

Meet The Professor

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

Philip A Philip, MD, PhD, FRCP

Kathryn Cramer Endowed Chair in Cancer Research

Professor of Oncology and Pharmacology

Leader, GI and Neuroendocrine Oncology

Vice President of Medical Affairs

Karmanos Cancer Institute

Wayne State University

Detroit, Michigan

Commercial Support

This activity is supported by an educational grant from Lilly.

Dr Love — Disclosures

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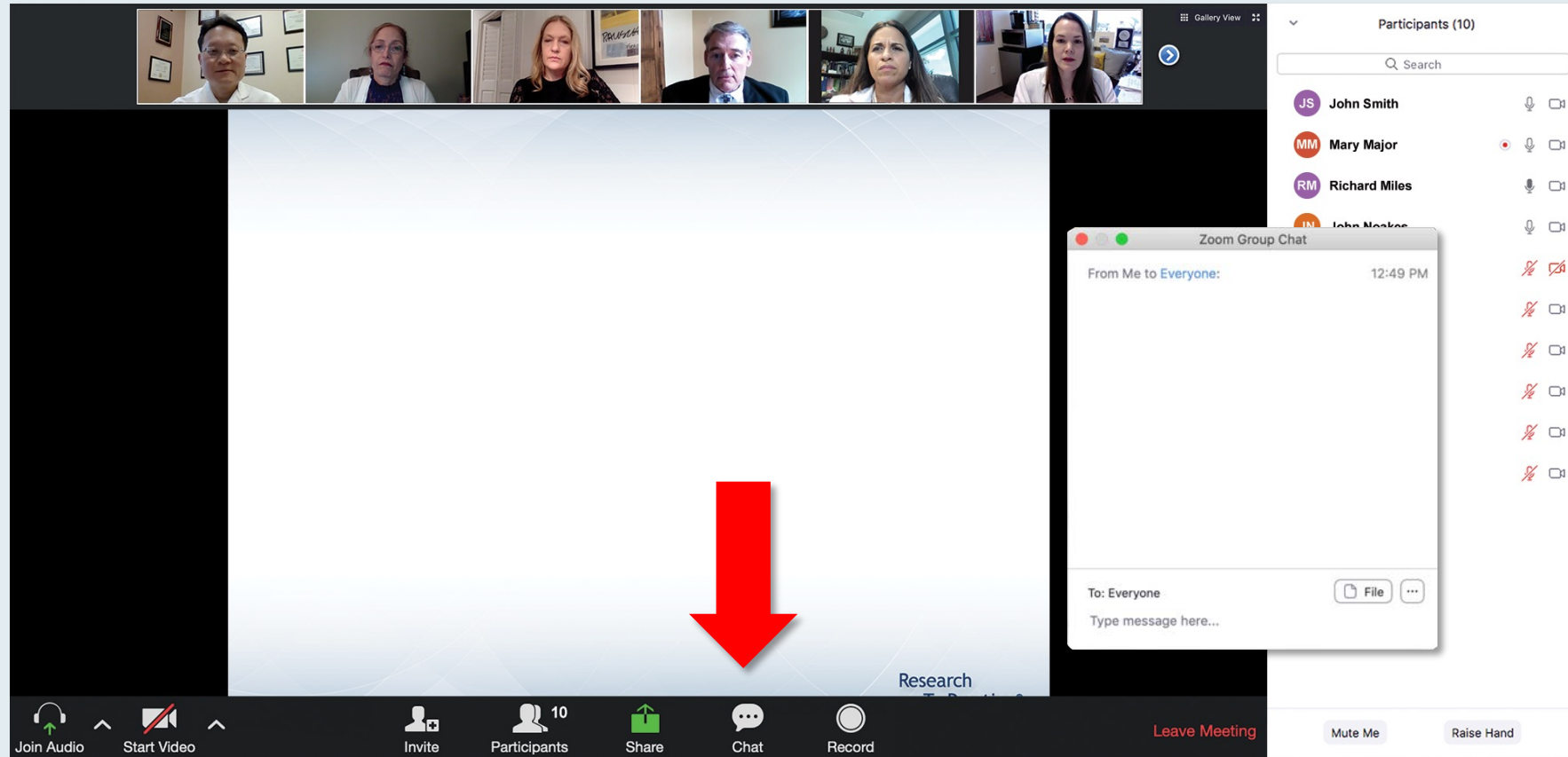
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Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

Dr Philip — Disclosures

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We Encourage Clinicians in Practice to Submit Questions



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

Familiarizing Yourself with the Zoom Interface

Expand chat submission box

The screenshot shows a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below the thumbnails is a slide titled "Meet The Professor Program Steering Committee" with six members listed:

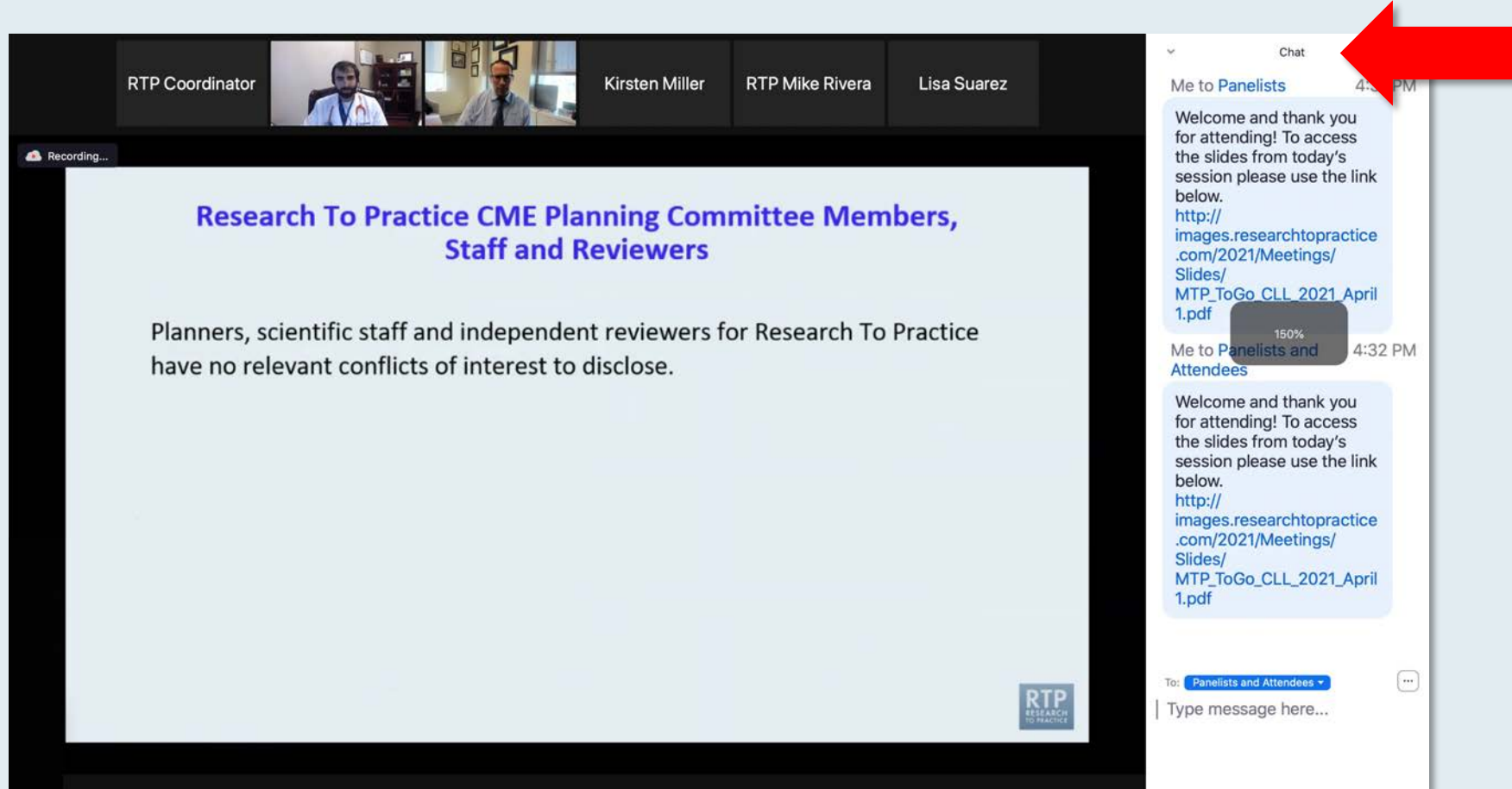
- John N Allan, MD**
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- Brian T Hill, MD, PhD**
Director, Lymphoid Malignancy Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio

On the right side, there is a chat window. It shows two messages from "Me to Panelists" and "Me to Panelists and Attendees" at 4:31 PM and 4:32 PM respectively. The messages contain a welcome message and a link to a PDF file: http://images.researchtopractice.com/2021/Meetings/Slides/MTP_ToGo_CLL_2021_April1.pdf. Below the messages is a "To:" dropdown menu set to "Panelists and Attendees" and a text input field labeled "Type message here...". A red arrow points to the white line above the text input field, indicating how to expand the chat submission box.

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

Familiarizing Yourself with the Zoom Interface

Increase chat font size



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

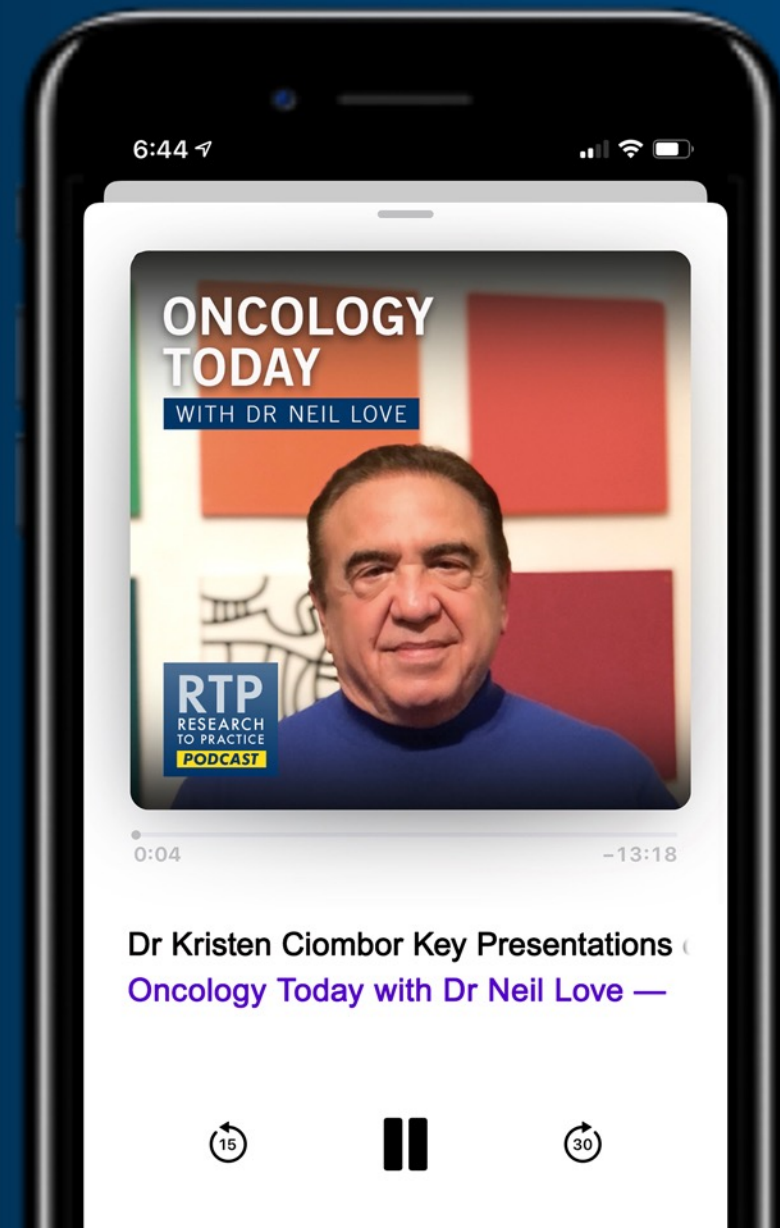
ONCOLOGY TODAY

WITH DR NEIL LOVE

Key Presentations on Gastrointestinal Cancers from the 2021 ASCO Annual Meeting



DR KRISTEN CIOMBOR
VANDERBILT-INGRAM CANCER CENTER



Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with Urothelial Bladder Carcinoma

**Tuesday, September 21, 2021
5:00 PM – 6:00 PM ET**

Faculty

Jonathan E Rosenberg, MD

Moderator

Neil Love, MD

Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with HER2-Positive Breast Cancer

Wednesday, September 22, 2021
5:00 PM – 6:00 PM ET

Faculty

Sara M Tolaney, MD, MPH

Moderator

Neil Love, MD

Meet The Professor

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

**Monday, September 27, 2021
5:00 PM – 6:00 PM ET**

Faculty

Zev Wainberg, MD, MSc

Moderator

Neil Love, MD

Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with Triple-Negative Breast Cancer

Tuesday, September 28, 2021
5:00 PM – 6:00 PM ET

Faculty

Professor Peter Schmid, MD, PhD

Moderator

Neil Love, MD

Meet The Professor

Optimizing the Clinical Management of Hodgkin and Non-Hodgkin Lymphomas

**Wednesday, September 29, 2021
5:00 PM – 6:00 PM ET**

Faculty

Brad S Kahl, MD

Moderator

Neil Love, MD

Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with Renal Cell Carcinoma

Friday, October 1, 2021

12:00 PM – 1:00 PM ET

Faculty

Hans Hammers, MD, 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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Section of Hematology and Oncology
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Oncology Program
Assistant Director, Translational Research
Comprehensive Cancer Center
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Meet The Professor Program Participating Faculty



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Aurora, Colorado



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The Madden Family Distinguished Professor of
Medical Oncology and Translational Research
Shorenstein Associate Director
Program Development
Helen Diller Family Comprehensive Cancer Center
University of California, San Francisco
San Francisco, California



Moderator

Neil Love, MD

Research To Practice
Miami, Florida



Zev Wainberg, MD, MSc

Co-Director, GI Oncology Program
Director of Early Phase Clinical Research
Jonsson Comprehensive Cancer Center
UCLA School of Medicine
Los Angeles, California

We Encourage Clinicians in Practice to Submit Questions

The screenshot displays a Zoom meeting interface. At the top, a gallery view shows six participants. The main area features a presentation slide with the text: "You may submit questions using the Zoom Chat option below" and a large red arrow pointing downwards. To the right, a "Participants (10)" list is visible, showing names like John Smith, Mary Major, Richard Miles, John Noakes, and Alice Suarez. A "Zoom Group Chat" window is open in the foreground, showing a message from "Me to Everyone" at 12:49 PM. The bottom toolbar includes icons for "Join Audio", "Start Video", "Invite", "Participants", "Share", "Chat", "Record", "Leave Meeting", "Mute Me", and "Raise Hand".

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

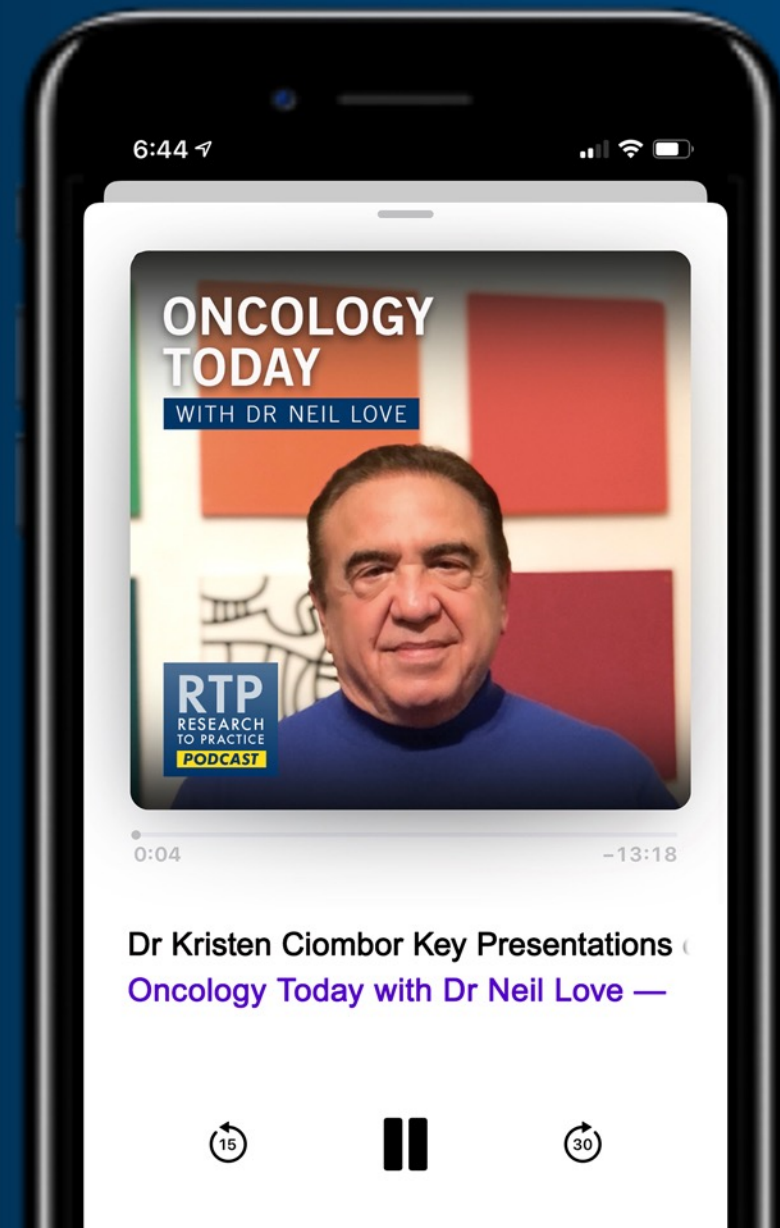
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Meet The Professor with Dr Philip

MODULE 1: Case Presentations

- Dr Meerasahib: A 58-year-old man with newly diagnosed localized esophageal carcinoma
- Dr Schafer: A 67-year-old woman with MSS, HER2-negative metastatic gastric cancer – PD-L1-negative
- Dr Gosain: An 80-year-old man with T3N1b colon cancer – MSS
- Dr Patel: A 74-year-old man with metastatic colon cancer – MSS, HER2 amplification
- Dr Brenner: A 58-year-old man with advanced hepatocellular carcinoma
- Dr Gupta: An 80-year-old woman with metastatic hepatocellular carcinoma
- Dr Dayyani: A 62-year-old woman with metastatic cholangiocarcinoma – FGFR2 rearrangement, MSS, TMB low

MODULE 2: ESMO 2021 Preview

MODULE 3: Beyond the Guidelines

MODULE 4: Key Data Sets

Exploring Key Issues Affecting the Care of Patients with BRAF-Mutant Metastatic Colorectal Cancer

A CME/MOC-Accredited Virtual Event

**Thursday, September 9, 2021
5:00 PM – 6:00 PM ET**

Faculty

Scott Kopetz, MD, PhD

Consulting Clinical Investigator

Wells A Messersmith, MD

Moderator

Neil Love, MD

Cases from the Practice of Dr Messersmith

Case 1: A 48-year-old woman with BRAF V600E-mutant metastatic colorectal cancer (mCRC) receives panitumumab/encorafenib after disease progression on FOLFOX/bevacizumab

Case 2: A 44-year-old nurse practitioner with BRAF V600E-mutant mCRC and lung metastases receives cetuximab/encorafenib

Case 3: A 45-year-old woman with BRAF-mutant mCRC experiences rapid disease progression on FOLFOX/bevacizumab and is switched to panitumumab/encorafenib

Meet The Professor with Dr Philip

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Case Presentation – Dr Meerasahib: A 58-year-old man with newly diagnosed localized esophageal carcinoma



Dr Anish Meerasahib

- Presented with dysphagia
- Endoscopy: Ulcerated 4-cm distal esophageal adenocarcinoma superior to the GE junction
- EBUS staging: Stage IIIA; PET-negative for distant disease
- Neoadjuvant chemoradiation therapy, with cisplatin/5-FU → Surgery
 - Tumor downstaged to 3.2 cm, node-negative out of 20 nodes examined

Questions

- Is adjuvant immunotherapy with nivolumab now the standard of care for every histology after preoperative therapy in esophageal cancer? Are there any exceptions to this rule?
- If you observe an excellent CR after chemoradiation therapy, do you still use adjuvant immunotherapy? Is there any role for adjuvant chemotherapy in this setting?
- Should we look at PD-L1 to decide on the role of or benefit from adjuvant immunotherapy?

Case Presentation – Dr Schafer: A 67-year-old woman with MSS, HER2-negative metastatic gastric cancer – PD-L1-negative



Dr Liudmila Schafer

- Stage III gastric cancer
- Peri-operative FLOT with severe hypersensitivity reaction to docetaxel
 - Radiologic response after 4 cycles of oxaliplatin, 5-FU and leucovorin
- Intraoperatively, identified metastatic disease
 - MSS, HER2-negative, PD-L1-negative
- Patient declined IV chemotherapy but was amenable to pills, immunotherapy or targeted treatment
- TAS-102, with stable disease x 2 years, with no toxicity and good QoL

Question

- What is the role for TAS-102 with VEGF inhibitors, such as bevacizumab?

Case Presentation – Dr Gosain: An 80-year-old man with T3N1b colon cancer – MSS



Dr Rahul Gosain

- PMH: hyperplastic polyp and tubular adenoma on screening colonoscopy in 2015
- October 2020: repeat colonoscopy shows a mass consistent with invasive moderately differentiated adenocarcinoma
- Hemi-colectomy and final pathology consistent with pT3N1b (2 out of 21 LNs positive)
- Molecular analyses: MSI stable, NRAS mutant, BRAF negative
- Capecitabine as a single agent (patient was comfortable in declining Oxaliplatin) with plan to complete 6 months

Questions

- Would you treat this patient differently if their tumor was MSI-high? Would you consider chemotherapy? Is there any data for adjuvant immunotherapy for patients such as this? Is it being studied in a clinical trial?

Case Presentation – Dr Patel: A 74-year-old man with metastatic colon cancer – MSS, HER2 amplification



Dr Ina Patel

- Diagnosed with metastatic colon adenocarcinoma with metastases to the liver
- Molecular analyses: MSS, KRAS WT, NRAS WT, BRAF WT, HER2 amplified
- Disease progression on multiple lines of therapy including FOLFOX, FOLFIRI plus aflibercept, cetuximab with irinotecan on protocol, and trastuzumab/pertuzumab on protocol
- Also diagnosed with urothelial bladder cancer and treated with combined chemoradiotherapy with cisplatin/5-FU
 - No signs of metastases and therapy is changed to CAPOX/bevacizumab followed by maintenance capecitabine/bevacizumab
- Tolerating treatment well but CEA has increased significantly from 7 to 20
- Planning to switch therapy to trastuzumab deruxtecan

Questions

- Have you used anti-HER2 therapy in the setting of metastatic colon cancer?
- What is the tolerability of trastuzumab deruxtecan in your experience? Have you seen ILD in your patients treated with this agent, and if so, how did you manage it? Would you rechallenge?

Case Presentation – Dr Brenner: A 58-year-old man with advanced hepatocellular carcinoma (HCC)



Dr Warren Brenner

- Presented with pruritus
- Diagnosed with HCC with extensive liver infiltration by the tumor
- He has underlying Child-Pugh B cirrhosis thought to be on the basis of steatohepatitis
- Bilirubin ~10 mg/dL
- Nivolumab

Questions

- What options are available for the treatment of patients with HCC who have Child-Pugh B disease and still have good functional status?
- What is the role of treatment if bilirubin is elevated from disease involvement rather than due to liver disease?
- Should we consider lenvatinib based on its higher response rates?

Case Presentation – Dr Gupta: An 80-year-old woman with metastatic HCC



Dr Ranju Gupta

- PMH: Diabetes, gastroparesis, GERD, hypertension
- 11/2020: Multifocal and metastatic HCC, with right lobe of the liver nearly completely replaced by HCC
 - CT scan: 8.7-cm right hepatic lobe mass, 2.6-cm mass in the posterior segment of the right hepatic lobe. No adenopathy. Liver biopsy consistent with HCC. Alpha-fetoprotein 90
- Patient not interested in systemic treatment because of her age and comorbid conditions
- 2/2021: Right lobar chemoembolization – 2 months later developed liver abscess, status post drainage and antibiotics
- 7/2021 Restaging scans: New right pleural effusion, lung metastases

Question

- Since the patient does not want to receive chemotherapy and in light of her age and comorbid conditions, what treatment would you recommend?

Case Presentation – Dr Dayyani: A 62-year-old woman with metastatic cholangiocarcinoma — FGFR2 rearrangement, MSS, TMB low



Dr Farshid Dayyani

- 7/2017: Diagnosed with intrahepatic cholangiocarcinoma
- 12/2017: Completed adjuvant gemcitabine/cisplatin x 5 cycles
- 1/2018: Underwent right hepatic lobectomy → capecitabine (d/c'ed due to colitis/mucositis
 - Patient switched to gemcitabine/cisplatin; completed 7/2018
- 3/2019: CT identifies suspected liver and lung metastases
- NGS: FGFR2-AHCYL1 fusion | MSS | TMB low
- 6/2019: Patient enrolled on MATCH trial and began treatment with erdafitinib
 - Multiple dose interruptions and reductions due to hyperphosphatemia, serous retinopathy (reversible), mucositis and increasing PPE
- 7/2020: Continued partial response in single liver lesion, and only lung micronodules
- 9/2020: Patient opted to come off trial due to recurrent PPE, mucositis on lowest dose

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ESMO 2021 Gastrointestinal Cancers Review

Colorectal Cancer

Siena S et al. **Exploratory biomarker analysis of DESTINY-CRC01, a phase II, multicenter, open-label study of trastuzumab deruxtecan (T-DXd, DS-8201) in patients (pts) with HER2-expressing metastatic colorectal cancer (mCRC).** ESMO 2021;Abstract 3860.

Cremolini C et al. **FOLFOXIRI plus bevacizumab (bev) plus atezolizumab (atezo) versus FOLFOXIRI plus bev as first-line treatment of unresectable metastatic colorectal cancer (mCRC) patients: Results of the phase II randomized AtezoTRIBE study by GONO.** ESMO 2021;Abstract LBA20.

Weiss J et al. **KRYSTAL-1: Adagrasib (MRTX849) as monotherapy or combined with cetuximab (cetux) in patients (pts) with colorectal cancer (CRC) harboring a KRASG12C mutation.** ESMO 2021;Abstract LBA6.

Mulcahy MF et al. **Radioembolization with chemotherapy for colorectal liver metastases: A randomized, open-label, international, multicenter, phase III trial (EPOCH study).** ESMO 2021;Abstract LBA21.

ESMO 2021 Gastrointestinal Cancers Review

Colorectal Cancer (cont)

Ding PR et al. **Neoadjuvant chemotherapy with oxaliplatin and capecitabine versus chemoradiation with capecitabine for locally advanced rectal cancer with uninvolved mesorectal fascia (CONVERT): Initial results of a multicenter randomised, open-label, phase III trial.** ESMO 2021;Abstract LBA22.

Ludford K et al. **Neoadjuvant pembrolizumab in localized/locally advanced solid tumors with mismatch repair deficiency.** ESMO 2021;Abstract 17580.

Groberuschkamp F et al. **Automated detection of microsatellite status in early colon cancer (CC) using artificial intelligence (AI) integrated infrared (IR) imaging on unstained samples from the AIO ColoPredictPlus 2.0 (CPP) registry study.** ESMO 2021;Abstract 3850.

ESMO 2021 Gastrointestinal Cancers Review

Gastric/GEJ/Esophageal

Janjigian Y et al. **Nivolumab (NIVO) plus chemotherapy (Chemo) or ipilimumab (IPI) vs chemo as first-line (1L) treatment for advanced gastric cancer/gastroesophageal junction cancer/esophageal adenocarcinoma (GC/GEJC/EAC): CheckMate 649 study.** ESMO 2021;Abstract LBA7.

Rau B et al. **The effect of hyperthermic intraperitoneal chemotherapy (HIPEC) upon cytoreductive surgery (CRS) in gastric cancer (GC) with synchronous peritoneal metastasis (PM): A randomized multicentre phase III trial (GASTRIPEC-I-trial).** ESMO 2021;Abstract 13760.

Hepatocellular Carcinoma

Fichtinger RS et al. **Laparoscopic versus open hemihepatectomy: The ORANGE II PLUS multicenter randomized controlled trial.** ESMO 2021;Abstract 3840.

Other

Qi C et al. **CLDN 18.2-targeted CAR-T cell therapy in patients with cancers of the digestive system.** ESMO 2021;Abstract 13720.

Oosting S et al. **Vaccination against SARS-CoV-2 in patients receiving chemotherapy, immunotherapy, or chemo-immunotherapy for solid tumors.** ESMO 2021;Abstract LBA8.

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Gastric/GEJ

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
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Dr Venook

Ramucirumab/
paclitaxel



Dr Catenacci

FOLFIRI/ramucirumab



Dr Wainberg

Ramucirumab/
paclitaxel

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 $\geq 10\%$**



Dr Venook

**Ramucirumab/
paclitaxel**



Dr Catenacci

**Continue trastuzumab
and switch
chemotherapy**



Dr Wainberg

**Trastuzumab
deruxtecan**

Colorectal Cancer

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**

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

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

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 + cetuximab

Hepatocellular

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

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

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

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

Meet The Professor with Dr Philip

MODULE 1: Case Presentations

- Dr Meerasahib: A 58-year-old man with newly diagnosed localized esophageal carcinoma
- Dr Schafer: A 67-year-old woman with MSS, HER2-negative metastatic gastric cancer – PD-L1-negative
- Dr Gosain: An 80-year-old man with T3N1b colon cancer – MSS
- Dr Patel: A 74-year-old man with metastatic colon cancer – MSS, HER2 amplification
- Dr Brenner: A 58-year-old man with advanced hepatocellular carcinoma
- Dr Gupta: An 80-year-old woman with metastatic hepatocellular carcinoma
- Dr Dayyani: A 62-year-old woman with metastatic cholangiocarcinoma – FGFR2 rearrangement, MSS, TMB low

MODULE 2: ESMO 2021 Preview

MODULE 3: Beyond the Guidelines

MODULE 4: Key Data Sets

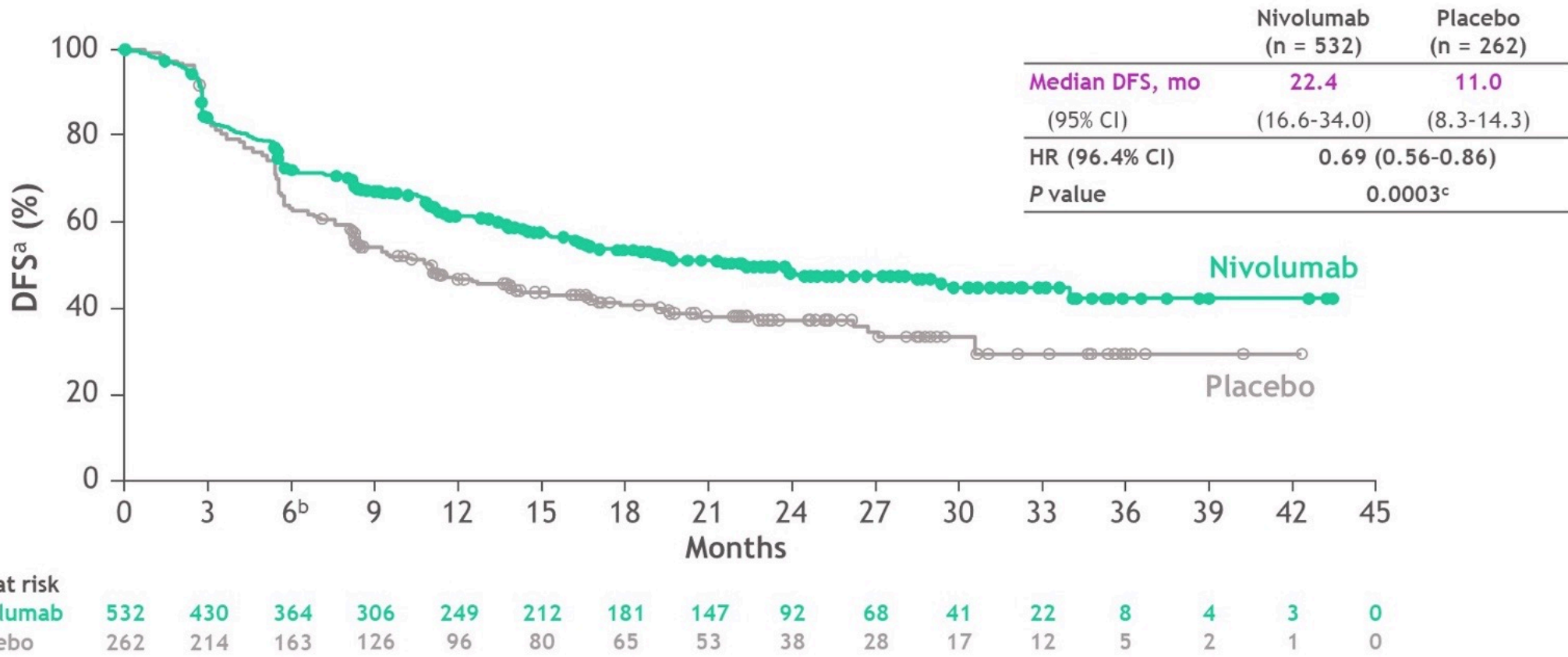
Gastric/GEJ Cancer/Esophageal

Adjuvant nivolumab in resected esophageal or gastroesophageal junction cancer following neoadjuvant chemoradiotherapy: expanded efficacy and safety analyses from CheckMate 577

Ronan J. Kelly,¹ Jaffer A. Ajani,² Jaroslaw Kuzdzal,³ Thomas Zander,⁴ Eric Van Cutsem,⁵ Guillaume Piessen,⁶ Guillermo Mendez,⁷ Josephine Feliciano,⁸ Satoru Motoyama,⁹ Astrid Lièvre,¹⁰ Hope Uronis,¹¹ Elena Elimova,¹² Cecile Grootsholten,¹³ Karen Geboes,¹⁴ Jenny Zhang,¹⁵ Samira Soleymani,¹⁵ Ming Lei,¹⁵ Prianka Singh,¹⁵ James M. Cleary,¹⁶ Markus Moehler¹⁷

¹The Charles A. Sammons Cancer Center at Baylor University Medical Center, Dallas, TX; ²The University of Texas MD Anderson Cancer Center, Houston, TX; ³Jagiellonian University, John Paul II Hospital, Cracow, Poland; ⁴University Hospital of Cologne, Cologne, Germany; ⁵University Hospitals Gasthuisberg, Leuven and KU Leuven, Leuven, Belgium; ⁶University of Lille, Claude Huriez University Hospital, Lille, France; ⁷Fundacion Favaloro, Buenos Aires, Argentina; ⁸Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore, MD; ⁹Akita University Hospital, Akita, Japan; ¹⁰CHU Pontchaillou, Rennes 1 University, Rennes, France; ¹¹Duke Cancer Institute, Durham, NC; ¹²Princess Margaret Cancer Centre, Toronto, ON, Canada; ¹³Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands; ¹⁴UZ Gent, Gent, Belgium; ¹⁵Bristol Myers Squibb, Princeton, NJ; ¹⁶Dana Farber Cancer Institute, Boston, MA; ¹⁷Johannes-Gutenberg University Clinic, Mainz, Germany

CheckMate 577: Disease-Free Survival



- Nivolumab provided superior DFS with a 31% reduction in the risk of recurrence or death and a doubling in median DFS versus placebo

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.

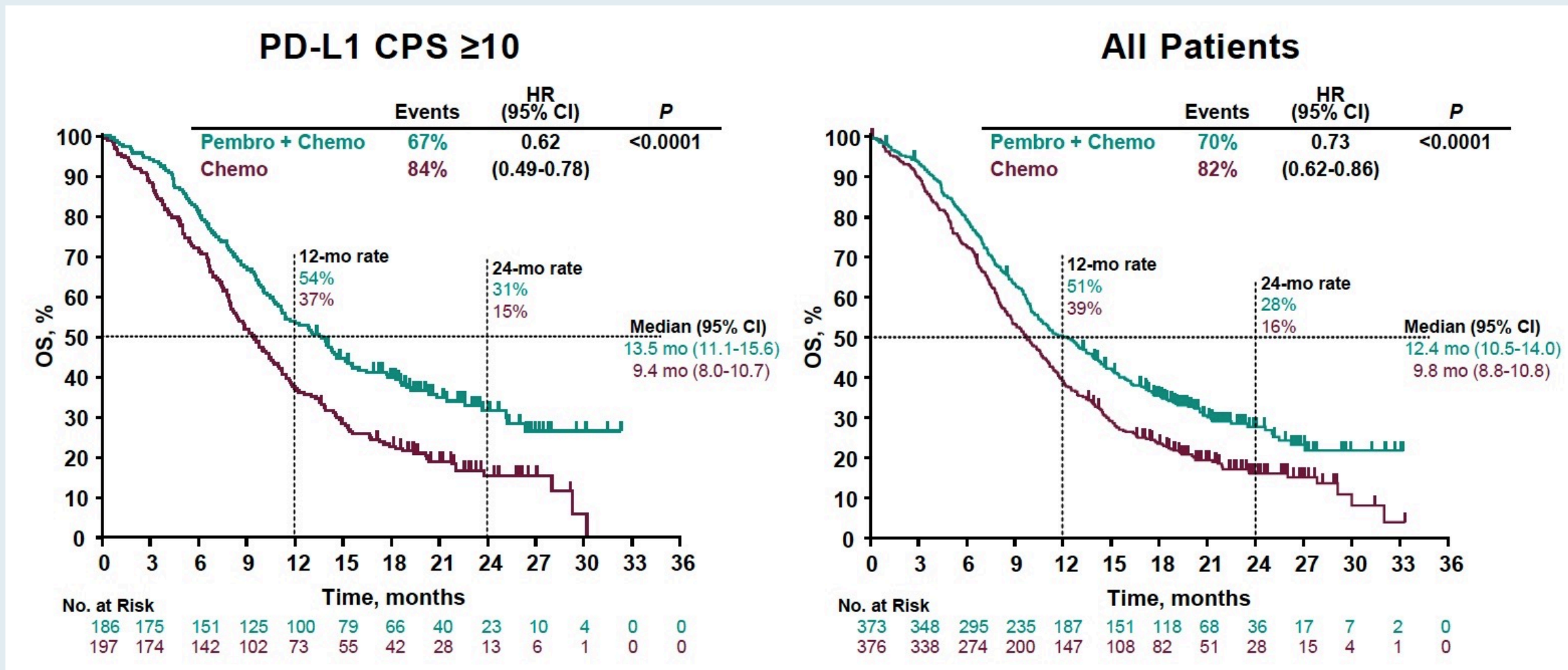
The recommended pembrolizumab dose for esophageal cancer is 200 mg every 3 weeks or 400 mg every 6 weeks.”

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.

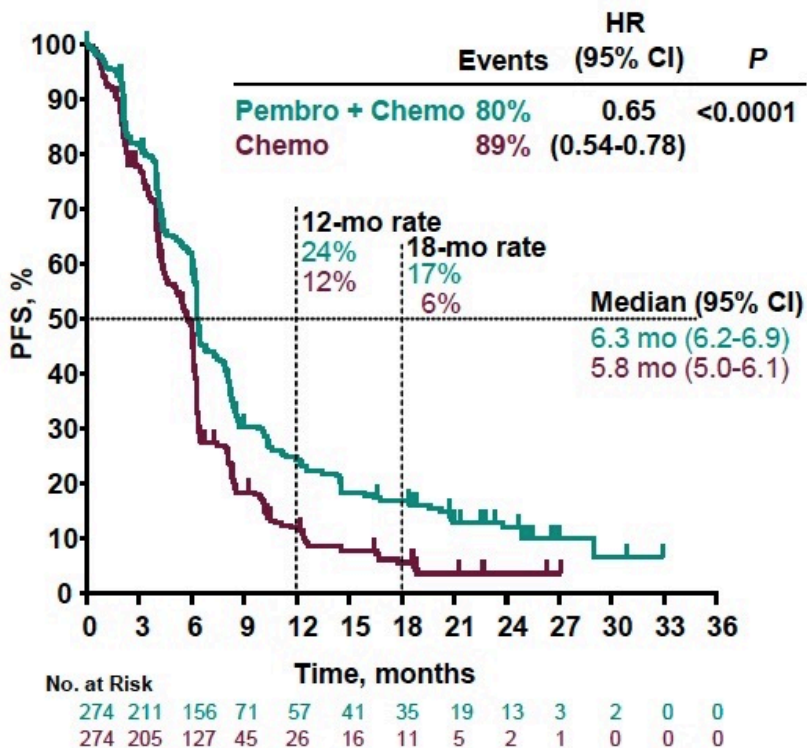
ESMO 2020;Abstract LBA8_PR.

KEYNOTE-590: Overall Survival

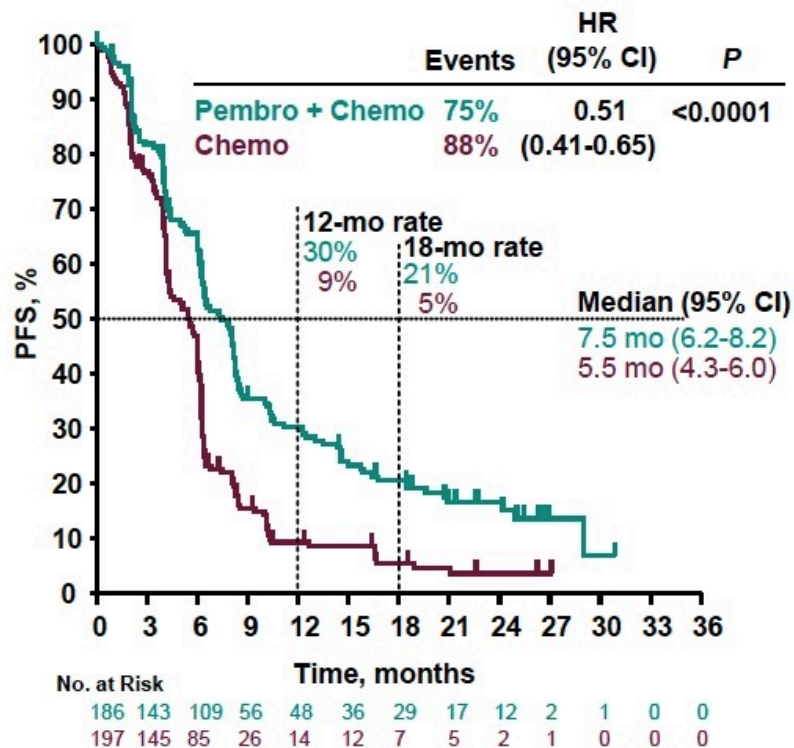


KEYNOTE-590: Progression-Free Survival

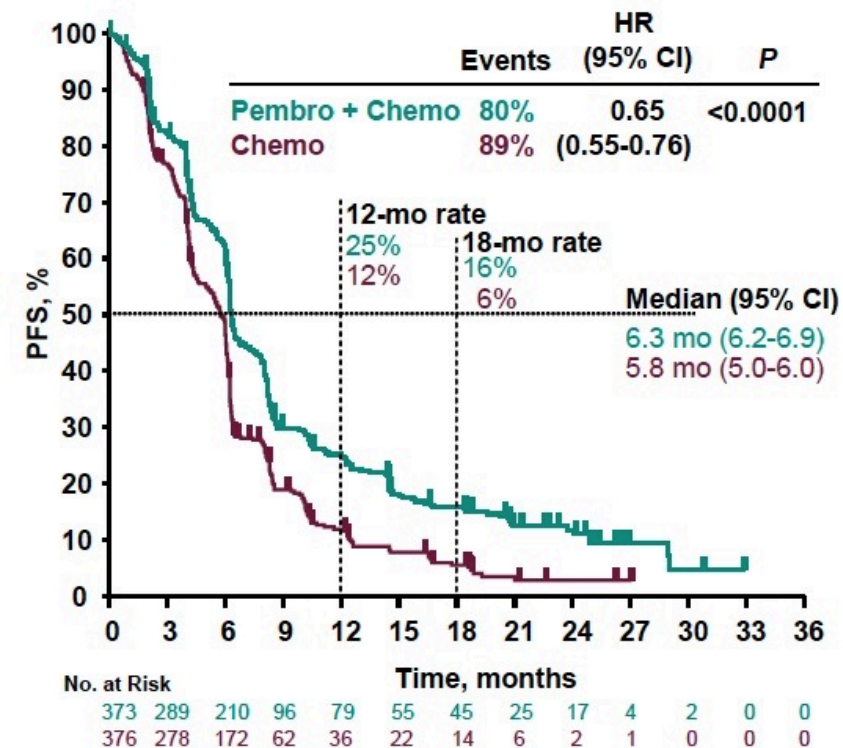
ESCC



PD-L1 CPS ≥10



All Patients



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=

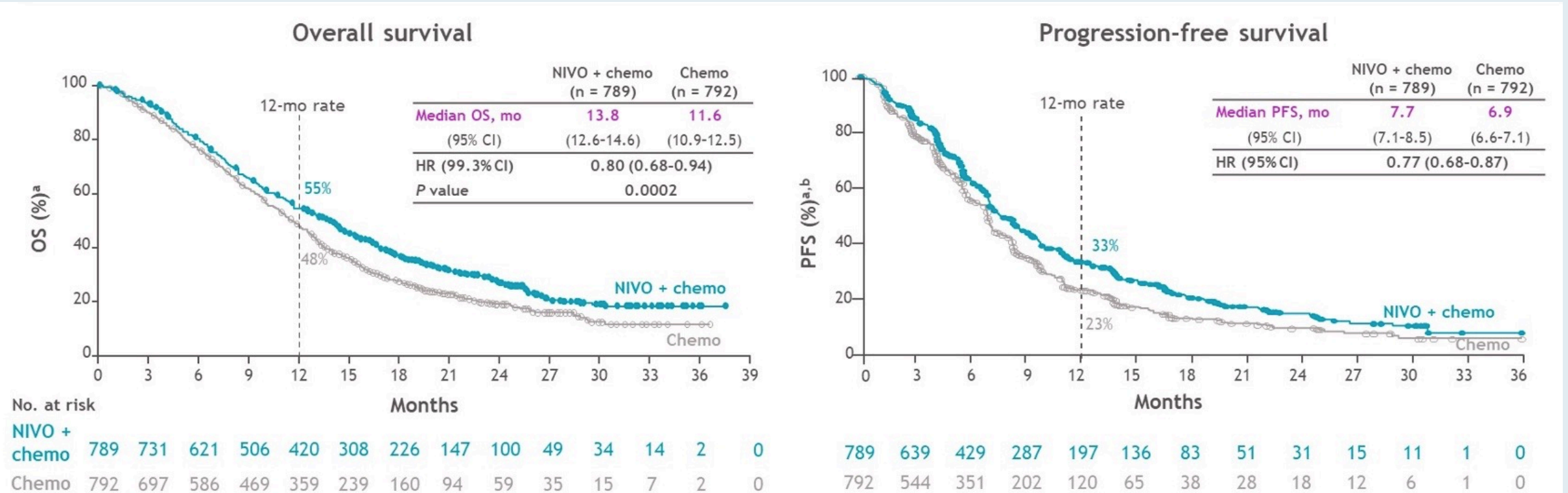
First-line nivolumab plus chemotherapy vs chemotherapy in advanced gastric cancer/gastroesophageal junction cancer/esophageal adenocarcinoma: expanded efficacy and safety data from CheckMate 649

Markus Moehler,¹ Kohei Shitara,² Marcelo Garrido,³ Pamela Salman,⁴ Lin Shen,⁵ Lucjan Wyrwicz,⁶ Kensei Yamaguchi,⁷ Tomasz Skoczytas,⁸ Arinilda Campos Bragagnoli,⁹ Tianshu Liu,¹⁰ Michael Schenker,¹¹ Patricio Yanez,¹² Mustapha Tehfe,¹³ Mingshun Li,¹⁴ Dana Cullen,¹⁴ Samira Soleymani,¹⁴ Ming Lei,¹⁴ Hong Xiao,¹⁴ Yelena Y. Janjigian,¹⁵ Jaffer A. Ajani¹⁶

¹Johannes-Gutenberg University Clinic, Mainz, Germany; ²National Cancer Center Hospital East, Kashiwa, Japan; ³Clinica San Carlos de Apoquindo, Pontificia Universidad Católica, Chile; ⁴Fundación Arturo López Pérez, Providencia, Chile; ⁵Department of Gastrointestinal Oncology, Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education/Beijing), Peking University Cancer Hospital and Institute, Beijing, China; ⁶Klinika Onkologii i Radioterapii, Narodowy Instytut Onkologii, Warszawa, Poland; ⁷Cancer Institute Hospital of JFCR, Tokyo, Japan; ⁸II Klinika Chirurgii Ogólnej, Gastroenterologicznej i Nowotworów Układu Pokarmowego, Medical University of Lublin, Lublin, Poland; ⁹Fundacao Pio Xii Hosp Cancer De Barretos, Barretos, Brazil; ¹⁰Zhongshan Hospital Fudan University, Shanghai, China; ¹¹SF Nectarie Oncology Center, Craiova, Romania; ¹²Universidad de La Frontera, Temuco, Chile; ¹³Oncology Center - Centre Hospitalier de l'Universite de Montreal, Montreal, QC, Canada; ¹⁴Bristol Myers Squibb, Princeton, NJ; ¹⁵Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College, New York, NY; ¹⁶The University of Texas MD Anderson Cancer Center, Houston, TX

Abstract Number 4002

CheckMate 649 Dual Primary Endpoints: PFS and OS



- Superior OS benefit and clinically meaningful PFS improvement in all randomized patients with NIVO + chemo vs chemo
- Median OS with NIVO + chemo vs chemo in patients with PD-L1 CPS ≥ 5 was 14.4 vs 11.1 months and median PFS was 7.7 vs 6.0 months¹

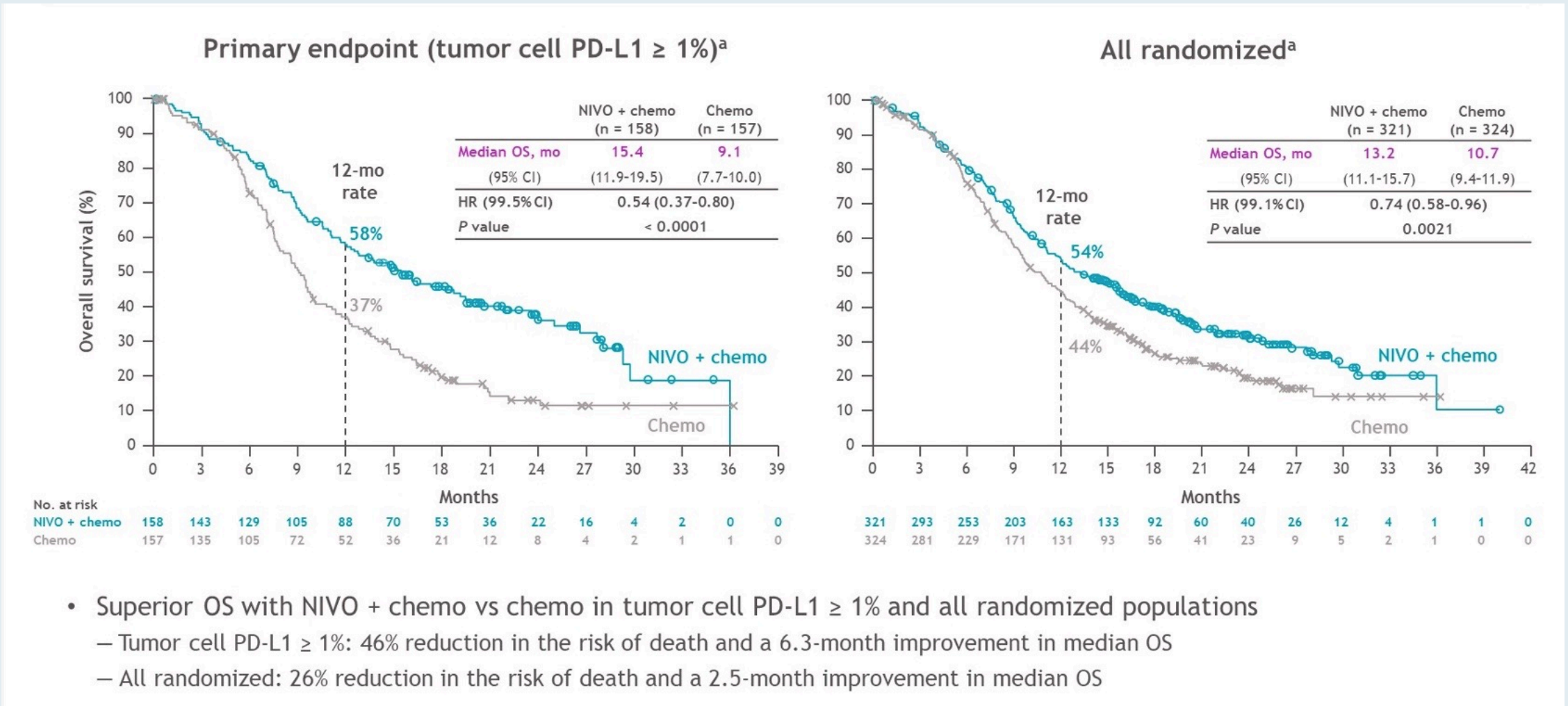
Nivolumab plus ipilimumab or nivolumab plus chemotherapy versus chemotherapy as first-line treatment for advanced esophageal squamous cell carcinoma: first results of the CheckMate 648 study

Ian Chau,¹ Yuichiro Doki,² Jaffer A. Ajani,³ Jianming Xu,⁴ Lucjan Wyrwicz,⁵ Satoru Motoyama,⁶ Takashi Ogata,⁷ Hisato Kawakami,⁸ Chih-Hung Hsu,⁹ Antoine Adenis,¹⁰ Farid el Hajbi,¹¹ Maria Di Bartolomeo,¹² Maria Ignez Braghiroli,¹³ Eva Holtved,¹⁴ Ioannis Xynos,¹⁵ Xuan Liu,¹⁵ Ming Lei,¹⁵ Kaoru Kondo,¹⁵ Ken Kato,¹⁶ Yuko Kitagawa¹⁷

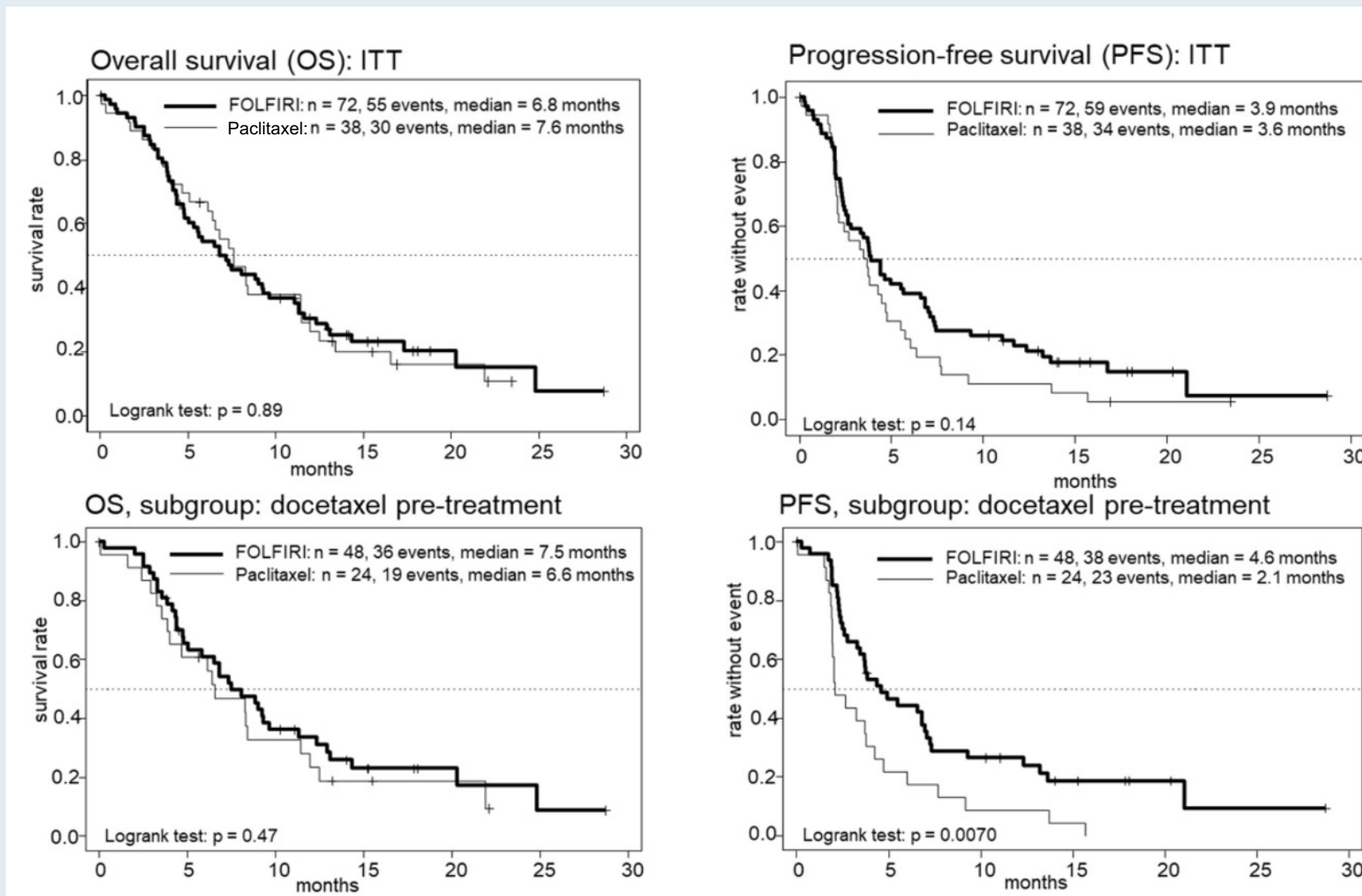
¹Royal Marsden Hospital, London & Surrey, UK; ²Osaka University Graduate School of Medicine, Osaka, Japan; ³The University of Texas MD Anderson Cancer Center, Houston, TX; ⁴Affiliated Hospital Cancer Center, Academy of Military Medical Sciences, Beijing, China; ⁵Klinika Onkologii i Radioterapii, Narodowy Instytut Onkologii, Warszawa, Poland; ⁶Akita University Hospital, Akita, Japan; ⁷Kanagawa Cancer Center, Kanagawa, Japan; ⁸Kindai University Faculty of Medicine, Osakasayama, Japan; ⁹National Taiwan University Hospital, Taipei, Taiwan; ¹⁰Institut du Cancer de Montpellier, Montpellier, France; ¹¹Centre Oscar Lambret, Lille, France; ¹²Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy; ¹³Institute of Cancer of São Paulo, University of São Paulo, São Paulo, Brazil; ¹⁴Odense University Hospital, Odense, Denmark; ¹⁵Bristol Myers Squibb, Princeton, NJ; ¹⁶National Cancer Center Hospital, Tokyo, Japan; ¹⁷Keio University School of Medicine, Tokyo, Japan

Abstract Number LBA4001

CheckMate 648: Overall Survival for Patients with PD-L1 $\geq 1\%$ (Primary Endpoint Along with PFS in PD-L1 $\geq 1\%$) and in ITT Population



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



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.”

Trastuzumab deruxtecan (T-DXd; DS-8201) in patients with human epidermal growth factor receptor 2–positive advanced gastric cancer or gastroesophageal junction adenocarcinoma: final overall survival results from a randomized, multicenter, open-label, phase 2 study (DESTINY-Gastric01)

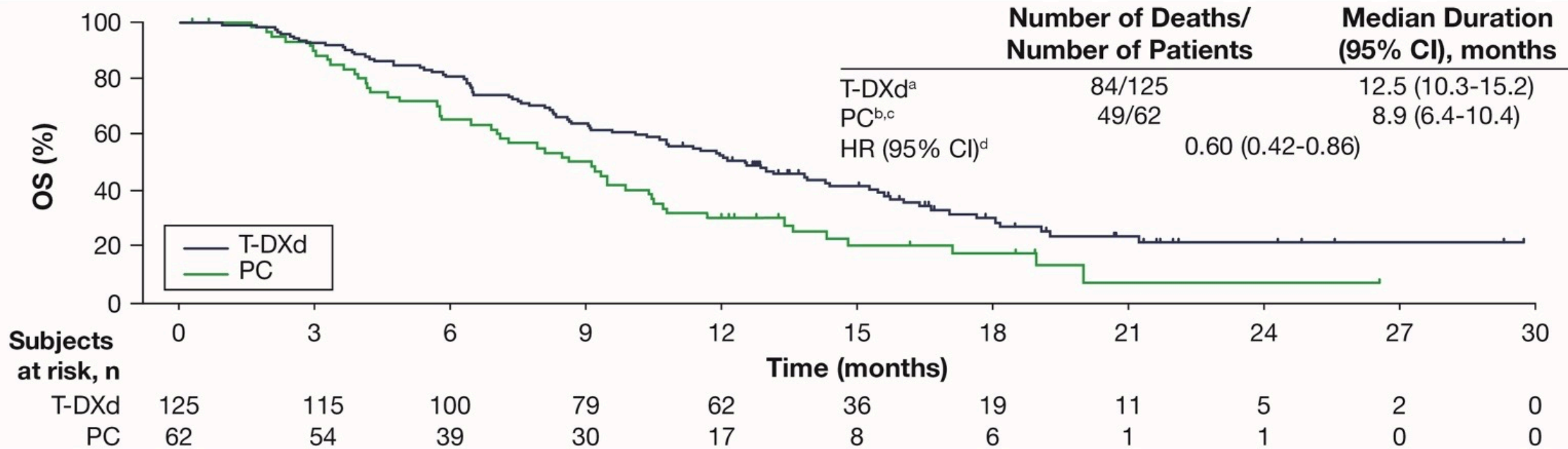
Kensei Yamaguchi

The Cancer Institute Hospital of JFCR, Tokyo, Japan
June 2021

ON BEHALF OF THE DESTINY-Gastric01 INVESTIGATORS

Additional authors: Yung-Jue Bang, Satoru Iwasa, Naotoshi Sugimoto, Min-Hee Ryu, Daisuke Sakai, Hyun Cheol Chung, Hisato Kawakami, Hiroshi Yabusaki, Jeeyun Lee, Kaku Saito, Yoshinori Kawaguchi, Takahiro Kamio, Akihito Kojima, Masahiro Sugihara, Kohei Shitara

DESTINY-Gastric01: Final Overall Survival Analysis



As in the primary analysis (101 OS events; 54.0% maturity), in this updated analysis (133 OS events; 71.1% maturity), T-DXd showed superior antitumor activity compared to PC

DESTINY-Gastric01: Selected Adverse Events

Preferred Term, %	T-DXd n = 125			PC Overall n = 62		
	Grade			Grade		
	Any	3	4	Any	3	4
Neutrophil count decreased ^b	64.8	38.4	12.8	35.5	16.1	8.1
Nausea	63.2	5.6	0	46.8	1.6	0
Decreased appetite	60.8	16.8	0	45.2	12.9	0
Anemia ^c	57.6	38.4	0	30.6	21.0	1.6
Platelet count decreased ^d	40.0	9.6	1.6	6.5	1.6	1.6
White blood cell count decreased ^e	38.4	20.8	0	35.5	8.1	3.2

DESTINY-Gastric01 AEs of Special Interest: Interstitial Lung Disorder

- 16 patients (12.8%) had T-DXd-related ILD, as determined by an independent adjudication committee
 - There were 13 grade 1 or 2, two grade 3, one grade 4, and no grade 5 events
 - There were four ILD events since the primary analysis; one grade 1 and three grade 2
 - Among the 16 total ILD events, the median time to first onset was 102.5 days (range, 36-638 days)
- There was one T-DXd-related death from pneumonia (non-ILD), as reported in the primary analysis

DESTINY-Gastric01: Exploratory Biomarker Analysis of Overall Survival in HER2-Positive or HER2-Low Advanced Gastric or GEJ Cancer

Exploratory Biomarker in Primary HER2-Positive Cohort	Median Overall Survival
Plasma HER2 amplification	
Not Amplified	12.1 mo
Amplified	13.0 mo
Plasma HER2 copy number*	
Above 6.0	21.2 mo
Below 6.0	12.0 mo
Exploratory Biomarker in Exploratory HER2-Low Cohort	
Plasma HER2 extracellular domain**	
Above 11.6 ng/mL	10.1 mo
Below 11.6 ng/mL	4.3 mo

*An exploratory cutoff (copy number = 6.0) value was determined, which minimized p-value, estimated by log-rank test. Below 6.0 includes patients without amplification; **An exploratory cutoff value of 11.6 ng/mL in exploratory cohorts was determined, which minimized p-value, estimated by log-rank test.

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.

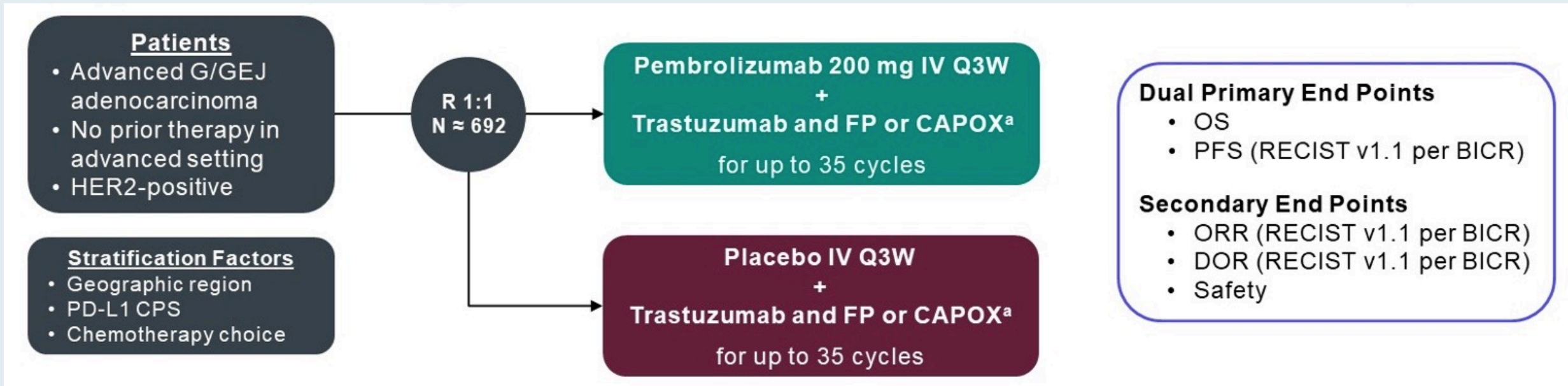
The main efficacy measure for this analysis was overall response rate (ORR) assessed by blinded independent review committee. The ORR was 74% in the pembrolizumab arm and 52% in the placebo arm (one-sided p-value < 0.0001, statistically significant). The median duration of response (DoR) was 10.6 months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

Pembrolizumab Plus Trastuzumab and Chemotherapy for HER2+ Metastatic Gastric or Gastroesophageal Junction Cancer: Initial Findings of the Global Phase 3 KEYNOTE-811 Study

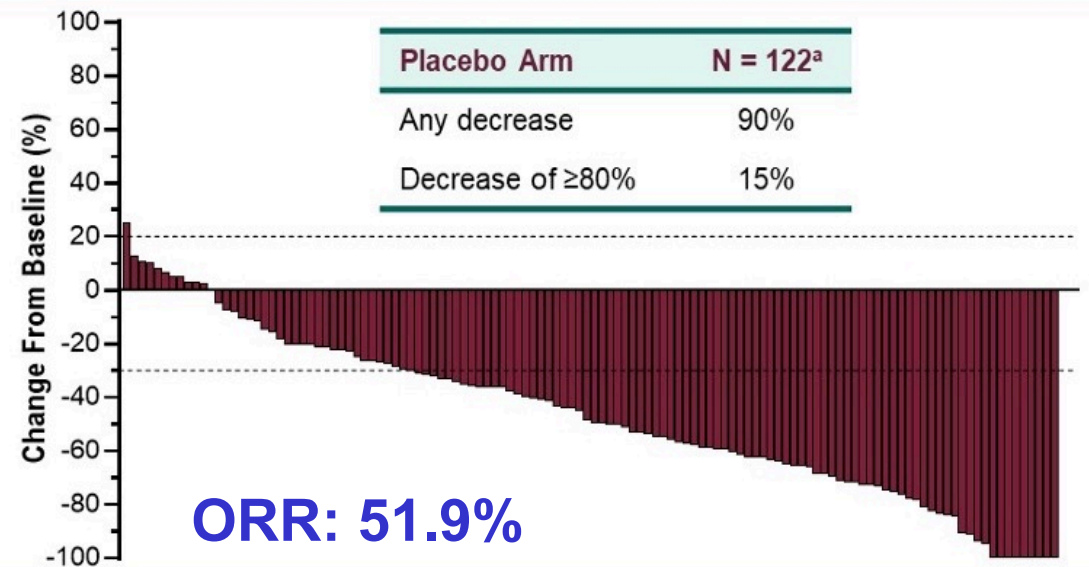
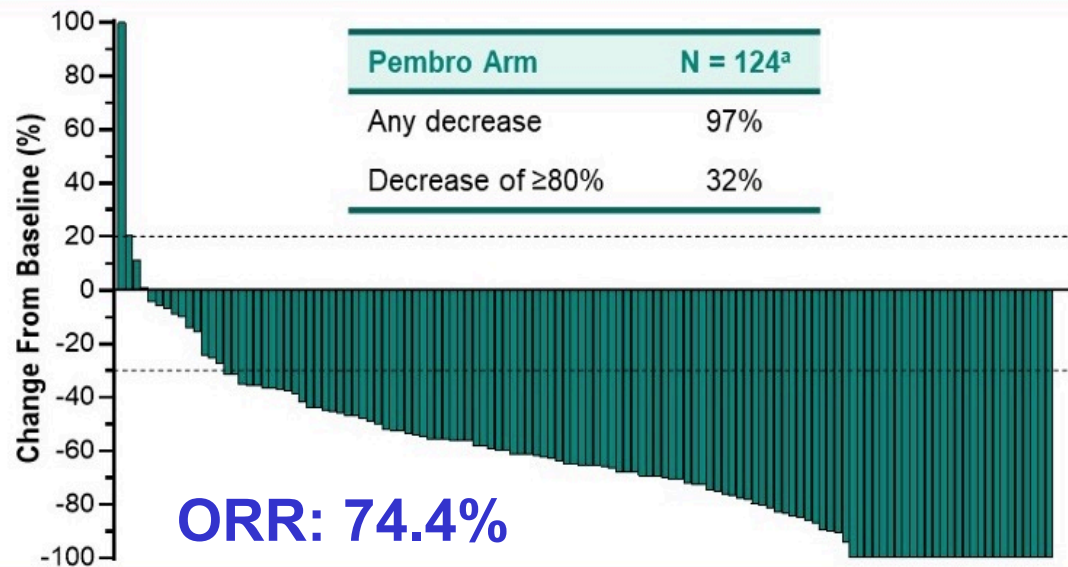
Yelena Y. Janjigian,¹ Akihito Kawazoe,² Patricio Yañez,³ Suxia Luo,⁴ Sara Lonardi,⁵ Oleksii Kolesnik,⁶
Olga Barajas,⁷ Yuxian Bai,⁸ Lin Shen,⁹ Yong Tang,¹⁰ Lucjan S. Wyrwicz,¹¹ Kohei Shitara,² Shukui Qin,¹²
Eric Van Cutsem,¹³ Josep Taberero,¹⁴ Lie Li,¹⁵ Chie-Schin Shih,¹⁵ Pooja Bhagia,¹⁵ Hyun Cheol Chung,¹⁶
on behalf of the KEYNOTE-811 Investigators

¹Memorial Sloan Kettering Cancer Center, New York, NY, USA; ²National Cancer Center Hospital East, Kashiwa, Japan; ³Universidad de La Frontera, James Lind Cancer Research Center, Temuco, Chile; ⁴Henan Cancer Hospital, the Affiliated Cancer Hospital of Zhengzhou University, Zhengzhou, China; ⁵Istituto Oncologico Veneto IOV-IRCCS, Padova, Italy; ⁶Medical Center “Oncolife”, Zaporizhzhia, Ukraine; ⁷Arturo López Pérez Foundation, Santiago, Chile; ⁸Harbin Medical University Cancer Hospital, Harbin, China; ⁹Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education/Beijing), Peking University Cancer Hospital & Institute, Beijing, China; ¹⁰Cancer Hospital Affiliated to Xinjiang Medical University, Xinjiang, China; ¹¹Maria Skłodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland; ¹²Cancer Center of People’s Liberation Army, Nanjing, China; ¹³University Hospitals Gasthuisberg and KU Leuven, Leuven, Belgium; ¹⁴Vall d’Hebron Hospital Campus and Institute of Oncology (VHIO), IOB-Quiron, UVic-UCC, Barcelona, Spain; ¹⁵Merck & Co., Inc., Kenilworth, NJ, USA; ¹⁶Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, South Korea

KEYNOTE-811 Phase III Study Design



KEYNOTE-811: Confirmed Response at First Interim Analysis



Colorectal Cancer

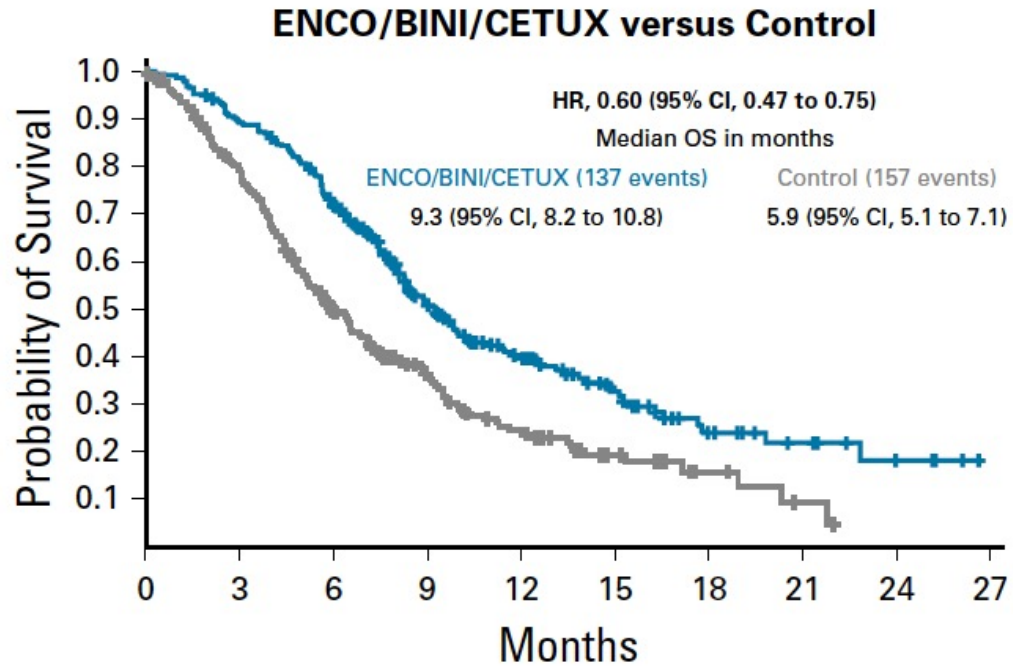
Encorafenib Plus Cetuximab as a New Standard of Care for Previously Treated *BRAF* V600E–Mutant Metastatic Colorectal Cancer: Updated Survival Results and Subgroup Analyses from the BEACON Study

Josep Tabernero, MD, PhD¹; Axel Grothey, MD²; Eric Van Cutsem, MD, PhD³; Rona Yaeger, MD⁴; Harpreet Wasan, MD⁵; Takayuki Yoshino, MD, PhD⁶; Jayesh Desai, MBBS⁷; Fortunato Ciardiello, MD, PhD⁸; Fotios Loupakis, MD, PhD⁹; Yong Sang Hong, MD, PhD¹⁰; Neeltje Steeghs, MD, PhD¹¹; Tormod Kyrre Guren, MD, PhD¹²; Hendrik-Tobias Arkenau, MD, PhD¹³; Pilar Garcia-Alfonso, MD¹⁴; Elena Elez, MD, PhD¹; Ashwin Gollerkeri, MD¹⁵; Kati Maharry, PhD¹⁵; Janna Christy-Bittel, MSN¹⁵; and Scott Kopetz, MD, PhD¹⁶

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

BEACON: Overall Survival Results

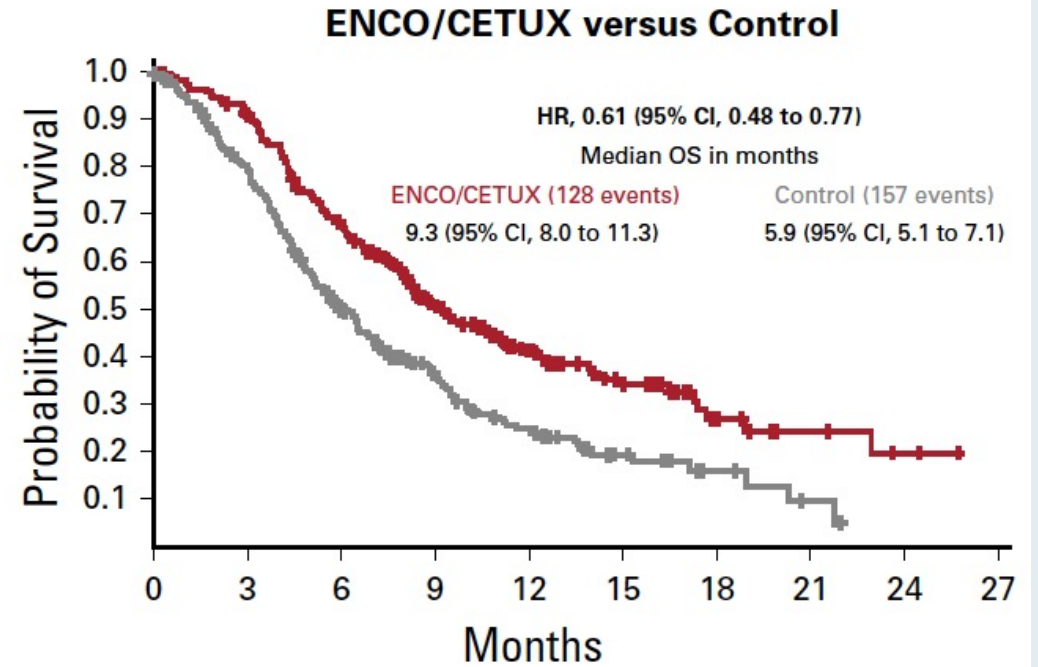
A



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

B



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

ANCHOR CRC: a single-arm, phase 2 study of encorafenib, binimetinib plus cetuximab in previously untreated $BRAF^{V600E}$ -mutant metastatic colorectal cancer

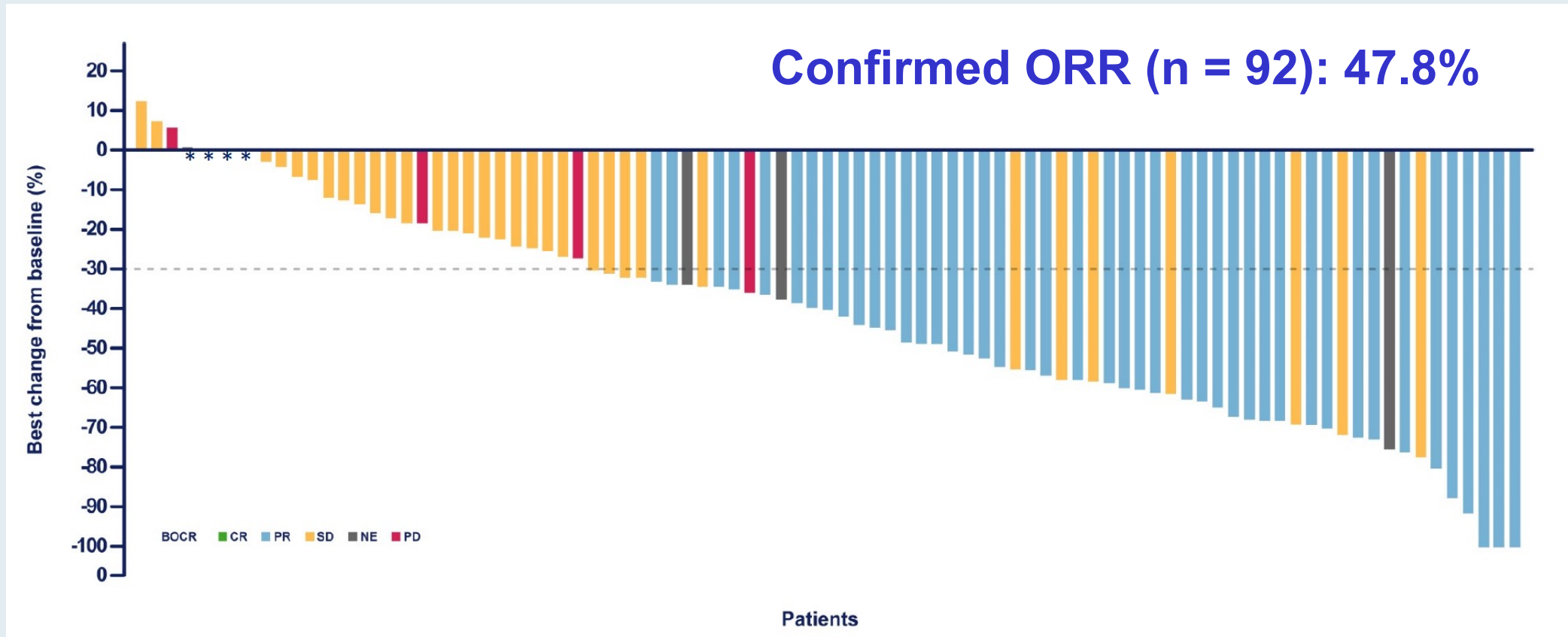
*Eric Van Cutsem**, Julien Taieb, Rona Yaeger, Takayuki Yoshino, Evaristo Maiello, Elena Elez Fernandez, Jeroen Dekervel, Paul Ross, Ana Ruiz Casado, Janet Graham, Takeshi Kato, Jose Carlos Ruffinelli, Thierry André, Edith Carrière Roussel, Isabelle Klauck, Mélanie Groc, Axel Grothey, Jean-Claude Vedovato, Josep Tabernero

* University Hospitals Leuven, Belgium

ANCHOR CRC: encorafenib, binimetinib and cetuximab in subjects with previously untreated BRAF-mutant Colorectal Cancer

ESMO World Congress on Gastrointestinal Cancer 2021; Abstract O-10.

ANCHOR CRC: Results Summary



- OS was 17.2 mos (with a median follow-up of 14.4 mos)
- The triplet combination was well-tolerated and there were no unexpected toxicities

BREAKWATER Study Design

An open-label, multicenter, randomized phase 3 study of 1st line encorafenib plus cetuximab with or without chemotherapy versus standard of care therapy in patients with metastatic *BRAF* V600E-mutant mCRC

Safety lead-in

Patients with *BRAF*^{V600E} mutant mCRC with 0 to 1 prior regimens in the metastatic setting

Phase 3

Patients with *BRAF*^{V600E} mutant mCRC and no prior systemic therapy in the metastatic setting

Encorafenib + cetuximab + mFOLFOX6
N=30
Encorafenib + cetuximab + FOLFIRI
N=30

Dosages

- Encorafenib, 300 mg PO QD
- Cetuximab, 500 mg/m² IV Q2W
- FOLFOX, full dose IV Q2W
- FOLFIRI, full dose IV Q2W

Randomize 1:1:1*

Arm A**
Encorafenib + cetuximab, N=290

Arm B**
Encorafenib + cetuximab + FOLFOX or
FOLFIRI^β, N=290

Control arm[§]
Physician's choice: FOLFOX, FOLFIRI,
FOLFOXIRI, CAPOX, all ± anti-VEGF
antibody, N=290

PRIMARY ENDPOINTS

PFS (BICR) Arm A vs Control
AND
PFS (BICR) Arm B vs Control
(BICR, blinded independent central review)

KEY SECONDARY ENDPOINTS

OS Arm A vs Control
AND
OS Arm B vs Control

OTHER ENDPOINTS

- Incidence of DLTs, adverse events, dose modifications/discontinuations due to AEs
- PK including drug-drug interactions

*Stratified by: ECOG PS 0 v. 1, Region US/Canada v. Western Europe v. ROW

**Same dosing as SLI; ^βFOLFOX or FOLFIRI based on SLI results; [§] No crossover.

ClinicalTrials.gov Identifier: NCT04607421

 BREAKWATER STUDY

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/m² 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 $\geq 25\%$) to cetuximab are cutaneous adverse reactions (including rash, pruritus, and nail changes), headache, diarrhea, and infection.”

Final Overall Survival for the Phase 3 KN177 Study: Pembrolizumab Versus Chemotherapy in Microsatellite Instability-High/Mismatch Repair Deficient Metastatic Colorectal Cancer

Thierry André,¹ Kai-Keen Shiu,² Tae Won Kim,³ Benny Vittrup Jensen,⁴ Lars Henrik Jensen,⁵ Cornelis Punt,⁶ Denis Smith,⁷ Rocio Garcia-Carbonero,⁸ Julia Alcaide-Garcia,⁹ Peter Gibbs,¹⁰ Christelle de la Fouchardiere,¹¹ Fernando Rivera,¹² Elena Elez,¹³ Johanna Bendell,¹⁴ Dung T. Le,¹⁵ Takayuki Yoshino,¹⁶ Wenyan Zhong,¹⁷ David Fogelman,¹⁸ Patricia Marinello,¹⁸ Luis A. Diaz Jr¹⁹

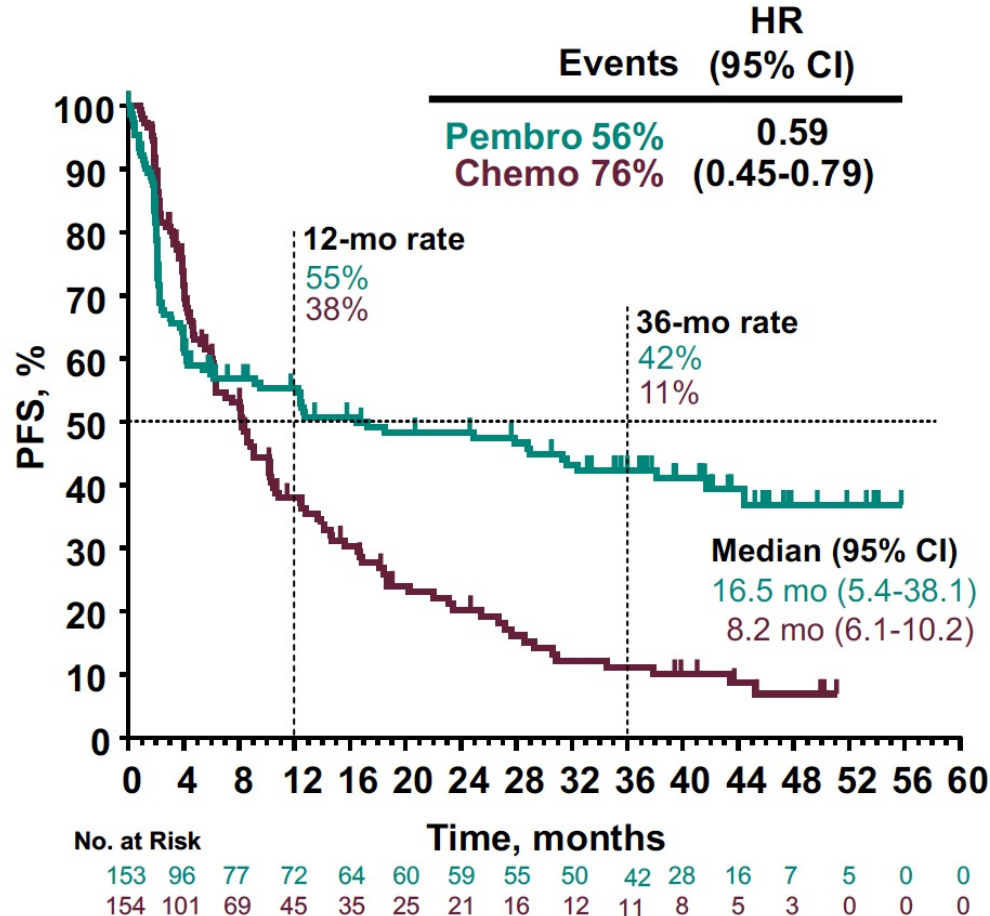
¹Sorbonne Université and Hôpital Saint Antoine, Paris, France; ²University College Hospital, NHS Foundation Trust, London, United Kingdom; ³Asan Medical Center, University of Ulsan, Seoul, Republic of Korea; ⁴Herlev and Gentofte Hospital, Herlev, Denmark; ⁵University Hospital of Southern Denmark, Vejle, Denmark; ⁶Amsterdam University Medical Centers, University of Amsterdam, Amsterdam, Netherlands; ⁷Bordeaux University Hospital, Bordeaux, France; ⁸Hospital Universitario 12 de Octubre, Ima12, CNIO, UCM, Madrid, Spain; ⁹Hospital Regional Universitario de Malaga, Malaga, Spain; ¹⁰Western Health, St Albans, Australia; ¹¹Léon Bérard Center, Lyon, France; ¹²Hospital Universitario Marques de Valdecilla, IDIVAL, Santander, Spain; ¹³Vall d'Hebron Institute of Oncology, Barcelona, Spain; ¹⁴Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN, USA; ¹⁵Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, USA; ¹⁶National Cancer Center Hospital East, Kashiwa, Japan; ¹⁷MSD China, Beijing, China; ¹⁸Merck & Co., Inc. Kenilworth, NJ, USA; ¹⁹Memorial Sloan Kettering Cancer Center, New York, NY, USA

ESMO World Congress on Gastrointestinal Cancer 2021; Abstract O-8.

KEYNOTE-177: Progression-Free Survival

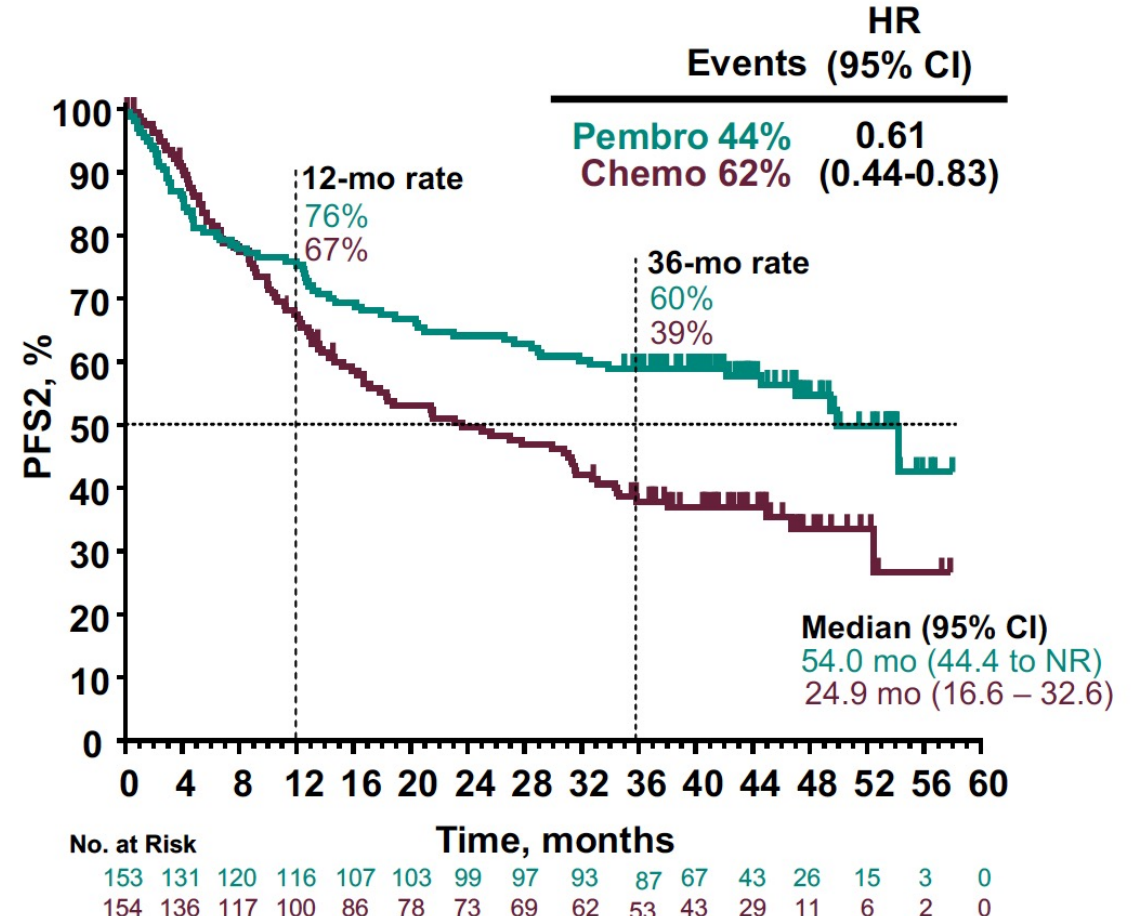
PFS

Time from randomization to progression or any cause death

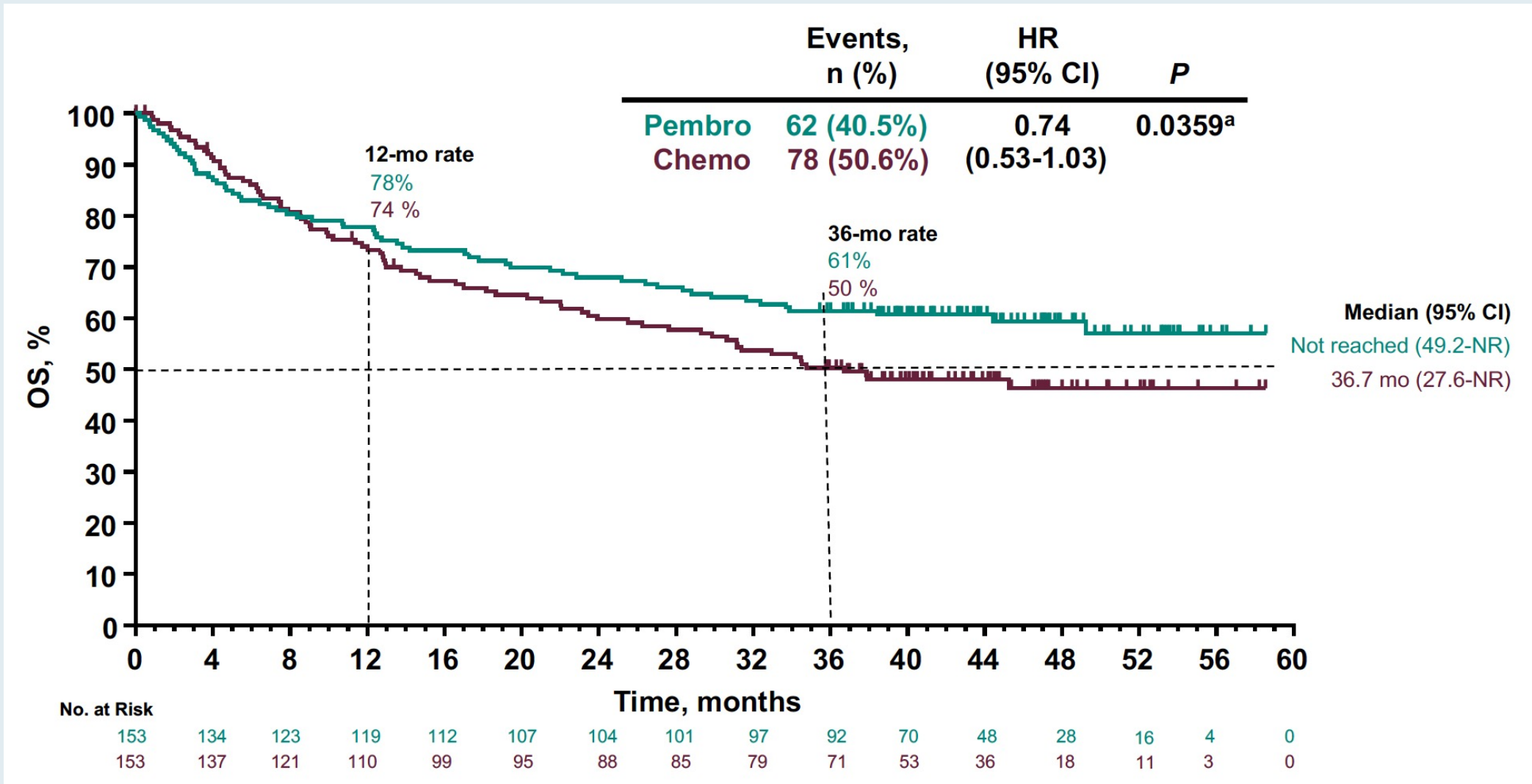


PFS2

Time from randomization to progression on next line therapy or any cause death



KEYNOTE-177: Overall Survival





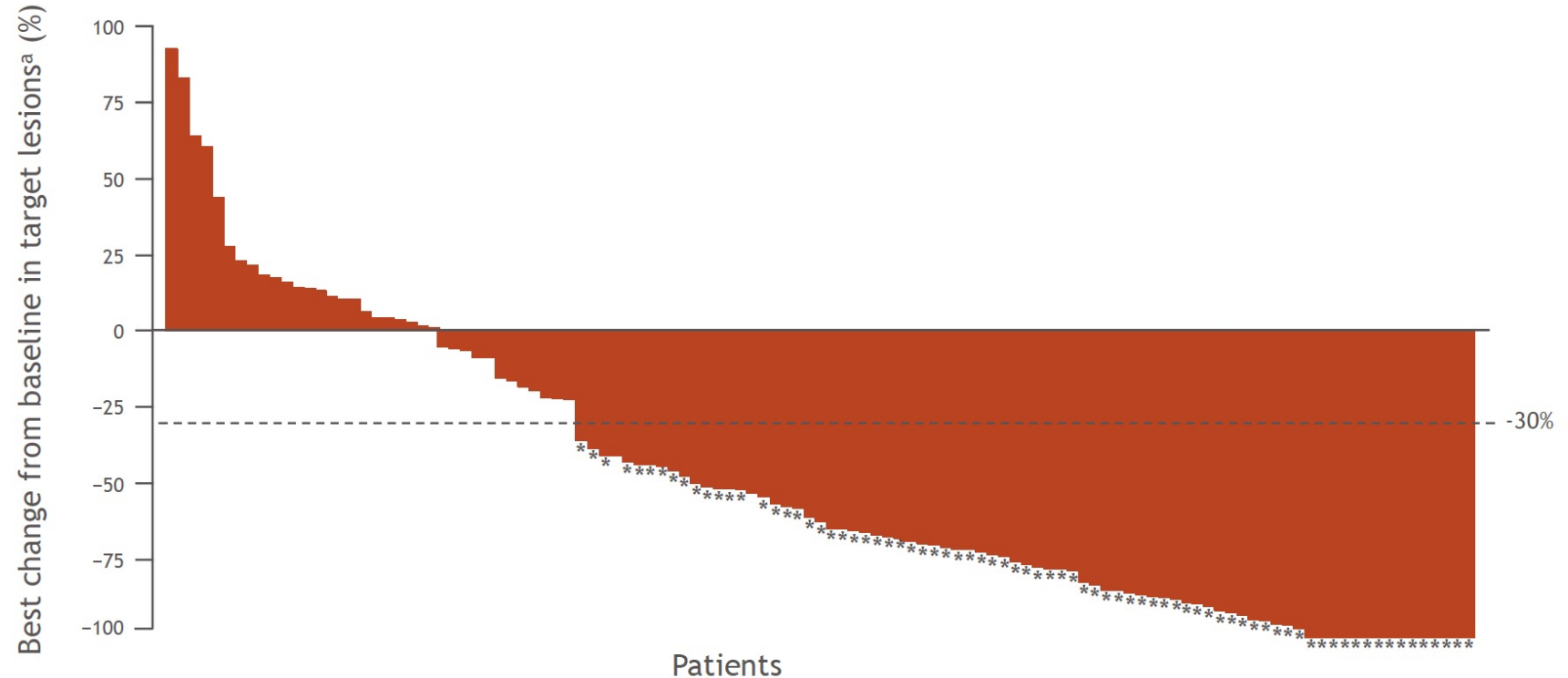
NIVOLUMAB PLUS LOW-DOSE IPILIMUMAB IN PREVIOUSLY TREATED PATIENTS WITH MICROSATELLITE INSTABILITY-HIGH/ MISMATCH REPAIR-DEFICIENT METASTATIC COLORECTAL CANCER: 4-YEAR FOLLOW-UP FROM CHECKMATE 142

Thierry André,¹ Sara Lonardi,² Ka Yeung Mark Wong,³ Heinz-Josef Lenz,⁴ Fabio Gelsomino,⁵ Massimo Aglietta,⁶ Michael A. Morse,⁷ Eric Van Cutsem,⁸ Ray McDermott,⁹ Andrew Hill,¹⁰ Michael B. Sawyer,¹¹ Alain Hendlisz,¹² Bart Neyns,¹³ Sandzhar Abdullaev,¹⁴ Arteid Memaj,¹⁴ Ming Lei,¹⁴ Scott Kopetz,¹⁵ Michael Overman¹⁵

¹Hôpital Saint Antoine, Assistance Publique Hôpitaux de Paris and Sorbonne Université, Paris, France; ²Istituto Oncologico Veneto IOV-IRCSS, Padova, Italy; ³Westmead Hospital, Sydney, NSW, Australia; ⁴University of Southern California Norris Comprehensive Cancer Center, Los Angeles, CA, USA; ⁵University Hospital of Modena, Modena, Italy; ⁶Candiolo Cancer Institute and University of Torino Medical School, Candiolo, Italy; ⁷Duke University Medical Center, Durham, NC, USA; ⁸University Hospitals Gasthuisberg/ Leuven and KU Leuven, Leuven, Belgium; ⁹St Vincent's University Hospital and Cancer Trials Ireland, Dublin, Ireland; ¹⁰Tasman Oncology Research, Ltd., Southport, QLD, Australia; ¹¹Cross Cancer Institute and University of Alberta, Edmonton, AB, Canada; ¹²Institut Jules Bordet, Brussels, Belgium; ¹³Universitair Ziekenhuis Brussel, Brussels, Belgium; ¹⁴Bristol Myers Squibb, Princeton, NJ, USA; ¹⁵MD Anderson Cancer Center, Houston, TX, USA

ESMO World Congress on Gastrointestinal Cancer 2021; Abstract SO-27.

CheckMate 142: Four-Year Update of Nivolumab/Ipilimumab as First-Line Therapy for MSI-H/dMMR mCRC



- Most patients (79%) had a reduction in tumor burden from baseline

- Median PFS and OS were not reached
- 48-month PFS rate: 53%
- 48-month OS rate: 70.5%

FDA Grants Accelerated Approval to Dostarlimab-gxly for dMMR Advanced Solid Tumors

Press Release – August 17, 2021

“The Food and Drug Administration granted accelerated approval to dostarlimab-gxly for adult patients with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.

Today, the FDA also approved the VENTANA MMR RxDx Panel as a companion diagnostic device to select patients with dMMR solid tumors for treatment with dostarlimab-gxly.

The efficacy of dostarlimab was evaluated in the GARNET Trial (NCT02715284), a non-randomized, multicenter, open-label, multi-cohort trial. The efficacy population consisted of 209 patients with dMMR recurrent or advanced solid tumors who progressed following systemic therapy and had no satisfactory alternative treatment.”

2021 ASCO[®]
ANNUAL MEETING

Abstract 3505

The logo for DESTINY-CRC01 features a stylized sun or globe icon above the text. The icon consists of a yellow arc on the left, a blue arc on the right, and a green arc at the bottom, all within a white circular frame. Below the icon, the text "DESTINY-CRC01" is written in a bold, dark blue, sans-serif font.

DESTINY-CRC01

Trastuzumab Deruxtecan (T-DXd; DS-8201) in Patients With HER2-expressing Metastatic Colorectal Cancer: Final Results From a Phase 2, Multicenter, Open-label Study (DESTINY-CRC01)

Takayuki Yoshino; National Cancer Center Hospital East, Kashiwa, Japan

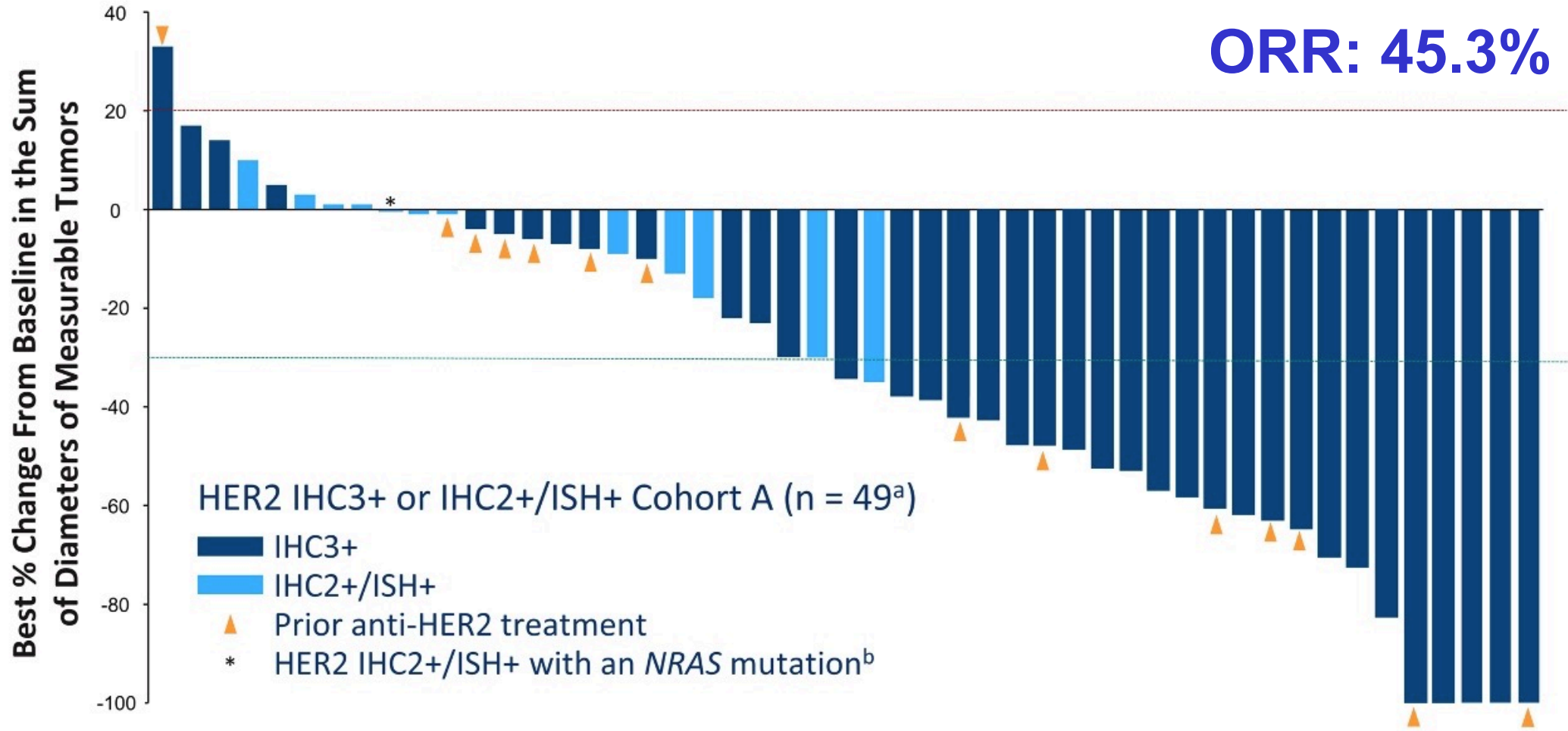
June 7, 2021

Additional authors: Maria Di Bartolomeo, Kanwal Raghav, Toshiki Masuishi, Fotios Loupakis, Hisato Kawakami, Kensei Yamaguchi, Tomohiro Nishina, Zev Wainberg, Elena Elez, Javier Rodriguez, Marwan Fakih, Fortunato Ciardiello, Kapil Saxena, Kojiro Kobayashi, Emarjola Bako, Yasuyuki Okuda, Gerold Meinhardt, Axel Grothey, Salvatore Siena

On behalf of the DESTINY-CRC01 investigators

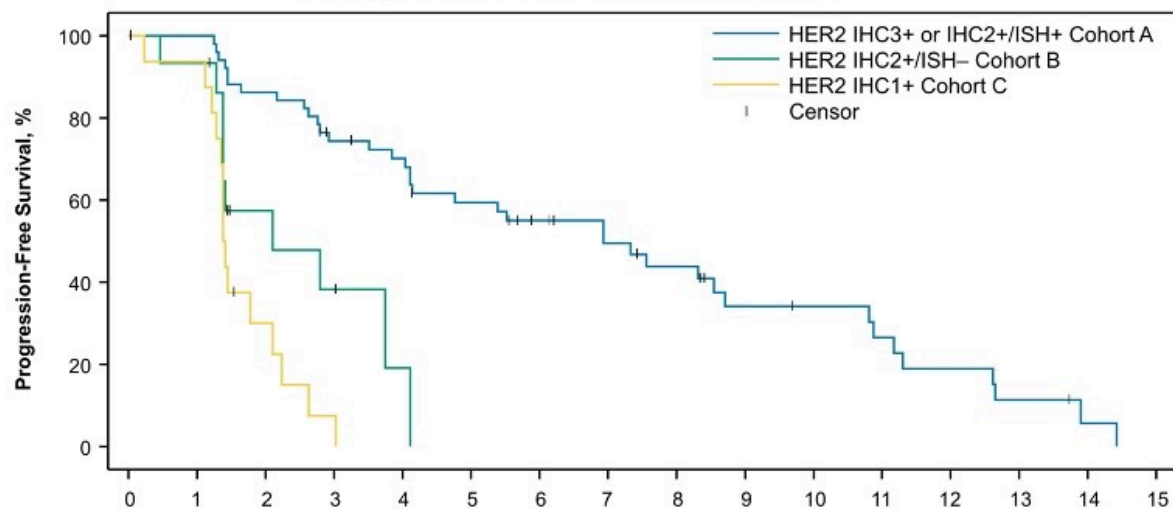
DESTINY-CRC01: Best Change in Tumor Size in Cohort A

ORR: 45.3%



DESTINY-CRC01: Progression-Free and Overall Survival

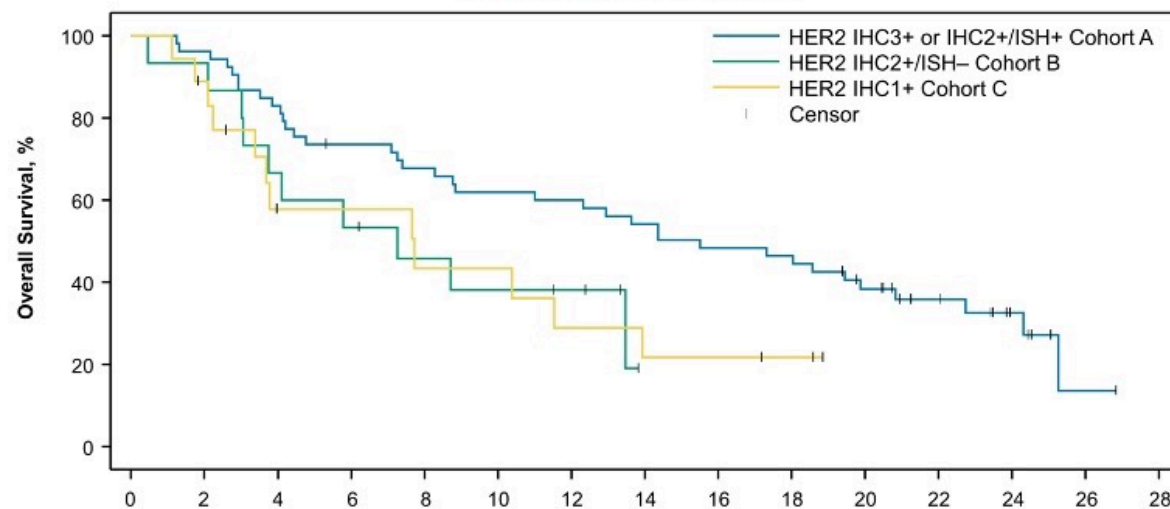
Progression-Free Survival



No. at Risk	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Cohort A	53	51	44	36	33	27	22	18	15	10	9	7	5	3	1	0
Cohort B	15	14	6	4	1	0	0	0	0	0	0	0	0	0	0	0
Cohort C	18	15	4	1	0	0	0	0	0	0	0	0	0	0	0	0

	HER2 IHC3+ or IHC2+/ISH+ Cohort A (n = 53)	HER2 IHC2+/ISH- Cohort B (n = 15)	HER2 IHC1+ Cohort C (n = 18)
mPFS (95% CI), months	6.9 (4.1-8.7)	2.1 (1.4-4.1)	1.4 (1.3-2.1)

Overall Survival



No. at Risk	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Cohort A	53	51	44	38	35	32	31	28	25	24	18	12	6	1	0
Cohort B	15	14	10	8	6	5	4	0	0	0	0	0	0	0	0
Cohort C	18	15	8	8	6	6	4	3	3	2	0	0	0	0	0

	HER2 IHC3+ or IHC2+/ISH+ Cohort A (n = 53)	HER2 IHC2+/ISH- Cohort B (n = 15)	HER2 IHC1+ Cohort C (n = 18)
mOS (95% CI), months	15.5 (8.8-20.8)	7.3 (3.0-NE)	7.7 (2.2-13.9)

DESTINY-CRC01 AEs of Special Interest: Interstitial Lung Disease

All Patients (N=86)	n (%)
Grade 1	0
Grade 2	4 (4.7)
Grade 3	1 (1.2)
Grade 4	0
Grade 5	3 (3.5) ^a
Any Grade/Total	8 (9.3) ^{b,c}

Adjudicated drug-related ILDs:

- Median time to adjudicated onset was 61.0 days (range, 9-165 days)
- 8 of 8 patients received corticosteroids
- 4 patients with grade 2 recovered and 1 patient with grade 3 did not recover (later died due to disease progression)
- Median time from adjudicated onset date to initiation of steroid treatment in the 8 ILD cases was 3.5 days, (range 0-50)

Grade 5 ILDs:

- In the 3 fatal cases adjudicated as drug-related ILD, onset was from 9 days to 120 days (median: 22 days); and death occurred 6-19 days after diagnosis (median: 6 days)

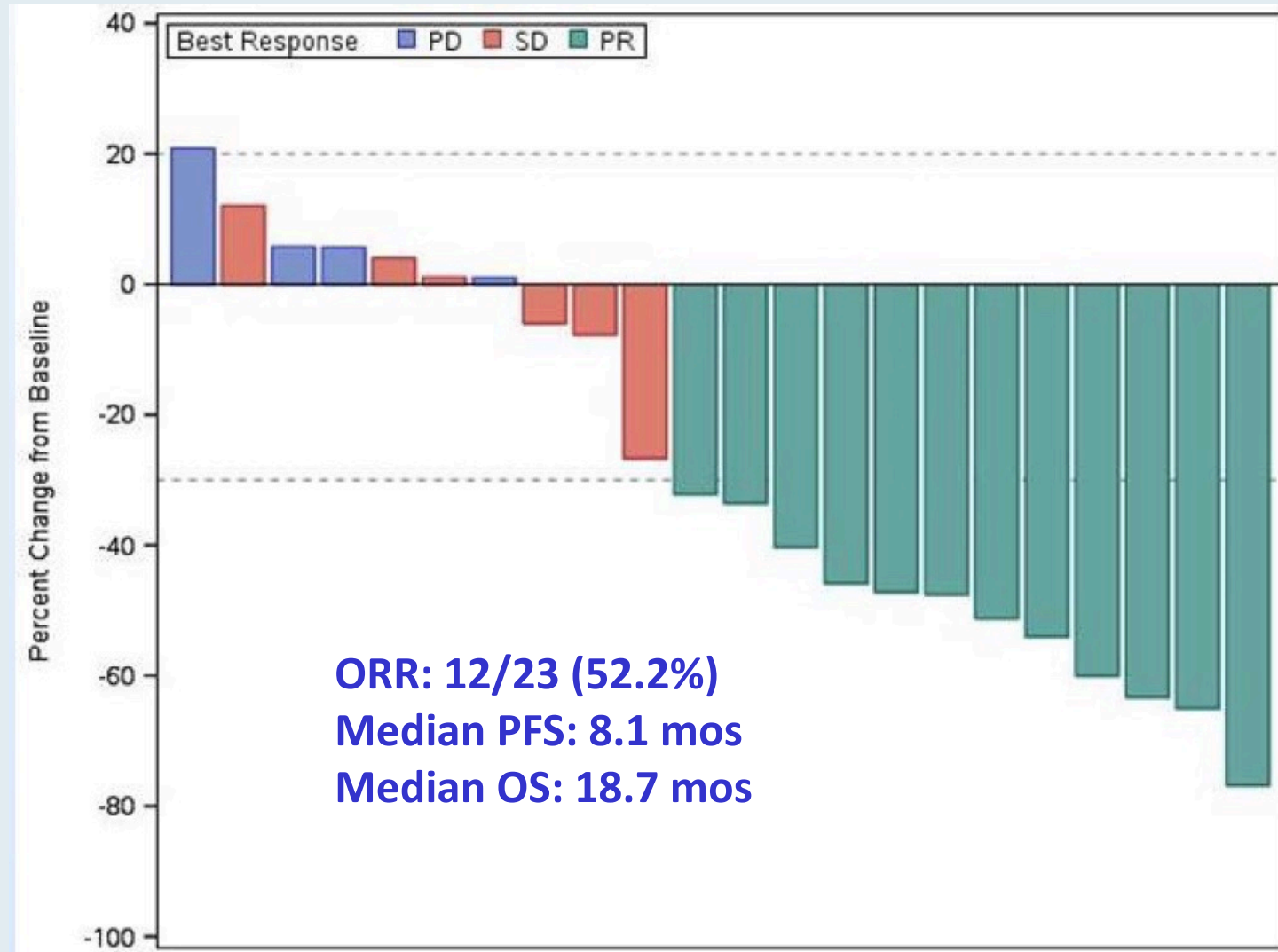
Updated ILD/pneumonitis guidelines recommend to monitor for symptoms, interrupt or discontinue T-DXd, conduct imaging (as clinically indicated), and start steroids as soon as ILD is suspected.

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



Hepatocellular Carcinoma

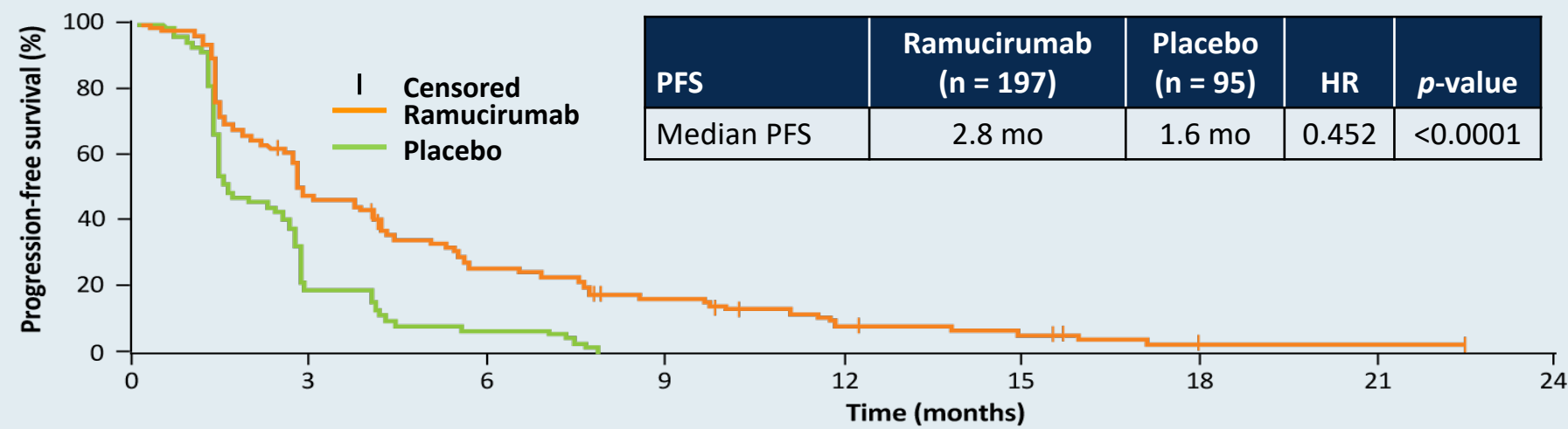
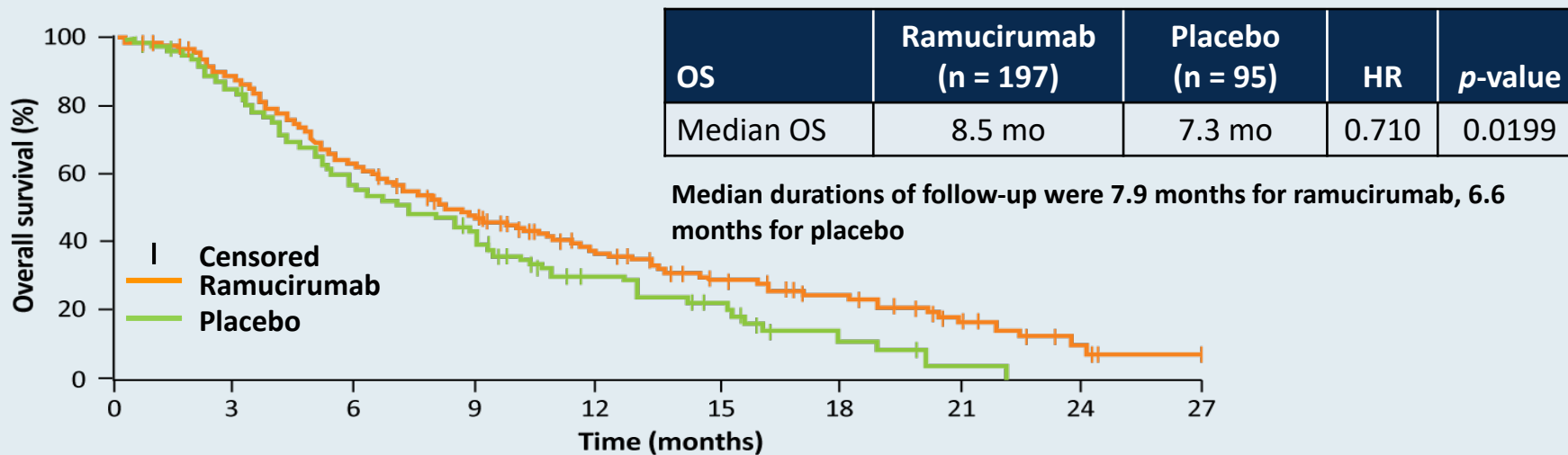


Ramucirumab after sorafenib in patients with advanced hepatocellular carcinoma and increased α -fetoprotein concentrations (REACH-2): a randomised, double-blind, placebo-controlled, phase 3 trial

*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



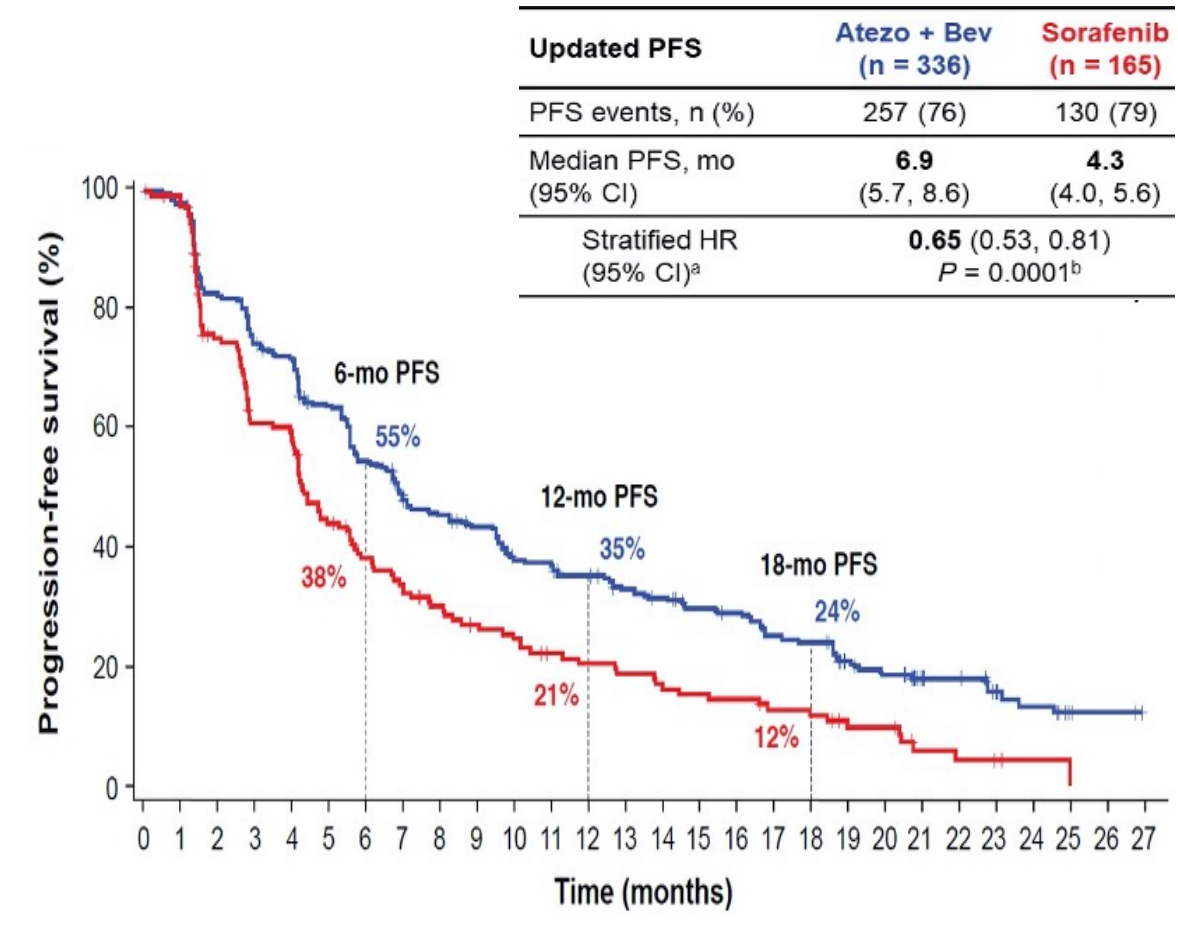
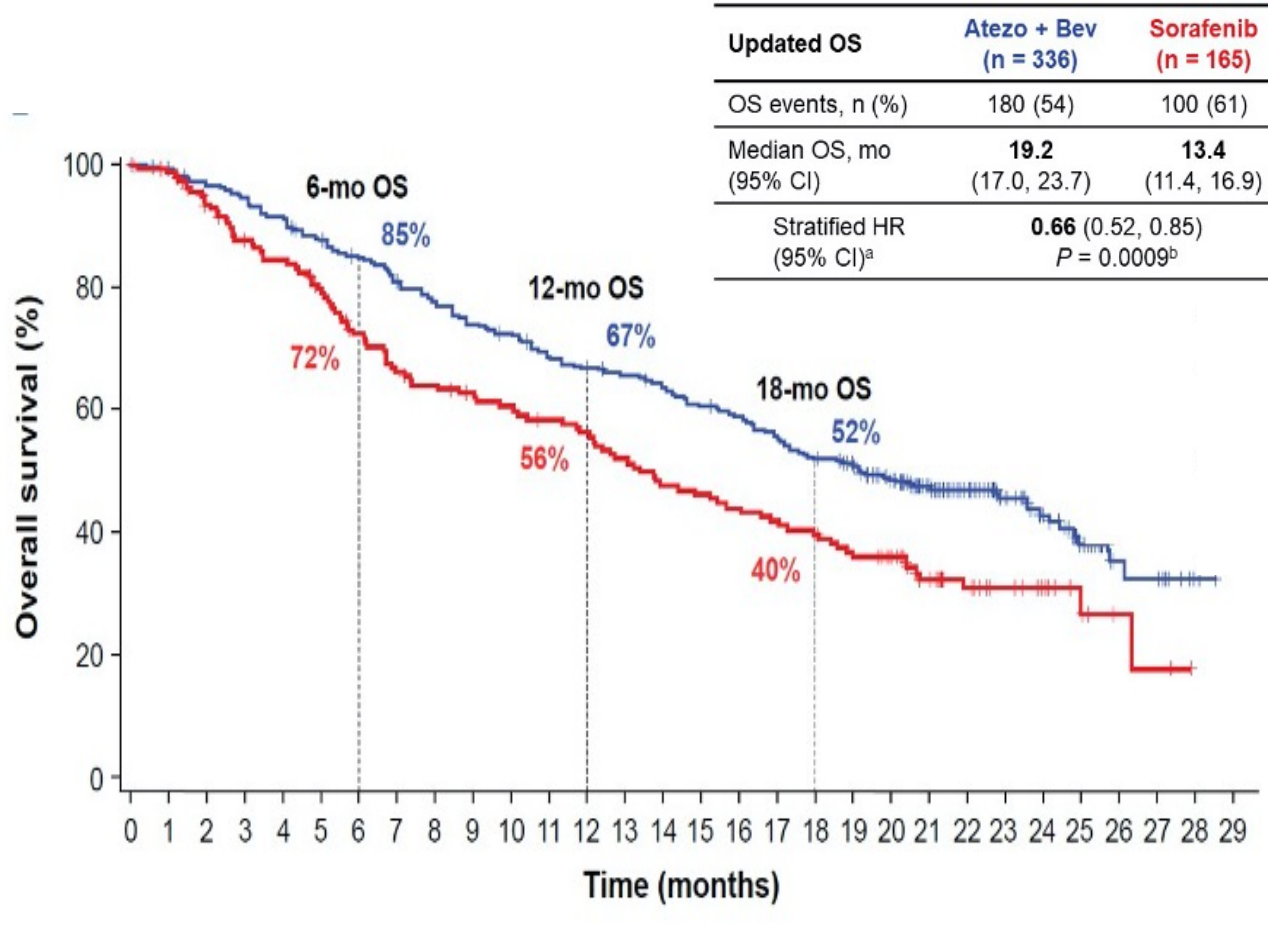
Grade ≥3 AEs associated with ramucirumab included hypertension and hyponatremia.

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)

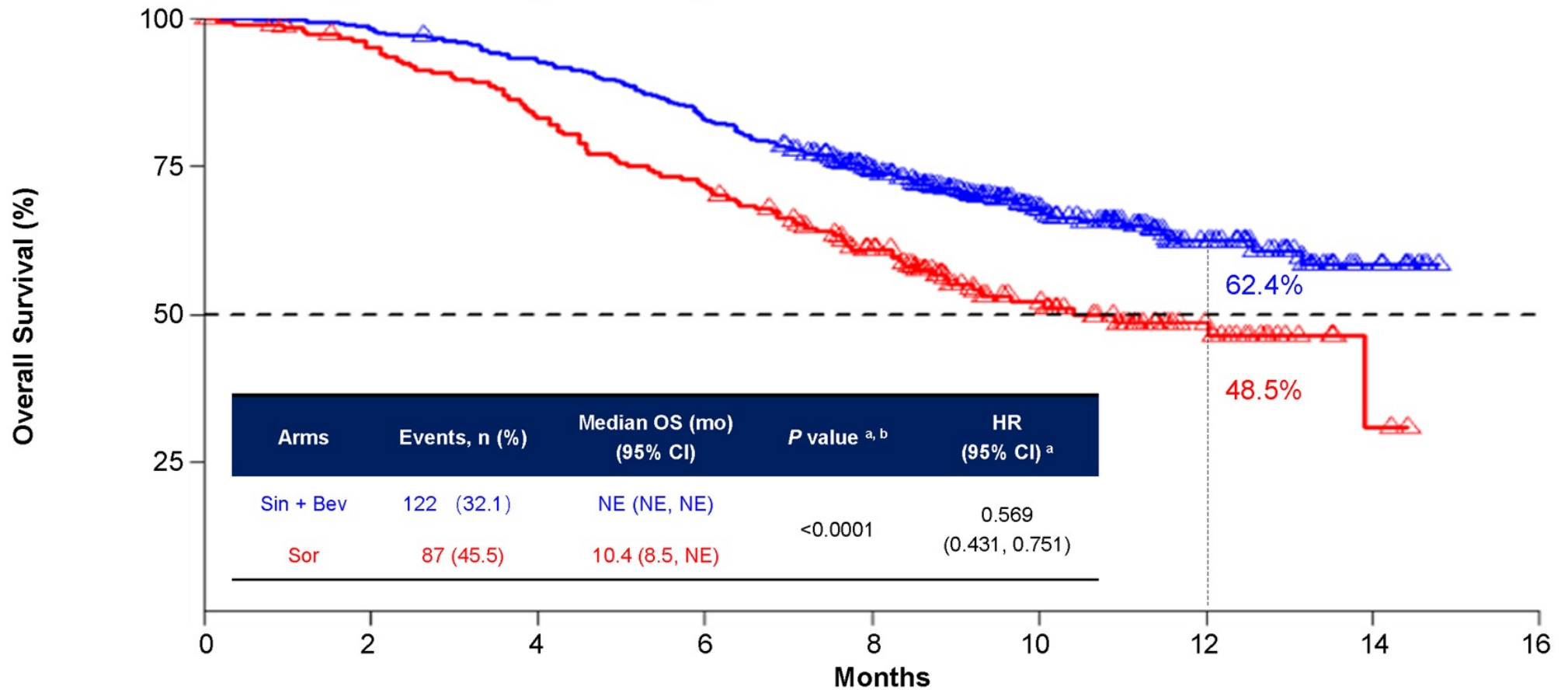


Sintilimab plus Bevacizumab Biosimilar vs Sorafenib as First-Line Treatment for Advanced Hepatocellular Carcinoma (ORIENT-32)

Ren Z et al.

ESMO Asia 2020;Abstract LBA2.

ORIENT-32 Coprimary Endpoint: Overall Survival



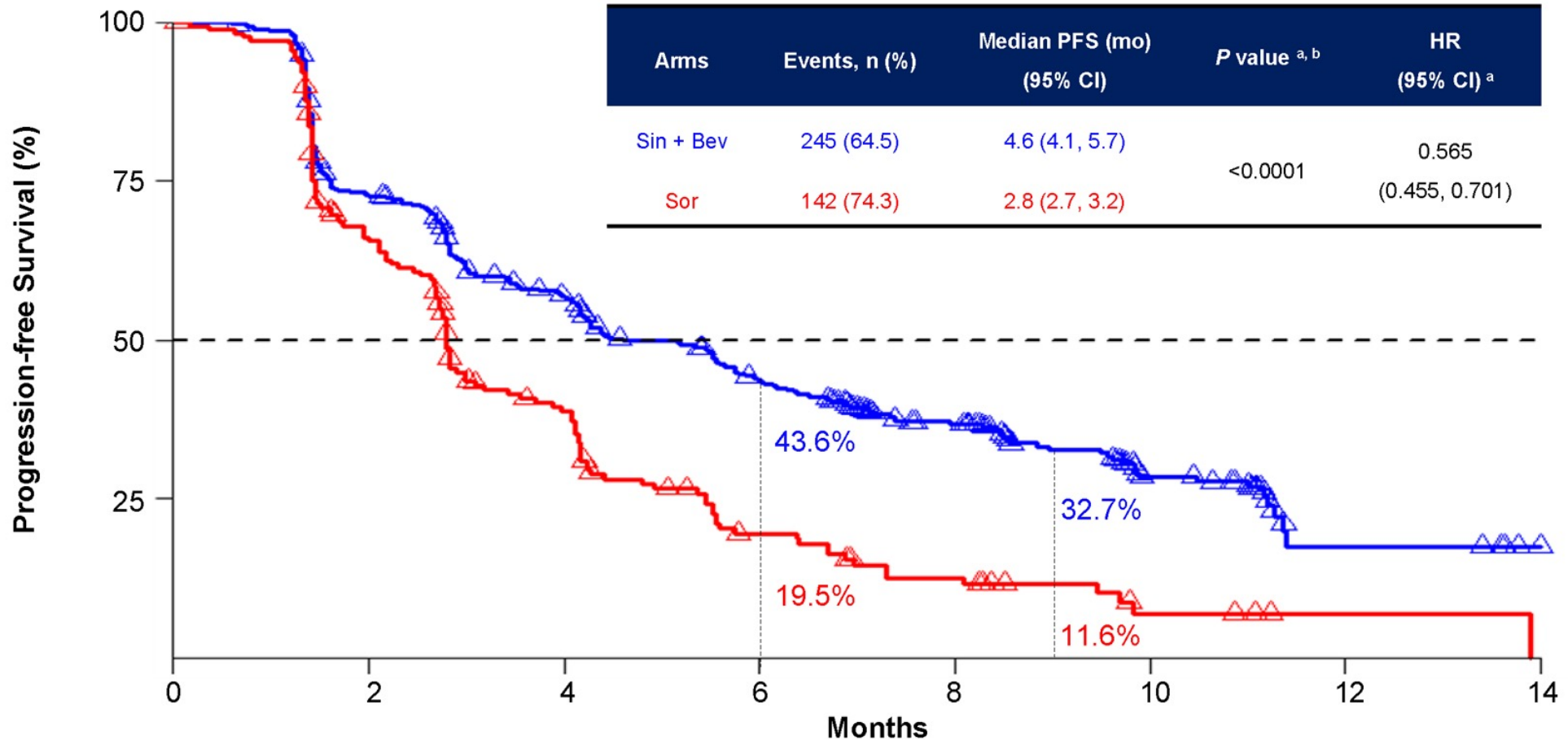
Number at risk

	0	2	4	6	8	10	12	14	16
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

ORIENT-32 Coprimary Endpoint: Progression-Free Survival



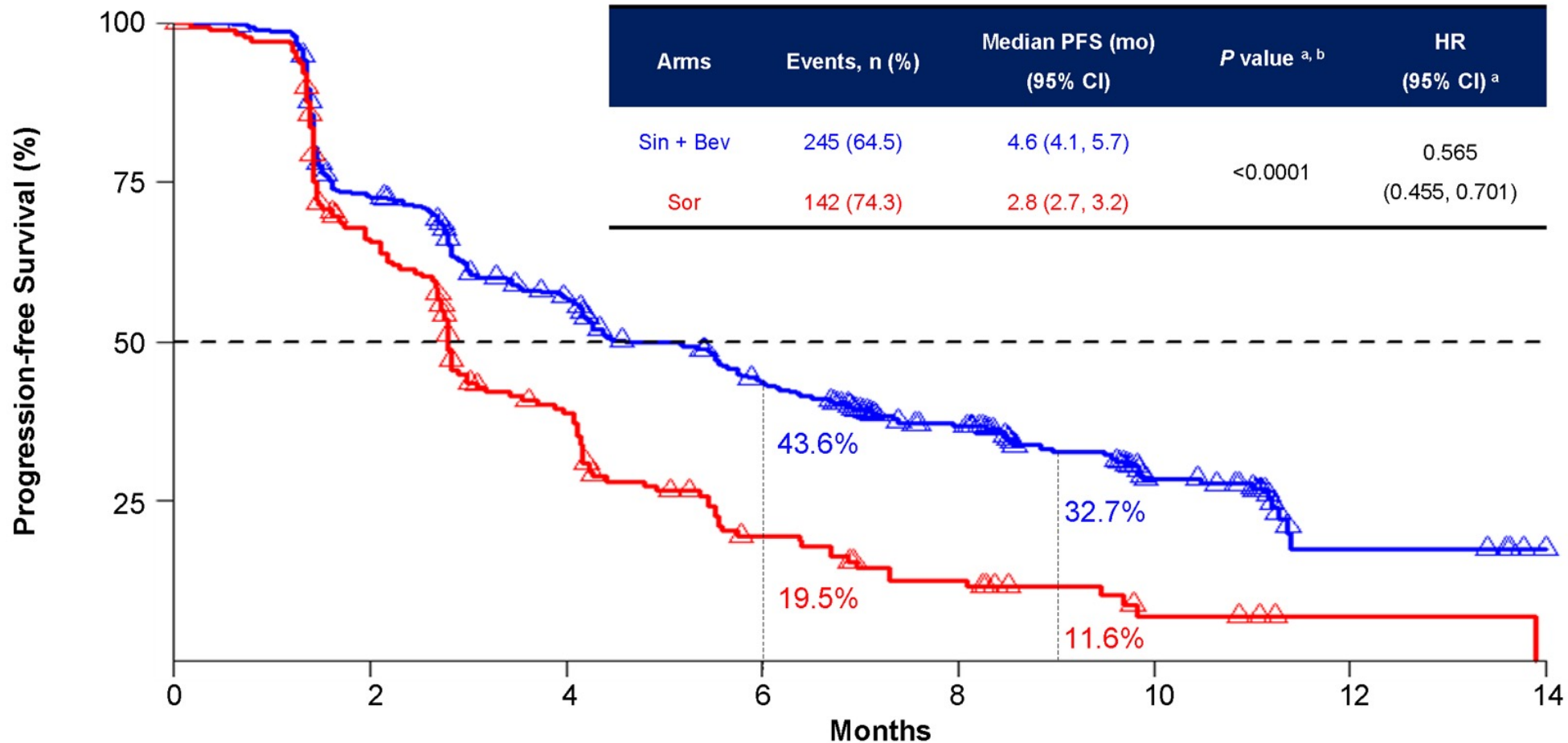
Number at risk

Months	0	2	4	6	8	10	12	14
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

ORIENT-32 Coprimary Endpoint: Progression-Free Survival



Number at risk		0	2	4	6	8	10	12	14
Sin + Bev	380	267	197	144	89	37	7	0	0
Sor	191	111	55	24	13	4	1	0	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

Faculty This Week

WCLC



Edward B Garon, MD, MS
Professor
Director, Thoracic Oncology Program
Director, Signal Transduction and Therapeutics
Research Program
David Geffen School of Medicine at UCLA
Jonsson Comprehensive Cancer Center
Los Angeles, California



Harvey I Pass, MD
Stephen E Banner Professor of Thoracic Oncology
Vice-Chairman, Research
Department of Cardiothoracic Surgery
Director, General Thoracic Surgery
NYU Langone Medical Center
New York, New York



Heather Wakelee, MD
Professor of Medicine
Chief, Division of Oncology
Stanford University School of Medicine
Deputy Director, Stanford Cancer Institute
Stanford, California

AUA Bladder



Arjun Balar, MD
Associate Professor, Department of Medicine
Director, Genitourinary Medical Oncology Program
Medical Director, Clinical Trials Office
NYU Perlmutter Cancer Center
New York, New York



Ashish M Kamat, MD, MBBS
Professor of Urologic Oncology (Surgery)
Wayne B Duddleston Professor of Cancer Research
Department of Urology, Division of Surgery
The University of Texas MD Anderson Cancer Center
Houston, Texas



Guru Sonpavde, MD
Bladder Cancer Director
Dana-Farber Cancer Institute
Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Faculty This Week



Robert Svatek, MD
Associate Professor
Department of Urology
UT Health Science Center
San Antonio, Texas



Maha Hussain, MD, FACP, FASCO
Genevieve Teuton Professor of Medicine
Division of Hematology/Oncology
Deputy Director
Robert H Lurie Comprehensive Cancer Center
Northwestern University Feinberg School of Medicine
Chicago, Illinois

AUA Prostate



Leonard G Gomella, MD
The Bernard W Godwin Professor of
Prostate Cancer
Chairman, Department of Urology
Senior Director, Clinical Affairs, Sidney Kimmel
Cancer Center
Enterprise VP for Urology, Jefferson Health System
Thomas Jefferson University and Hospital
Philadelphia, Pennsylvania



A Oliver Sartor, MD
Laborde Professor for Cancer Research
Medical Director, Tulane Cancer Center
Assistant Dean for Oncology
Tulane Medical School
New Orleans, Louisiana



Neal D Shore, MD
Director, CPI, Carolina Urologic Research Center
Chief Medical Officer, Surgery/Urology
GenesisCare, US
Medical Director, CUSP: Clinical Research
Consortium
Myrtle Beach, South Carolina

Faculty This Week

Meet The Professor: RCC



Neeraj Agarwal, MD

Professor of Medicine
Senior Director for Clinical Research Innovation
Huntsman Cancer Institute Presidential Endowed Chair
of Cancer Research
Director, Center of Investigational Therapeutics
Director, Genitourinary Oncology Program
Huntsman Cancer Institute, University of Utah
Salt Lake City, Utah

Meet The Professor: Lymphomas



Loretta J Nastoupil, MD

Associate Professor
Section Chief, Indolent Lymphoma
Section Chief, New Drug Development
Department of Lymphoma/Myeloma
The University of Texas MD Anderson
Cancer Center
Houston, Texas

Video Case Presenters

Sunday, WLCC



Jarushka Naidoo, MB BCH, MHS
Consultant Medical Oncologist
Beaumont Hospital
Dublin, Ireland
Adjunct Assistant Professor of Oncology
Johns Hopkins University
Baltimore, Maryland



Jason Hafron, MD
Chief Medical Officer
Director of Clinical Research
Michigan Institute of Urology
Professor of Urology
Oakland University William
Beaumont School of Medicine
Bloomfield, Michigan

Monday, AUA



Gordon A Brown, DO
Associate Professor of Urology
Rowan University SOM
Medical Director of Advanced
Therapeutics
New Jersey Urology
Director of Robotic Surgery
Jefferson Health New Jersey
Sewell, New Jersey



Sulfi Ibrahim, MD
Hematology/Oncology
Reid Health
Richmond, Indiana



David S Morris, MD
President and Co-Director of
Advanced Therapeutics Center
Urology Associates
Nashville, Tennessee

Video Case Presenters

Tuesday, Meet The Professor: RCC



Hans Hammers, MD, PhD
Eugene P Frenkel, MD Scholar in
Clinical Medicine
Co-Leader, Kidney Cancer Program
Co-Leader, Experimental Therapeutics
Associate Professor, Internal Medicine
Division of Hematology and Oncology
UT Southwestern Medical Center
Dallas, Texas



Eric Jonasch, MD
Professor of Medicine
Department of Genitourinary
Medical Oncology
The University of Texas
MD Anderson Cancer Center
Houston, Texas



Elizabeth R Plimack, MD, MS
Chief, Division of Genitourinary Medical
Oncology
Director, Genitourinary Clinical Research
Professor, Department of Hematology/
Oncology
Fox Chase Cancer Center, Temple Health
Philadelphia, Pennsylvania



Thomas Powles, MBBS, MRCP, MD
Professor of Genitourinary Oncology
Barts Cancer Institute
Director of Barts Cancer Centre
Queen Mary University of London
London, United Kingdom

Thursday, Meet The Professor: Lymphomas



Mitchell R Smith, MD, PhD
Clinical Professor of Medicine
George Washington University
Washington, DC

Meet The Professor

Optimizing the Selection and Sequencing of Therapy for Patients with Urothelial Bladder Carcinoma

**Tuesday, September 21, 2021
5:00 PM – 6:00 PM ET**

Faculty

Jonathan E Rosenberg, MD

Moderator

Neil Love, MD

Thank you for joining us!

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