Meet The Professor
Immunotherapy and Novel Agents in Gynecologic Cancers

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The University of Texas
MD Anderson Cancer Center
Houston, Texas

Commercial Support

This activity is supported by educational grants from Eisai Inc, Genmab and Seagen Inc, Merck, and Tesaro, A GSK Company.

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Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, Adaptive Biotechnologies Corporation, ADC Therapeutics, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Coherus BioSciences, Daiichi Sankyo Inc, Eisai Inc, Epizyme Inc, Exact Sciences Inc, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Genmab, Gilead Sciences Inc, GlaxoSmithKline, Grail Inc, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Natera Inc, Novartis, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seagen Inc, Servier Pharmaceuticals LLC, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc and Verastem Inc.

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

Dr Westin — Disclosures

Consulting Agreements	Agenus Inc, AstraZeneca Pharmaceuticals LP, Clovis Oncology, Eisai Inc, EQRx, Genentech, a member of the Roche Group, GlaxoSmithKline, Lilly, Merck, Mereo BioPharma, Novartis, Zentalis Pharmaceuticals
Contracted Research	AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Clovis Oncology, Cotinga Pharmaceuticals, Genentech, a member of the Roche Group, GlaxoSmithKline, Mereo BioPharma, Novartis, OncXerna Therapeutics Inc, Zentalis Pharmaceuticals

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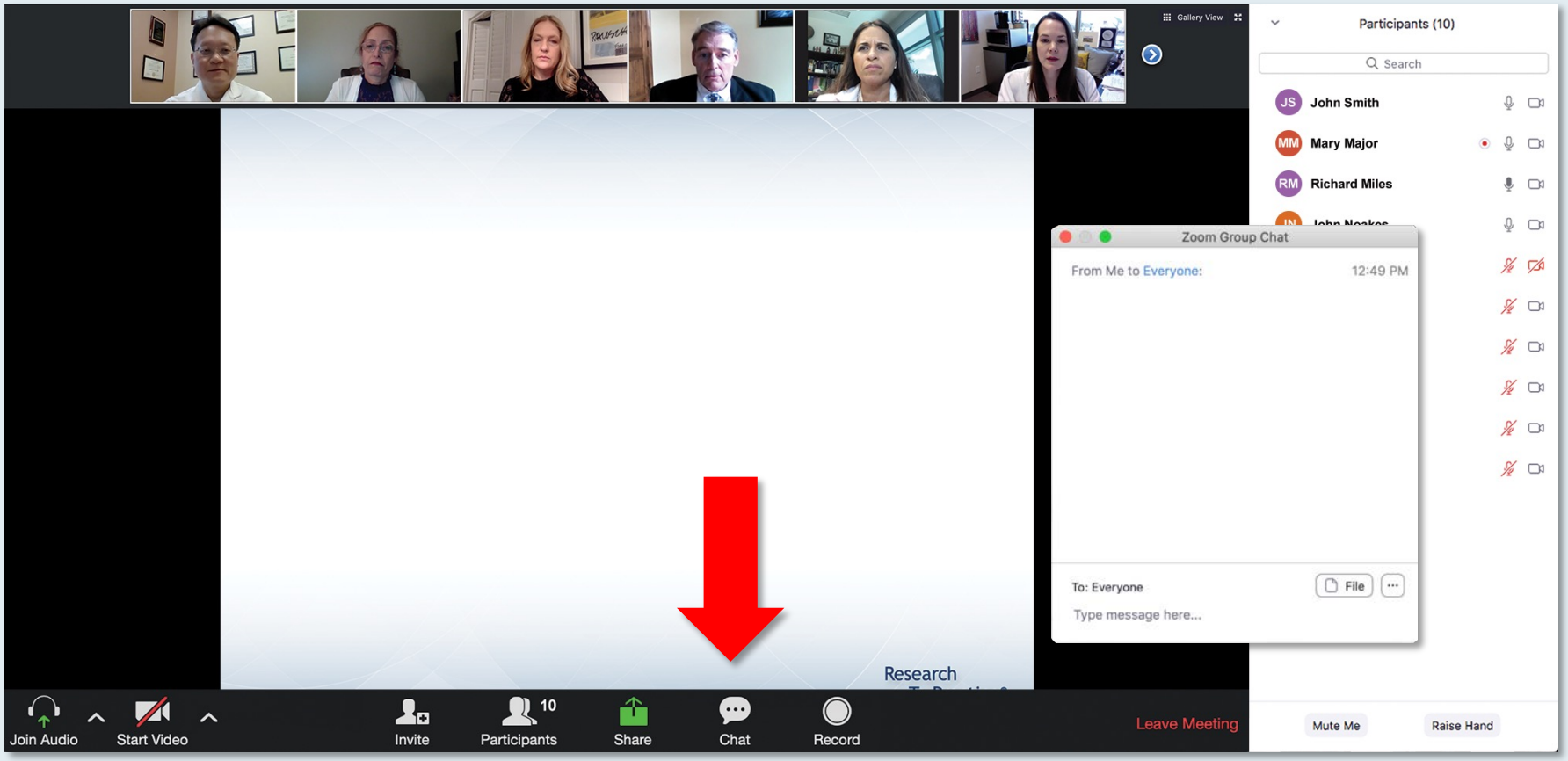

Feel free to submit questions now before the program begins and throughout the program.

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Familiarizing Yourself with the Zoom Interface

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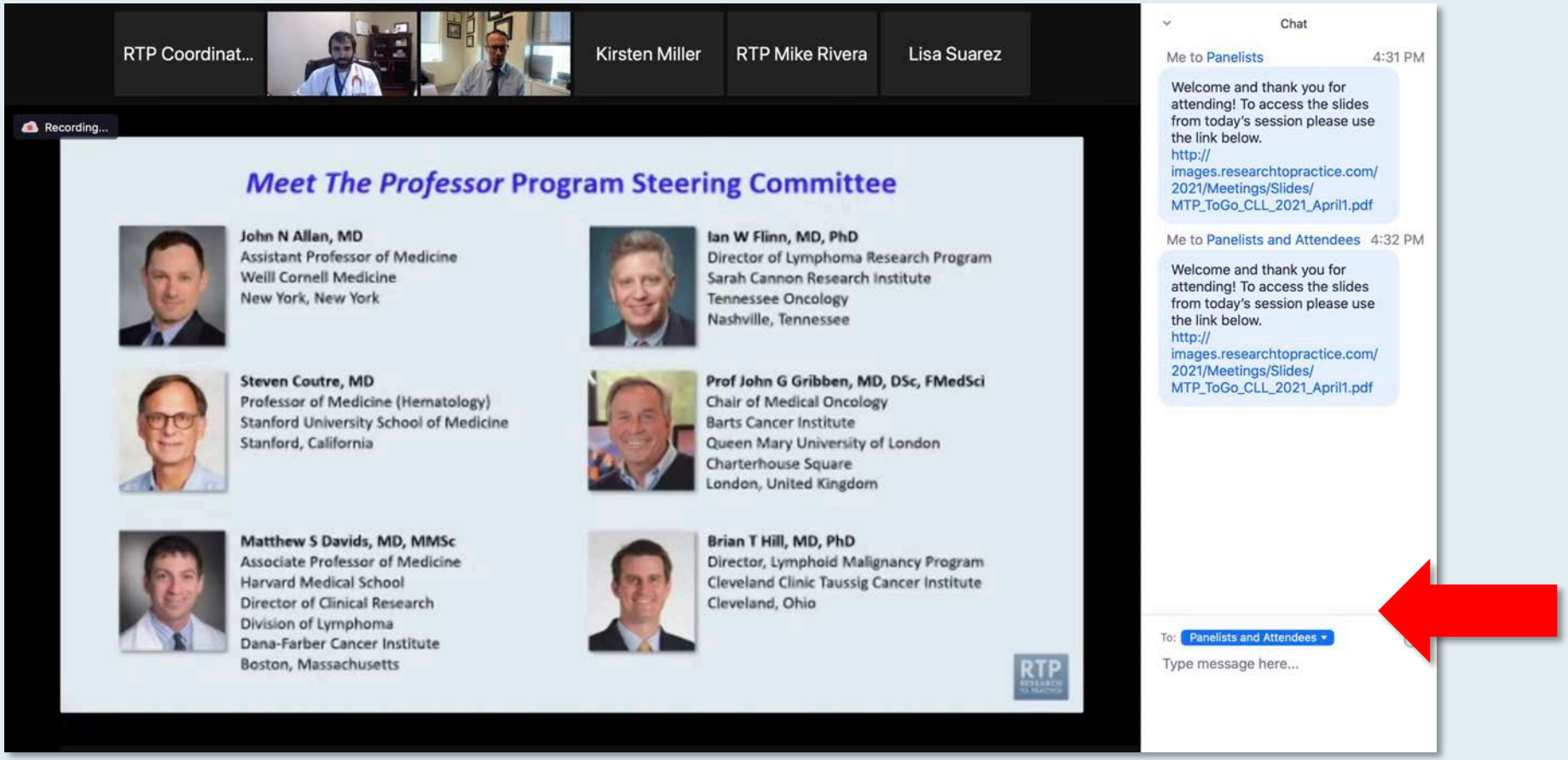

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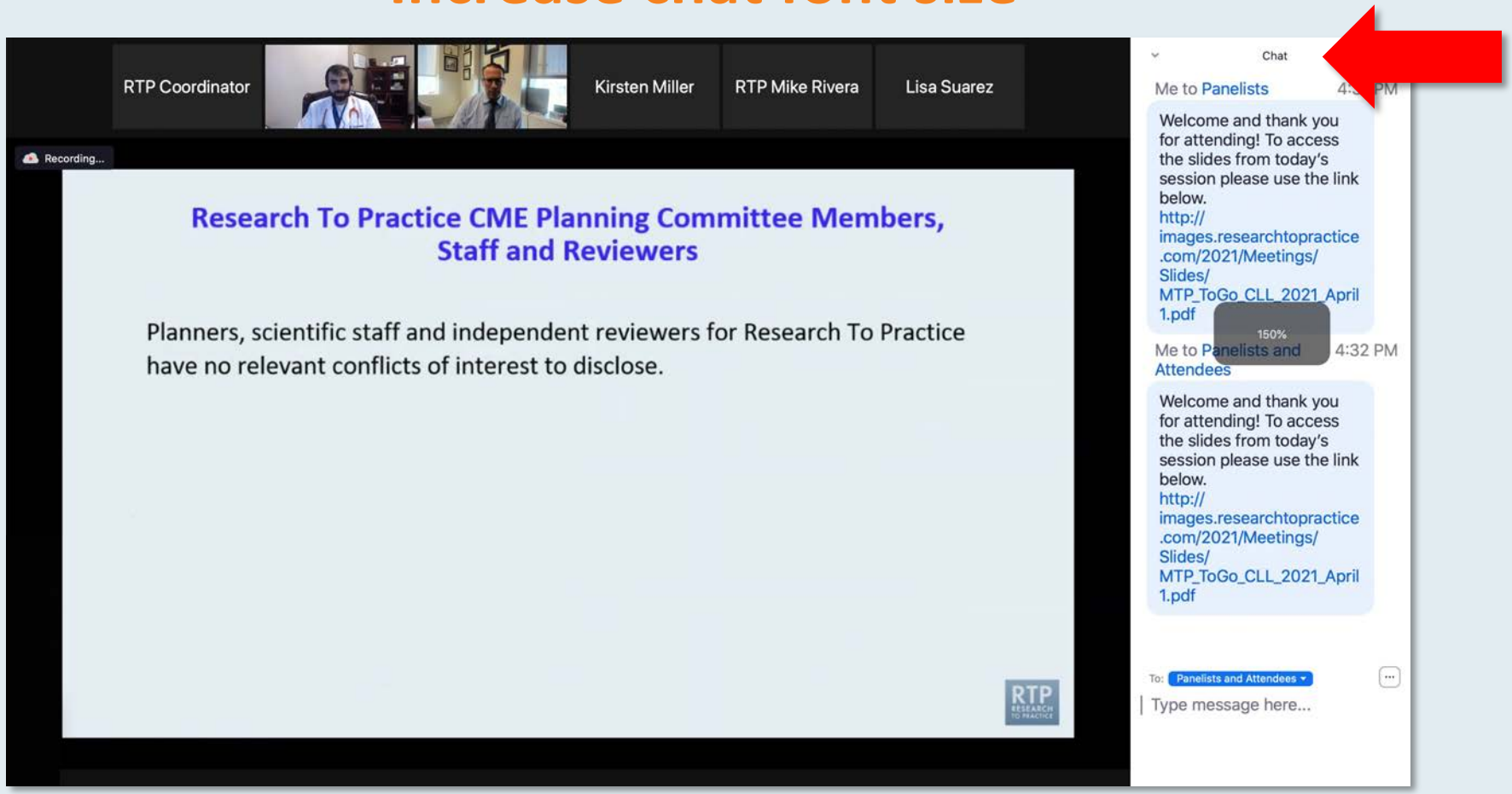

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Key Presentations on Gynecologic Cancers from the 2021 ASCO Annual Meeting

DR KATHLEEN MOORE

UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER

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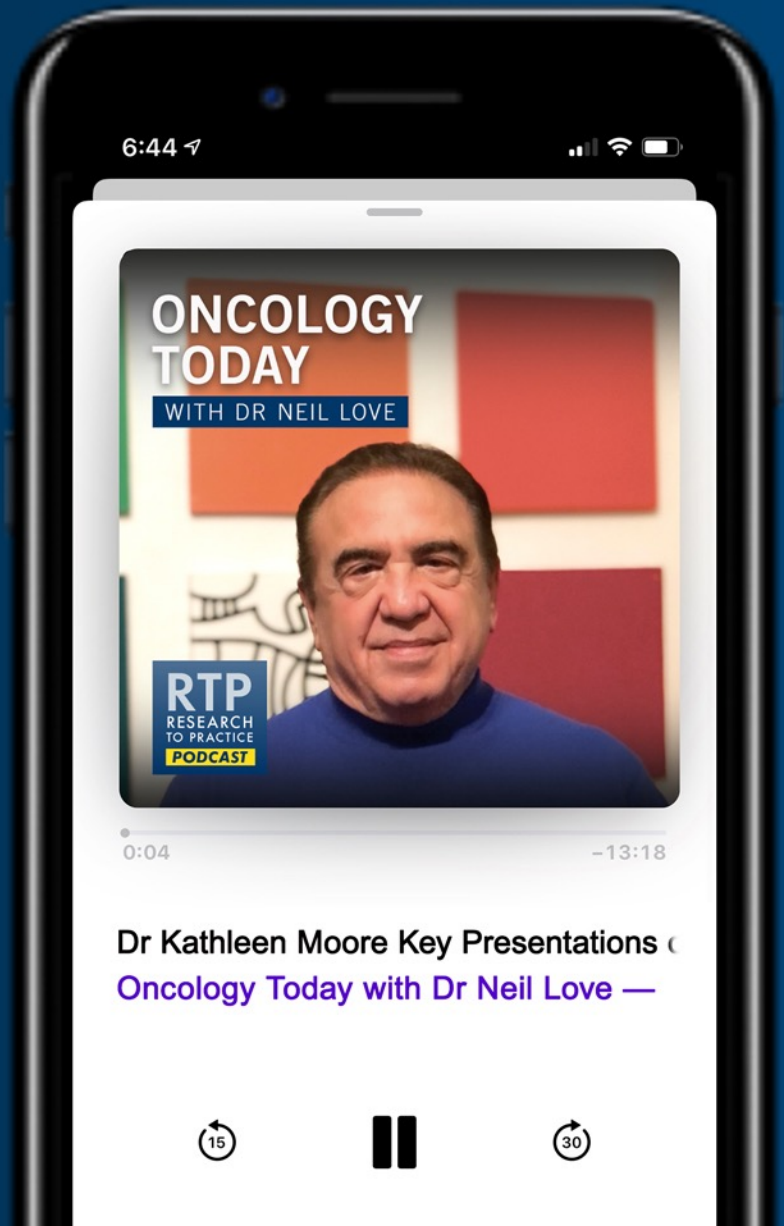

Meet The Professor

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

Wednesday, October 13, 2021
5:00 PM – 6:00 PM ET

Faculty

Erika Hamilton, MD

Moderator

Neil Love, MD

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Meet The Professor

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

Wednesday, October 20, 2021
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Aditya Bardia, MD, MPH

Moderator

Neil Love, MD

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Recent Advances and Future Directions in Oncology: A Daylong Multitumor Educational Webinar in Partnership with Florida Cancer Specialists

A CME-MOC/NCPD Accredited Virtual Event

Saturday, October 23, 2021
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Tanios Bekaii-Saab, MD
Kristen K Ciombor, MD, MSCI
Brad S Kahl, MD
Mark Levis, MD, PhD
Mark D Pegram, MD
Daniel P Petrylak, MD
Noopur Raje, MD
David Sallman, MD
Lecia V Sequist, MD, MPH
David R Spigel, MD
Saad Zafar Usmani, MD, MBA
Andrew D Zelenetz, MD, PhD
Additional faculty to be announced.

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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Meet The Professor Program Participating Faculty

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Professor of Gynecology and Obstetrics
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Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
Baltimore, Maryland

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Director, Winthrop P Rockefeller Cancer Institute
Director, Cancer Service Line
University of Arkansas for Medical Sciences
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University of Arizona College of Medicine
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Member, Board of Directors, GOG Foundation
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Co-Director, Gynecologic Oncology Phase I Program
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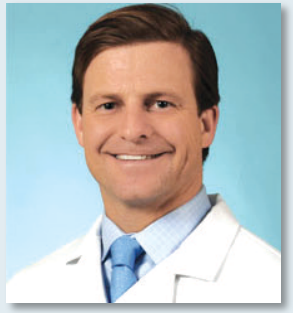
Head of Gynaecologic Cancer Programme
Vall d'Hebron Institute of Oncology
Hospital Universitari Vall d'Hebron
Vall d'Hebron Barcelona Hospital Campus
Barcelona, Spain



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Brian M Slomovitz, MD
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Krishnansu S Tewari, MD
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Professor Ignace Vergote
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University Hospital Leuven
Leuven, Belgium

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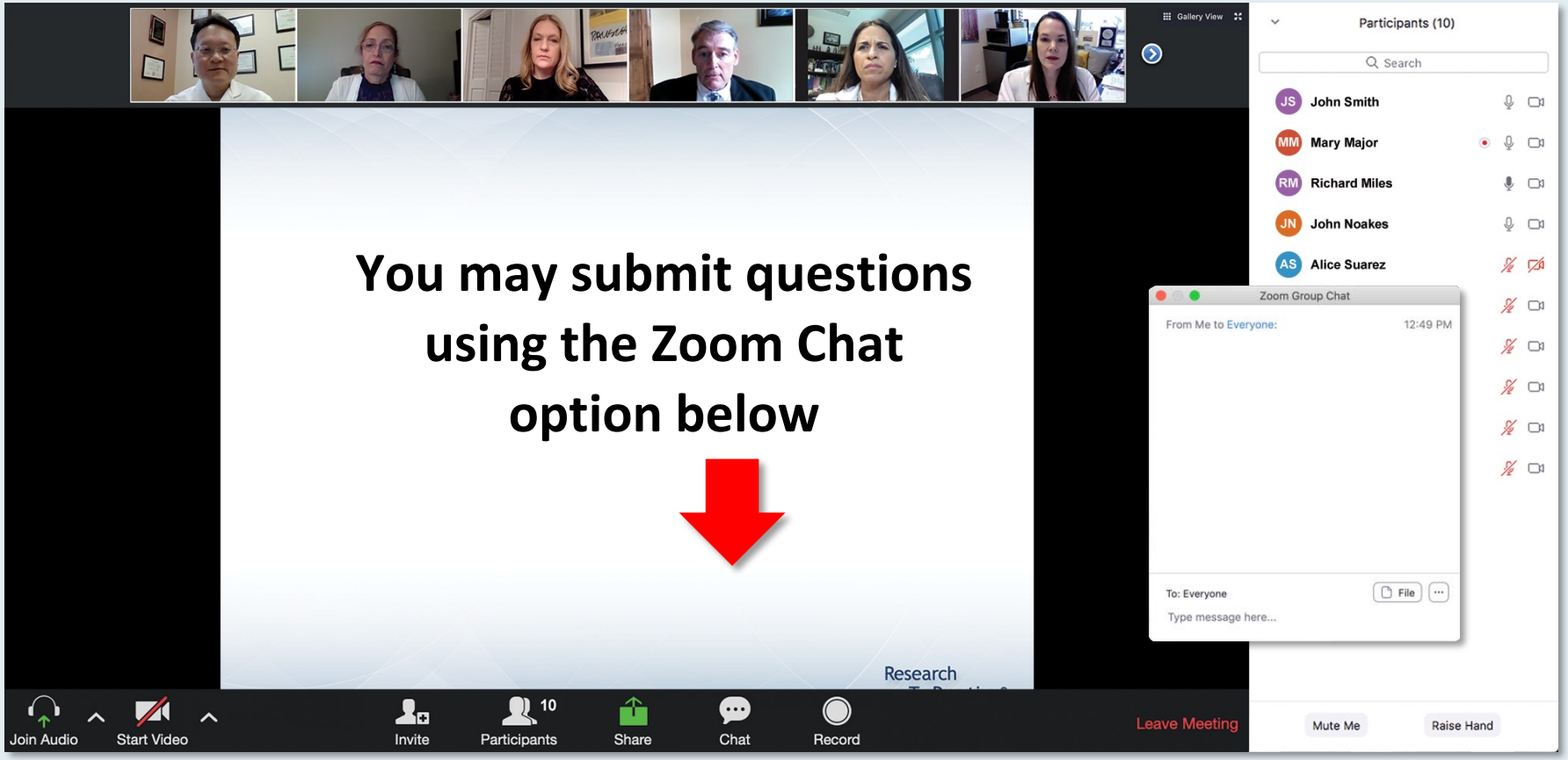

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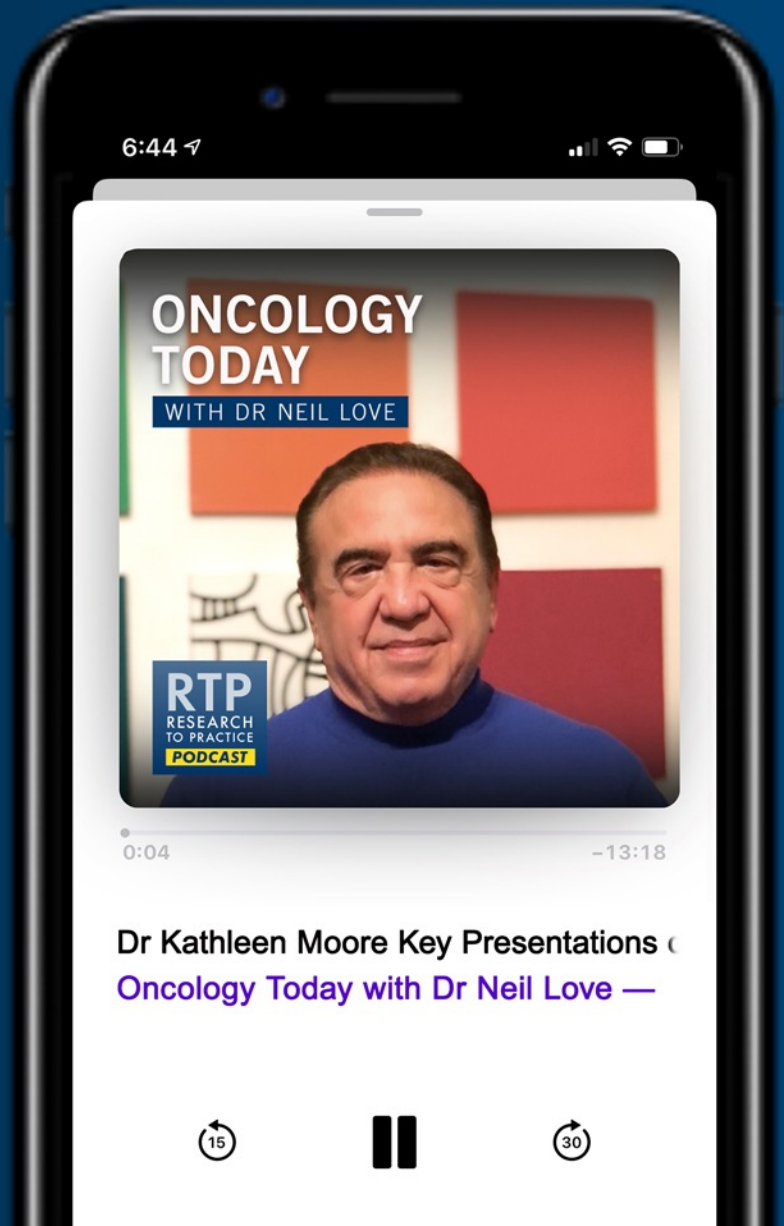

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Module 1: Breast Cancer – 9:30 AM – 10:20 AM

Module 2: Lung Cancer – 10:30 AM – 11:20 AM

Module 3: Gastrointestinal Cancers – 11:30 AM – 12:20 PM

Module 4: Genitourinary Cancers – 12:30 PM – 1:20 PM

Module 5: CLL and Lymphomas – 1:30 PM – 2:20 PM

Module 6: Multiple Myeloma – 2:30 PM – 3:20 PM

Module 7: AML and MDS – 3:30 PM – 4:20 PM

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Murfreesboro, Tennessee

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Women's Cancer Care Associates
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Ina J Patel, DO
Assistant Professor of Internal Medicine
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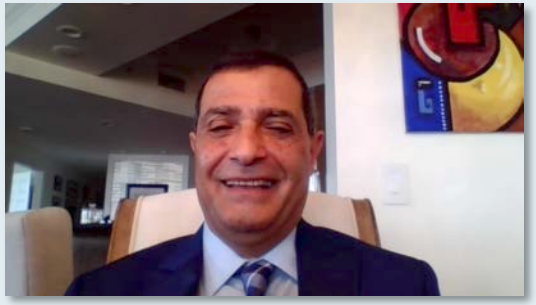
Fort Worth, Texas



Atif Hussein, MD, MMM
Program Director, Hematology/Oncology Fellowship
Medical Director, Oncology Clinical Research
Chairman, Cancer Committee
Memorial Healthcare System
Clinical Associate Professor
Florida International University Herbert Wertheim College of Medicine
Hollywood, Florida

Richard T Penson, MD, MRCP
Associate Professor of Medicine
Harvard Medical School
Clinical Director, Medical Gynecologic Oncology
Massachusetts General Hospital
Boston, Massachusetts

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Division of Gynecologic Oncology
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New York, New York

Kelly Yap, MD
Assistant Clinical Professor
City of Hope
Arcadia, California

Meet The Professor with Dr Westin

MODULE 1: Introduction

MODULE 2: Case Presentations

MODULE 3: Journal Club with Dr Westin

MODULE 4: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

MODULE 5: Other Key Recent Data Sets

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MODULE 4: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

MODULE 5: Other Key Recent Data Sets

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Meet The Professor Immunotherapy and Novel Agents in Gynecologic Cancers Series
August 28, 2020 to October 12, 2021

Webinar	Faculty	Total attendees
10/12/2021	Shannon N Westin, MD, MPH	—
9/24/2021	Martee L Hensley, MD, MSc	152
9/01/2021	Joyce F Liu, MD, MPH	166
6/01/2021	Deborah K Armstrong, MD	166
5/12/2021	Michael J Birrer, MD, PhD	164
4/05/2021	Bradley J Monk, MD	254
12/09/2020	Gottfried E Konecny, MD	120
11/13/2020	Krishnansu S Tewari, MD	164

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August 28, 2020 to October 12, 2021

Webinar	Faculty	Total attendees
10/30/2020	Richard T Penson, MD, MRCP	186
10/08/2020	Brian M Slomovitz, MD	201
9/24/2020	David M O'Malley, MD	234
9/03/2020	Professor Ignace Vergote	263
8/28/2020	Michael J Birrer, MD, PhD	239
TOTAL		**2,309**

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Spencer Henick Bachow, MD
Hematologist/Oncologist at Lynn Cancer Institute
Affiliate Assistant Professor of Medicine at FAU Schmidt College of Medicine
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Linda R Duska, MD, MPH
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Dana M Chase, MD
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Associate Professor, Creighton University School of Medicine
Assistant Professor, University of Arizona College of Medicine
Phoenix, Arizona

Allan Freedman, MD
Physician with Suburban Hematology-Oncology Associates
Snellville, Georgia

Gigi Chen, MD
Diablo Valley Oncology and Hematology Medical Group
Pleasant Hill, California

Heidi E Godoy, DO
Women's Cancer Care Associates
Albany, New York

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Memorial Healthcare System
Clinical Associate Professor
Florida International University
Herbert Wertheim College of Medicine
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Mansoor Raza Mirza, MD
Medical Director
Nordic Society of Gynaecological Oncology – Clinical Trial Unit
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Faculty Member, European Society of Gynaecological Oncology
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Neil Morganstein, MD
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Clinical Director, Medical Gynecologic Oncology
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Medical Oncologist
Oncology Specialists of Charlotte
Charlotte, North Carolina

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New York University Grossman School of Medicine
New York, New York

Brian M Slomovitz, MD
Professor, OB-GYN, Florida International University
Director, Gynecologic Oncology
Co-Chair, Cancer Research Committee
Mount Sinai Medical Center
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Erik J Rupard, MD
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Tower Health – McGlinn Cancer Institute
West Reading, Pennsylvania

Shannon N Westin, MD, MPH
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Lyndsay J Willmott, MD
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Division of Gynecologic Oncology
Creighton University School of Medicine at
Dignity Health St Joseph's Hospital and Medical Center
Assistant Professor
University of Arizona
Arizona Oncology
The US Oncology Network
Phoenix, Arizona

John Yang, MD
Oncologist
Fall River, Massachusetts

Meet The Professor with Dr Westin

MODULE 1: Introduction

MODULE 2: Case Presentations

- Dr Hussein: A 51-year-old woman with recurrent cervical squamous cell carcinoma on long-term maintenance bevacizumab
- Dr Ma: A 61-year-old woman with metastatic cervical cancer and borderline renal failure
- Dr Pothuri: A 64-year-old woman with recurrent squamous vulvar cancer – PD-L1-positive
- Dr Chen: A 66-year-old woman with MSI-high metastatic endometrial cancer – BRCA2 mutation
- Dr Hussein: A 77-year-old woman with recurrent MSS adenocarcinoma – HER2-positive, PTEN abnormality
- Dr Godoy: An 85-year-old woman with MSI-high metastatic ovarian cancer
- Dr Yap: A 48-year-old woman with MSS metastatic endometrial adenocarcinoma with multiple genetic abnormalities
- Dr Penson: A 59-year-old woman with metastatic mesonephric adenocarcinoma of the cervix
- Dr Hussein: A 46-year-old woman with recurrent uterine high-grade leiomyosarcoma
- Dr Hussein: A 66-year-old woman with MSS recurrent uterine adenocarcinoma with multiple actionable targets

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Case Presentation – Dr Hussein: A 51-year-old woman with recurrent cervical squamous cell carcinoma on long-term maintenance bevacizumab

Dr Atif Hussein

- Diagnosed with Stage IIB cervical squamous cell carcinoma, papillary exophytic subtype
- High-risk human papilloma virus detected
- PET/CT: Multiple FDG avid pelvic lymph nodes
- 12/2014: External beam radiation therapy with concurrent weekly cisplatin → Boost RT and brachytherapy
- 6/2016 PET/CT: 2.3 x 2.1 subcarinal adenopathy → EBUS: Recurrent cervical carcinoma
- 9/2016: Cisplatin/paclitaxel/bevacizumab x 3, with CR → Cisplatin/paclitaxel/bevacizumab x 3
- Continues on maintenance bevacizumab without side effects, NED (9/2021: 84 cycles of bevacizumab)

Questions

- When you treat based on GOG-240, do you discontinue treatment after a CR?
- Based on KEYNOTE-826, would you consider pembrolizumab/chemotherapy, with or without bevacizumab, as the new standard first-line therapy? If yes, would you add bevacizumab for everybody, or does it depend on the PD-L1 CPS or other variables?

The NEW ENGLAND JOURNAL of MEDICINE

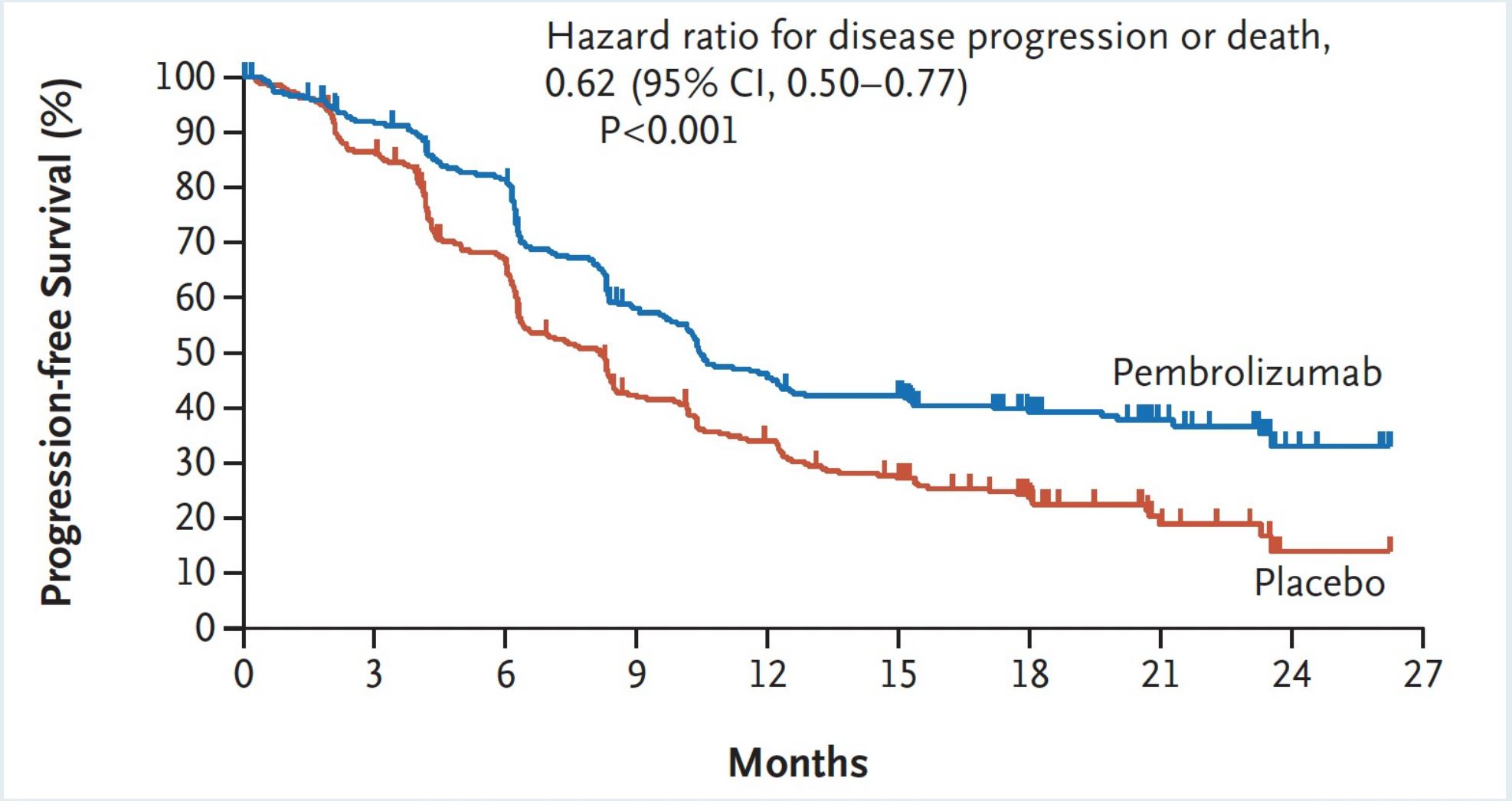
N Engl J Med 2021;[Online ahead of print].

ORIGINAL ARTICLE

Pembrolizumab for Persistent, Recurrent, or Metastatic Cervical Cancer

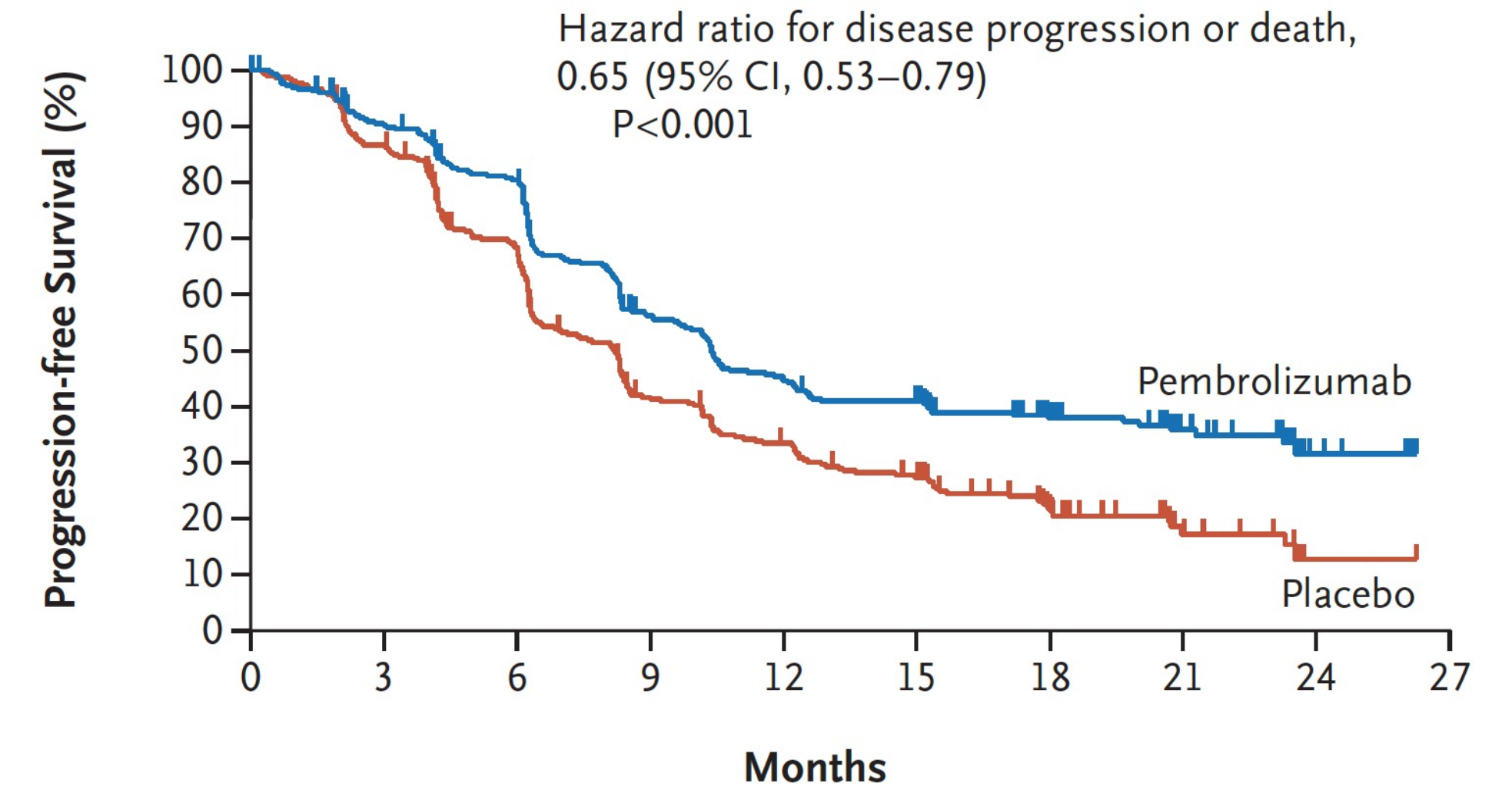
N. Colombo, C. Dubot, D. Lorusso, M.V. Caceres, K. Hasegawa, R. Shapira-Frommer, K.S. Tewari, P. Salman, E. Hoyos Usta, E. Yañez, M. Gümüş, M. Olivera Hurtado de Mendoza, V. Samouëlian, V. Castonguay, A. Arkhipov, S. Toker, K. Li, S.M. Keefe, and B.J. Monk, for the KEYNOTE-826 Investigators*

KEYNOTE-826: PFS for Patients with a PD-L1 Combined Positive Score of ≥1



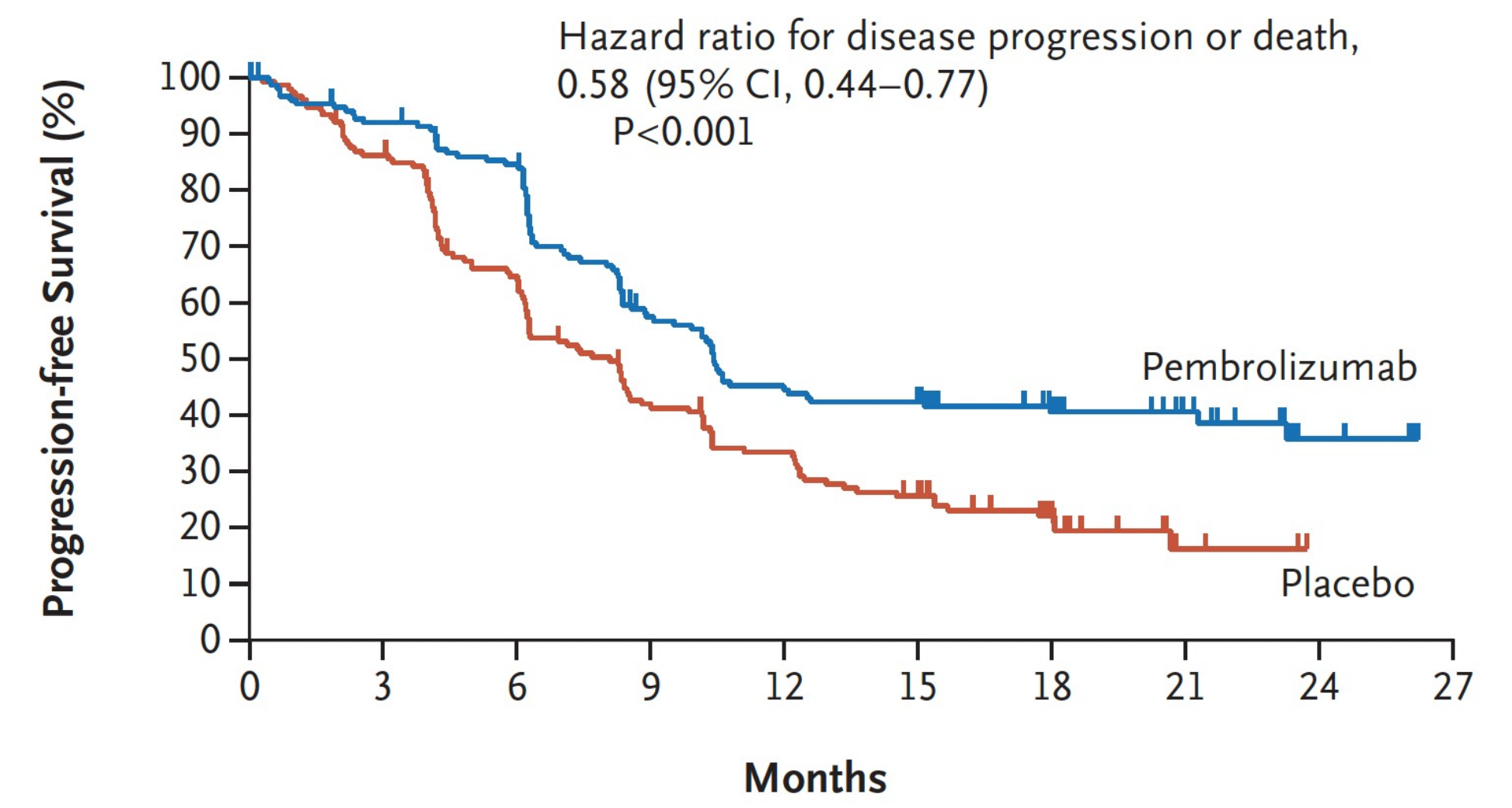
Colombo N et al. *N Engl J Med* 2021;[Online ahead of print].

KEYNOTE-826: PFS in Intention-to-Treat Population



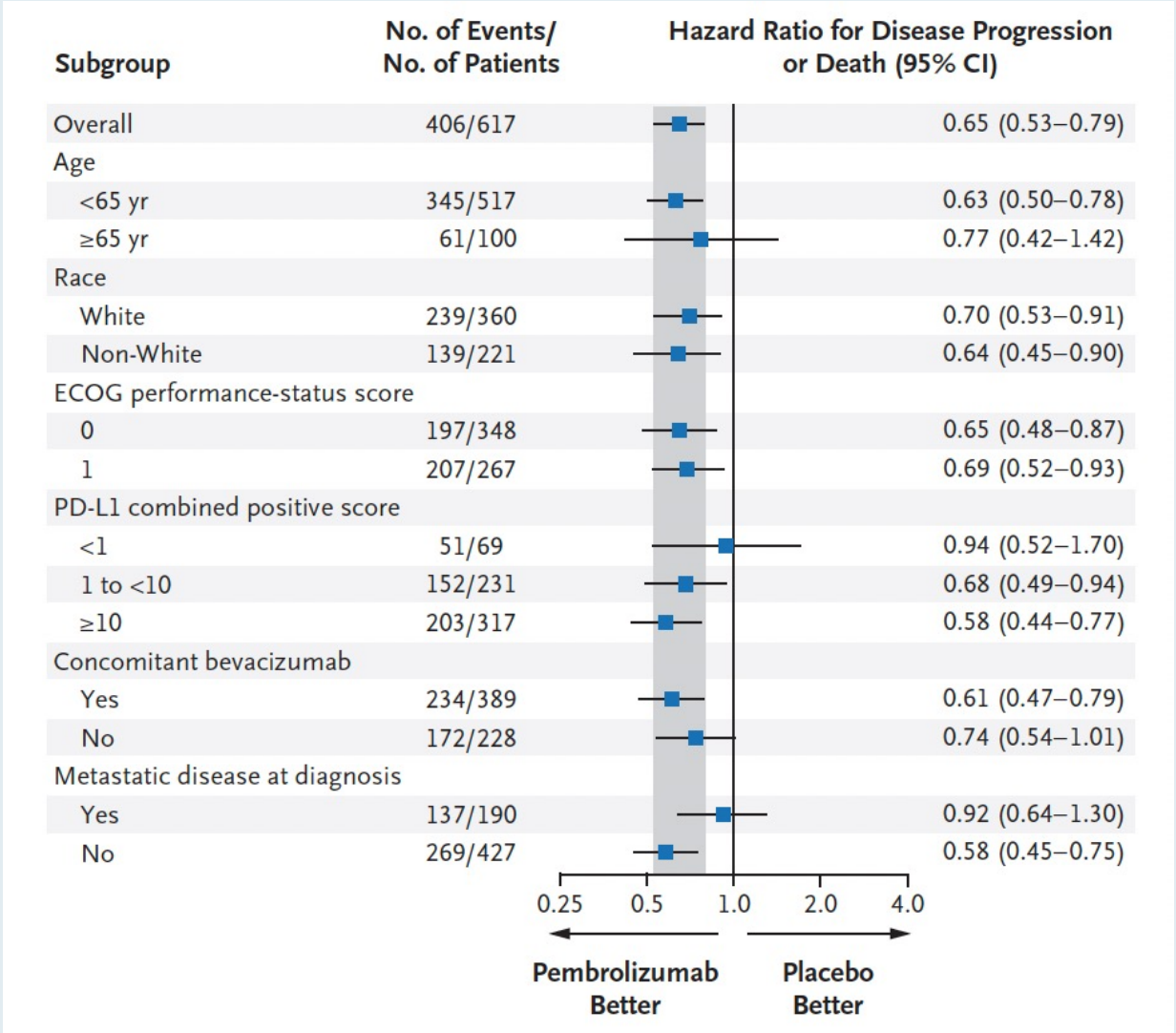
Colombo N et al. *N Engl J Med* 2021;[Online ahead of print].

KEYNOTE-826: PFS for Patients with a PD-L1 Combined Positive Score of ≥10



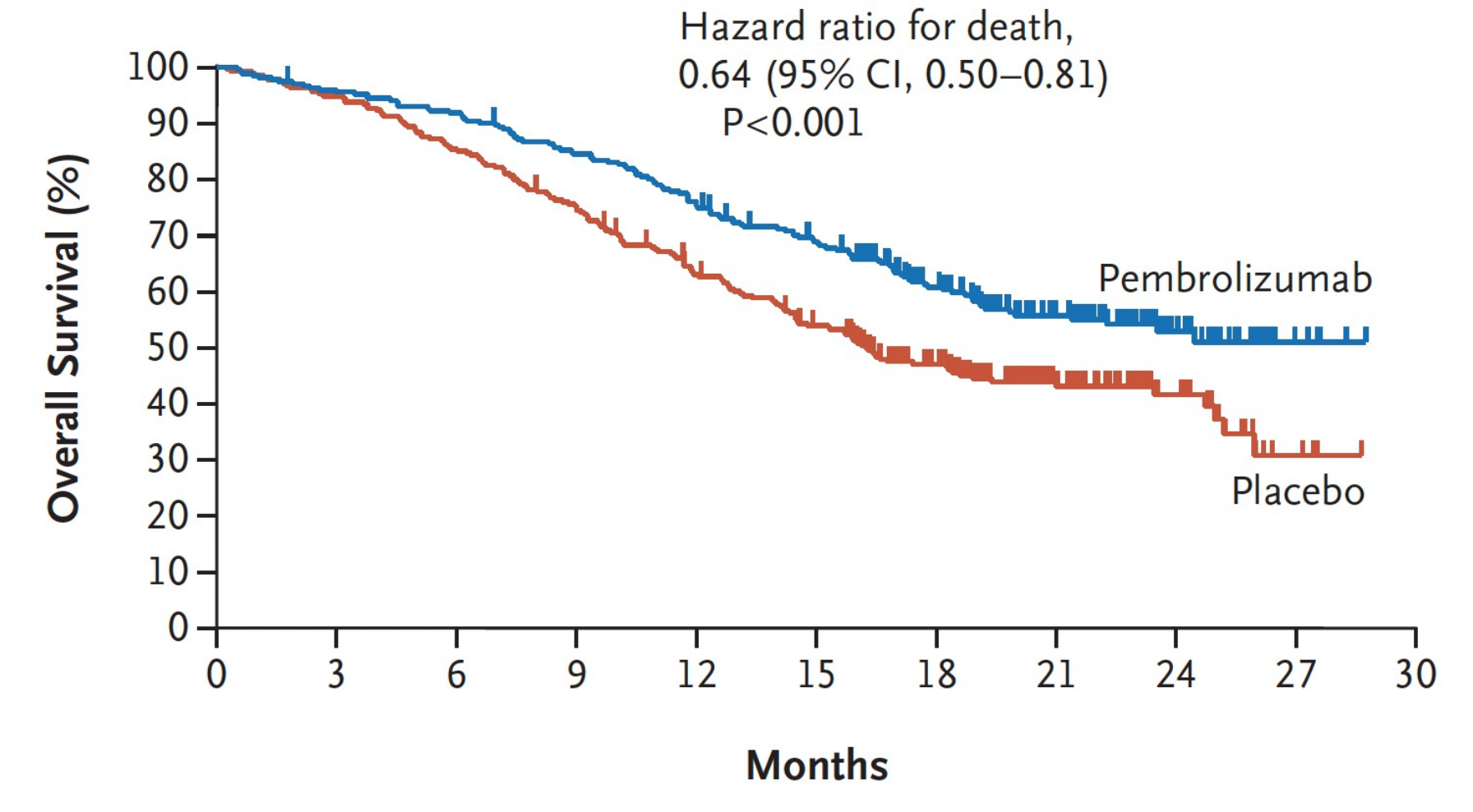
Colombo N et al. *N Engl J Med* 2021;[Online ahead of print].

KEYNOTE-826: PFS Subgroup Analysis in Intention-to-Treat Population



Colombo N et al. *N Engl J Med* 2021;[Online ahead of print].

KEYNOTE-826: OS for Patients with a PD-L1 Combined Positive Score of ≥1



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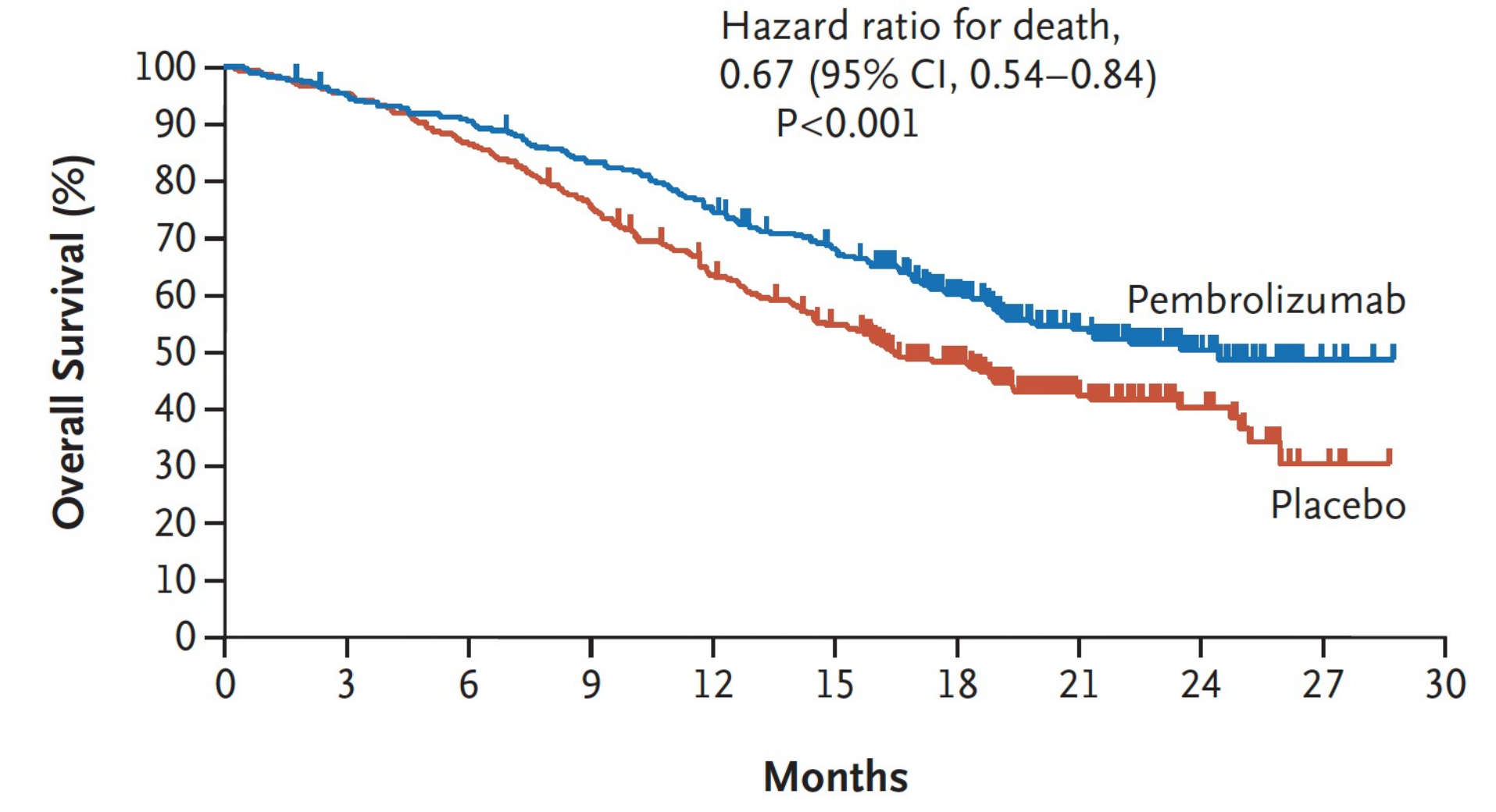

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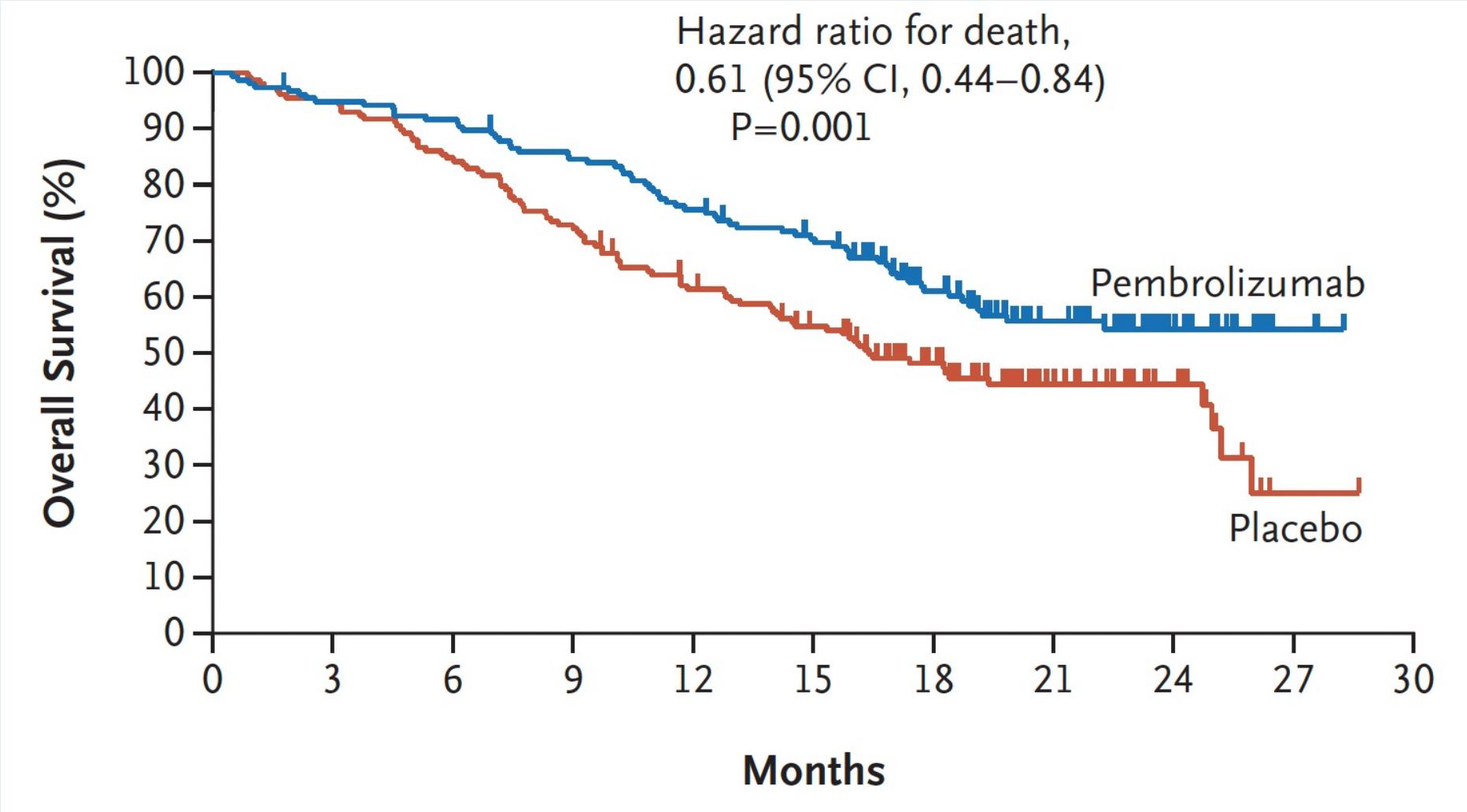

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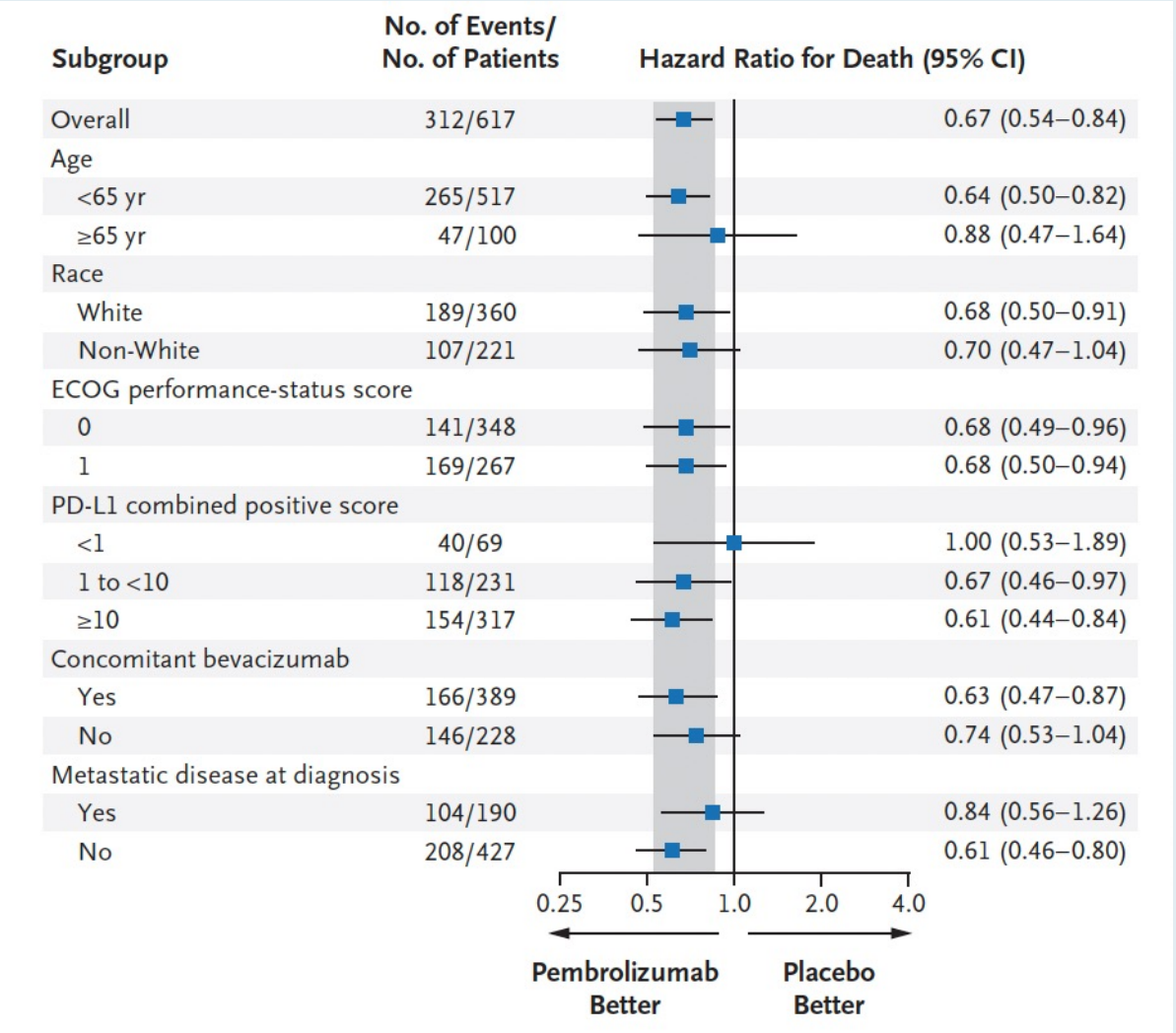


Colombo N et al. *N Engl J Med* 2021;[Online ahead of print].

Case Presentation – Dr Ma: A 61-year-old woman with metastatic cervical cancer and borderline renal failure

Dr Yanjun Ma

- 2014: S/p pelvic RT for Stage IB2 adenocarcinoma of the endocervix
- 2016: S/p debulking surgery and colon resection for biopsy-proven splenic metastases
- Dose-dense carboplatin/paclitaxel/bevacizumab → Maintenance bevacizumab
- 3/2018: Vesicovaginal fistula → Pt refused diverting urostomy → Bevacizumab held then resumed
- 10/2018: Rectovaginal fistula → Pelvic exenteration
- 1/2019: Repeat carboplatin/paclitaxel/bevacizumab → Maintenance bevacizumab
- 10/2019 PD and recurrent ureteral obstruction and ESRD with GFR of 10
- Pembrolizumab, with disease control until 6/2020 → Nivolumab/ipilimumab → 11/2020: PD
- 12/2020: Irinotecan, with severe diarrhea despite dose reduction

Questions

- For a patient with worsening renal function who may need dialysis, would a newer antibody-drug conjugate, such as tisotumab vedotin, be an option?

FDA Accelerated Approval Granted to Tisotumab Vedotin-tftv for Previously Treated Recurrent or Metastatic Cervical Cancer

Press Release – September 20, 2021

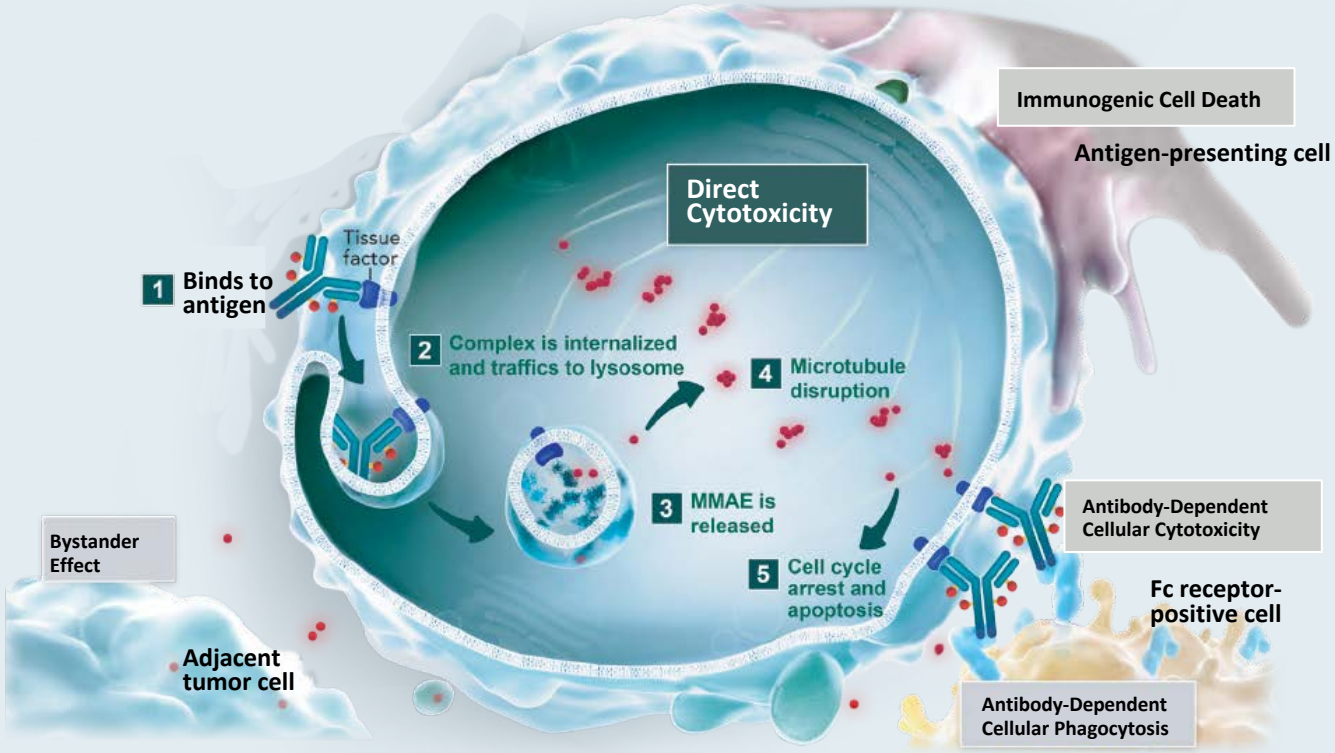
"[It was announced today that the FDA] has granted accelerated approval to tisotumab vedotin-tftv, the first and only approved antibody-drug conjugate (ADC) for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tisotumab vedotin-tftv is approved under the FDA's Accelerated Approval Program based on tumor response and the durability of the response. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials."

The accelerated approval is based on results from the innovaTV 204 trial. InnovaTV 301, a global, randomized Phase III clinical trial intended to support global registrations, is under way. The prescribing information for tisotumab vedotin-tftv includes a BOXED WARNING for ocular toxicity and warnings for peripheral neuropathy, hemorrhage, pneumonitis and embryo-fetal toxicity.

https://investor.seagen.com/press-releases/news-details/2021/Seagen-and-Genmab-Announce-FDA-Accelerated-Approval-for-TIVDAK-tisotumab-vedotin-tftv-in-Previously-Treated-Recurrent-or-Metastatic-Cervical-Cancer/default.aspx

Mechanism of Action of Tisotumab Vedotin

- Tissue factor (TF) is aberrantly expressed in a broad range of solid tumours, including cervical cancer,[1,2] and TF expression has been associated with higher tumour stage and grade, higher metastatic burden and poor prognosis[2]
- TF expression in cervical cancer makes TF a novel target for patients with cervical cancer
- ADC targets TF
  - Monoclonal Antibody targets TF
  - Payload: Microtubule disrupting MMAE
- Allowing for direct cytotoxicity and bystander killing, as well as antibody-dependent cellular cytotoxicity[3,4]



1. Förster Y, et al. *Clin Chim Acta,* 2006. 2. Cocco E, et al. *BMC Cancer,* 2011.
3. Breij EC, et al. *Cancer Res,* 2014. 4. De Goeij BE, et al. *Mol Cancer Ther,* 2015.

Courtesy of David M O'Malley, MD

RTP RESEARCH TO PRACTICE

Tisotumab Vedotin in Previously Treated Recurrent or Metastatic Cervical Cancer: Results from the Phase II innovaTV 204/GOG-3023/ENGOT-cx6 Study

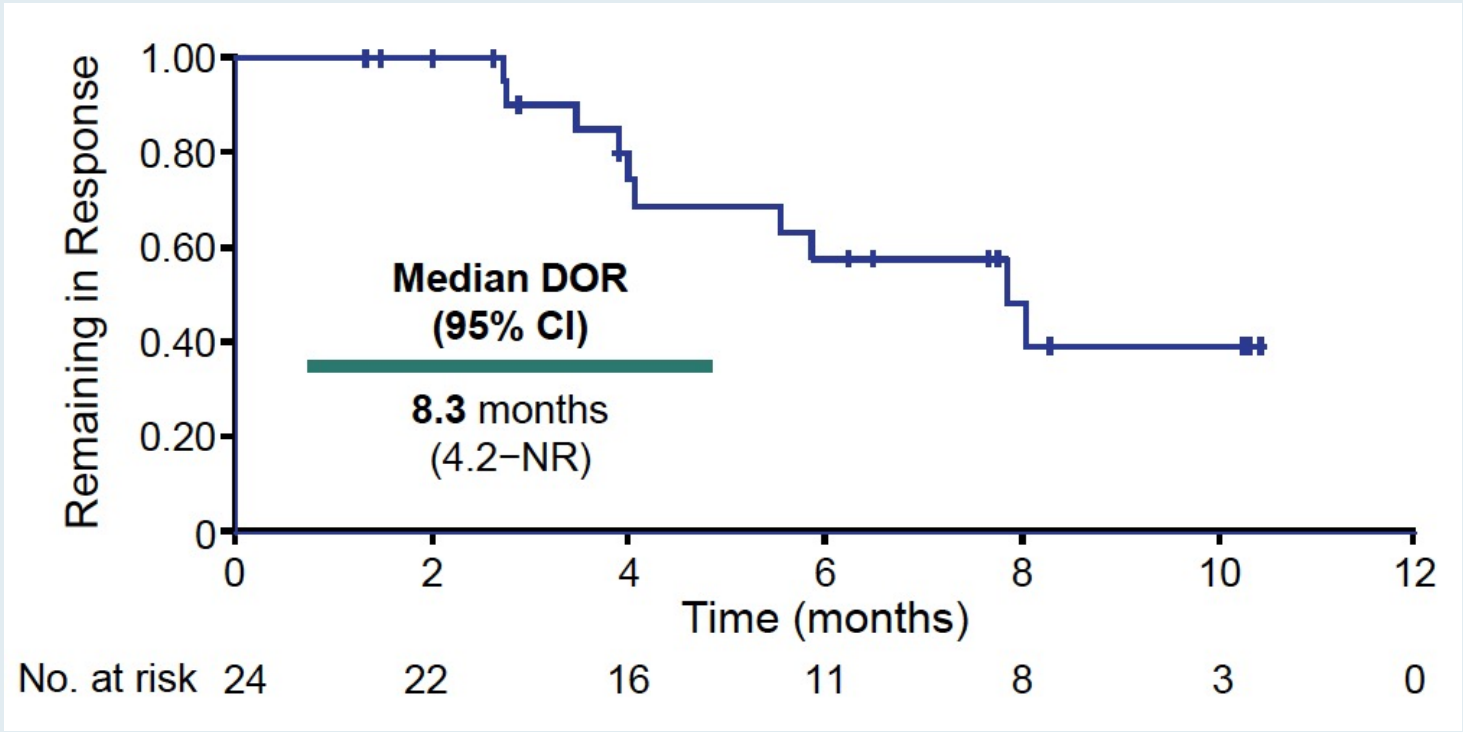
Coleman RL et al.

ESMO 2020;Abstract LBA32.

innovaTV 204: Antitumor Activity by IRC Assessment

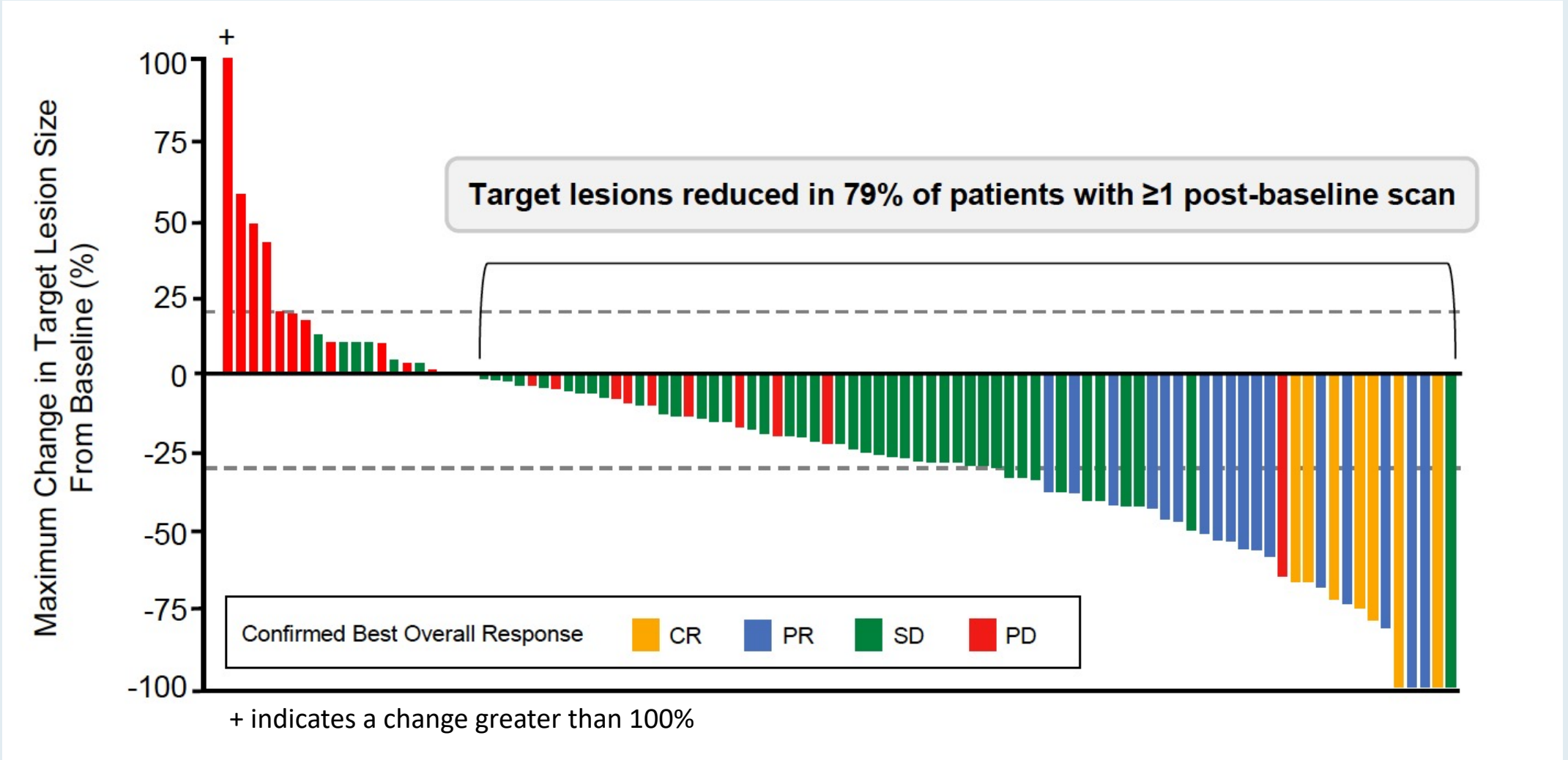
Clinical Variable	N = 101
Confirmed ORR	24%
CR	7%
PR	17%
SD	49%
PD	24%
Not evaluable	4%

Duration of Response



Coleman RL et al. *ESMO* 2020;Abstract LBA32.

innovaTV 204: Maximum Change in Target Lesion Size by IRC Assessment



+ indicates a change greater than 100%

Coleman RL et al. *ESMO* 2020;Abstract LBA32.

Tisotumab Vedotin + Carboplatin in First-Line or + Pembrolizumab in Previously Treated Recurrent/Metastatic Cervical Cancer: Interim Results of ENGOT-Cx8/GOG-3024/innovaTV 205

Ignace Vergote,[1] Bradley J. Monk,[2] Roisin E. O'Cearbhaill,[3] Anneke Westermann,[4] Susana Banerjee,[5] Dearbhaile Catherine Collins,[6] Mansoor Raza Mirza,[7] David O'Malley,[8] Christine Gennigens,[9] Sandro Pignata,[10] Bohuslav Melichar,[11] Azmat Sadozye,[12] Frederic Forget,[13] Krishnansu S. Tewari,[14] Eelke Gort,[15] Ibrahima Soumaoro,[16] Camilla Mondrup Andreassen,[17] Leonardo Viana Nicacio,[18] Els Van Nieuwenhuysen,[1] Domenica Lorusso[19]

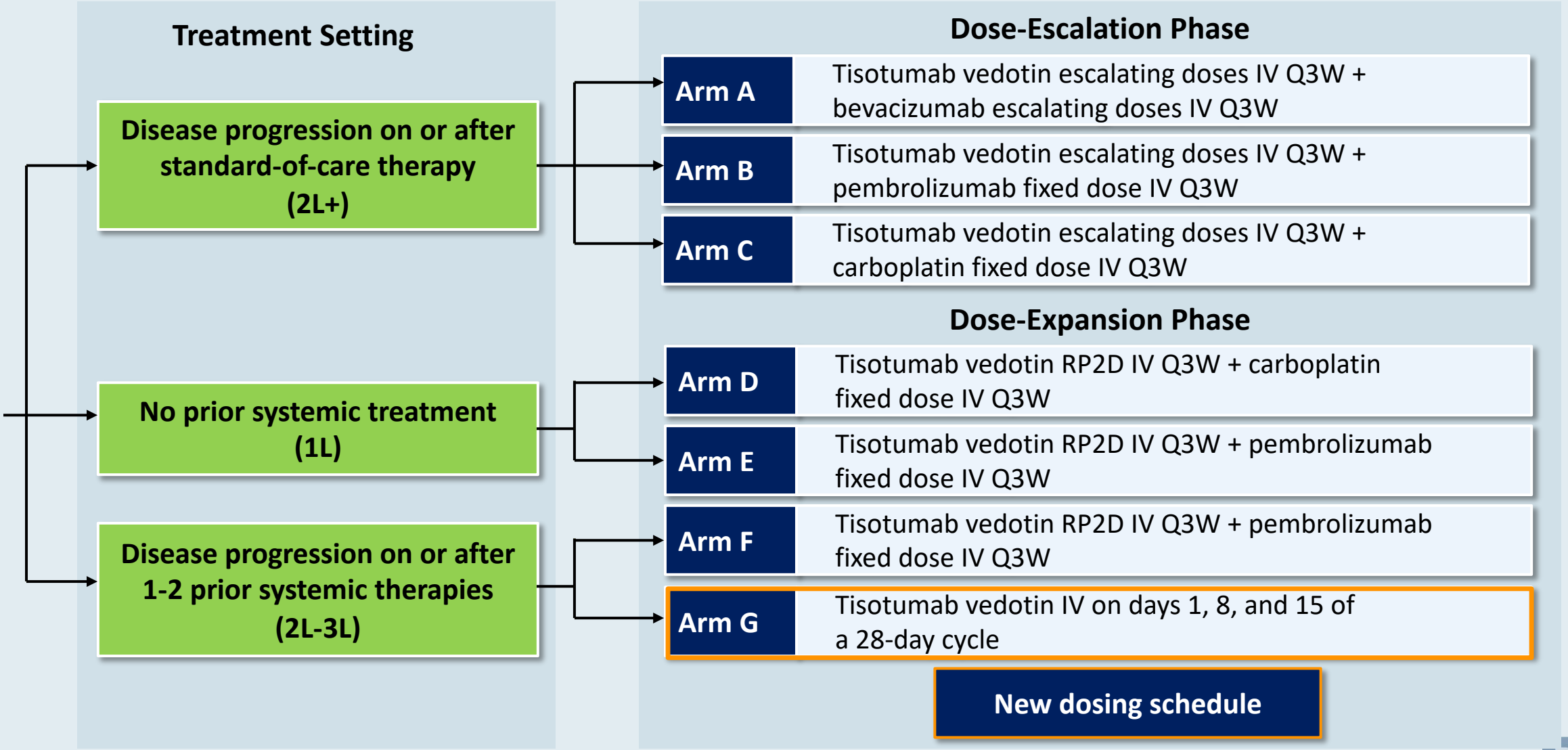
[1]Belgium and Luxembourg Gynaecological Oncology Group, University of Leuven, Leuven Cancer Institute, Leuven, Belgium; [2]Arizona Oncology (US Oncology Network), University of Arizona College of Medicine, Creighton University School of Medicine, Phoenix, AZ, USA; [3]Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College, New York, NY, USA; [4]Amsterdam University Medical Centers, Amsterdam, Netherlands; [5]The Royal Marsden NHS Foundation Trust, London, UK; [6]Cork University Hospital/Oncology Trials Unit, Cork, Ireland; [7]Rigshospitalet Copenhagen University Hospital, Copenhagen, Denmark; [8]Division of Gynecology Oncology, Department of Gynecology and Obstetrics, The Ohio State University College of Medicine, Columbus, Ohio, USA; [9]Department of Medical Oncology, Liège University Hospital, Liège, Belgium; [10]Istituto Nazionale Tumori IRCCS Fondazione G. Pascale, Naples, Italy; [11]Palacký University Medical School and Teaching Hospital, Olomouc, Czech Republic ; [12]NHS Greater Glasgow and Clyde, Glasgow, United Kingdom; [13]Centre Hospitalier de l'Ardenne, Libramont, Belgium; [14]University of California, Irvine Medical Center, Orange, CA, USA; [15]University Medical Center Utrecht, Utrecht, Netherlands; [16]Genmab US, Inc., Princeton, NJ, USA; [17]Genmab A/S, Copenhagen, Denmark; [18]Seagen Inc., Bothell, WA, USA; [19]Fondazione IRCCS, Foundation Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy

2021 ESMO congress

Ignace Vergote

ESMO 2021; Abstract 723MO

innovaTV 205 (GOG 3024): Recurrent or Metastatic Cervical Cancer



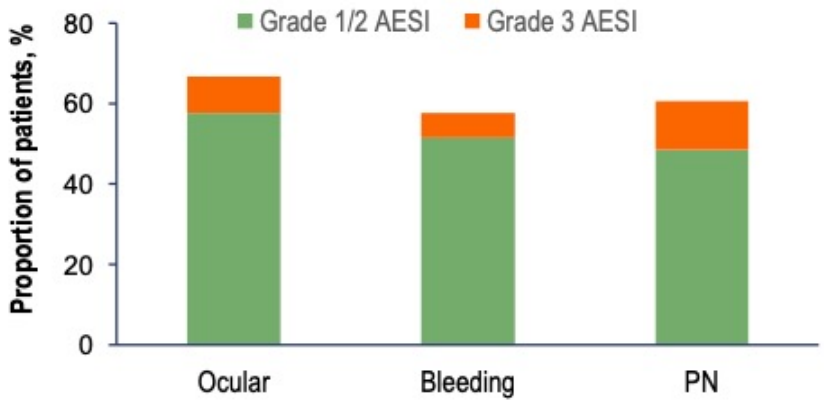
Courtesy of David M O'Malley, MD

Summary of Efficacy & Safety for 1L TV + Carbo

Parameters	1L TV + Carbo (N = 33) Median FU: 7.9 months
Median duration of exposure, months (range)	TV: 4.9 (1 – 9) Carbo: 4.1 (1 – 9)
Median number of cycles initiated (range)	TV: 6.0 (1 – 12) Carbo: 6.0 (1 – 12)
Confirmed response rate, n (%) [95% CI] Complete response, n (%) Partial response, n (%) Stable disease, n (%) Progressive disease, n (%) Not evaluable, n (%)	18 (55) [36 – 72] 4 (12) 14 (42) 12 (36) 2 (6) 1 (3)
Median duration of response, months (95% CI)	8.3 (4.2 – NR)
Median time to response, months (range)	1.4 (1.1 – 4.4)
Median PFS, months (95% CI)	9.5 (4.0 – NR)
Median OS, months (range)	NR (0.8+ – 14.1+)

Treatment ongoing in 9 patients. +, censored.

	TV + Carbo (N=33)
Patients with ≥1 TEAE, n (%) AE related to TV	33 (100.0) 32 (97.0)
Grade ≥3 AE, n (%) Grade ≥3 AE related to TV	26 (78.8) 19 (57.6)
SAE, n (%) SAE related to TV	14 (42.4) 5 (15.2)
Fatal AE, n (%) Fatal AE related to TV	0 0



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Vergote I., et al.

1L, first-line; AE, adverse event; AESI, adverse event of special interest; carbo, carboplatin; FU, follow-up; NR, not reached; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PN; peripheral neuropathy; r/mCC, recurrent/metastatic cervical cancer; SAE, serious adverse event; TEAE, treatment-emergent adverse event; TV, tisotumab vedotin.

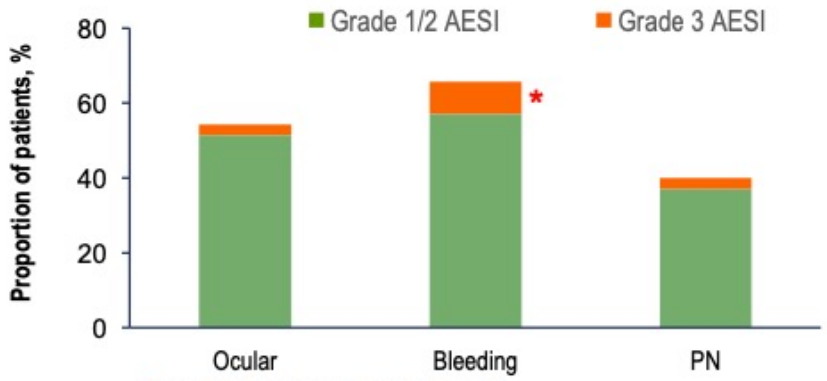
Vergote I et al. ESMO 2021;Abstract 723MO.

Summary of Efficacy & Safety for 2L/3L TV + Pembro

Parameters	2L/3L TV + Pembro (N = 34)[a] Median FU: 13.0 months
Median duration of exposure, months (range)	TV: 4.1 (1 – 16) Pembro: 4.3 (1 – 17)
Median number of cycles initiated (range)	TV: 6.0 (1 – 21) Pembro: 6.0 (1 – 25)
Confirmed response rate, n (%) [95% CI] Complete response, n (%) Partial response, n (%) Stable Disease, n (%) Progressive disease, n (%) Not evaluable, n (%)	13 (38) [22 – 56] 2 (6) 11 (32) 12 (35) 7 (21) 2 (6)
Median DOR, months (95% CI)	13.8 (2.8 – NR)
Median time to response, months (range)	1.4 (1.3 - 5.8)
Median PFS, months (95% CI)	5.6 (2.7 – 13.7)
Median OS, months (range)	NR (1.3 – 17.5+)

[a]1 pt was excluded from the full analysis set as they didn't have any target or non-target lesions at baseline. Treatment ongoing in 4 patients.

	TV + Pembro (N = 35)
Patients with ≥1 TEAE, n (%) AE related to TV	35 (100.0) 34 (97.1)
Grade ≥3 AE, n (%) Grade ≥3 AE related to TV	26 (74.3) 16 (45.7)
SAE, n (%) SAE related to TV	18 (51.4) 5 (14.3)
Fatal AE, n (%) Fatal AE related to TV	1 (2.9) 0



*One patient had a grade 4 bleeding event.

2021 ESMO congress

Vergote I., et al.

+, censored; 1L, first-line; AE, adverse event; AESI, adverse event of special interest; DOR, duration of response; FU, follow-up; NR, not reached; ORR, objective response rate; OS, overall survival; pembro, pembrolizumab; PFS, progression-free survival; PN; peripheral neuropathy; r/mCC, recurrent/metastatic cervical cancer; SAE, serious adverse event; TEAE, treatment-emergent adverse event; TV, tisotumab vedotin.

Vergote I et al. ESMO 2021;Abstract 723MO.

Case Presentation – Dr Pothuri: A 64-year-old woman with recurrent squamous vulvar cancer – PD-L1-positive

Dr Bhavana Pothuri

- 7/2019: S/p radical left hemi-vulvectomy and excision of right vulva for Stage IB vulvar cancer
- 7/2020: Recurrence right lung, pre-carinal and hilar lymph nodes
- 8/2020: Carboplatin/paclitaxel/bevacizumab → PD on left arm and vulva
  - Pathology: Squamous carcinoma, P16-positive, PD-L1-positive

Questions

- Would you consider using tisotumab vedotin or would your choice of therapy be pembrolizumab?
- Does her PD-L1 score affect your treatment choice?

Dose Reductions of Lenvatinib for Management of Toxicity with the Combination Lenvatinib/Pembrolizumab

Dr Ina Patel

Dr Bhavana Pothuri

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Case Presentation – Dr Chen: A 66-year-old woman with microsatellite instability (MSI)-high metastatic endometrial cancer – BRCA2 mutation

Dr Gigi Chen

- PMH: Well-controlled DM type 2
- FIGO grade 1, Stage IIIA endometrial adenocarcinoma, s/p debulking surgery
- Adjuvant carboplatin/paclitaxel x 6 → 2 months later, recurrent para-aortic lymph nodes
- NGS: MSI-high; TMB 18 mut/Mb; BRCA2, ARID1A, CHEK2, PIK3CA, MAP3K1 mutations
- Pembrolizumab
  - Proteinuria after 6 cycles

Questions

- How often do you see immune-mediated nephritis, and what would be the best course of management in this setting, in a patient who has had development of the immune nephritis?

Case Presentation – Dr Hussein: A 77-year-old woman with recurrent microsatellite stable (MSS) adenocarcinoma – HER2-positive, PTEN abnormality

Dr Atif Hussein

- 3/2019: Uterine sarcoma, s/p Hysterectomy/BSO/pelvic and periaortic lymph node dissection
  - 4-cm pT2N0 serous carcinoma, involving the cervical stroma and < one-half of the myometrium
  - HER2 IHC3+, FISH-positive, ER-positive IHC2+, MSS, MMR-proficient, TMB-low, PD-L1-negative, BRCA1/2 wildtype, NTRK1/2/3 wildtype, PTEN IHC positive 2+ 100%
- 8/2019: Carboplatin/paclitaxel x 6 → PET/CT: No hypermetabolic uptake
- 11/2019: Adjuvant radiation therapy and brachytherapy to pelvis
- 12/2020: Progressive weakness and ataxia → MRI brain: Cerebellar mass → Resection → RT
  - Metastatic high-grade serous carcinoma
- 5/2021 CT abdomen/pelvis: 6 x 4-cm left pelvic mass (HER2 IHC 3+, FISH-positive, ER IHC 2+)

Questions

- Since she is HER2-positive – not only overexpressed but also amplified – would you consider anti-HER2 therapy?

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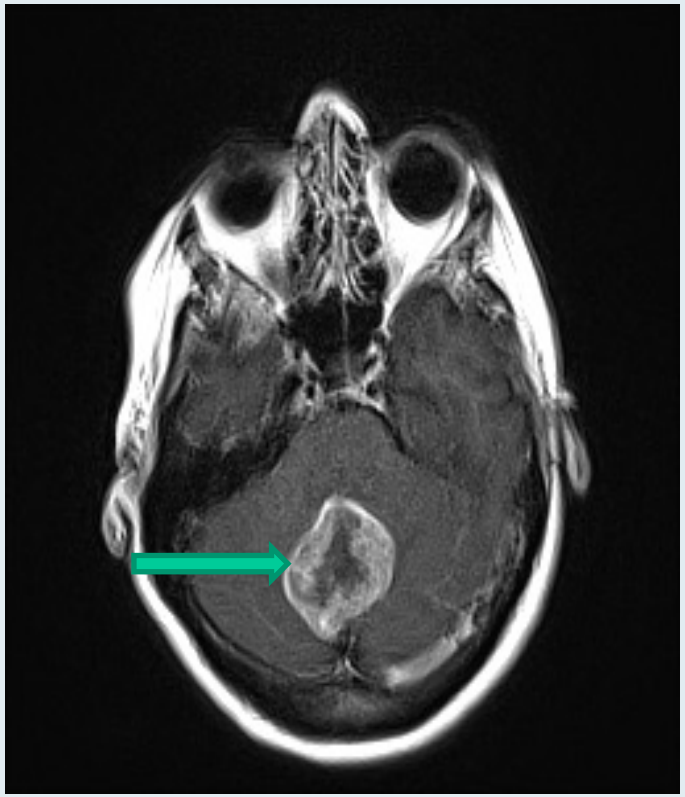
Case Presentation – Dr Hussein: A 77-year-old woman with recurrent MSS adenocarcinoma – HER2-positive, PTEN abnormality (continued)

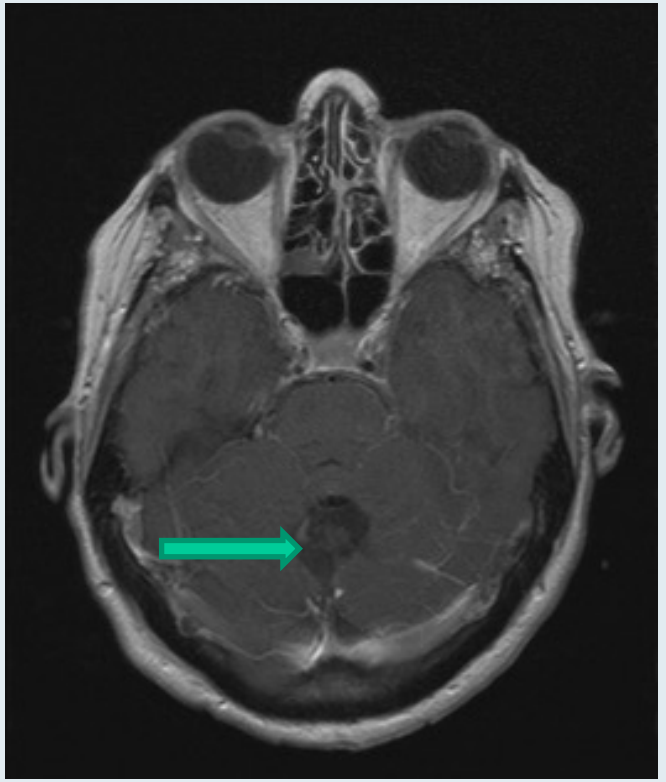
Dr Atif Hussein

Brain MRI before and post resection of a single cerebellar mass

12/11/2020



12/13/2020



Case Presentation – Dr Godoy: An 85-year-old woman with MSI-high metastatic ovarian cancer

Dr Heidi Godoy

- Presented with a large pelvic mass and ascites
- 7/2013: S/p exploratory laparotomy, TAH/BSO and suboptimal tumor debulking surgery
- 9/2013: Carboplatin/paclitaxel
- 8/2018: Peri-hepatic mass
- Carboplatin/pegylated liposomal doxorubicin x 6, with CR
- 5/2019: Resection of solitary hepatic metastasis, biopsy c/w high-grade serous adenocarcinoma, MSI-H
- 6/2019: Pembrolizumab, dose-reduced due to toxicity then held for C. difficile treatment
- 1/2020: New hepatic lesion → Carboplatin/gemcitabine
- NGS: TMB-high, MSI-intermediate, FGFR1 amplification

Questions

- In your frail, elderly patients receiving pembrolizumab do you do any dose reductions?
- How do you manage immune-mediated side effects, such as thyroid dysfunction, colitis, etc?
- Do we have targeted therapies to offer patients with FGFR1 amplification?

Case Presentation – Dr Yap: A 48-year-old woman with MSS metastatic endometrial adenocarcinoma with multiple genetic abnormalities

Dr Kelly Yap

- Stage IV endometrial adenocarcinoma, endometrioid type
- Carboplatin/paclitaxel → PD → doxorubicin
- NGS: PD-L1 1%, MSS, TMB 4 mut/Mb, ARID1A mutation, ERBB3 amplification, PIK3CA mutation, ESR1 mutation, FGFR2 fusion, BRCA1 rearrangement; Germline testing: Negative
- Lenvatinib/pembrolizumab
  - Pembrolizumab delayed 1 month due to insurance issues
  - CA-125 decreased by 40% within 1 month of starting lenvatinib

Questions

- Should all metastatic cancers be sequenced up front for more effective personalized treatment?
- Is there any role for anti-HER2 therapy as a future treatment option?
- Is a PARP inhibitor an option for future treatment?

Case Presentation – Dr Penson: A 59-year-old woman with metastatic mesonephric adenocarcinoma of the cervix

Dr Richard Penson

- 2015: Diagnosed with Stage IB2 mesonephric adenocarcinoma of the cervix
- SNaPshot KRAS Gly13dup (c.36_38dupTGG)
- 2017: RT/cisplatin
- 2018: Cisplatin/paclitaxel/bevacizumab
- 2019: Cisplatin/gemcitabine
- 2019: Phase II study of trametinib/navitoclax

Question

- Would you give her immunotherapy?

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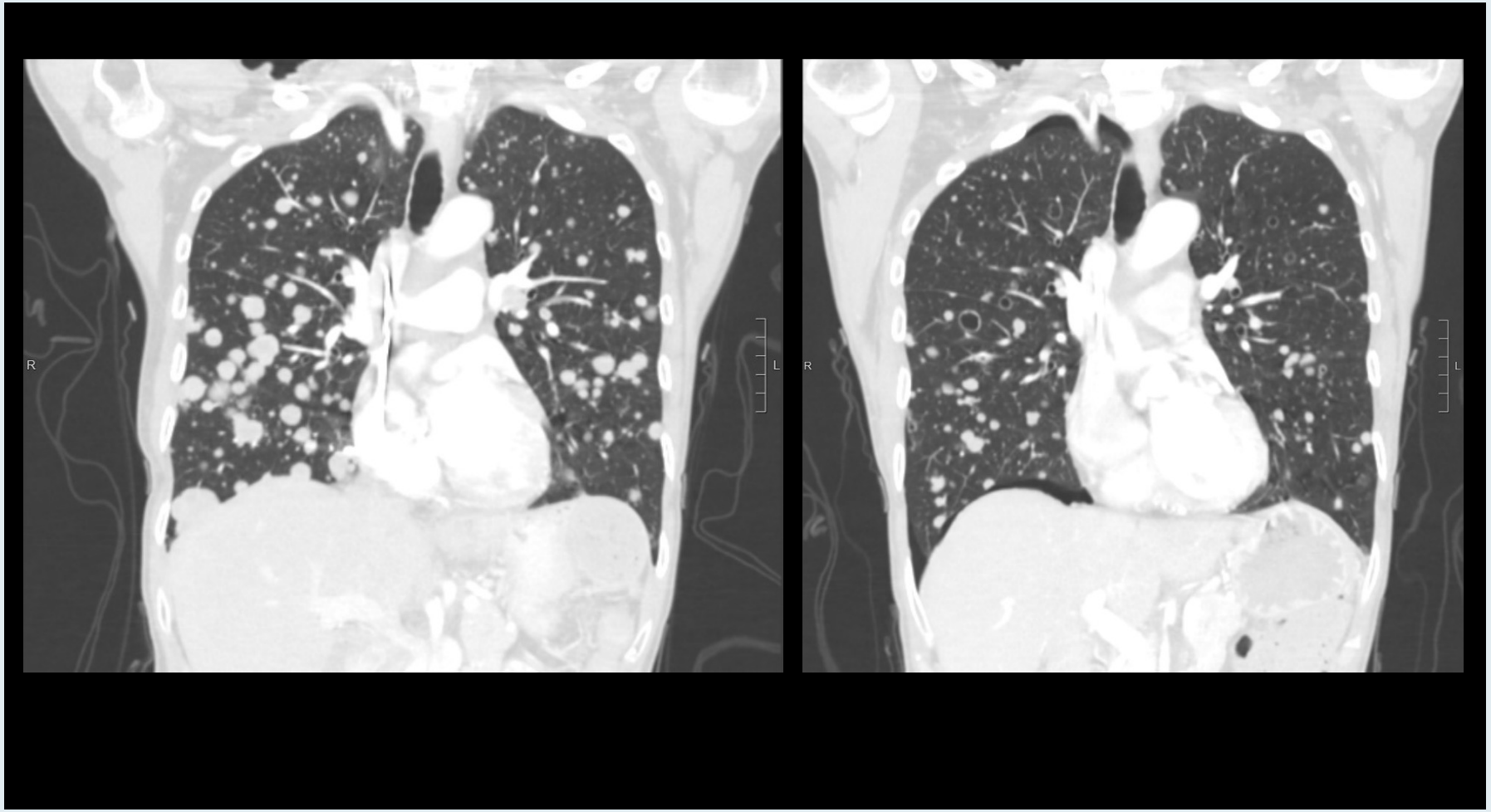
Case Presentation – Dr Penson: A 59-year-old woman with metastatic mesonephric adenocarcinoma of the cervix (continued)

Dr Richard Penson

Chest X-ray showing "shotgun metastases"



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Case Presentation – Dr Penson: A 59-year-old woman with metastatic mesonephric adenocarcinoma of the cervix (continued)

Dr Richard Penson

- 2015: Diagnosed with Stage IB2 mesonephric adenocarcinoma of the cervix
- SNaPshot KRAS Gly13dup (c.36_38dupTGG)
- 2017: RT/cisplatin
- 2018: Cisplatin/paclitaxel/bevacizumab
- 2019: Cisplatin/gemcitabine
- 2019: Phase II study of trametinib/navitoclax
- ***2020: Carboplatin/paclitaxel, with "amazing" response***

Question

- ***What's your experience with ipilimumab and nivolumab in later lines of therapy for metastatic cervical cancer?***

Case Presentation – Dr Hussein: A 46-year-old woman with recurrent uterine high-grade leiomyosarcoma

Dr Atif Hussein

- 1/2019: 12.5-cm uterine mass arising from the uterus
- Biopsy: Grade 2 leiomyosarcoma
- 2/2019: TAH/BSO and pelvic lymphadenectomy
  - 13.5-cm dedifferentiated leiomyosarcoma, Grade 3/3
- Doxorubicin/mesna/ifosfamide x 5 → RT between cycles 3 and 4
- 6/2021 scans: New soft tissue mass within the superior and mid-line of the pelvis 7 x 5 x 5 cm
- Core biopsy: High-grade leiomyosarcoma
- 8/2021 resection (R1): High-grade sarcoma with a positive margin close to the urinary bladder

Questions

- What therapy would you recommend next?
- How do you compare the prognosis and the response to therapy in women with uterine leiomyosarcoma versus women with ex-uterine leiomyosarcoma? Do you treat them differently? What about compared to men with leiomyosarcoma?
- How active are checkpoint inhibitors in uterine leiomyosarcoma?
- When you utilize radiation therapy or chemotherapy in the adjuvant setting, in what setting and in what sequence?

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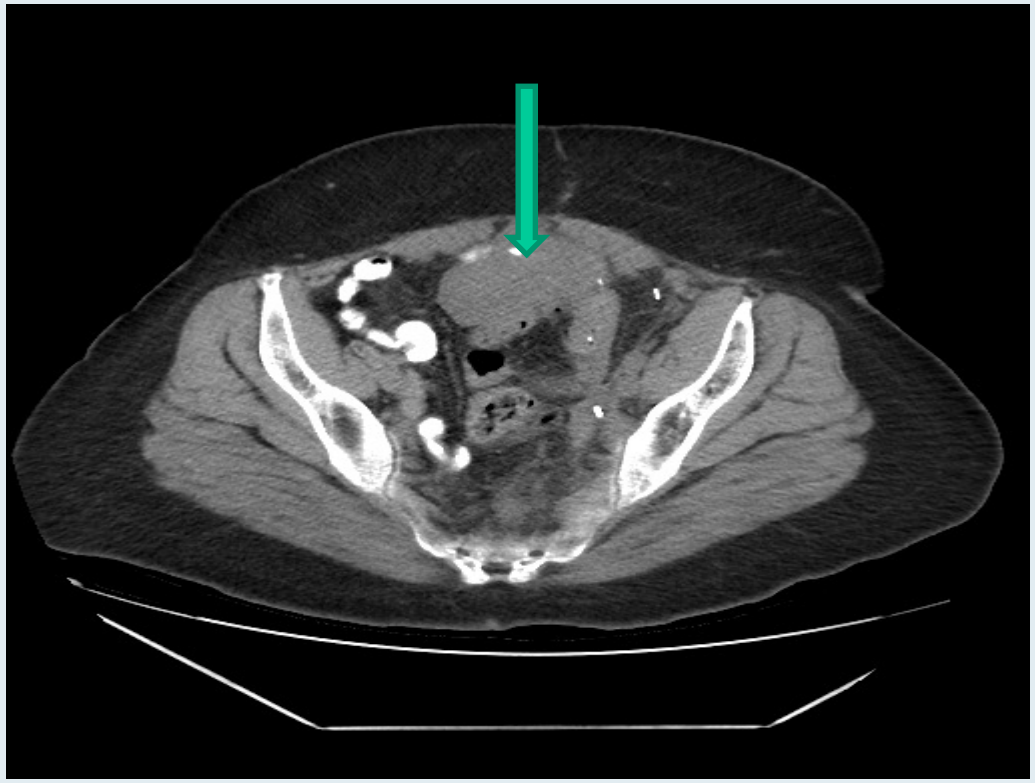
Case Presentation – Dr Hussein: A 46-year-old woman with recurrent uterine high-grade leiomyosarcoma (continued)

Dr Atif Hussein

Uterine leiomyosarcoma with a new soft tissue mass located between the small bowel loops and colon within the superior and mid-line of the pelvis. A portion of this measures 6.9 x 4.7 x 5.1 cm

06/2021



Case Presentation – Dr Hussein: A 66-year-old woman with MSS recurrent uterine adenocarcinoma with multiple actionable targets

Dr Atif Hussein

- 10/2018: Two separate primaries identified — Stage II colon and uterine adenocarcinomas
- 8/2019: Paclitaxel/carboplatin x 3 → TAH/BSO and lymphadenectomy → paclitaxel/carboplatin x 3
- 8/2019 NGS: MMR-proficient, MSS, TMB-low; ER-positive (1+), HER2-negative (2+), ARID1/BRCA1/2, POLE wildtype, PD-L1 IHC 0%, PIK3CA pathogenic variant, deletion p53
- 5/2021 Biopsy of pelvic mass: Adenocarcinoma c/w gynecologic origin → paclitaxel/carboplatin

Questions

- After 3 cycles of carboplatin/paclitaxel without reduction in the recurrent disease, what therapy would you recommend? What's the role of lenvatinib and pembrolizumab?
- Is PIK3CA a driver mutation in uterine adenocarcinoma? If so, would you give a PIK3CA inhibitor, like alpelisib?
- The HER2 in this patient was 2+ but CISH couldn't be done. Would you consider this low HER2 and use HER2 targeted therapy, like trastuzumab deruxtecan?
- Is there any role for hormonal therapy in the setting of estrogen receptor positivity?
- Are there any promising clinical trials targeting deletion p53 that we see in this patient?

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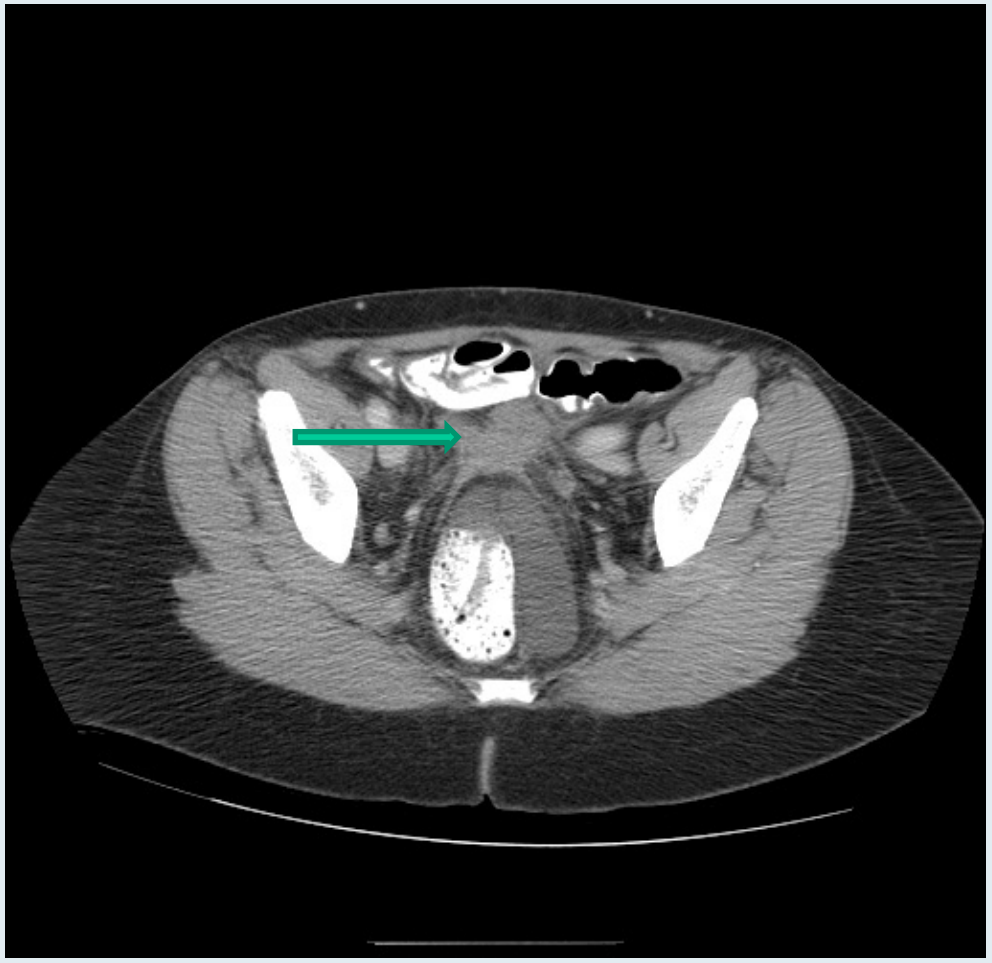
Case Presentation – Dr Hussein: A 66-year-old woman with MSS recurrent uterine adenocarcinoma with multiple actionable targets (continued)

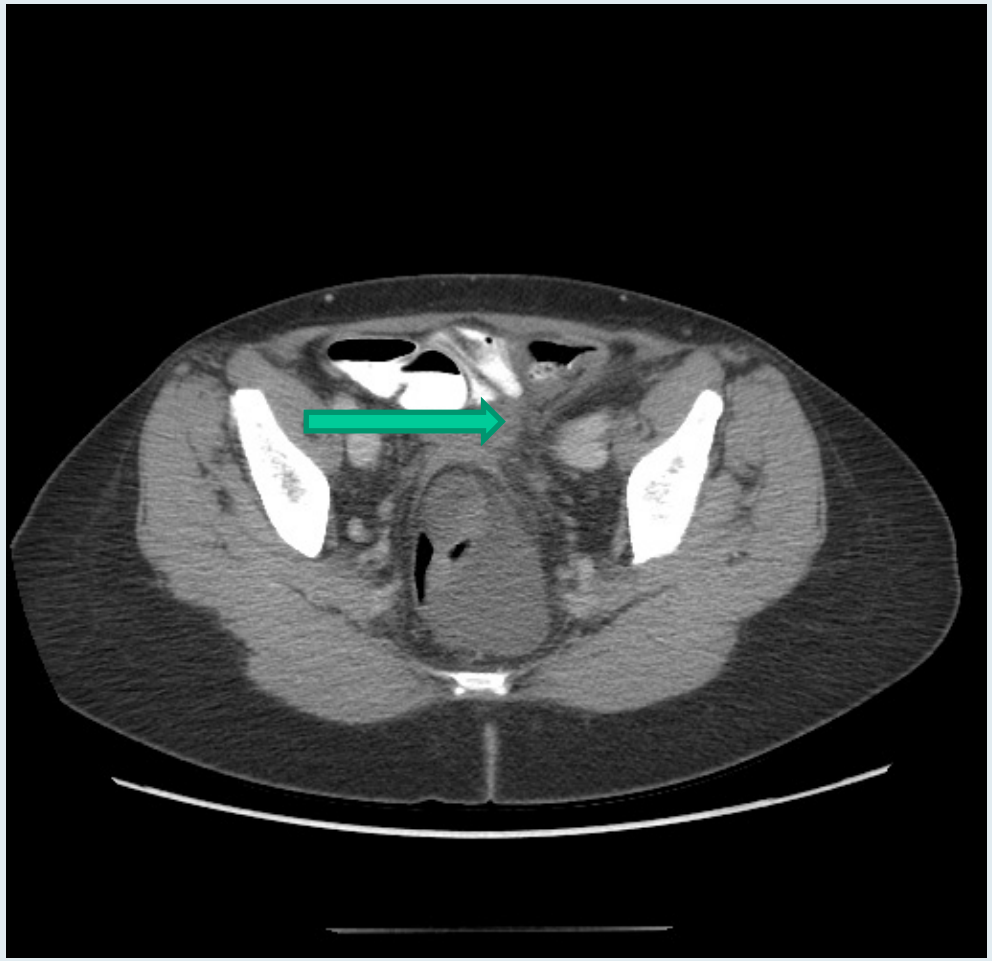
Dr Atif Hussein

Stable pelvic mass post 3 cycles of chemotherapy post recurrence

05/2021



08/2021



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Meet The Professor with Dr Westin

MODULE 1: Introduction

MODULE 2: Case Presentations

MODULE 3: Journal Club with Dr Westin

MODULE 4: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

MODULE 5: Other Key Recent Data Sets

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Journal Club with Dr Westin

- How JA et al. **Toxicity and efficacy of the combination of pembrolizumab with recommended or reduced starting doses of lenvatinib for treatment of recurrent endometrial cancer.** *Gynecol Oncol* 2021;162(1):24-31.
- Kurnit KC, Westin SN. **Slow and steady wins the race: Precision medicine for low risk endometrial cancer.** *Int J Gynecol Cancer* 2020;30(6):724-5.
- Baxter E et al. **Improving response to progestin treatment of low-grade endometrial cancer.** *Int J Gynecol Cancer* 2020;30(11):1811-23.
- Stasenko M et al. **Clinical patterns and genomic profiling of recurrent 'ultra-low risk' endometrial cancer.** *Int J Gynecol Cancer* 2020;30(6):717-23.
- Obermair A et al. **Fertility-sparing treatment in early endometrial cancer: Current state and future strategies.** *Obstet Gynecol Sci* 2020;63(4):417-31.

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Journal Club with Dr Westin (continued)

- Stewart KI et al. **Pushing the envelope: Expanding fertility sparing treatment of endometrial cancer.** *J Gynecol Oncol* 2020;31(5):e82.
- Falcone F et al. **Fertility-sparing treatment for intramucous, moderately differentiated, endometrioid endometrial cancer: A Gynecologic Cancer Inter-Group (GCIG) study.** *J Gynecol Oncol* 2020;31(5):e74.
- Westin SN et al. **Prospective phase II trial of levonorgestrel intrauterine device: nonsurgical approach for complex atypical hyperplasia and early-stage endometrial cancer.** *Am J Obstet Gynecol* 2021;224(2):191.e1-15.
- Frumovitz M et al. **Phase II study of pembrolizumab efficacy and safety in women with recurrent small cell neuroendocrine carcinoma of the lower genital tract.** *Gynecol Oncol* 2020;158(3):570-5.
- How JA et al. **The clinical efficacy and safety of single-agent pembrolizumab in patients with recurrent granulosa cell tumors of the ovary: A case series from a phase II basket trial.** *Invest New Drugs* 2021;39(3):829-35.

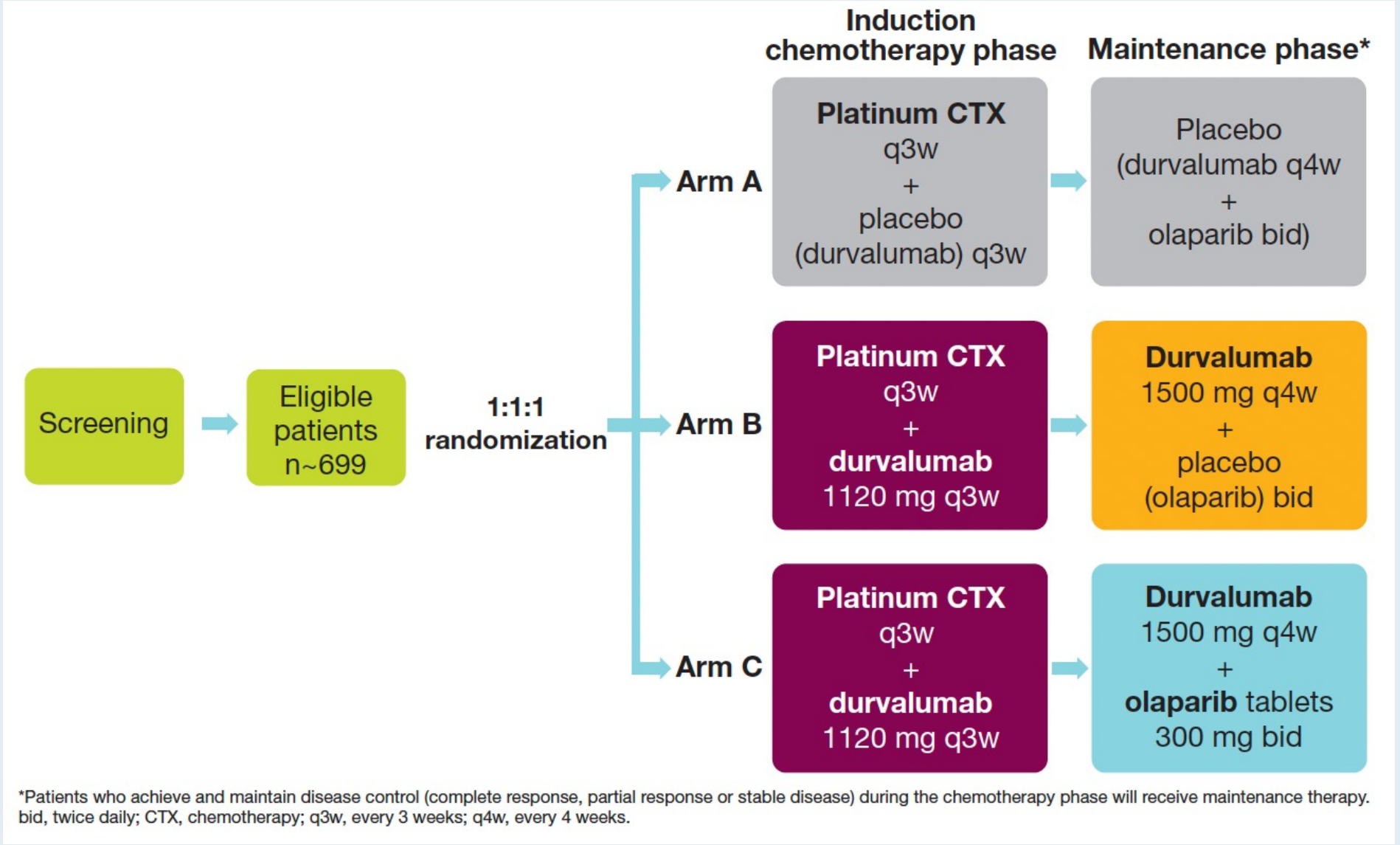
RTP RESEARCH TO PRACTICE

DUO-E/GOG-3041/ENGOT-EN10: A Randomized Phase III Trial of First-Line Carboplatin (Carb) and Paclitaxel (Pac) in Combination with Durvalumab (Durva), Followed by Maintenance Durva with or without Olaparib (Ola), in Patients (Pts) with Newly Diagnosed (Nd) Advanced or Recurrent Endometrial Cancer (EC)

Westin SN et al.

ASCO 2020;Abstract TPS6108.

DUO-E Study Design



*Patients who achieve and maintain disease control (complete response, partial response or stable disease) during the chemotherapy phase will receive maintenance therapy.
bid, twice daily; CTX, chemotherapy; q3w, every 3 weeks; q4w, every 4 weeks.

Westin SN et al. ASCO 2020;Abstract TPS6108.

RTP RESEARCH TO PRACTICE

Journal of Cancer Research and Clinical Oncology 2021;[Online ahead of print].
https://doi.org/10.1007/s00432-021-03778-1

ORIGINAL ARTICLE – CANCER RESEARCH

Immune microenvironment composition in high-grade serous ovarian cancers based on *BRCA* mutational status

Sara Corvigno[1] · Jared K. Burks[2] · Wei Hu[1] · Yanping Zhong[3,4] · Nicholas B. Jennings[1] · Nicole D. Fleming[1] · Shannon N. Westin[1] · Bryan Fellman[5] · Jinsong Liu[3] · Anil K. Sood[1,6]

Meet The Professor with Dr Westin

MODULE 1: Introduction

MODULE 2: Case Presentations

MODULE 3: Journal Club with Dr Westin

MODULE 4: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

MODULE 5: Other Key Recent Data Sets

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Cervical Cancer

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Regulatory and reimbursement issues aside, in general, what would be your preferred second-line therapy for a patient with MSS metastatic cervical cancer who experiences disease progression on carboplatin/paclitaxel/bevacizumab?

1. Other chemotherapy
2. Test for PD-L1 CPS and administer pembrolizumab if 1% or higher
3. Pembrolizumab
4. Cemiplimab
5. Tisotumab vedotin
6. Other

In general, what would be your preferred second-line therapy for a patient with MSS metastatic cervical cancer who experienced disease progression on carboplatin/paclitaxel/bevacizumab?

 Dr Birrer	Pembrolizumab	 Dr Penson	Test for PD-L1 CPS and administer pembrolizumab if 1% or higher
 Dr Coleman	Test for PD-L1 CPS and administer pembrolizumab if 1% or higher	 Dr Powell	Test for PD-L1 CPS and administer pembrolizumab if 1% or higher
 Dr Oaknin	Anti-PD-1/PD-L1 antibody in general	 Dr Slomovitz	Test for PD-L1 CPS and administer pembrolizumab if 1% or higher
 Dr O'Malley	Test for PD-L1 CPS and administer pembrolizumab if 1% or higher	 Dr Tewari	Test for PD-L1 CPS and administer pembrolizumab if 1% or higher

RTP RESEARCH TO PRACTICE

Endometrial Cancer

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RESEARCH
TO PRACTICE

In general, what treatment would you recommend for a patient with microsatellite-stable metastatic endometrial cancer who experienced disease progression on carboplatin/paclitaxel?

1. Cisplatin/doxorubicin
2. Carboplatin/docetaxel
3. Lenvatinib/pembrolizumab
4. Test for PD-L1 combined positive score (CPS) and administer pembrolizumab if 1% or higher
5. Pembrolizumab
6. Other chemotherapy
7. Other

In general, what treatment would you recommend for a patient with metastatic endometrial cancer who experienced disease progression on carboplatin/paclitaxel if their disease was microsatellite stable (MSS)?

 Dr Birrer	Lenvatinib/ pembrolizumab	 Dr Penson	Lenvatinib/ pembrolizumab
 Dr Coleman	Lenvatinib/ pembrolizumab	 Dr Powell	Lenvatinib/ pembrolizumab
 Dr Oaknin	Lenvatinib/ pembrolizumab	 Dr Slomovitz	Lenvatinib/ pembrolizumab
 Dr O'Malley	Lenvatinib/ pembrolizumab	 Dr Tewari	Lenvatinib/ pembrolizumab

RTP RESEARCH TO PRACTICE

In general, what treatment would you recommend for a patient with MSI-high metastatic endometrial cancer who experienced disease progression on carboplatin/paclitaxel?

1. Cisplatin/doxorubicin
2. Carboplatin/docetaxel
3. Lenvatinib/pembrolizumab
4. Pembrolizumab
5. Other chemotherapy
6. Other

In general, what treatment would you recommend for a patient with metastatic endometrial cancer who experienced disease progression on carboplatin/paclitaxel if their disease was MSI high?

 Dr Birrer	Pembrolizumab	 Dr Penson	Pembrolizumab
 Dr Coleman	Pembrolizumab	 Dr Powell	Pembrolizumab
 Dr Oaknin	Dostarlimab	 Dr Slomovitz	Pembrolizumab
 Dr O'Malley	Pembrolizumab	 Dr Tewari	Pembrolizumab

RTP RESEARCH TO PRACTICE

For a patient with MSI-high metastatic endometrial cancer, outside of a clinical trial setting and regulatory and reimbursement issues aside, what is the earliest point at which you would introduce an anti-PD-1/PD-L1 antibody?

 Dr Birrer	Second line	 Dr Penson	First line
 Dr Coleman	Second line	 Dr Powell	Second line
 Dr Oaknin	Second line	 Dr Slomovitz	Second line
 Dr O'Malley	First line	 Dr Tewari	Second line

RTP RESEARCH TO PRACTICE

Ovarian Cancer

Do you generally evaluate microsatellite instability status in your patients with advanced ovarian cancer?

1. Yes
2. No

Do you generally evaluate microsatellite instability status in your patients with advanced ovarian cancer?

 Dr Birrer	Yes	 Dr Penson	Yes
 Dr Coleman	Yes	 Dr Powell	Yes
 Dr Oaknin	No	 Dr Slomovitz	No
 Dr O'Malley	Yes	 Dr Tewari	No

RTP RESEARCH TO PRACTICE

Meet The Professor with Dr Westin

MODULE 1: Introduction

MODULE 2: Case Presentations

MODULE 3: Journal Club with Dr Westin

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TO PRACTICE

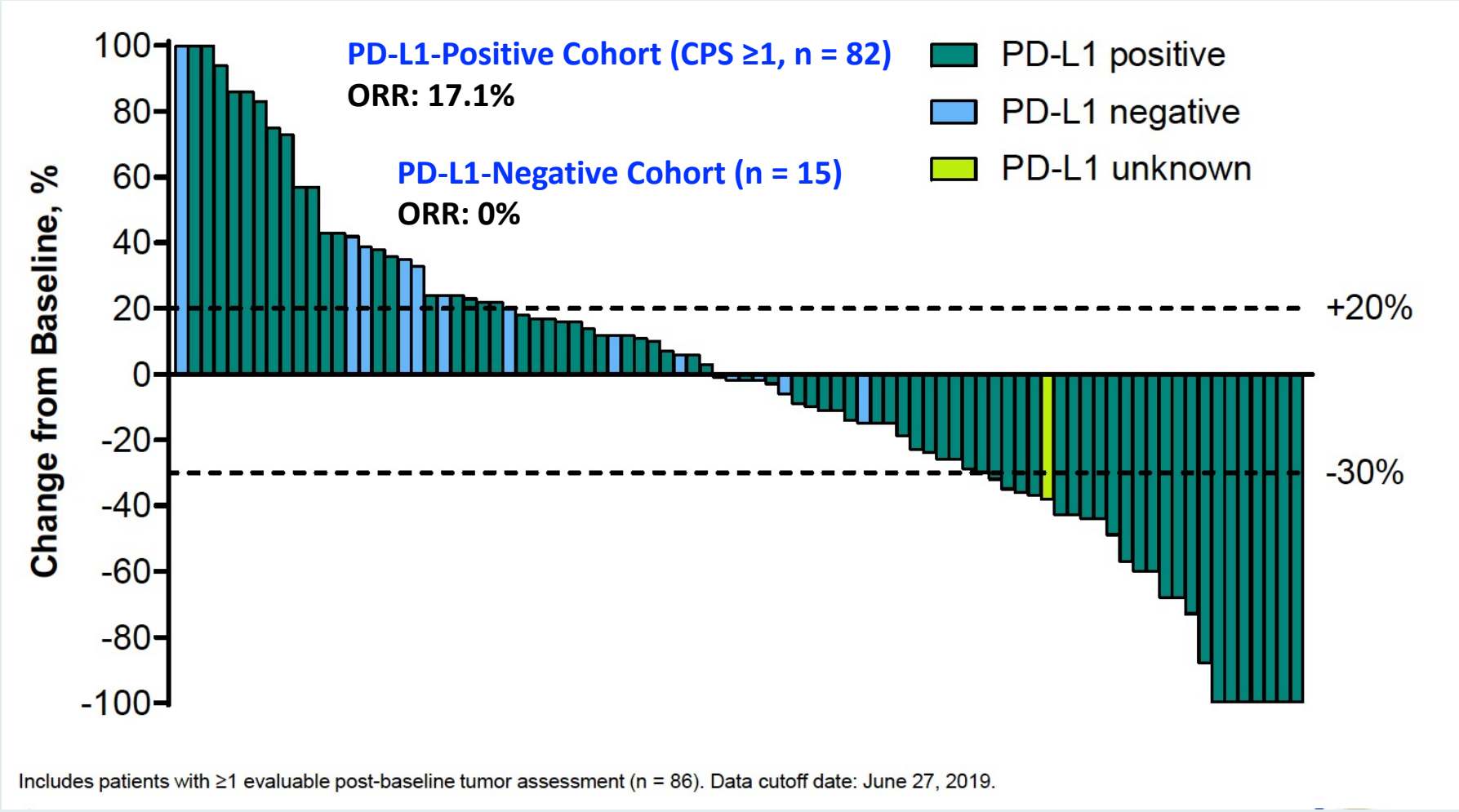
Immunotherapeutic Approaches in Cervical Cancer

Pembrolizumab Treatment of Advanced Cervical Cancer: Updated Results from the Phase II KEYNOTE-158 Study

Chung HC et al.

SGO 2021;Abstract 10440.

Phase II KEYNOTE-158: Updated Results with Pembrolizumab for Previously Treated Advanced Cervical Cancer



Includes patients with ≥1 evaluable post-baseline tumor assessment (n = 86). Data cutoff date: June 27, 2019.

Combined Positive Score (CPS) = PD-L1+ cells (tumor cells, lymphocytes, macrophages) / Total number of tumor cells x 100

Chung HC et al. SGO 2021;Abstract 10440.

RTP RESEARCH TO PRACTICE

ESMO 2021;Abstract VP4

2021 ESMO congress

EMPOWER GOG FOUNDATION ENGOT European Network of Gynaecological Oncological Trial groups

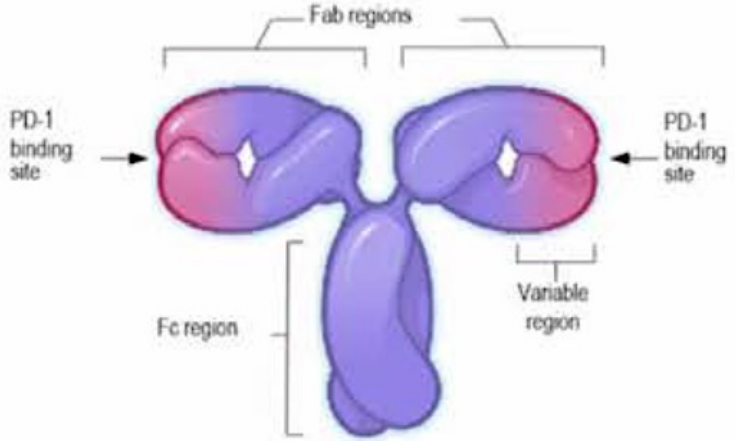
EMPOWER-Cervical 1/GOG-3016/ENGOT-cx9: Results of Phase 3 trial of cemiplimab vs investigator's choice (IC) chemotherapy (chemo) in recurrent/metastatic (R/M) cervical carcinoma

Krishnansu S Tewari,*† Bradley J Monk,* Ignace Vergote, Austin Miller, Andreia Cristina de Melo, Hee Seung Kim, Yong Man Kim, Alla Lisyanskaya, Vanessa Samouëlian, Domenica Lorusso, Fernanda Damian, Chih-Long Chang, Evgeniy A Gotovkin, Shunji Takahashi, Daniella Ramone, Joanna Pikiel, Beata Maćkowiak-Matejczyk, Eva Maria Guerra, Nicoletta Colombo, Yulia Makarova, Jingjin Li, Shaheda Jamil, Vladimir Jankovic, Chieh-I Chen, Frank Seebach, David M Weinreich, George D Yancopoulos, Israel Lowy, Melissa Mathias, Matthew G Fury, and Ana Oaknin

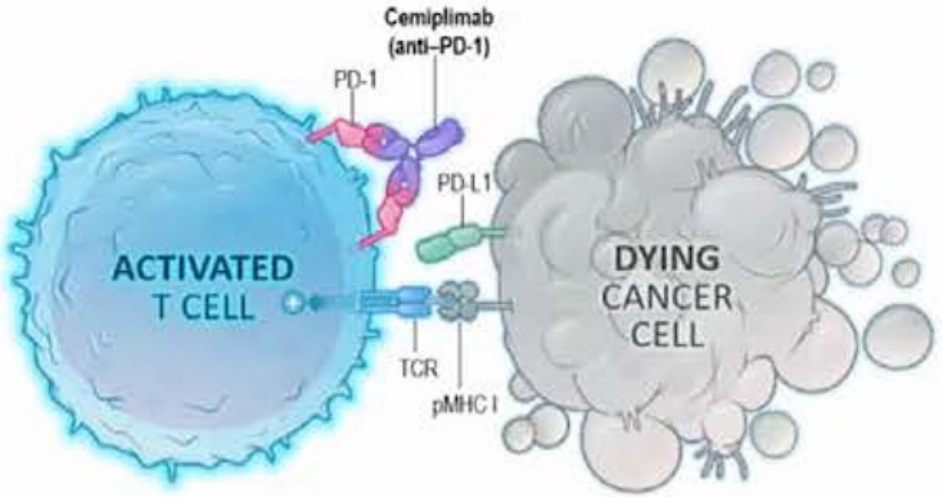
*Contributed equally to this presentation.
†Department of Obstetrics & Gynecology, University of California, Irvine.
Portions of the following were previously presented at the May 2021 ESMO Virtual Plenary.

Cemiplimab

Cemiplimab Molecular Structure



Cemiplimab Mechanism of Action



- High-affinity, human, hinge-stabilised IgG4 monoclonal antibody to the PD-1 receptor[1]
- Phase 1 R/M cervical cancer (n=23; includes Dose Escalation + Expansion Cohorts)[2]
  - Safety profile similar to that of other PD-1 inhibitors[2]
  - 17% ORR[2]

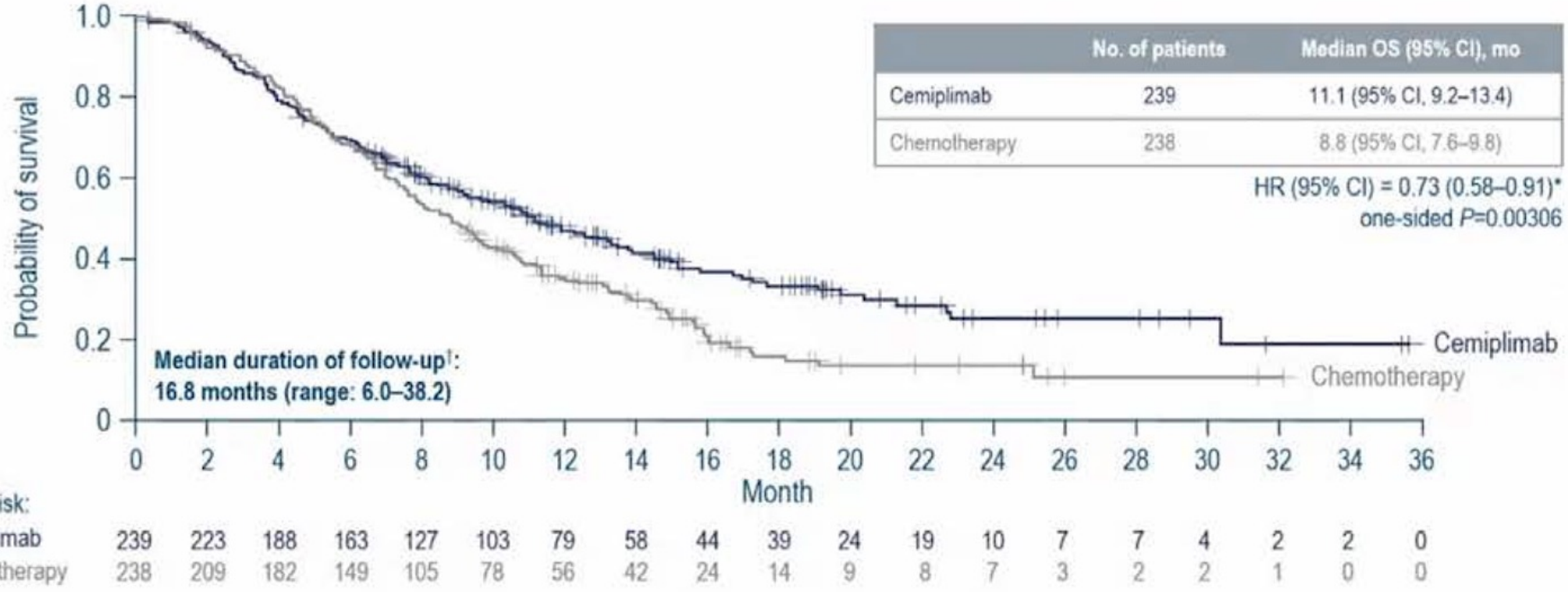
Ig, immunoglobin; Fc, fragment crystallizable; ORR, objective response rate; PD-1, programmed cell death-1; PD-L1, PD-ligand 1; pMHC I, peptide-bound major histocompatibility complex I; R/M, recurrent or metastatic; TCR, T-cell receptor.

1. Burova E et al. *Mol Cancer Ther*. 2017;16:861–870. 2. Rischin D et al. *Gynecol Oncol*. 2020;159:322–328.

Tewari KS et al. ESMO 2021;Abstract VP4.

Survival Analysis for SCC Population

- At second interim analysis (85% of total OS events), IDMC recommended trial be stopped early for efficacy



	No. of patients	Median OS (95% CI), mo
Cemiplimab	239	11.1 (95% CI, 9.2–13.4)
Chemotherapy	238	8.8 (95% CI, 7.6–9.8)

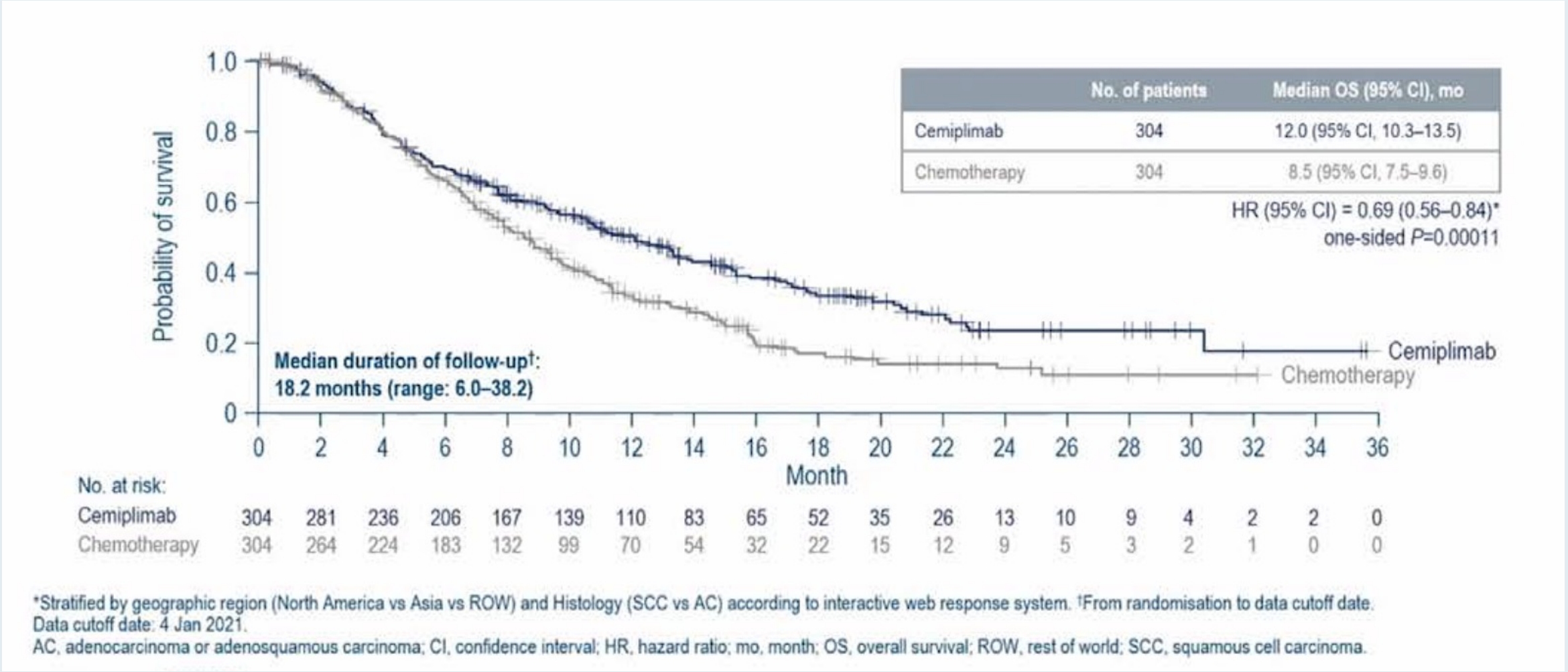
HR (95% CI) = 0.73 (0.58–0.91)*
one-sided *P*=0.00306

*Stratified by geographic region (North America vs Asia vs ROW) according to interactive web response system. †From randomisation to data cutoff date.
Data cutoff date: 4 Jan 2021.
CI, confidence interval; HR, hazard ratio; IDMC, Independent Data Monitoring Committee; mo, month; OS, overall survival; ROW, rest of world; SCC, squamous cell carcinoma.

Tewari KS et al. ESMO 2021;Abstract VP4.

RTP RESEARCH TO PRACTICE

Survival Analysis for the Total Population



	No. of patients	Median OS (95% CI), mo
Cemiplimab	304	12.0 (95% CI, 10.3–13.5)
Chemotherapy	304	8.5 (95% CI, 7.5–9.6)

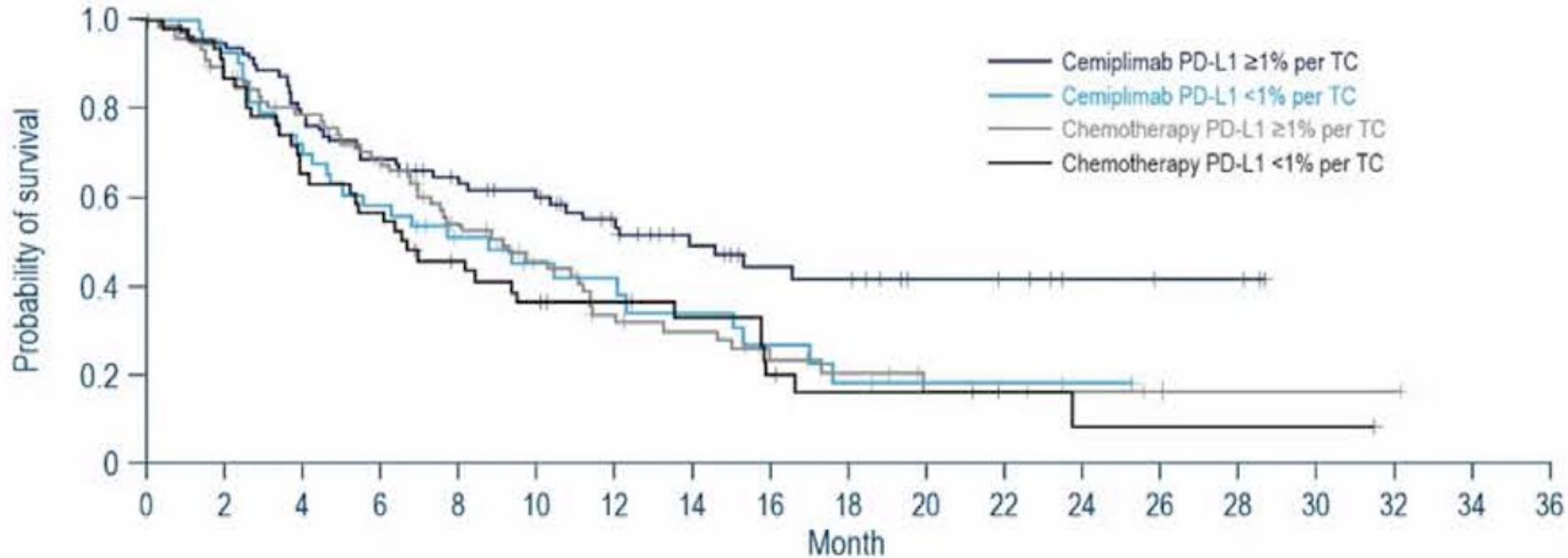
HR (95% CI) = 0.69 (0.56–0.84)*
one-sided *P*=0.00011

*Stratified by geographic region (North America vs Asia vs ROW) and Histology (SCC vs AC) according to interactive web response system. †From randomisation to data cutoff date.
Data cutoff date: 4 Jan 2021.
AC, adenocarcinoma or adenosquamous carcinoma; CI, confidence interval; HR, hazard ratio; mo, month; OS, overall survival; ROW, rest of world; SCC, squamous cell carcinoma.

Tewari KS et al. ESMO 2021;Abstract VP4.

RTP RESEARCH TO PRACTICE

Survival Analysis by PD-L1 Status



No. at risk:																			
Cemiplimab PD-L1 ≥1% per TC	82	78	65	55	45	39	30	22	16	15	10	9	4	3	3	0	0	0	0
Cemiplimab PD-L1 <1% per TC	44	41	30	25	18	13	11	9	6	4	3	3	1	0	0	0	0	0	0
Chemotherapy PD-L1 ≥1% per TC	80	69	58	50	36	28	20	16	10	8	5	5	4	2	1	1	1	0	0
Chemotherapy PD-L1 <1% per TC	48	40	30	26	19	15	12	10	6	4	4	2	1	1	1	1	0	0	0

*Associations between efficacy outcomes and PD-L1 expression (detected using the SP263 monoclonal antibody) in tumor cells was evaluated using exploratory analyses.
Of 608 randomized patients, 254 had valid baseline PD-L1 samples: cemiplimab (n=126) and chemotherapy (n=128).
Data cutoff date: 4 Jan 2021.
PD-L1, programmed cell death-ligand 1; TC, tumor cells.

Tewari KS et al. ESMO 2021;Abstract VP4.

Anti-PD-1/PD-L1 Checkpoint Inhibitors in Endometrial Cancer

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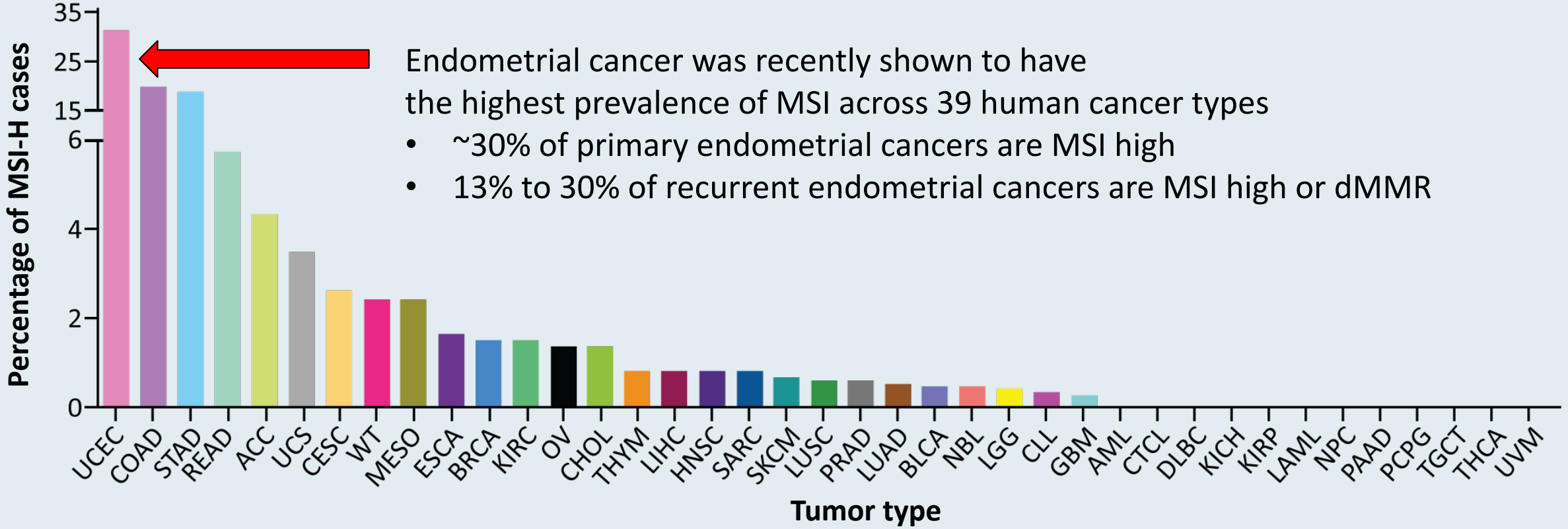
TO PRACTICE

High MSI Across 39 Cancer Types

Whole-exome data from 11,139 tumor-normal pairs from The Cancer Genome Atlas and Therapeutically Applicable Research to Generate Effective Treatments projects



Endometrial cancer was recently shown to have the highest prevalence of MSI across 39 human cancer types

- ~30% of primary endometrial cancers are MSI high
- 13% to 30% of recurrent endometrial cancers are MSI high or dMMR

UCEC = uterine corpus endometrial carcinoma

Bonneville R et al. *JCO Precis Oncol* 2017;2017:10.1200/PO.17.00073; Green AK et al. *ASCO Educational Book* 2020.

RTP RESEARCH TO PRACTICE

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.

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.

The primary efficacy endpoints were overall response rate (ORR) and duration of response (DoR) as determined by blinded independent central review according to RECIST 1.1. The ORR was 41.6% (95% CI: 34.9, 48.6), with 9.1% complete response rate and 32.5% partial response rate. Median DOR was 34.7 months (range 2.6, 35.8+), with 95.4% of patients with duration ≥6 months."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dostarlimab-gxly-dmmr-advanced-solid-tumors

FDA Grants Accelerated Approval to Dostarlimab-gxly for dMMR Endometrial Cancer

Press Release – April 22, 2021

"The Food and Drug Administration granted accelerated approval to dostarlimab-gxly for adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following a prior platinum-containing regimen.

Efficacy was evaluated based on cohort (A1) in GARNET Trial (NCT02715284), a multicenter, multicohort, open-label trial in patients with advanced solid tumors. The efficacy population consisted of 71 patients with dMMR recurrent or advanced endometrial cancer who progressed on or after a platinum-containing regimen. Patients received dostarlimab-gxly, 500 mg intravenously, every 3 weeks for 4 doses followed by 1,000 mg intravenously every 6 weeks.

The main efficacy endpoints were overall response rate (ORR) and duration of response (DOR), as assessed by blinded independent central review (BICR) according to RECIST 1.1. Confirmed ORR was 42.3%. The complete response rate was 12.7% and partial response rate was 29.6%. Median DOR was not reached, with 93.3% of patients having durations ≥6 months (range: 2.6 to 22.4 months, ongoing at last assessment)."

https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-dostarlimab-gxly-dmmr-endometrial-cancer

Interim Analysis of the Immune-Related Endpoints of the Mismatch Repair Deficient (dMMR) and Proficient (MMRp) Endometrial Cancer Cohorts from the GARNET Study

Pothuri B et al.

SGO 2021;Abstract 10417.

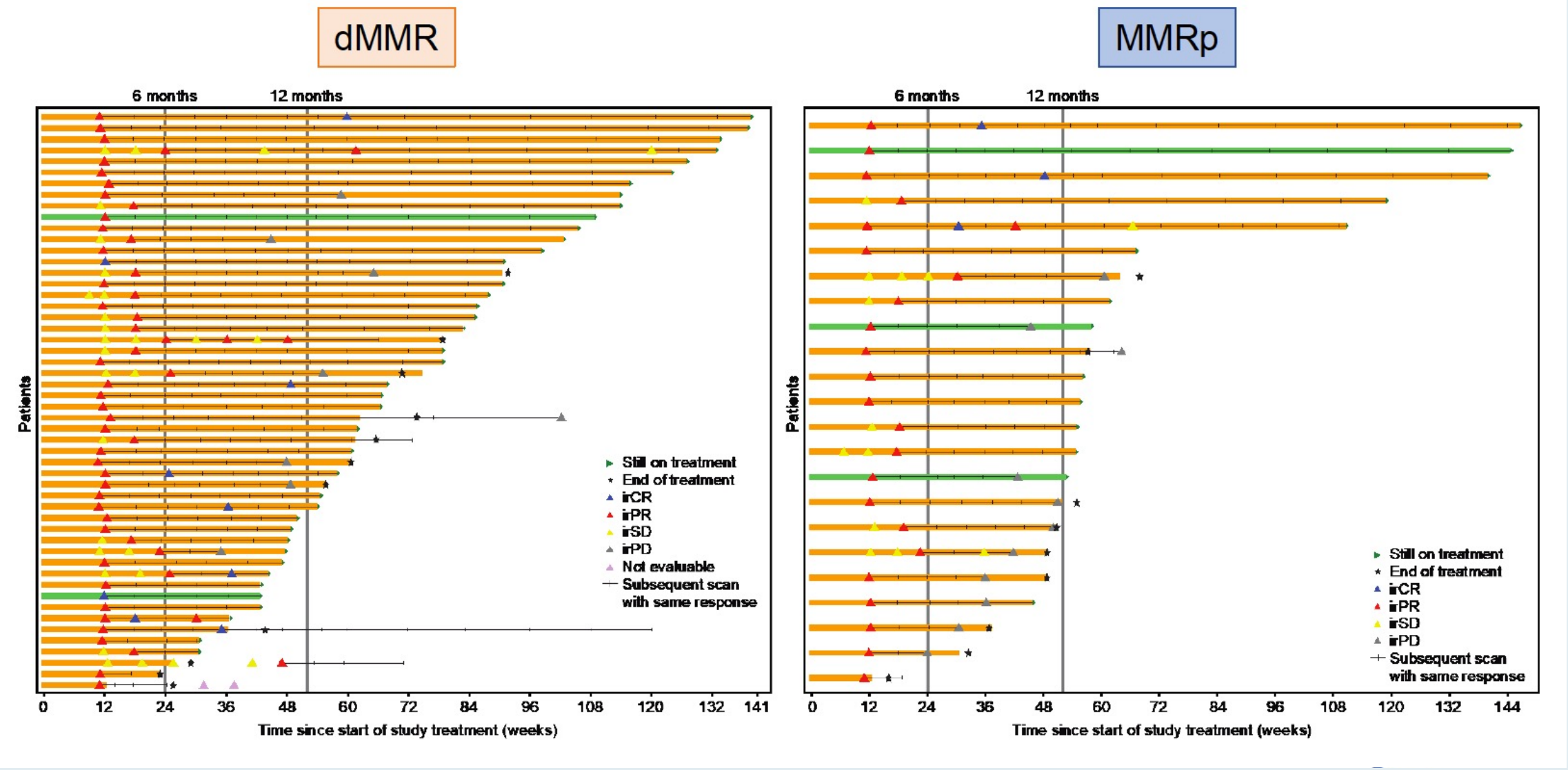
GARNET: Immune-Related Secondary Endpoints

(irRECIST by investigator assessment)		
Variable	dMMR N=110	MMRp N=144
Follow-up, median (range), months	16.5 (0.03–30.6)	13.7 (0.03–33.1)
irORR, n (%)	50 (45.5)	20 (13.9)
irCR	7 (6.4)	3 (2.1)
irPR	43 (39.1)	17 (11.8)
irSD	20 (18.2)	41 (28.5)
irPD	36 (32.7)	63 (43.8)
NE	4 (3.6)	20 (13.9)
irDCR,[a] n (%)	70 (63.6)	61 (42.4)
irDOR,[b] months	NR	12.2

[a]Includes CR, PR, and SD ≥12 weeks; [b]Only includes responders.

Pothuri B et al. SGO 2021;Abstract 10417.

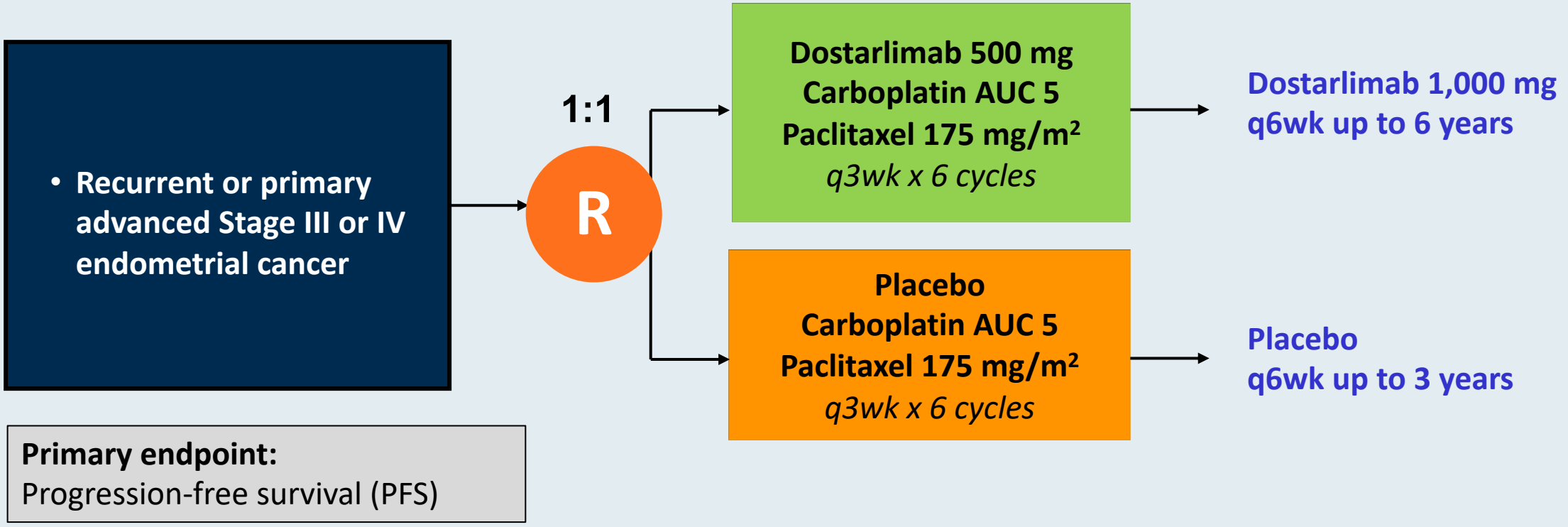
GARNET: Duration of Response



Pothuri B et al. SGO 2021;Abstract 10417.

RTP RESEARCH TO PRACTICE

ENGOT-EN6/NSGO-RUBY Phase III Schema



Mirza MR et al. ASCO 2020;Abstract TPS6107.

ASCO 2021;Abstract 2565

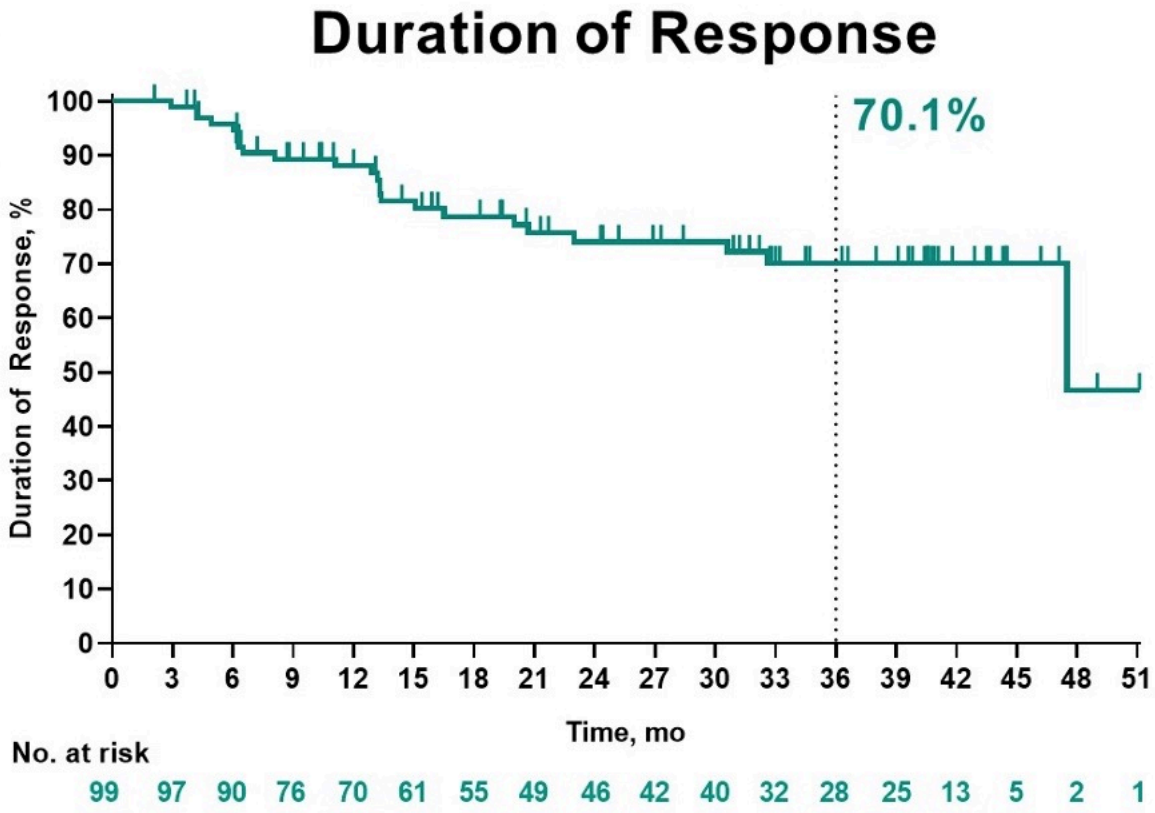
Pembrolizumab in Microsatellite Instability High/Mismatch Repair–Deficient Cancers: Updated Analysis From Phase 2 KEYNOTE-158 Study

M. Maio[1]; P.A. Ascierto[2]; L. Manzyuk[3]; D. Motola-Kuba[4]; N. Penel[5]; P.A. Cassier[6]; G. Mendonca Bariani[7]; A. De Jesus Acosta[8]; T. Doi[9]; F. Longo Muñoz[10]; W.H. Miller, Jr[11]; D.-Y. Oh[12]; M. Gottfried[13]; R. Wang[14]; F. Jin[14]; K. Norwood[14]; A. Marabelle[15]

[1]Center for Immuno-Oncology, University Hospital of Siena, Siena, Italy; [2]Istituto Nazionale Tumori Istituto di Ricovero e Cura a Carattere Scientifico Fondazione Pascale, Naples, Italy; [3]NN Blokhin National Medical Research Center of Oncology, Moscow, Russia; [4]COMOP A.C., Clinical Investigation, Mexico City, Mexico; [5]Centre Oscar Lambret and Lille University, Lille, France; [6]Department of Medical Oncology, Centre Léon Bérard, Lyon, France; [7]Instituto do Câncer do Estado de São Paulo, Universidade de São Paulo, São Paulo, Brazil; [8]Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD; [9]National Cancer Center Hospital East, Kashiwa, Japan; [10]Hospital Universitario Ramón y Cajal, IRYCIS, CIBERONC, Madrid, Spain; [11]Jewish General Hospital and McGill University, Montréal, QC, Canada; [12]Department of Internal Medicine, Seoul National University Hospital, and Cancer Research Institute, Seoul National University College of Medicine, Seoul, Republic of Korea; [13]Meir Medical Center, Tel Aviv, Israel; [14]Merck & Co., Inc., Kenilworth, NJ, USA; [15]Gustave Roussy, Institut National de la Santé et de la Recherche Médicale U1015, Villejuif, France.

KEYNOTE-158: Updated Response Analyses

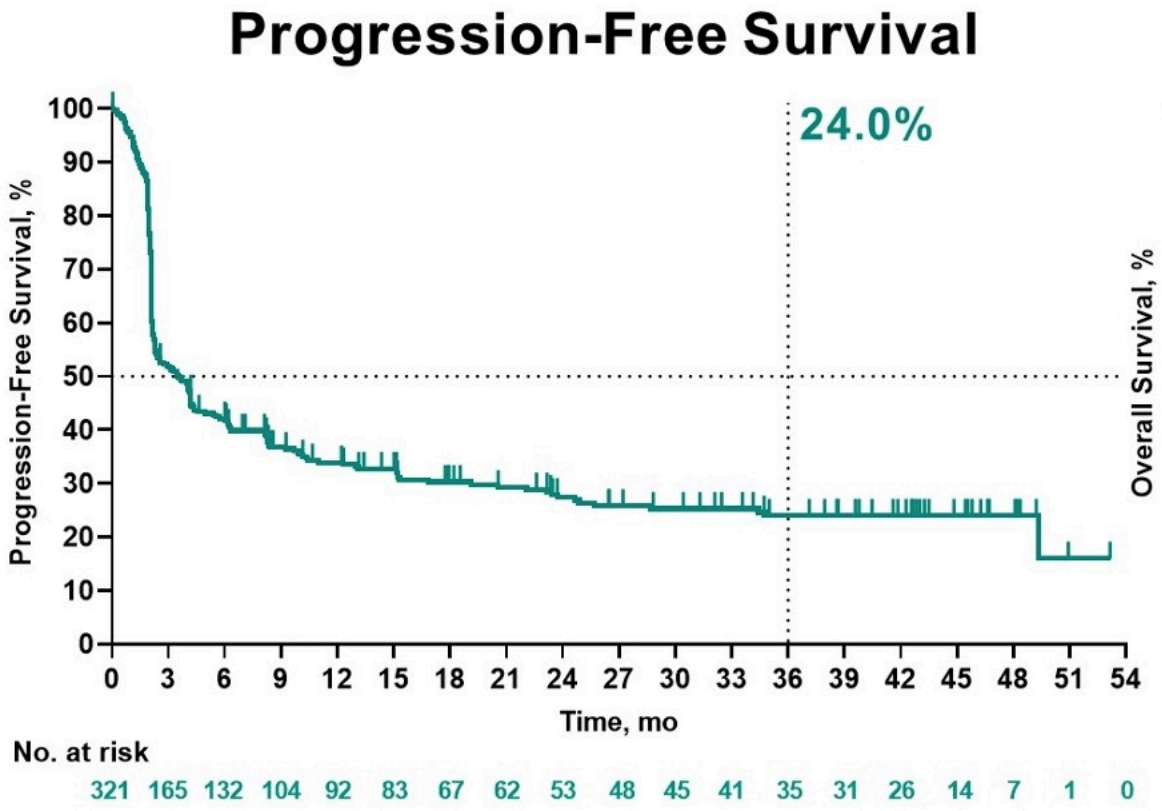
Efficacy Analysis Population	N = 321
ORR, % (95% CI)	**30.8 (25.8–36.2)**
CR	27 (8.4)
PR	72 (22.4)
SD	61 (19.0)
PD	131 (40.8)
Nonevaluable	3 (0.9)
No assessment[a]	27 (8.4)

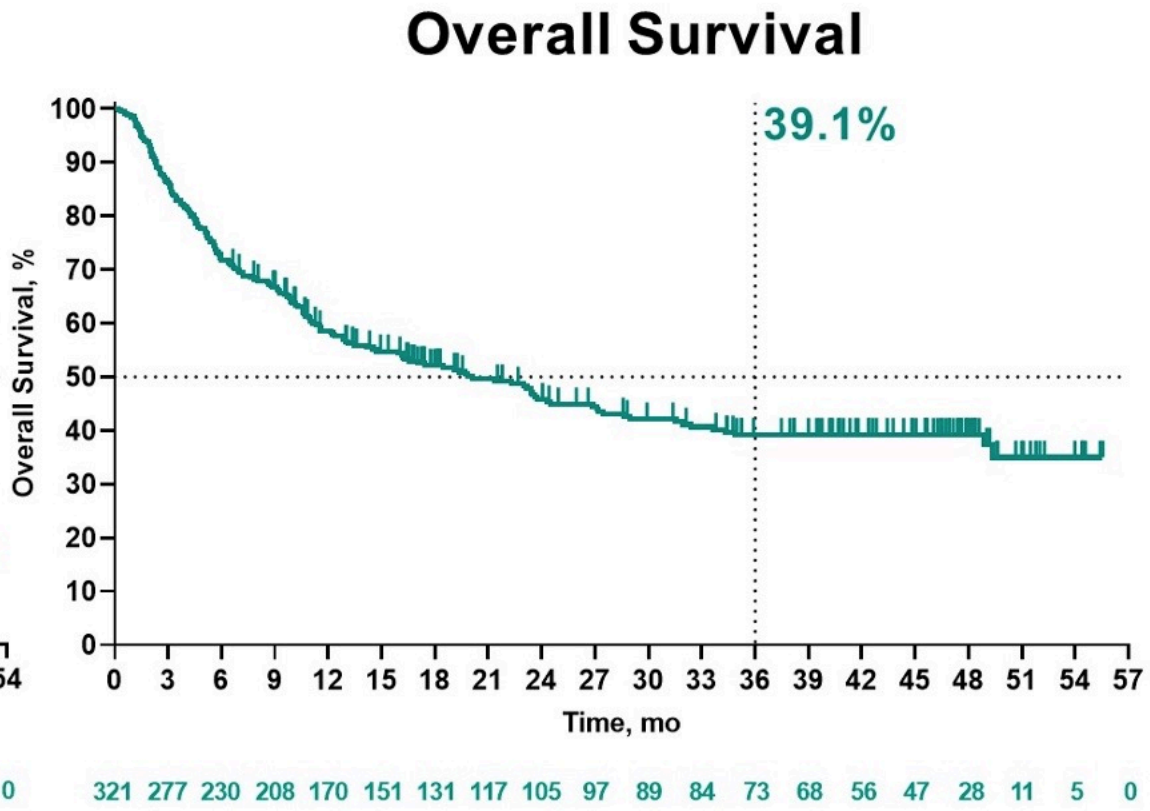


CI, confidence interval. "+" indicates no PD by the time of last disease assessment.
[a]Patients who had no postbaseline imaging assessment.
Data cutoff: October 5, 2020

Maio M et al. ASCO 2021;Abstract 2565.

KEYNOTE-158: Updated Survival Analyses





Data cutoff: October 5, 2020

Maio M et al. ASCO 2021;Abstract 2565.

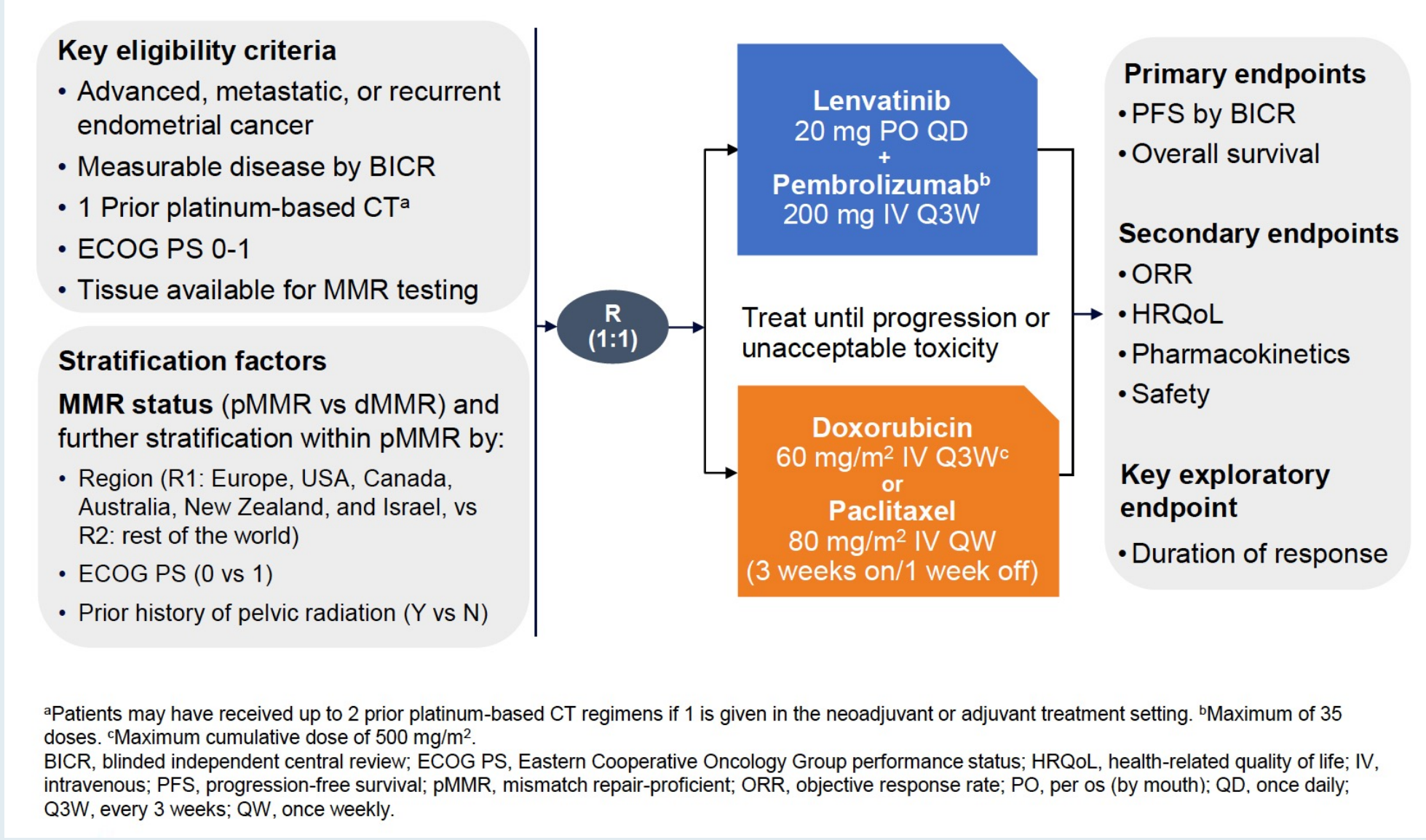
RTP RESEARCH TO PRACTICE

A Multicenter, Open-Label, Randomized, Phase III Study to Compare the Efficacy and Safety of Lenvatinib in Combination with Pembrolizumab versus Treatment of Physician's Choice in Patients with Advanced Endometrial Cancer: Study 309/KEYNOTE-775

Makker V et al.

SGO 2021;Abstract 11512.

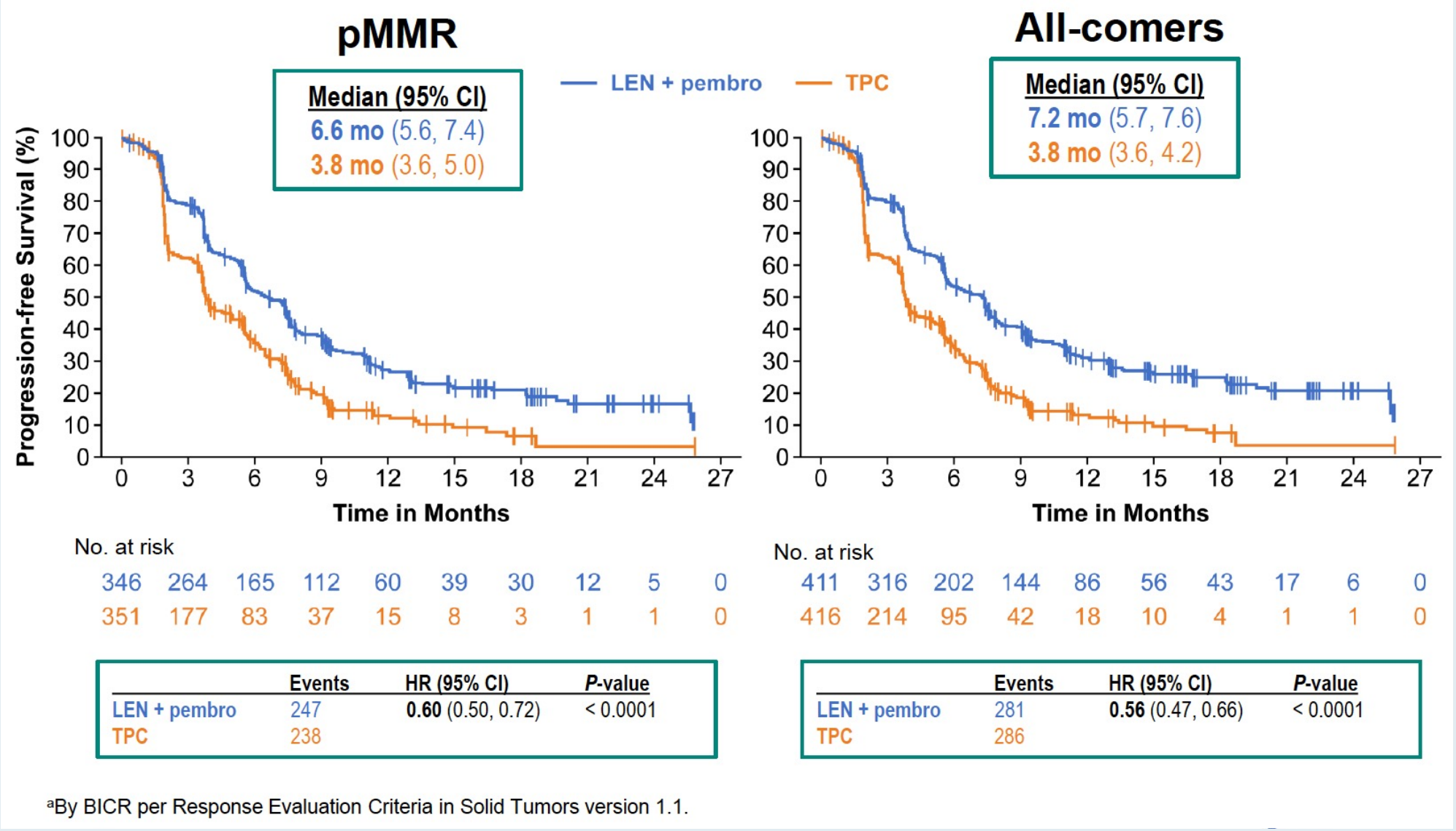
Study 309/KEYNOTE-775: Phase III Trial Schema



[a]Patients may have received up to 2 prior platinum-based CT regimens if 1 is given in the neoadjuvant or adjuvant treatment setting. [b]Maximum of 35 doses. [c]Maximum cumulative dose of 500 mg/m^2.
BICR, blinded independent central review; ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; IV, intravenous; PFS, progression-free survival; pMMR, mismatch repair-proficient; ORR, objective response rate; PO, per os (by mouth); QD, once daily; Q3W, every 3 weeks; QW, once weekly.

Makker V et al. SGO 2021;Abstract 11512.

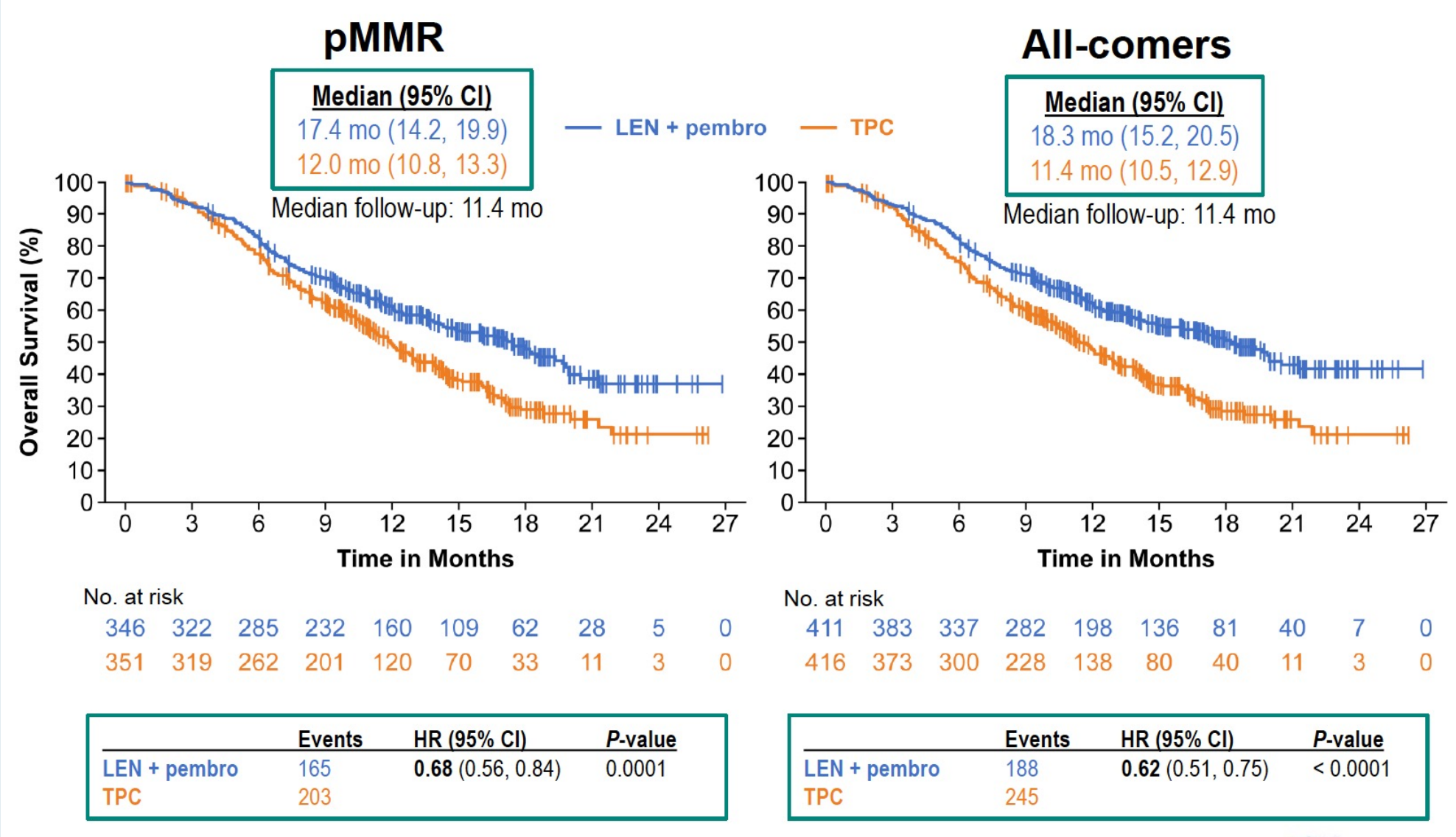
Study 309/KEYNOTE-775: Progression-Free Survival



[a]By BICR per Response Evaluation Criteria in Solid Tumors version 1.1.

Makker V et al. SGO 2021;Abstract 11512.

Study 309/KEYNOTE-775: Overall Survival



Makker V et al. SGO 2021;Abstract 11512.

Anti-PD-1/PD-L1 Antibodies in Ovarian Cancer

An Open-Label Phase 2 Study of Dostarlimab, Bevacizumab, and Niraparib Combination in Patients with Platinum-Resistant Ovarian Cancer: Cohort A of the OPAL Trial

Joyce F. Liu,[1] Stéphanie Gaillard,[2] Andrea E. Wahner Hendrickson,[3] John W. Moroney,[4] Oladapo Yeku,[5] Elisabeth Diver,[6] Camille Gunderson,[7] Rebecca Arend,[8] Elena Ratner,[9] Vivek Samnotra,[10] Divya Gupta,[10] Lena Evilevitch,[10] Zebin Wang,[10] Ping Wang,[10] Joseph Tang,[10] Emeline Bacqué,[10] Xiaohong Liu,[10] Gottfried E. Konecny[11]

Poster #23

[1]Dana-Farber Cancer Institute, Boston, MA, USA; [2]Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, USA; [3]Mayo Clinic Rochester, Rochester, NY, USA; [4]University of Chicago Medicine Comprehensive Cancer Center, Chicago, IL, USA; [5]Massachusetts General Cancer Center, Boston, MA, USA; [6]Stanford Women's Cancer Center, Palo Alto, CA, USA; [7]University of Oklahoma Stephenson Cancer Center, Oklahoma City, OK, USA; [8]The University of Alabama at Birmingham, UAB Comprehensive Cancer Center, Birmingham, AL, USA; [9]Yale University, New Haven, CT, USA; [10]GlaxoSmithKline, Waltham, MA, USA; [11]Ronald Reagan UCLA Medical Center, Los Angeles, CA, USA.

SGO 2021 VIRTUAL ANNUAL MEETING ON WOMEN'S CANCER®

Abstract 10415

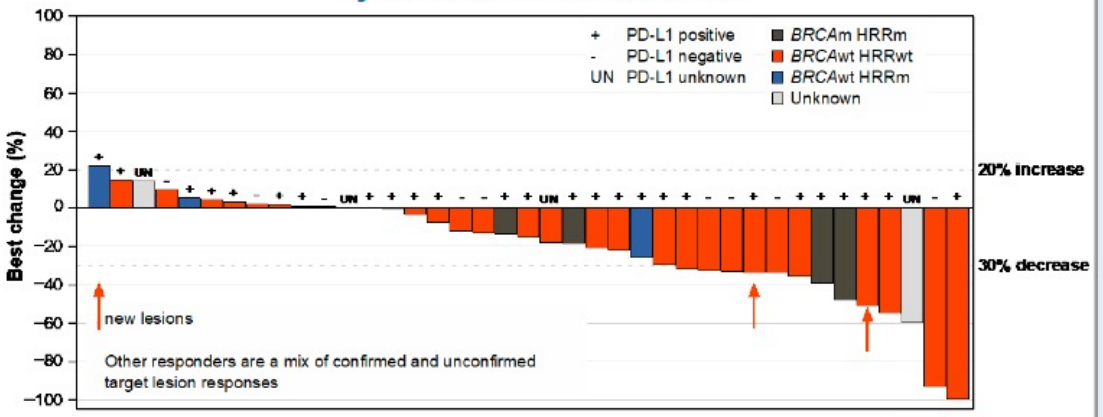
Society of Gynecologic Oncology

Antitumor Activity

- Antitumor activity was assessed in the response-evaluable population (n=39)
  - 2 patients in the safety population did not have a postbaseline scan and were excluded from the response-evaluable population
- Response data required that patients with a best response of complete response or partial response had a confirmation scan ≥4 weeks after the first scan in which a response was observed

Antitumor Activity per RECIST v1.1	
Variable, n (%)	**Response-evaluable population (n=39)**
Complete response	0
Partial response	7 (17.9)
Stable disease	23 (59.0)
Progressive disease	8 (20.5)
Inconclusive	1 (2.6)
ORR (90% CI), %	17.9 (8.7–31.1)
DCR (90% CI), %	76.9 (63.2–87.4)

Best Percent Change from Baseline Sum of Target Lesions by HRR and PD-L1 Status



*BRCA*m, *BRCA* mutation; *BRCA*wt, *BRCA* wild type; HRRm, homologous recombination repair mutation; HRRwt, homologous recombination repair wild type; PD-L1, programmed death ligand 1.

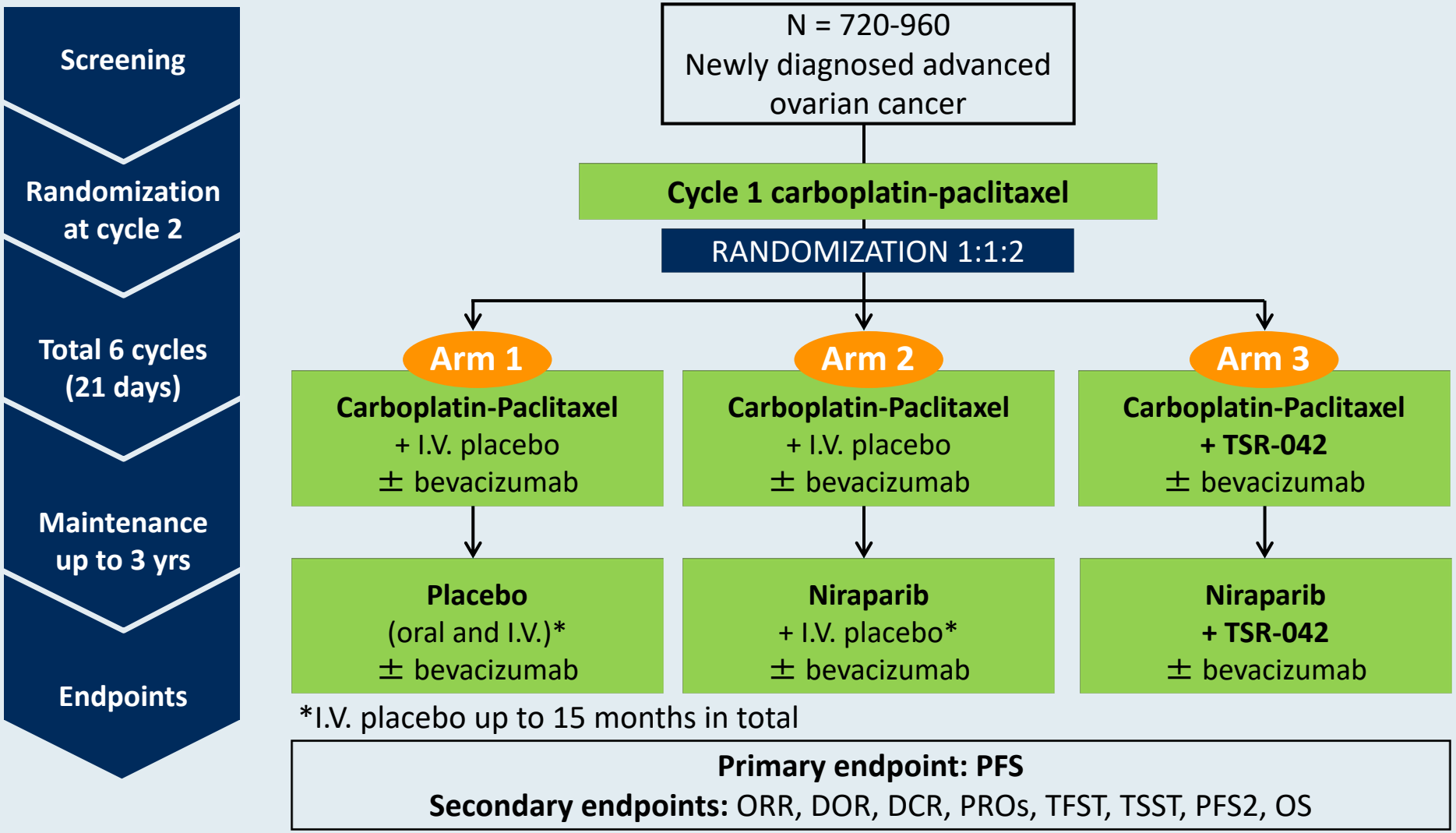
SGO 2021 VIRTUAL ANNUAL MEETING ON WOMEN'S CANCER®

Society of Gynecologic Oncology

Liu JF et al. SGO 2021;Abstract 10415.

RTP RESEARCH TO PRACTICE

FIRST Phase III Trial of Dostarlimab (TSR-042) in Newly Diagnosed Ovarian Cancer



www.clinicaltrials.gov/ct2/show/NCT03602859

Courtesy of Ursula Matulonis, MD

Phase II MOONSTONE Study Design

Eligibility

- Completed 1-3 prior lines of therapy for advanced or metastatic ovarian cancer
- Previously treated with platinum-based chemo, taxane and bevacizumab
- Resistant to last administered platinum agent
- No known BRCA 1 or 2 mutation

N=150

Niraparib + Dostarlimab

Primary endpoint: ORR
Secondary endpoints: DOR, PFS, OS, DCR

https://clinicaltrials.gov/ct2/show/NCT03955471?term=MOONSTONE&draw=2&rank=1

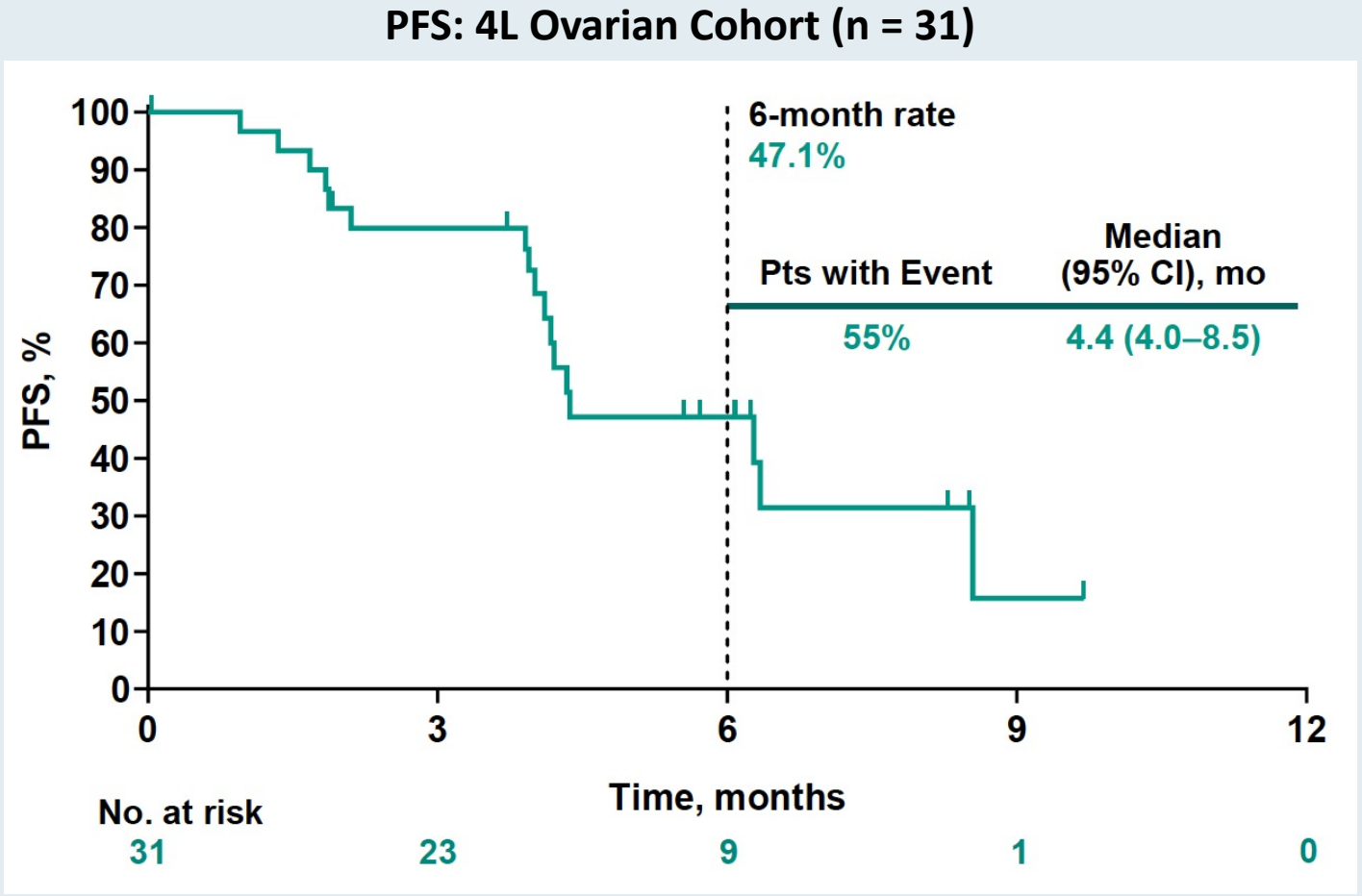
LEAP-005: Phase II Study of Lenvatinib (Len) plus Pembrolizumab (Pembro) in Patients (Pts) with Previously Treated Advanced Solid Tumours

Lwin Z et al.

ESMO 2020;Abstract LBA41.

LEAP-005: Antitumor Activity in Ovarian Cancer Cohort

	4L Ovarian Cohort (n = 31)
ORR	32.3%
CR	3%
PR	29%
DCR	74.2%
DoR (median, mo)	NR



Lwin Z et al. *ESMO* 2020;Abstract LBA41.

2021 ASCO ANNUAL MEETING

Abstract 5500

GINECO

EFFICACY AND SAFETY RESULTS FROM NEOPEMBROV STUDY. A RANDOMIZED PHASE II TRIAL OF NEOADJUVANT CHEMOTHERAPY (CT) WITH OR WITHOUT PEMBROLIZUMAB (P) FOLLOWED BY INTERVAL DEBULKING SURGERY AND STANDARD SYSTEMIC THERAPY ± P FOR ADVANCED HIGH GRADE SEROUS CARCINOMA (HGSC). A GINECO STUDY.

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Isabelle Ray-Coquard, Centre Leon Bérard

May, 2021

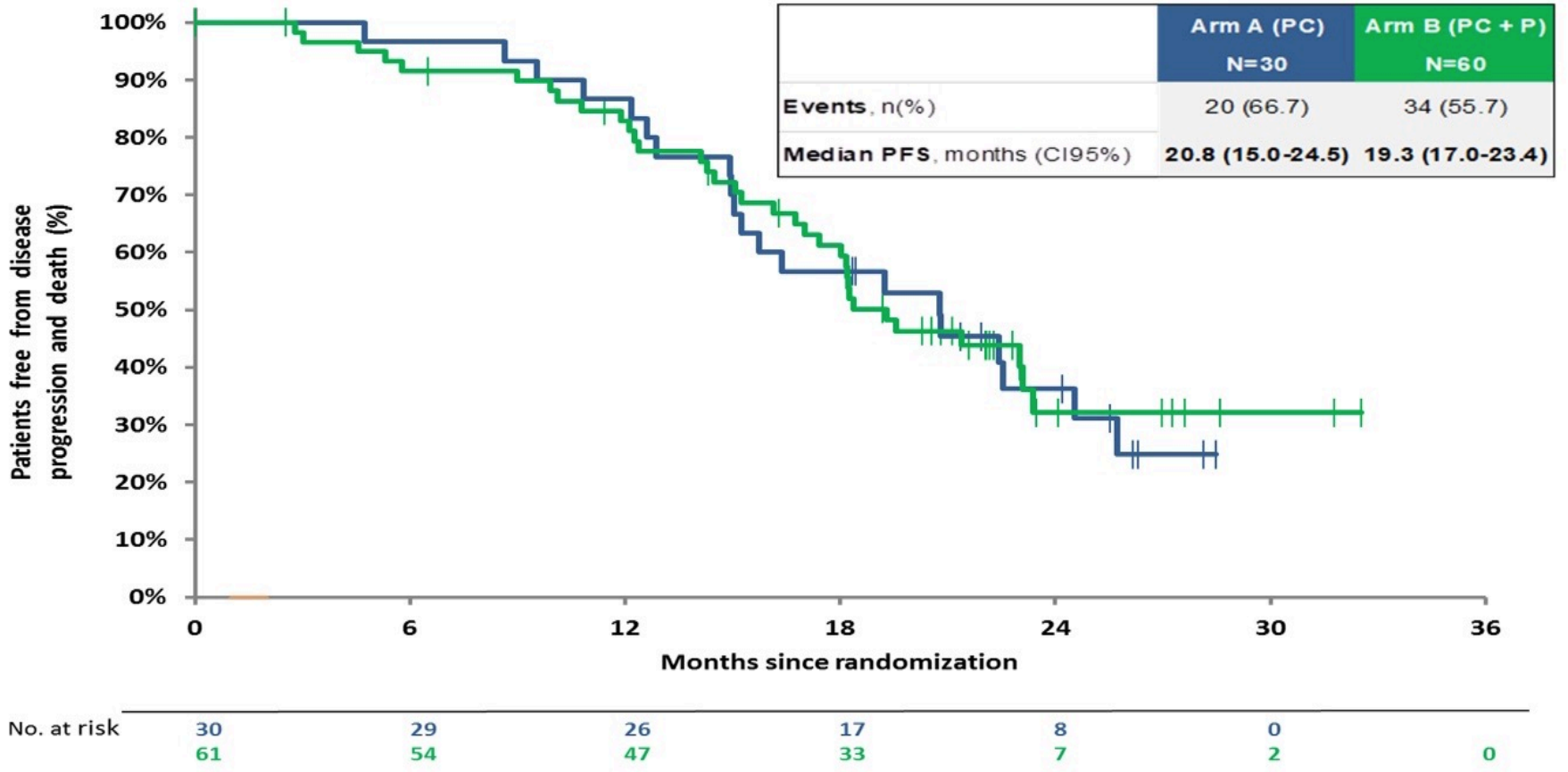
RTP RESEARCH TO PRACTICE

NEOPEMBROV: Response to CT with or without Bevacizumab with or without Pembrolizumab

	Arm A (CP ± Bev) N = 30	Arm B (CP+ P ± Bev) N = 61
Interval debulking surgery performed (%)		
Yes	29 (96.7)	58 (95.1)
No	1 (3.3)	3 (4.9)
Response at IDS (PCI Decrease)		
mean [std]	- 9.58 [8.58]	- 10.19 [9.27]
Not evaluable	3	6
Primary Endpoint (ITT) Rate of complete debulking % [95% CI]	***70% [53.5% -]***	***73.8% [62.9% -]***
Complete cytoreductive surgery (CC0)	21 (72.4)	45 (77.5)
CC1	0	2 (3.4)
CC ≥ 3 or biopsies only	8 (27.6)	11 (18.9)
	N = 29	N = 58
Response Rate after 4 cy NACT (RECIST) (%)		
Complete response	2 (6.9)	2 (3.3)
Partial response	16 (55.2)	42 (70.0)
Stable	11 (37.9)	14 (23.3)
Progression	0 (0.0)	2 (3.3)
Not evaluable	1	1
ORR (95% CI)	***62.1% [42.3-79.3]***	***73.3% [60.3-83.9]***
Best Overall Response (%)		
Complete response	22 (75.9)	45 (75.0)
Partial response	3 (10.3)	10 (16.7)
Stable	4 (13.8)	5 (8.3)
Not evaluable	1	1
CR+PR	*25 (83.3)*	*55 (90.1)*
Ca125 normalization	22 (73.3)	46 (75.4)

Ray-Coquard IL et al. ASCO 2021;Abstract 5500.

NEOPEMBROV: Progression-Free Survival



Median Follow-up of 22 months (min=6.8, max = 32.5)

Presented By: Isabelle Ray-Coquard

2021 ASCO ANNUAL MEETING

Ray-Coquard IL et al. ASCO 2021;Abstract 5500.

Meet The Professor

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

Wednesday, October 13, 2021
5:00 PM – 6:00 PM ET

Faculty

Erika Hamilton, MD

Moderator

Neil Love, MD

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Thank you for joining us!

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

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