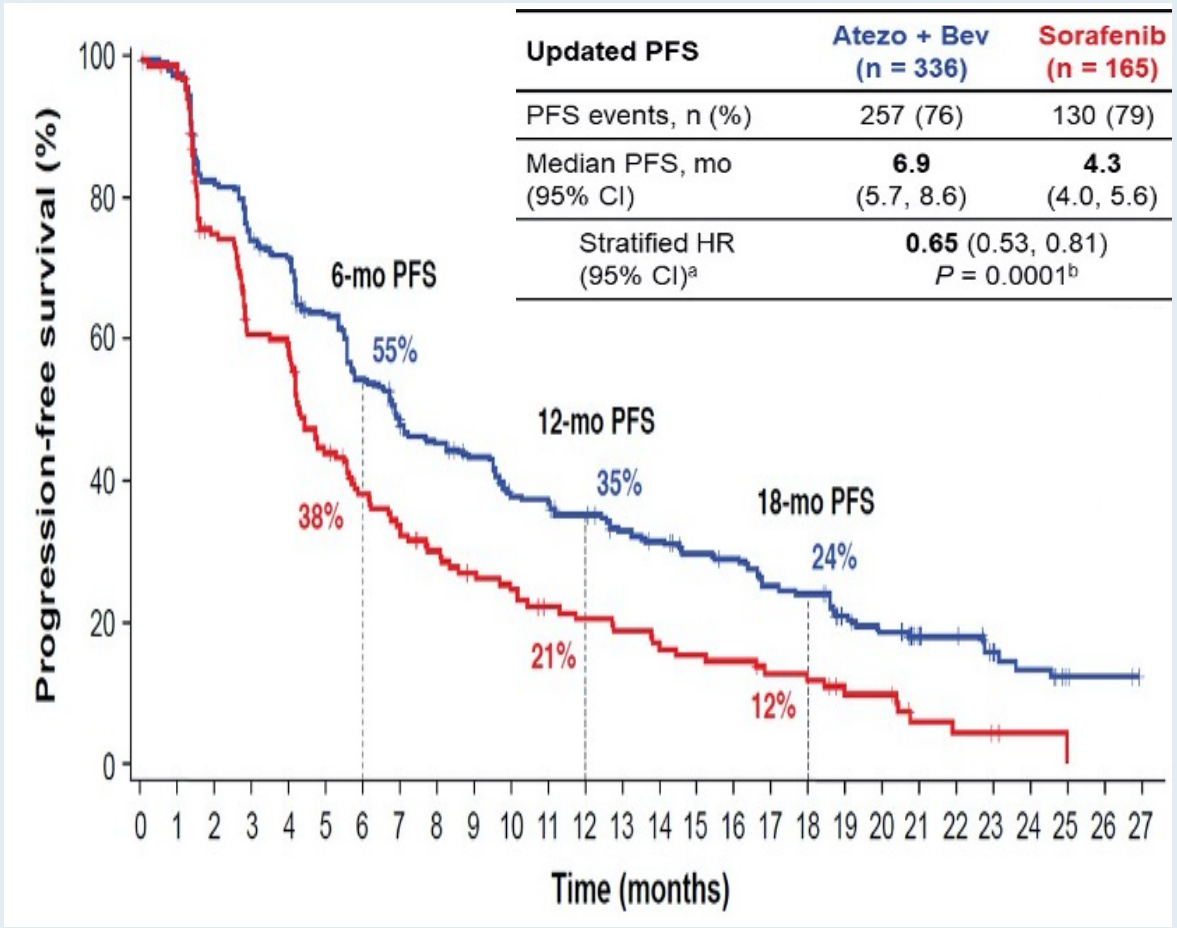
Finn RS et al.

Gastrointestinal Cancers Symposium 2021;Abstract 267.

IMbrave150: Updated OS and PFS (Median Follow-Up = 15.6 Months)



Updated OS	Atezo + Bev (n = 336)	Sorafenib (n = 165)
OS events, n (%)	180 (54)	100 (61)
Median OS, mo (95% CI)	**19.2** (17.0, 23.7)	**13.4** (11.4, 16.9)
Stratified HR (95% CI)[a]	**0.66** (0.52, 0.85) *P* = 0.0009[b]	



Updated PFS	Atezo + Bev (n = 336)	Sorafenib (n = 165)
PFS events, n (%)	257 (76)	130 (79)
Median PFS, mo (95% CI)	**6.9** (5.7, 8.6)	**4.3** (4.0, 5.6)
Stratified HR (95% CI)[a]	**0.65** (0.53, 0.81) *P* = 0.0001[b]	

Finn RS et al. Gastrointestinal Cancers Symposium 2021;Abstract 267.

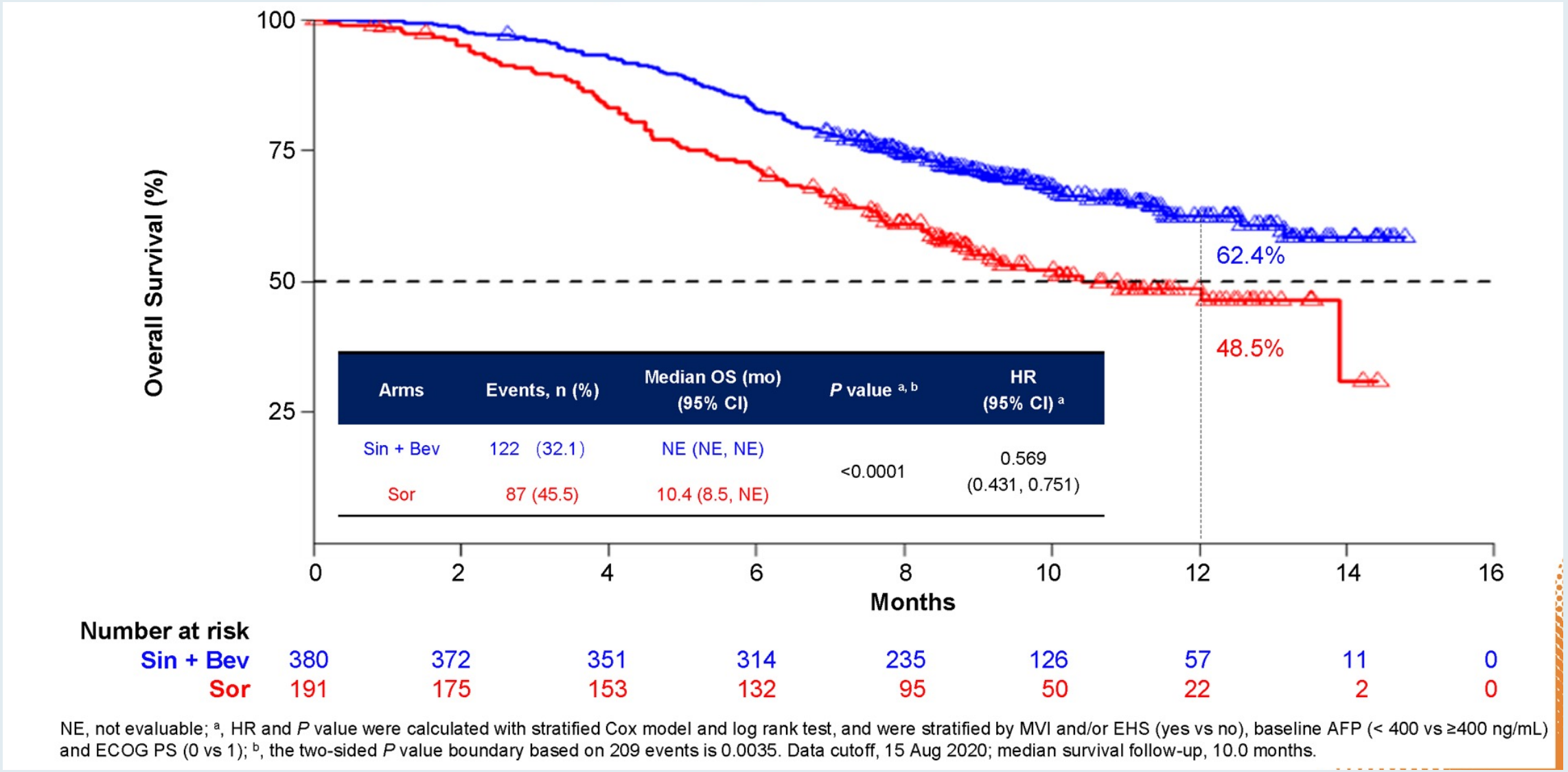
RTP RESEARCH TO PRACTICE

Sintilimab plus Bevacizumab Biosimilar vs Sorafenib as First-Line Treatment for Advanced Hepatocellular Carcinoma (ORIENT-32)

Ren Z et al.

ESMO Asia 2020;Abstract LBA2.

ORIENT-32 Coprimary Endpoint: Overall Survival



Arms	Events, n (%)	Median OS (mo) (95% CI)	*P* value [a, b]	HR (95% CI) [a]
Sin + Bev	122 (32.1)	NE (NE, NE)	<0.0001	0.569 (0.431, 0.751)
Sor	87 (45.5)	10.4 (8.5, NE)		

Number at risk

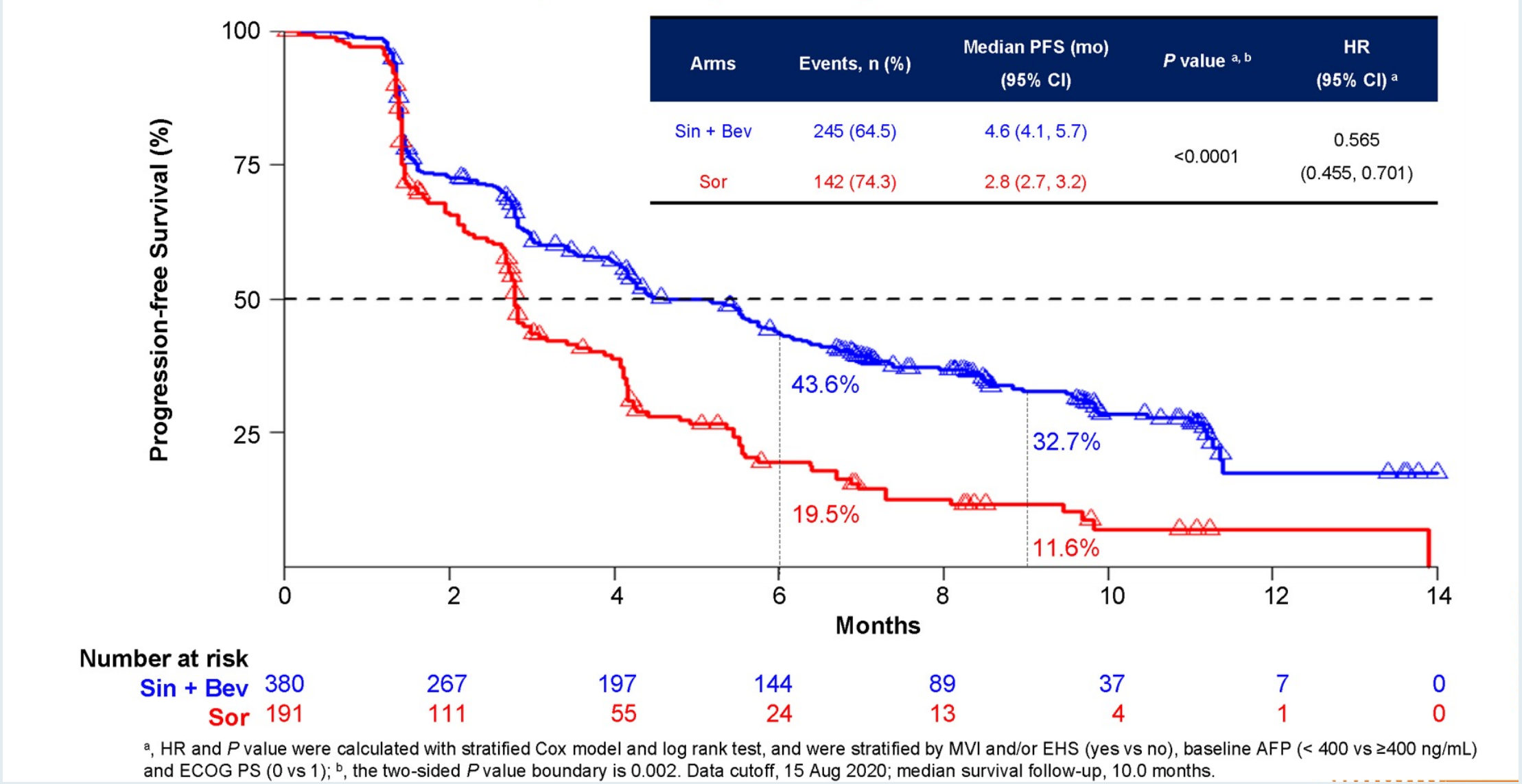
Sin + Bev	380	372	351	314	235	126	57	11	0
Sor	191	175	153	132	95	50	22	2	0

NE, not evaluable; [a], HR and *P* value were calculated with stratified Cox model and log rank test, and were stratified by MVI and/or EHS (yes vs no), baseline AFP (< 400 vs ≥400 ng/mL) and ECOG PS (0 vs 1); [b], the two-sided *P* value boundary based on 209 events is 0.0035. Data cutoff, 15 Aug 2020; median survival follow-up, 10.0 months.

The superior OS benefit with sintilimab plus bev biosimilar was generally consistent across all subgroups

Ren Z et al. ESMO Asia 2020;Abstract LBA2.

ORIENT-32 Coprimary Endpoint: Progression-Free Survival



Arms	Events, n (%)	Median PFS (mo) (95% CI)	*P* value [a, b]	HR (95% CI) [a]
Sin + Bev	245 (64.5)	4.6 (4.1, 5.7)	<0.0001	0.565 (0.455, 0.701)
Sor	142 (74.3)	2.8 (2.7, 3.2)		

Number at risk								
Sin + Bev	380	267	197	144	89	37	7	0
Sor	191	111	55	24	13	4	1	0

[a], HR and *P* value were calculated with stratified Cox model and log rank test, and were stratified by MVI and/or EHS (yes vs no), baseline AFP (< 400 vs ≥400 ng/mL) and ECOG PS (0 vs 1); [b], the two-sided *P* value boundary is 0.002. Data cutoff, 15 Aug 2020; median survival follow-up, 10.0 months.

The superior PFS benefit with sintilimab plus bev biosimilar was generally consistent across all subgroups

Ren Z et al. ESMO Asia 2020;Abstract LBA2.

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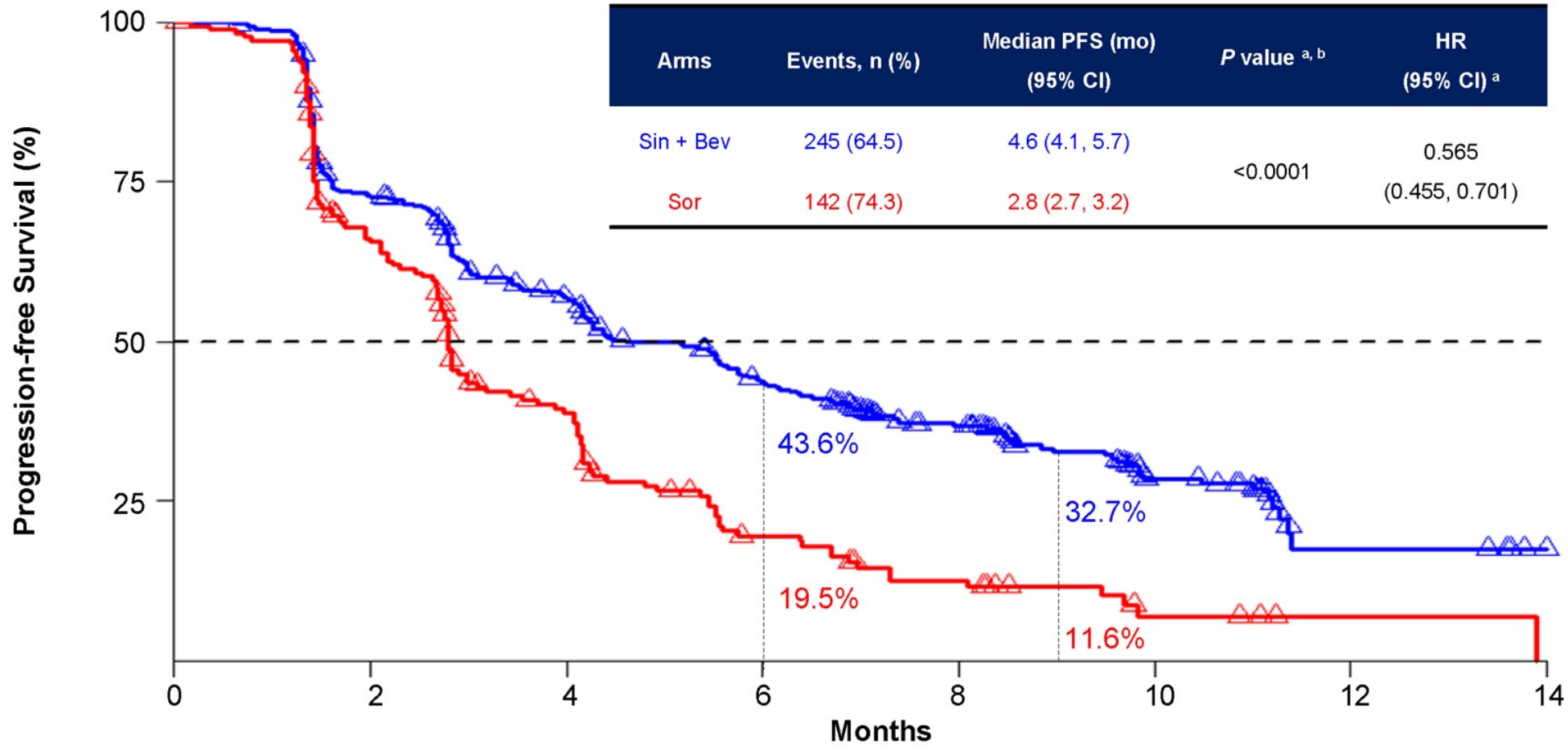
ORIENT-32 Coprimary Endpoint: Progression-Free Survival



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Ren Z et al. ESMO Asia 2020;Abstract LBA2.

Mol Cancer Ther. 2020 March ; 19(3): 847–857. doi:10.1158/1535-7163.MCT-19-0631.

Efficacy of FGFR inhibitors and combination therapies for acquired resistance in FGFR2-fusion cholangiocarcinoma

Melanie A. Krook[1], Alexandria Lenyo[1], Max Wilberding[1], Hannah Barker[1], Mikayla Dantuono[1], Kelly M. Bailey[2], Hui-Zi Chen[1,3], Julie W. Reeser[1], Michele R. Wing[1], Jharna Miya[1], Eric Samorodnitsky[1], Amy M. Smith[1], Thuy Dao[1], Dorrelyn M. Martin[1], Kristen K. Ciombor[4], John Hays[1,5], Aharon G. Freud[1,6], Sameek Roychowdhury[1,5]

Summer Oncology Nursing Series

A Complimentary NCPD-Accredited Virtual Curriculum

Chronic Lymphocytic Leukemia: Session 1

Thursday, June 10, 2021
5:00 PM – 6:00 PM ET

Faculty

Jennifer Woyach, MD
Kristen E Battiato, AGNP-C

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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