Meet The Professor
Immunotherapy and Novel Agents in Gynecologic Cancers

Deborah K Armstrong, MD
Professor of Oncology
Professor of Gynecology and Obstetrics
Skip Viragh Outpatient Cancer Building
Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
Baltimore, Maryland

Commercial Support

These activities are supported by educational grants from Eisai Inc, Merck, Seagen Inc and Tesaro, A GSK Company.

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Dr Love — Disclosures

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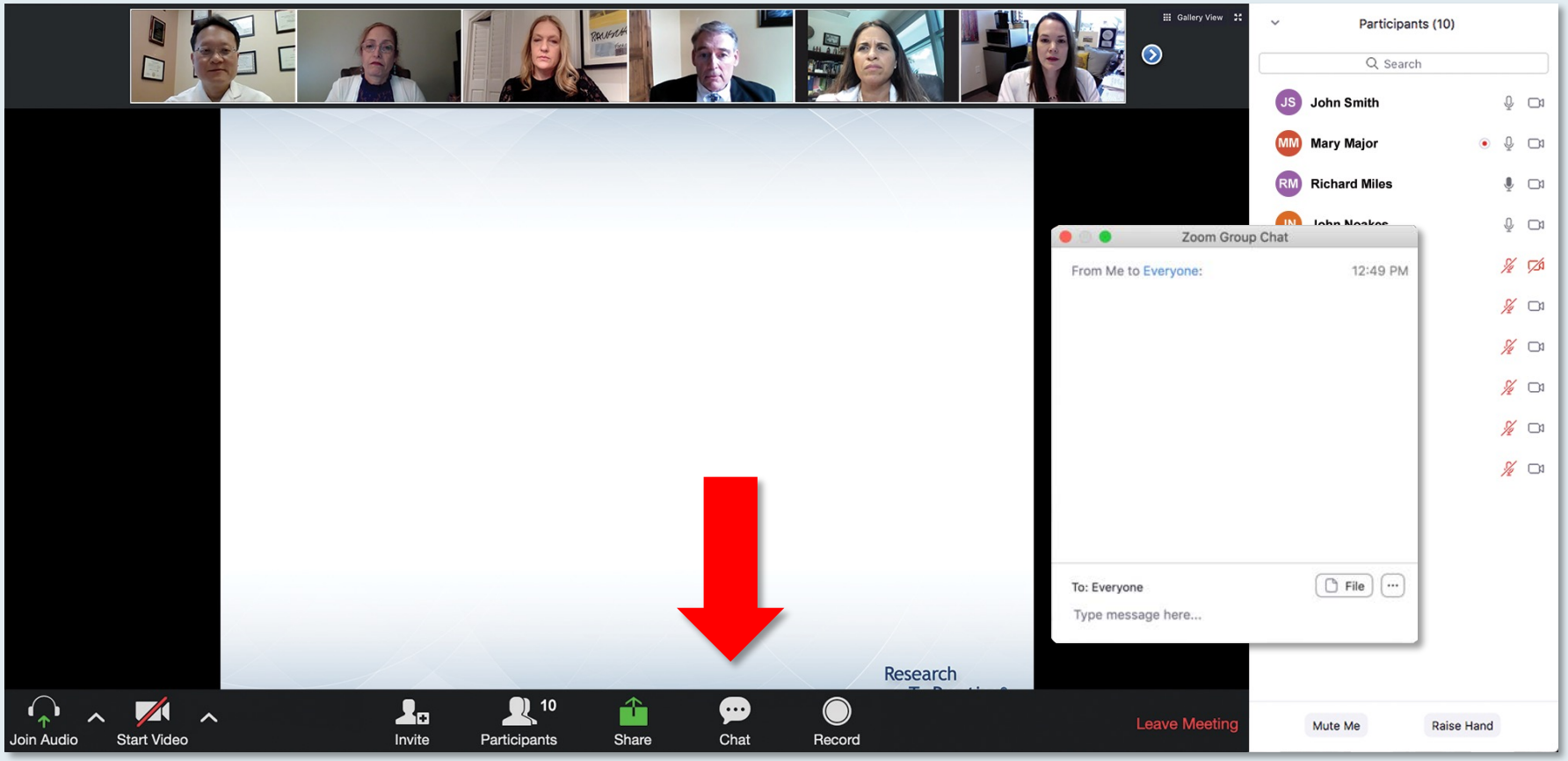
We Encourage Clinicians in Practice to Submit Questions



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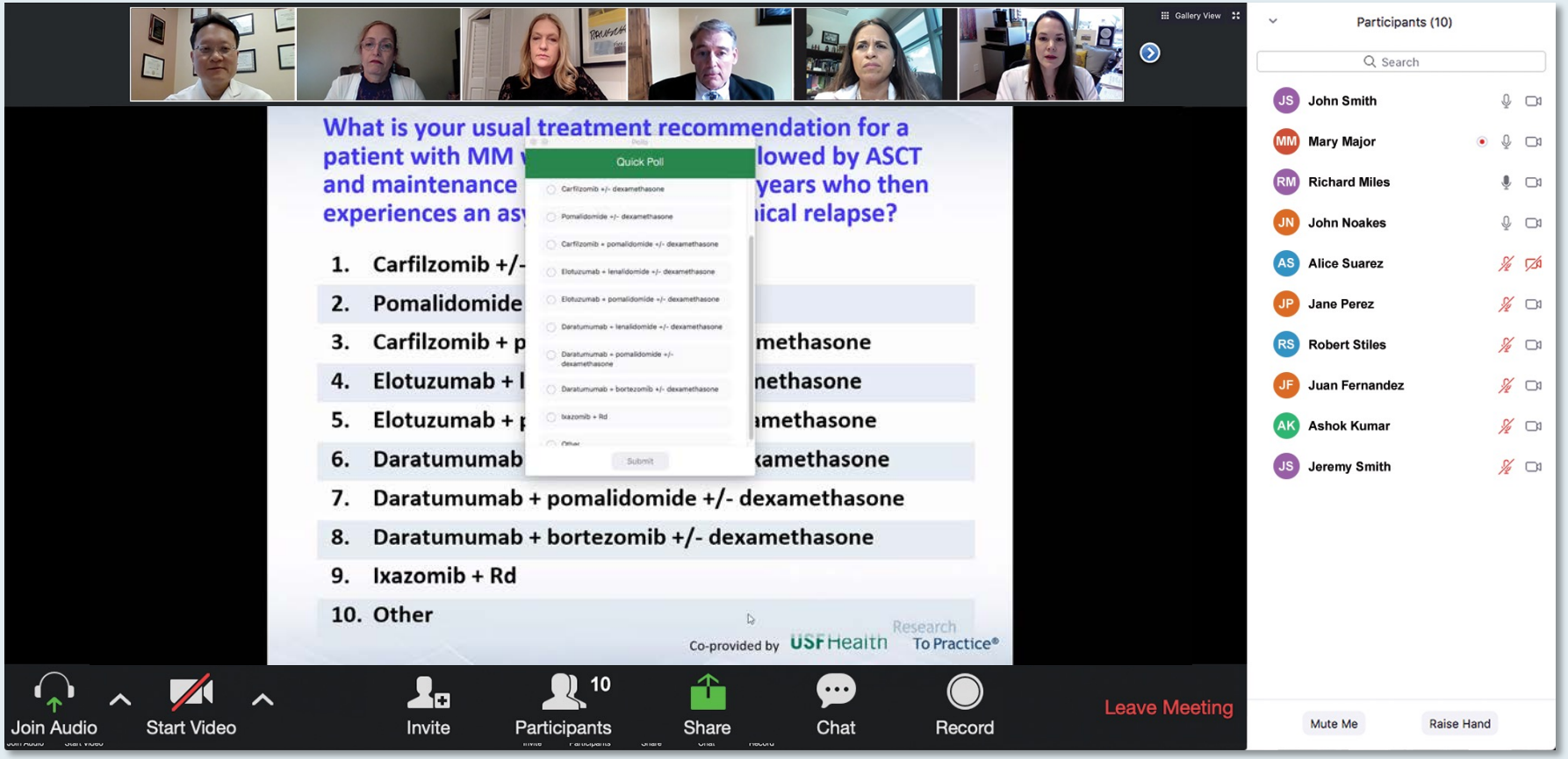

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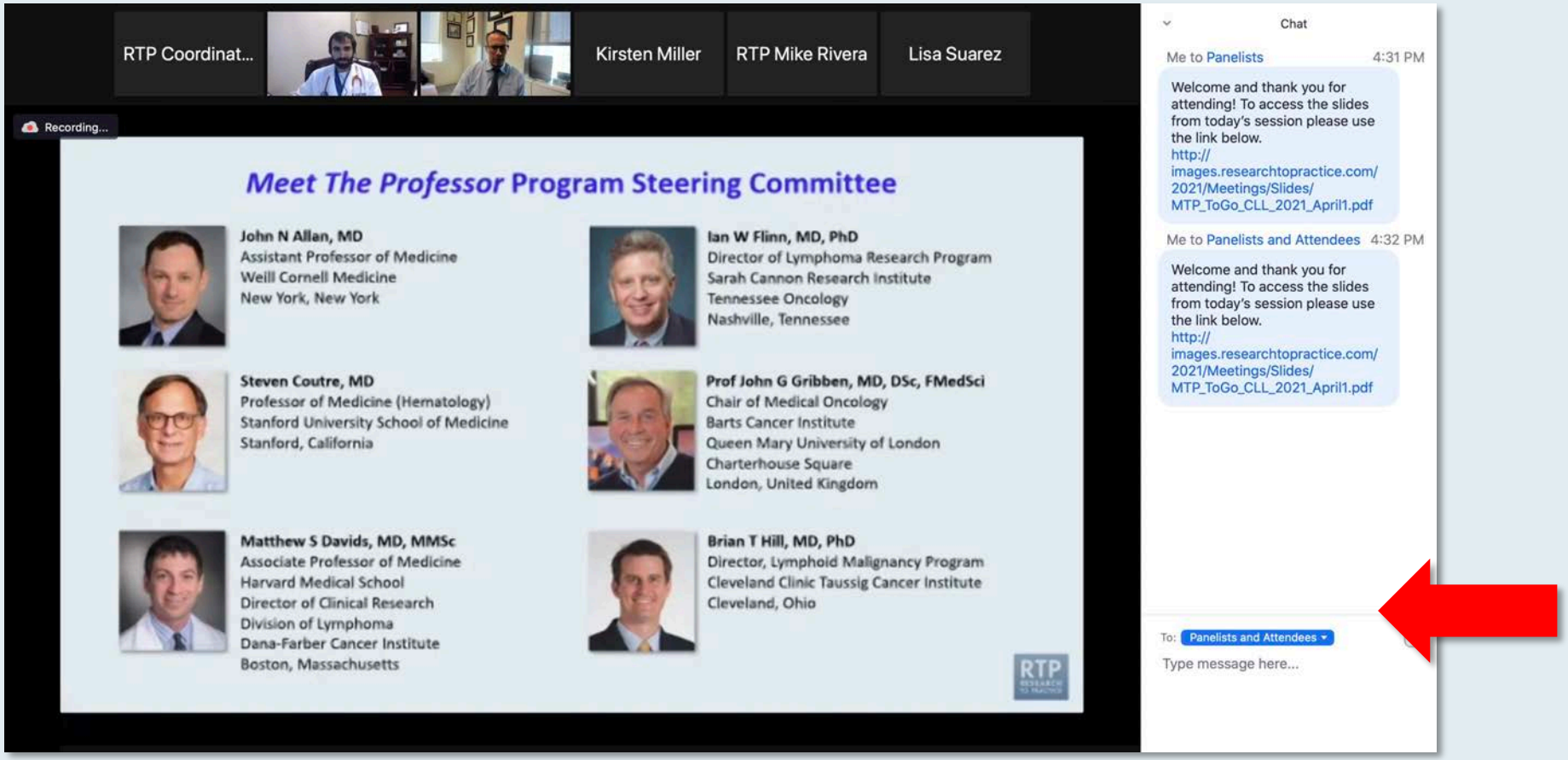
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



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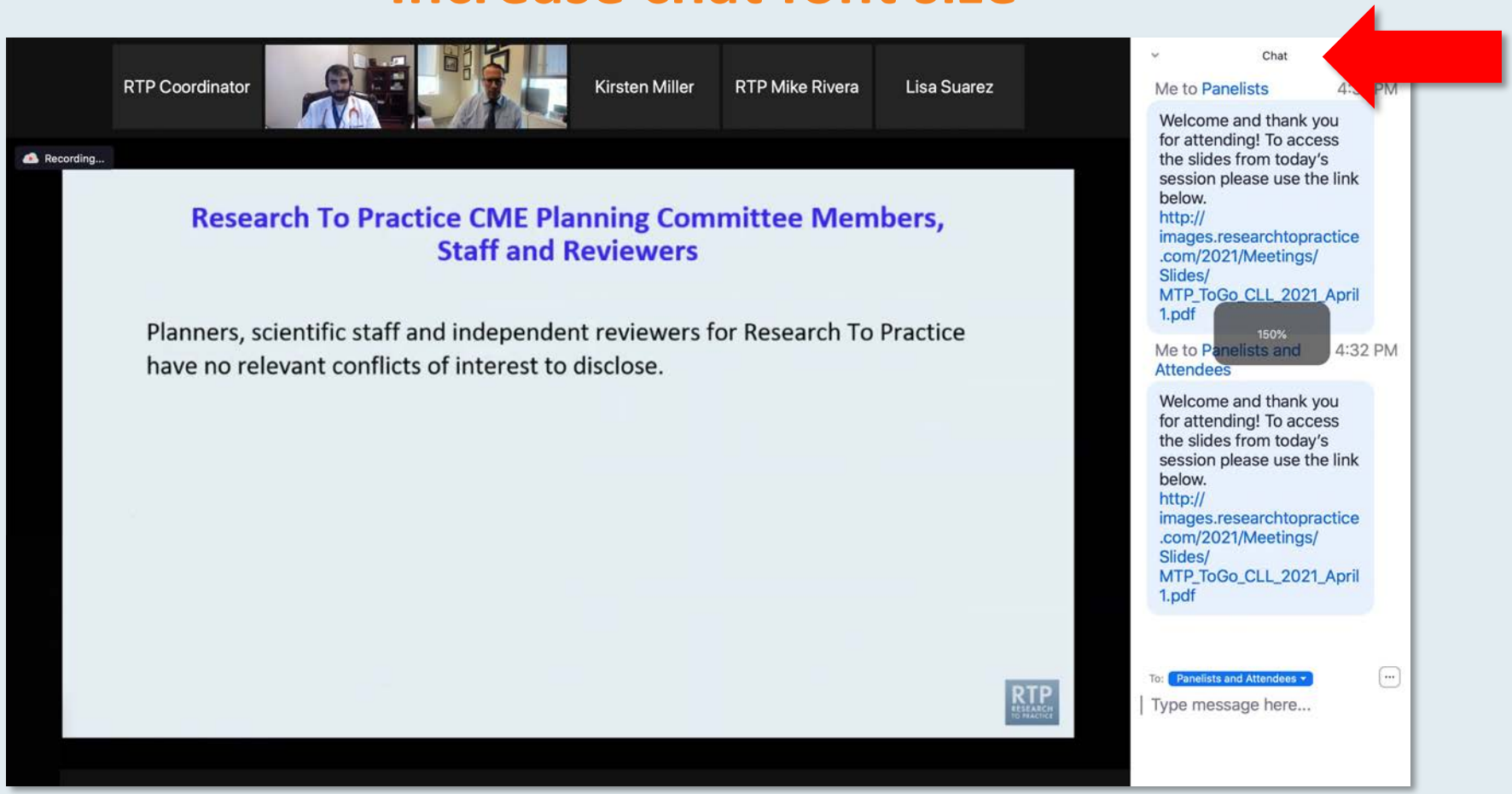

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You may do this as many times as you need for readability.

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PARP Inhibitors in Ovarian Cancer

DR ANTONIO GONZÁLEZ-MARTÍN
CLÍNICA UNIVERSIDAD DE NAVARRA

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

In Partnership with Project Echo® and Florida Cancer Specialists

Wednesday, June 2, 2021
5:00 PM – 6:00 PM ET

Faculty

Walter Stadler, MD

Moderator

Neil Love, MD

Meet The Professor

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

Monday, June 7, 2021
5:00 PM – 6:00 PM ET

Faculty

Kristen K Ciombor, MD, MSCI

Moderator

Neil Love, MD

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Meet The Professor

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Wednesday, June 16, 2021
5:00 PM – 6:00 PM ET

Faculty

Thomas E Hutson, DO, PharmD

Moderator

Neil Love, MD

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

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Saturday, June 26, 2021
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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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Director, Winthrop P Rockefeller Cancer Institute
Director, Cancer Service Line
University of Arkansas for Medical Sciences
Little Rock, Arkansas

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Gynecologic Oncology
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UCLA Medical Center
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University of Arizona College of Medicine
Creighton University School of Medicine at St Joseph's Hospital
Medical Director, US Oncology Network (McKesson) Gynecologic Program
Co-Director, GOG Partners
Member, Board of Directors, GOG Foundation
Phoenix, Arizona

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Meet The Professor Program Participating Faculty

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Hospital Universitari Vall d'Hebron
Vall d'Hebron Barcelona Hospital Campus
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Co-Director, Gyn Oncology Phase I Program
The Ohio State University and The James Cancer Center
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Clinical Director, Medical Gynecologic Oncology
Massachusetts General Hospital
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Irvine, California

Professor Ignace Vergote
Chairman, Department of Obstetrics and Gynaecology
Gynaecological Oncologist
Leuven Cancer Institute
University Hospital Leuven
Leuven, Belgium

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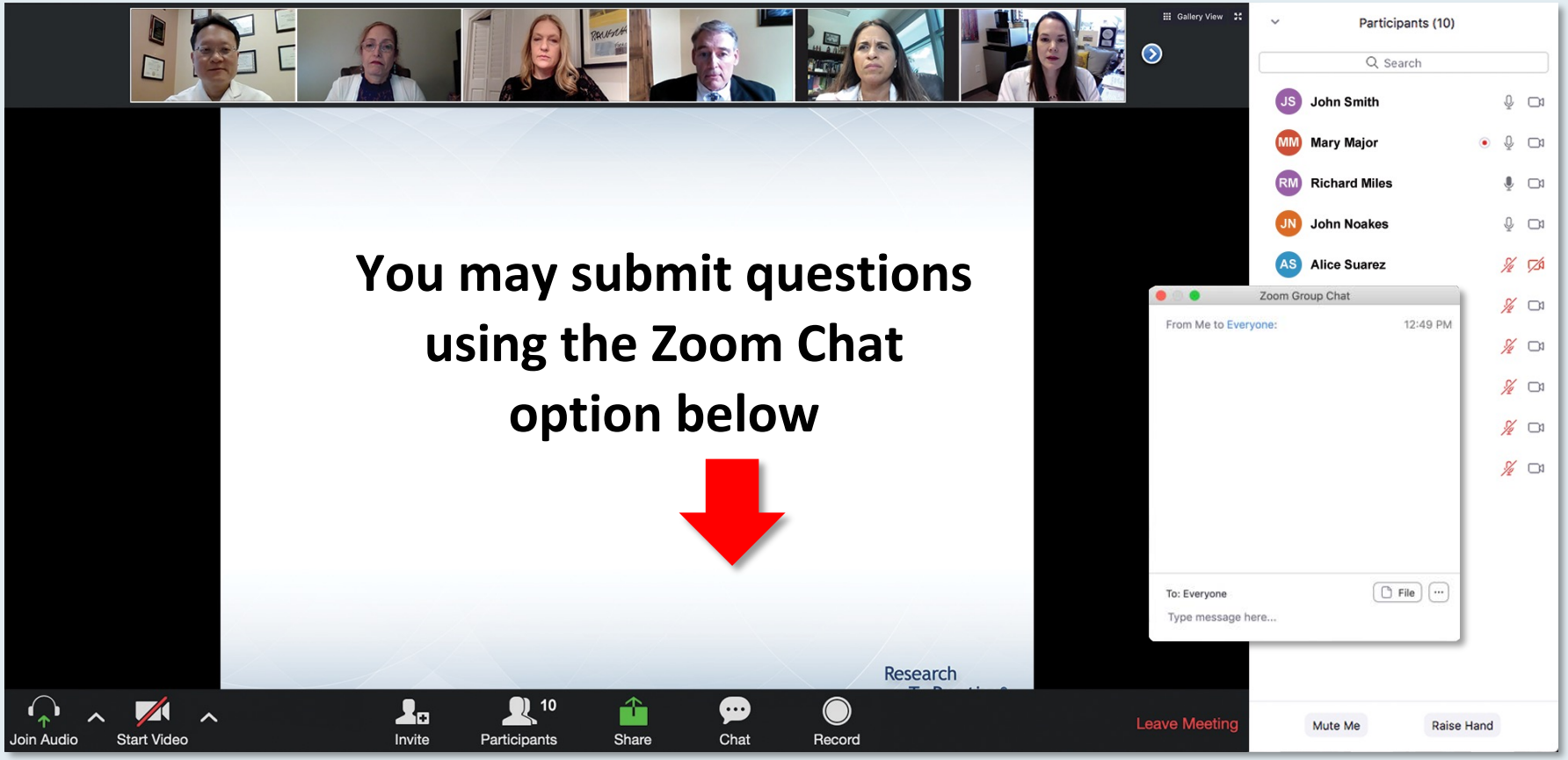

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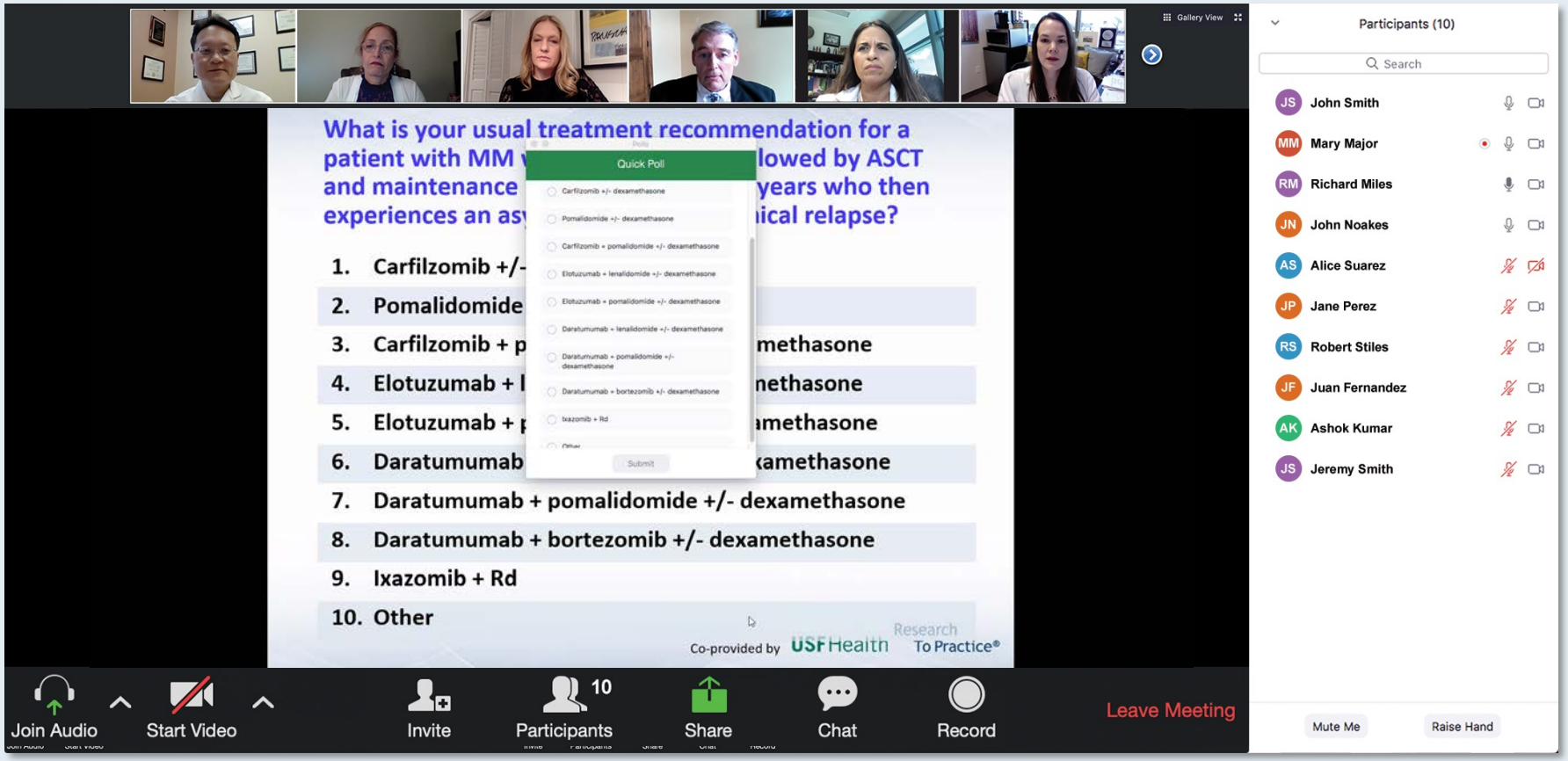

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Director, Early Drug Development
Department of Gynecologic Oncology and Reproductive Medicine
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Houston, Texas

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Meet The Professor with Dr Armstrong

MODULE 1: Cases from the Practice of Dr Shannon Westin

- A 70-year-old woman with ER/PR-positive, MSI-high endometrioid adenocarcinoma
- A 48-year-old woman with MSS, HER2-positive uterine serous carcinoma
- A 42-year-old woman with PD-L1-positive, metastatic cervical cancer

MODULE 2: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

MODULE 3: Key Recent Data Sets

MODULE 4: Appendix

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How long have you been in the field of oncology?

1. Less than 5 years
2. 5-10 years
3. 11-20 years
4. 21-30 years
5. 31-40 years
6. More than 40 years

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In general, do you discuss the issue of the gut microbiome and the use of antibiotics with your patients who are receiving checkpoint inhibitors?

1. Yes
2. No
3. I am not familiar with this issue

Meet The Professor with Dr Armstrong

MODULE 1: Cases from the Practice of Dr Shannon Westin

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MODULE 4: Appendix

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Case Presentation – Dr Westin: A 70-year-old woman with ER/PR-positive, microsatellite instability (MSI)-high endometrioid adenocarcinoma (Part 1)

Dr Shannon Westin

- Presents with postmenopausal bleeding x 2 weeks
- D & C pathology: FIGO grade 2 endometrioid adenocarcinoma of the endometrium
- Total laparoscopic hysterectomy, bilateral oophorectomy, pelvic/paraaortic lymph node dissection
  - Pathology: 3-cm FIGO grade 2 endometrioid adenocarcinoma of the endometrium invading 4/11 mm, LVSI-positive, lymph node-negative, ER/PR-positive, MSI-high

Questions

- How would you treat this patient?

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Case Presentation – Dr Westin: A 70-year-old woman with ER/PR-positive, MSI-high endometrioid adenocarcinoma (Part 2)

Dr Shannon Westin

- Presents with postmenopausal bleeding x 2 weeks
- D & C pathology: FIGO grade 2 endometrioid adenocarcinoma of the endometrium
- Total laparoscopic hysterectomy, bilateral oophorectomy, pelvic/paraaortic lymph node dissection
  - Pathology: 3-cm FIGO grade 2 endometrioid adenocarcinoma of the endometrium invading 4/11 mm, LVSI-positive, lymph node-negative, ER/PR-positive, MSI-high
- ***Cuff brachytherapy → NED x 2 years***
- ***Biopsy of abdominal wall nodule c/w recurrent disease → Abdominal wall resection***
  - ***Pathology c/w metastatic endometrioid adenocarcinoma with negative margins***

Questions

- ***How would you approach treatment at this point?***

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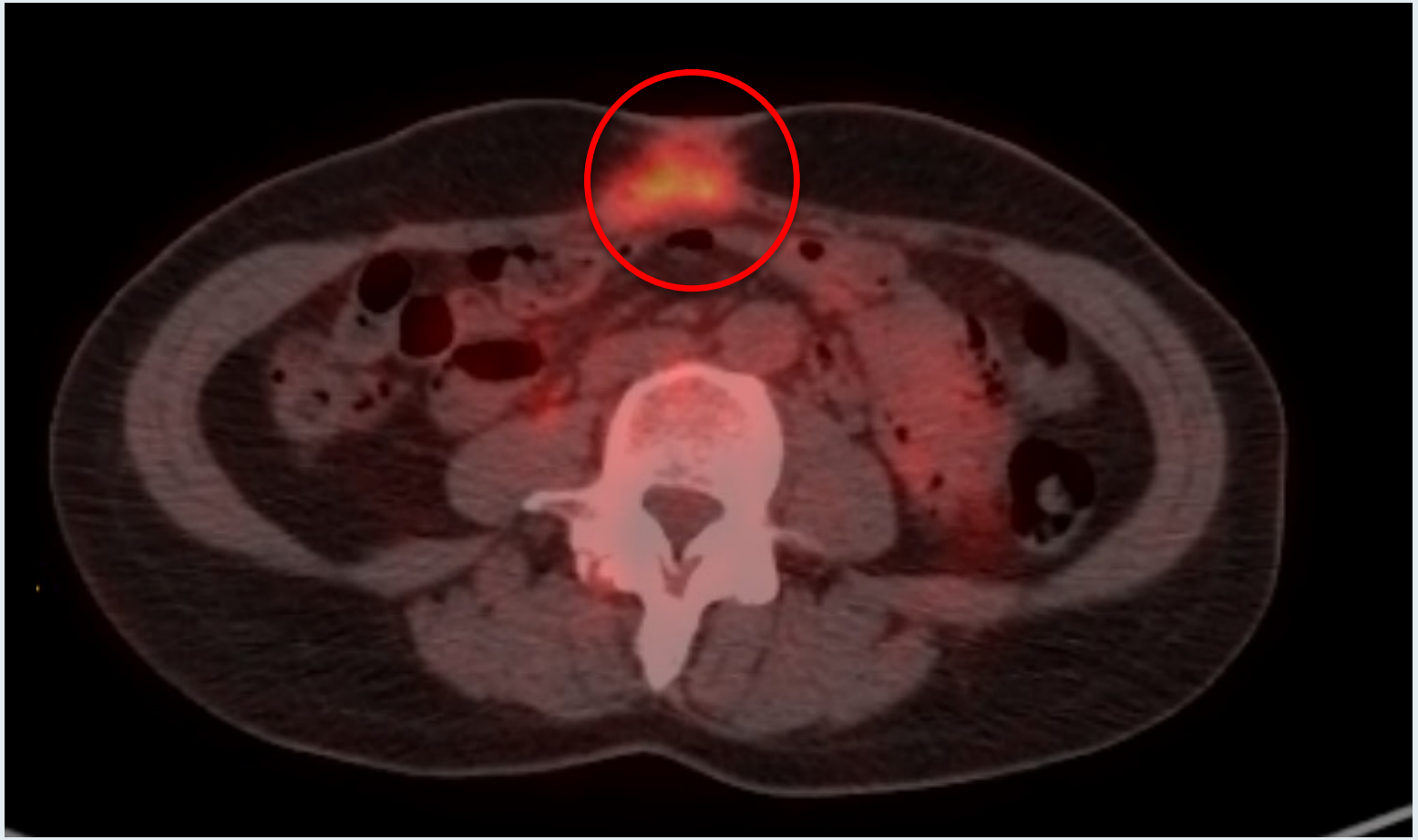
Case Presentation – Dr Westin: A 70-year-old woman with ER/PR-positive, MSI-high endometrioid adenocarcinoma

Dr Shannon Westin

Abdominal Wall Nodule



Case Presentation – Dr Westin: A 70-year-old woman with ER/PR-positive, MSI-high endometrioid adenocarcinoma (Part 3)

Dr Shannon Westin

- Presents with postmenopausal bleeding x 2 weeks
- D & C pathology: FIGO grade 2 endometrioid adenocarcinoma of the endometrium
- Total laparoscopic hysterectomy, bilateral oophorectomy, pelvic/paraaortic lymph node dissection
  - Pathology: 3-cm FIGO grade 2 endometrioid adenocarcinoma of the endometrium invading 4/11 mm, LVSI-positive, lymph node-negative, ER/PR-positive, MSI-high
- Cuff brachytherapy → NED x 2 years
- Biopsy of abdominal wall nodule c/w recurrent disease → Abdominal wall resection
  - Pathology c/w metastatic endometrioid adenocarcinoma with negative margins
- ***Postoperative RT to operative bed → NED x 12 months → Presents with persistent cough***
- ***Imaging and biopsy: Multiple lung nodules c/w recurrent endometrioid adenocarcinoma***

Questions

- ***What are her treatment options – chemotherapy, hormonal therapy, hormonal therapy plus everolimus, or immunotherapy?***

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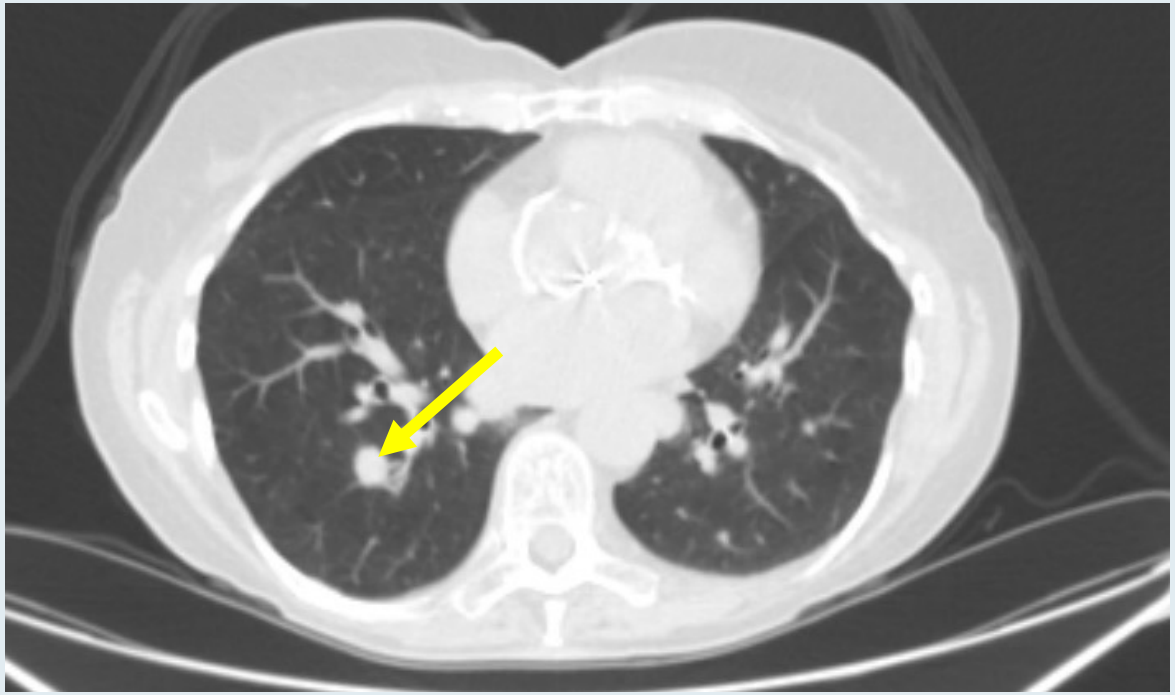
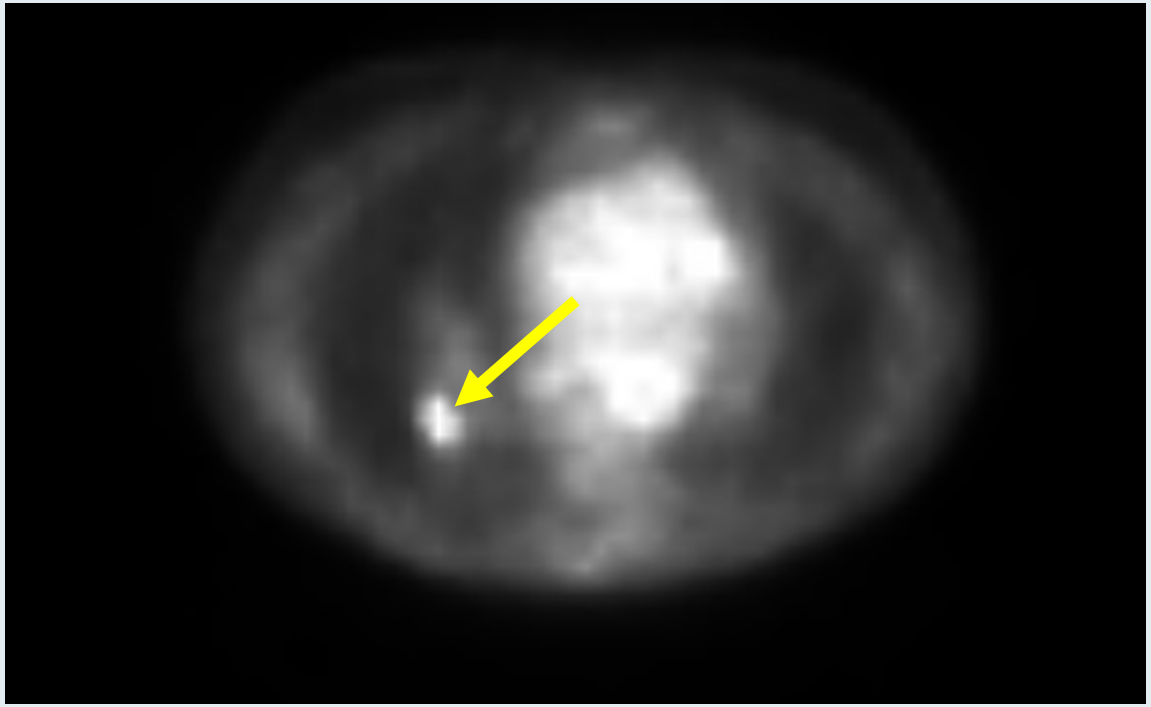
Case Presentation – Dr Westin: A 70-year-old woman with ER/PR-positive, MSI-high endometrioid adenocarcinoma

Dr Shannon Westin

Imaging: Multiple Lung Nodules



PET



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Case Presentation – Dr Westin: A 70-year-old woman with ER/PR-positive, MSI-high endometrioid adenocarcinoma (Part 4)

Dr Shannon Westin

- Biopsy of abdominal wall nodule c/w recurrent disease → Abdominal wall resection
  - Pathology c/w metastatic endometrioid adenocarcinoma with negative margins
- Postoperative RT to operative bed → NED x 12 months → Presents with persistent cough
- Imaging and biopsy: Multiple lung nodules c/w recurrent endometrioid adenocarcinoma
- ***Due to an upcoming wedding, patient desires to avoid chemotherapy → Recurrence in her lungs***
- ***Megestrol acetate and tamoxifen x 12, with CR***
- ***Pembrolizumab x 9 months, with PR***
  - ***Diarrhea treated with antidiarrheals, steroids***

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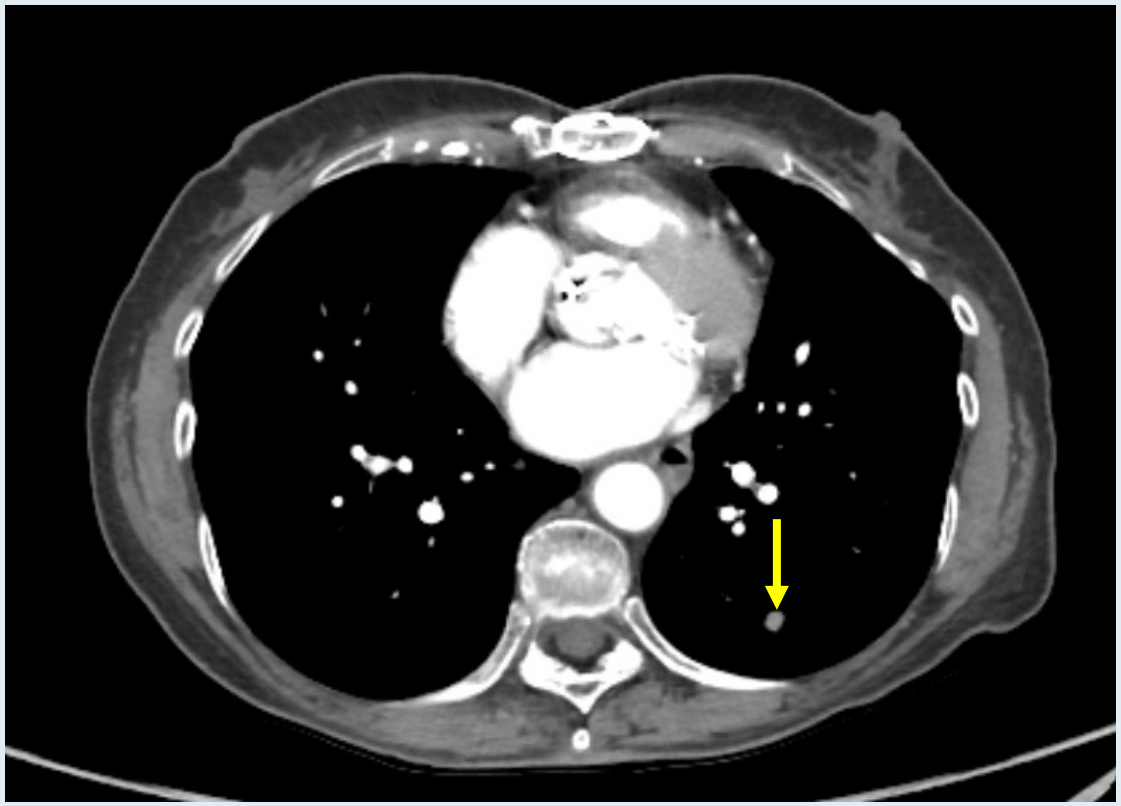
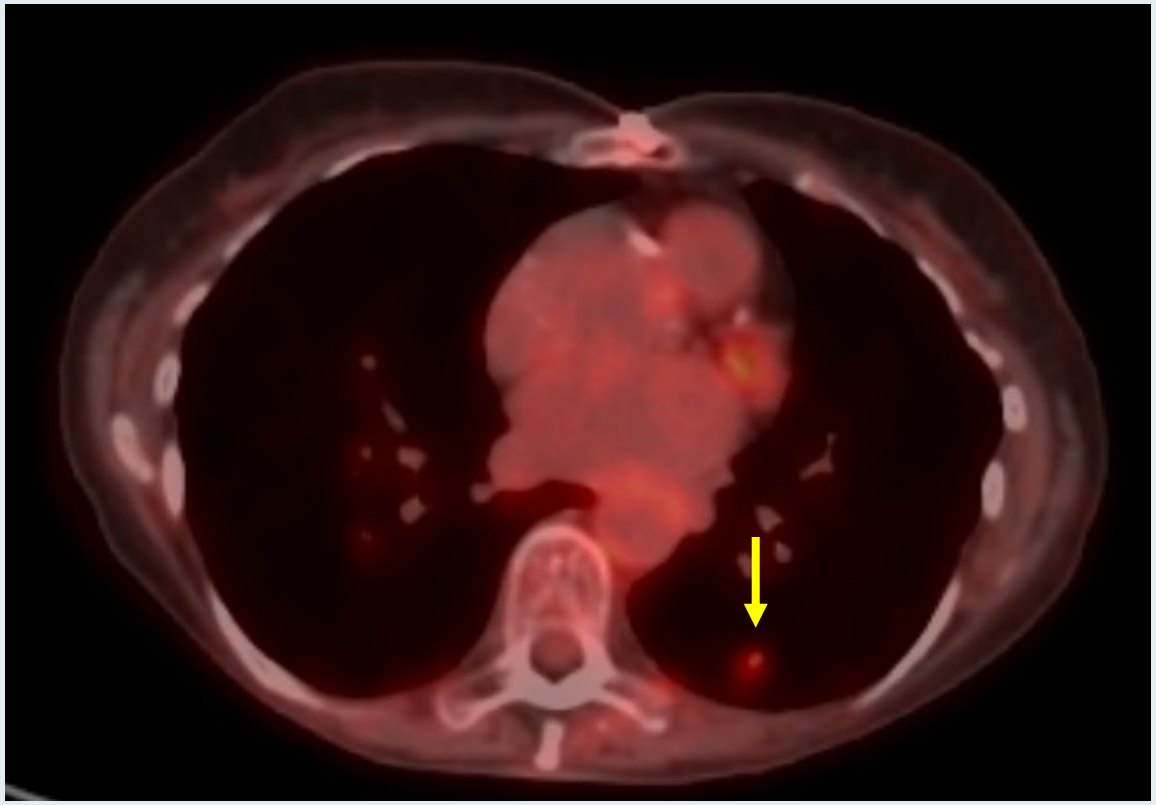
Case Presentation – Dr Westin: A 70-year-old woman with ER/PR-positive, MSI-high endometrioid adenocarcinoma

Dr Shannon Westin

Recurrence in the Lungs





Case Presentation – Dr Westin: A 48-year-old woman with microsatellite-stable (MSS), HER2-positive uterine serous carcinoma (Part 1)

Dr Shannon Westin

- Presents with bloating, abdominal pain and irregular menses for several years
- Endometrial biopsy: Uterine serous carcinoma, CA125: 200

Questions

- Should we operate on this patient with Stage IV uterine serous carcinoma? What is the data for neoadjuvant therapy in a patient like this woman?

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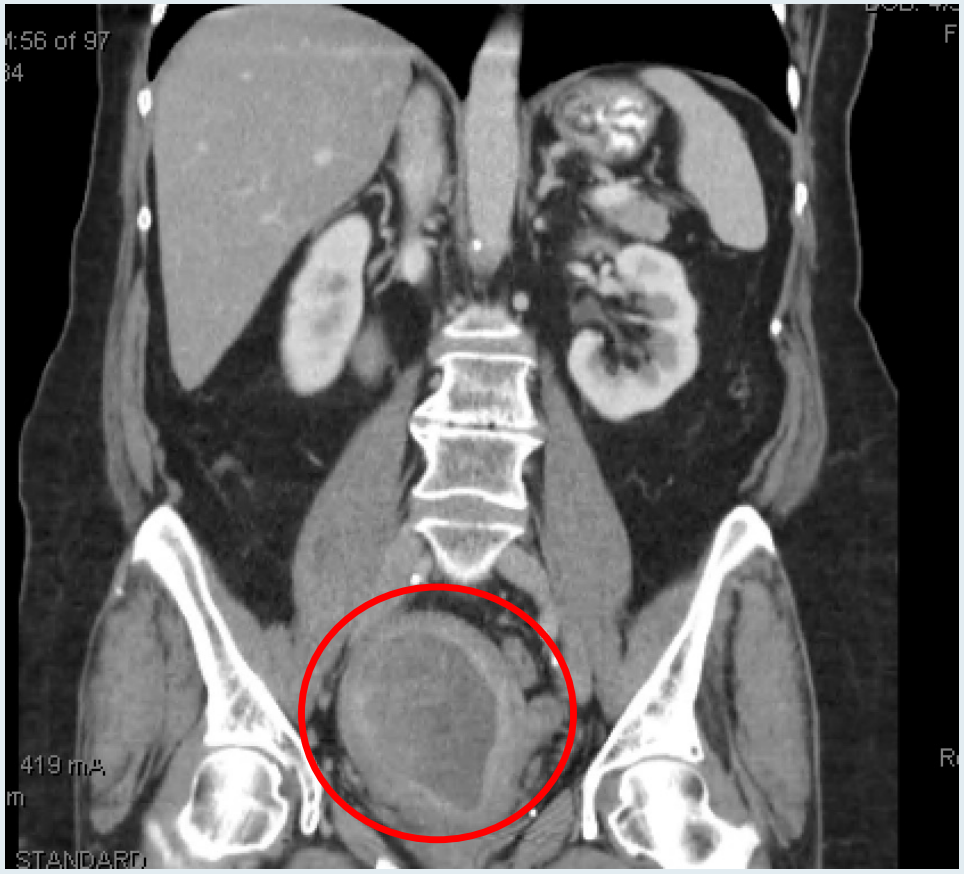
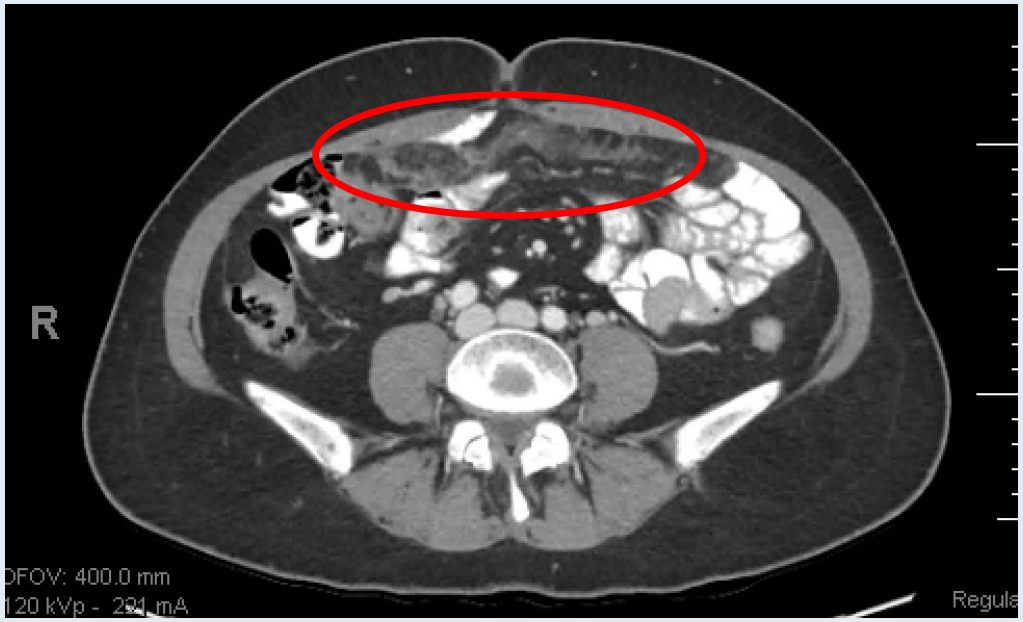
Case Presentation – Dr Westin: A 48-year-old woman with MSS, HER2-positive uterine serous carcinoma

Dr Shannon Westin

Large, Bulky Uterus at Diagnosis



Omental Caking



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Case Presentation – Dr Westin: A 48-year-old woman with MSS, HER2-positive uterine serous carcinoma (Part 2)

Dr Shannon Westin

- Presents with bloating, abdominal pain and irregular menses for several years
- Endometrial biopsy: Uterine serous carcinoma, CA125: 200
- ***TAH/BSO, omentectomy, liver resection, diaphragm stripping to complete gross resection***
  - ***Final pathology: Stage IV uterine serous carcinoma***
  - ***HER2 IHC 3+, MSS***

Questions

- ***What do you do for this patient now that she has undergone successful tumor reductive surgery without any complications? How do you treat her now?***

Case Presentation – Dr Westin: A 48-year-old woman with MSS, HER2-positive uterine serous carcinoma (Part 3)

Dr Shannon Westin

- Presents with bloating, abdominal pain and irregular menses for several years
- Endometrial biopsy: Uterine serous carcinoma, CA125: 200
- TAH/BSO, omentectomy, liver resection, diaphragm stripping to complete gross resection
  - Final pathology: Stage IV uterine serous carcinoma
  - HER2 IHC 3+, MSS
- ***Carboplatin/paclitaxel/trastuzumab x 6, with NED → Trastuzumab maintenance x 6 months***
- ***Increasing abdominal pain and bloating → Imaging shows recurrent disease in the spleen and potentially in the diaphragm and liver as well***

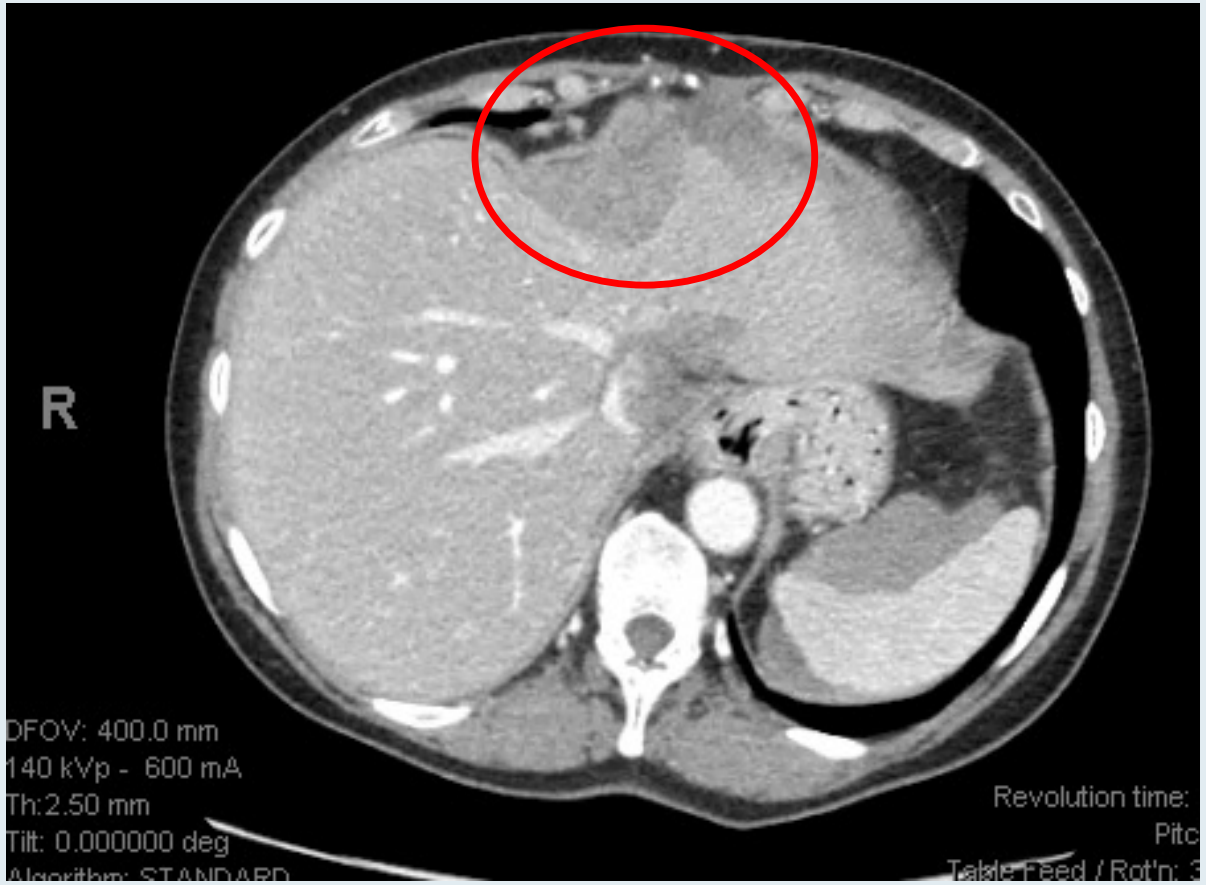
Questions

- ***What are her therapeutic options at this point?***

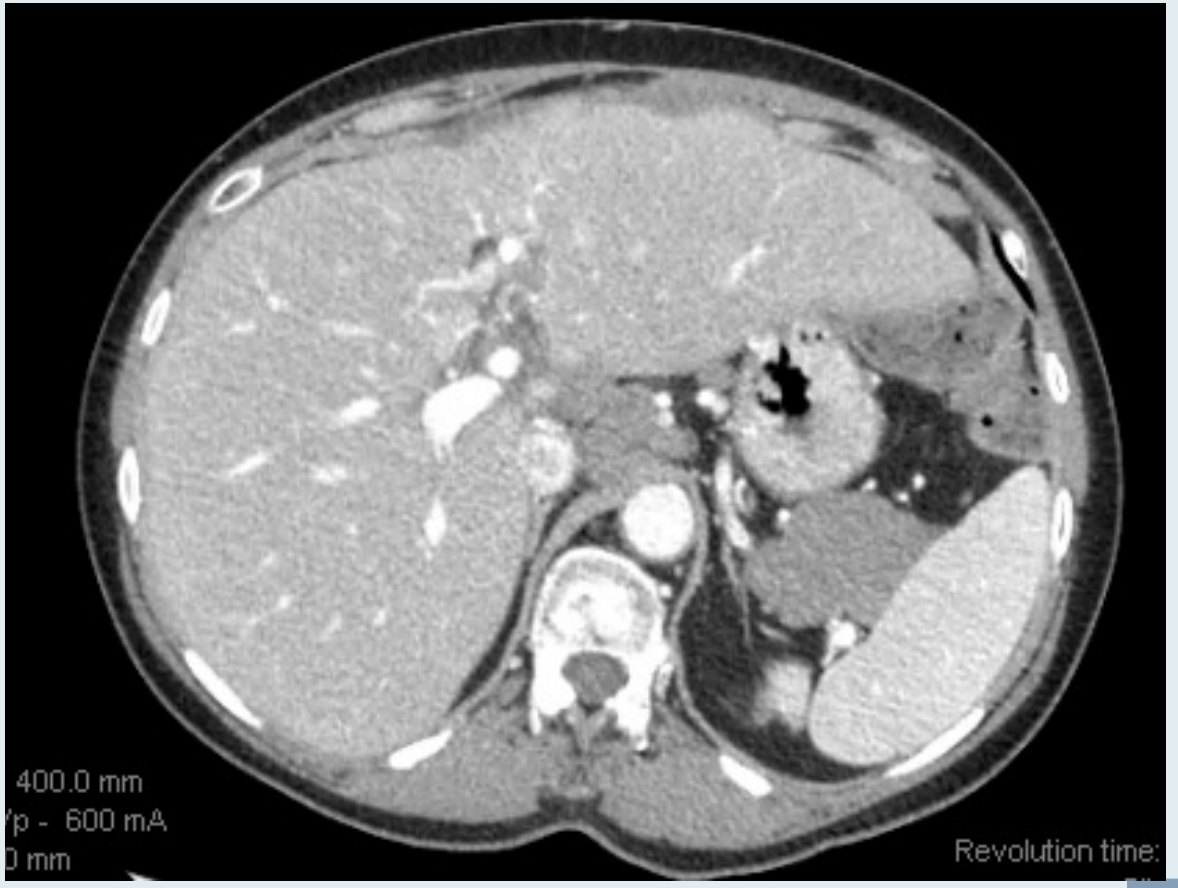
Case Presentation – Dr Westin: A 48-year-old woman with MSS, HER2-positive uterine serous carcinoma

Dr Shannon Westin

Recurrent Disease in the Diaphragm, Possibly Liver



Recurrent Disease in the Spleen



Case Presentation – Dr Westin: A 48-year-old woman with MSS, HER2-positive uterine serous carcinoma (Part 4)

Dr Shannon Westin

- Presents with bloating, abdominal pain and irregular menses for several years
- Endometrial biopsy: Uterine serous carcinoma, CA125: 200
- TAH/BSO, omentectomy, liver resection, diaphragm stripping to complete gross resection
  - Final pathology: Stage IV uterine serous carcinoma
  - HER2 IHC 3+, MSS
- Carboplatin/paclitaxel/trastuzumab x 6 to NED → Trastuzumab maintenance x 6 months
- Increasing abdominal pain and bloating → Imaging shows recurrent disease in the spleen and potentially in the diaphragm and liver as well
- ***Lenvatinib/pembrolizumab, with hypertension and Grade 3/4 fatigue***
  - ***Lenvatinib dose interruption → dose reduction to 14 mg qd***
  - ***After 4 cycles, significant disease reduction and good tolerability and QoL***

Pertuzumab plus Trastuzumab (P+T) in Patients (Pts) with Uterine Cancer (UC) with ERBB2 or ERBB3 Amplification, Overexpression or Mutation: Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study

Ali-Ahmad HM et al.

ASCO 2021;Abstract 5508.

Gynecologic Cancer Oral Abstract Session, Monday, June 7th 8:00 – 11:00 AM

RTP RESEARCH TO PRACTICE

Case Presentation – Dr Westin: A 42-year-old woman with PD-L1-positive, metastatic cervical cancer (Part 1)

Dr Shannon Westin

- Diagnosed with Grade 2 squamous carcinoma of the cervix, s/p cut-through hysterectomy
  - 3.5-cm tumor invading more than half the cervical thickness with some lymphovascular space invasion
- Imaging shows no other evidence of disease

Questions

- What would you recommend next for this patient?

Case Presentation – Dr Westin: A 42-year-old woman with PD-L1-positive, metastatic cervical cancer (Part 2)

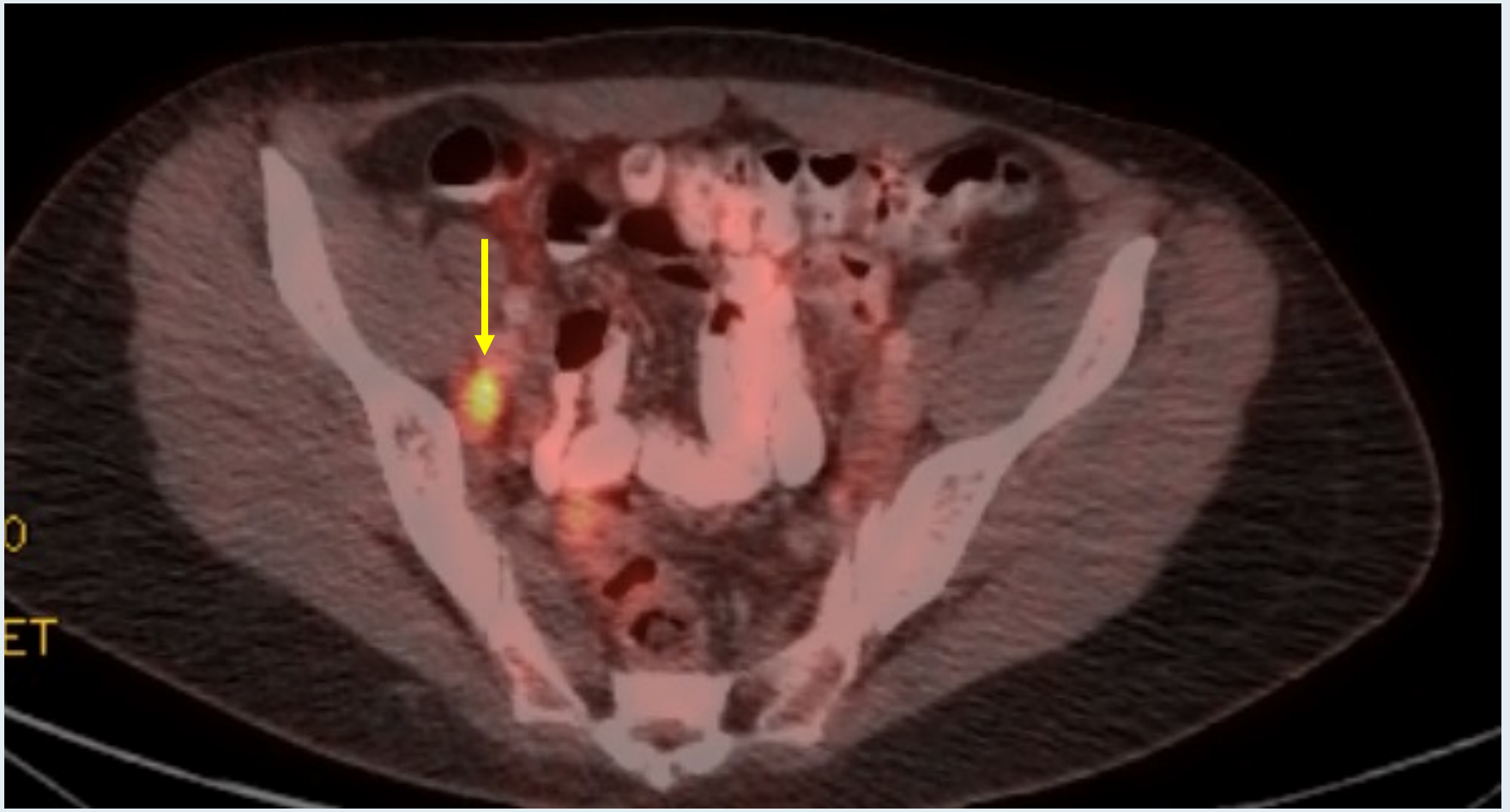
Dr Shannon Westin

- Diagnosed with Grade 2 squamous carcinoma of the cervix, s/p cut-through hysterectomy
  - 3.5-cm tumor invading more than half the cervical thickness with some lymphovascular space invasion
- Imaging shows no other evidence of disease
- ***IMRT with concurrent cisplatin chemosensitization → complete response***
- ***9 months later, she presents with abdominal pain***
- ***Imaging detects activity in right pelvic node confirmed by pathology to be recurrence***
- ***Pembrolizumab, with complete response after 3 cycles***
  - ***After 6 cycles, worsening SOB and cough; pulmonary work up negative for infection → prednisone and dapsone x weeks***
  - ***Pembrolizumab discontinued at 2 years***

Case Presentation – Dr Westin: A 42-year-old woman with PD-L1-positive, metastatic cervical cancer (Part 2)

Dr Shannon Westin

Pelvic Node Recurrence



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TO PRACTICE

Meet The Professor with Dr Armstrong

MODULE 1: Cases from the Practice of Dr Shannon Westin

- A 70-year-old woman with ER/PR-positive, MSI-high endometrioid adenocarcinoma
- A 48-year-old woman with MSS, HER2-positive uterine serous carcinoma
- A 42-year-old woman with PD-L1-positive, metastatic cervical cancer

MODULE 2: Beyond the Guidelines – Clinical Investigator Approaches to Common Clinical Scenarios

MODULE 3: Key Recent Data Sets

MODULE 4: Appendix

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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

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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

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. 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

A patient with PD-L1-positive metastatic cervical cancer experiences disease progression on platinum-based therapy and has significant symptoms from her disease. If tisotumab vedotin and cemiplimab were accessible, what would likely be your next line of treatment?

1. Pembrolizumab
2. Cemiplimab
3. Tisotumab vedotin
4. Other

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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 Armstrong

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- A 48-year-old woman with MSS, HER2-positive uterine serous carcinoma
- A 42-year-old woman with PD-L1-positive, metastatic cervical cancer

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

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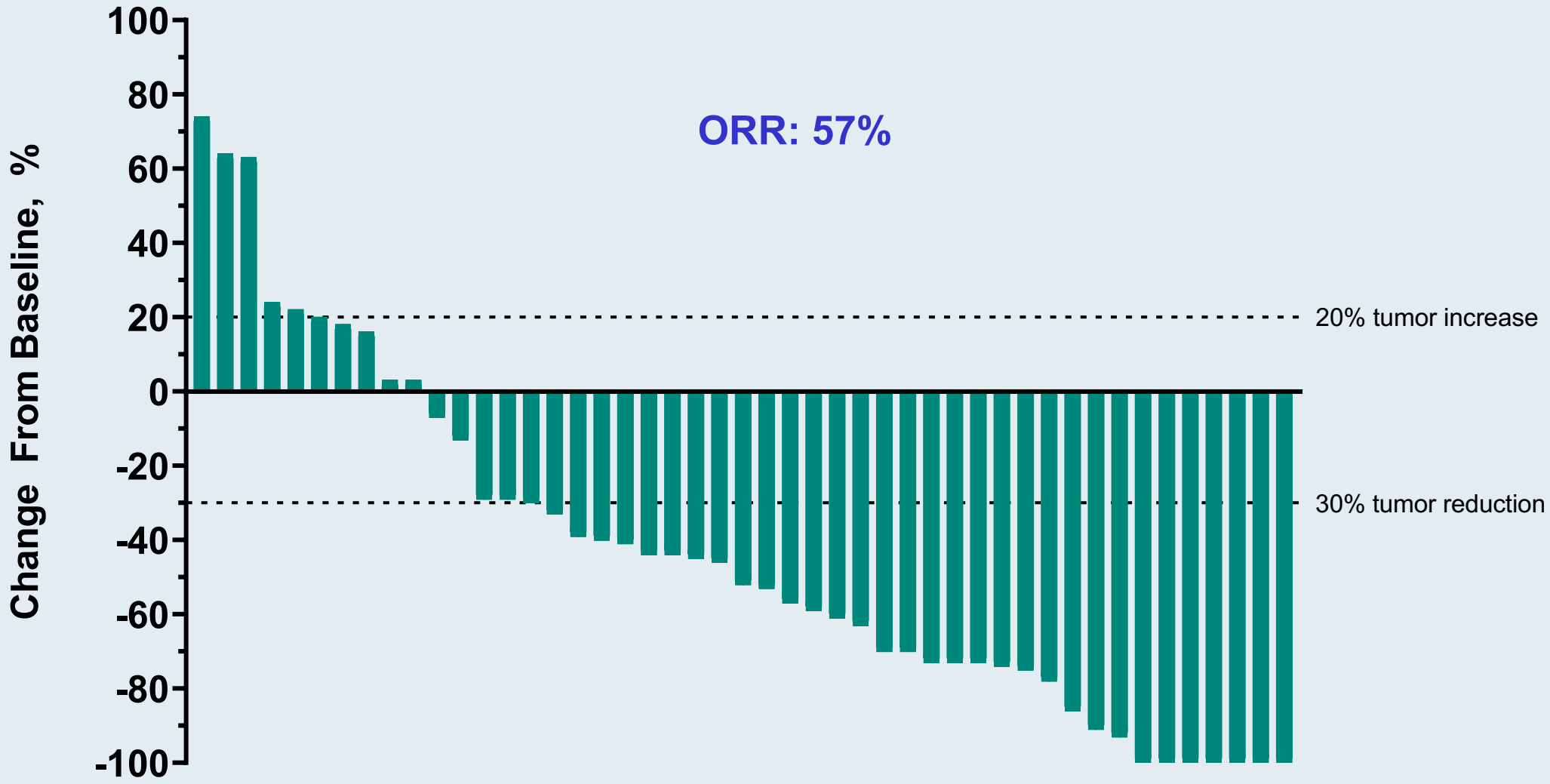
Pembrolizumab in Patients with MSI-H Advanced Endometrial Cancer from the KEYNOTE-158 Study

O’Malley D et al.

ESMO 2019;Abstract 1044P.

KEYNOTE-158: Best Percentage Change from Baseline in Target Lesion Size with Pembrolizumab Monotherapy in MSI-High Endometrial Cancer



O'Malley D et al. ESMO 2019;Abstract 1044P.

RTP RESEARCH TO PRACTICE

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.

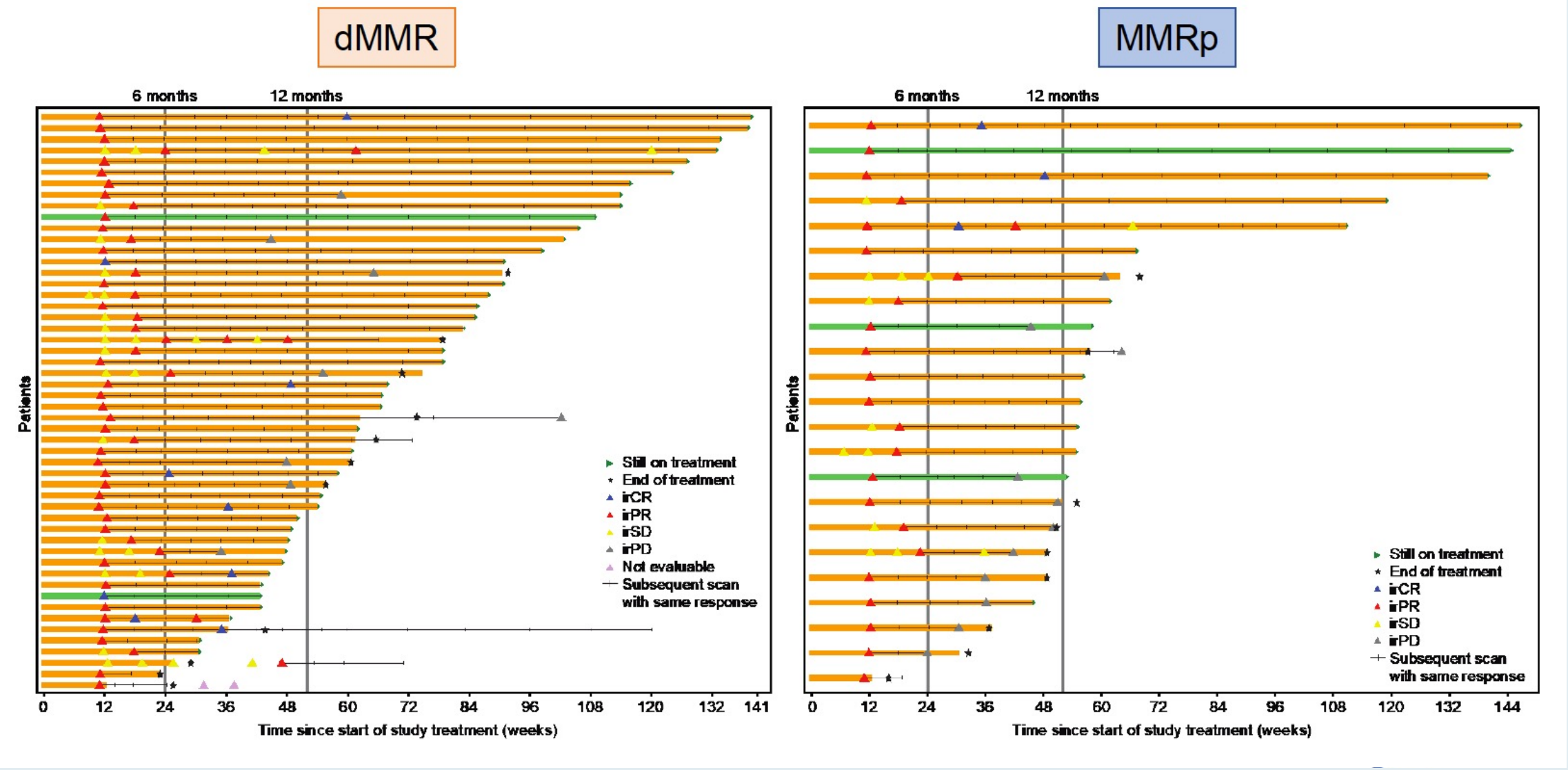
GARNET: Immune-Related Secondary Endpoints

(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.

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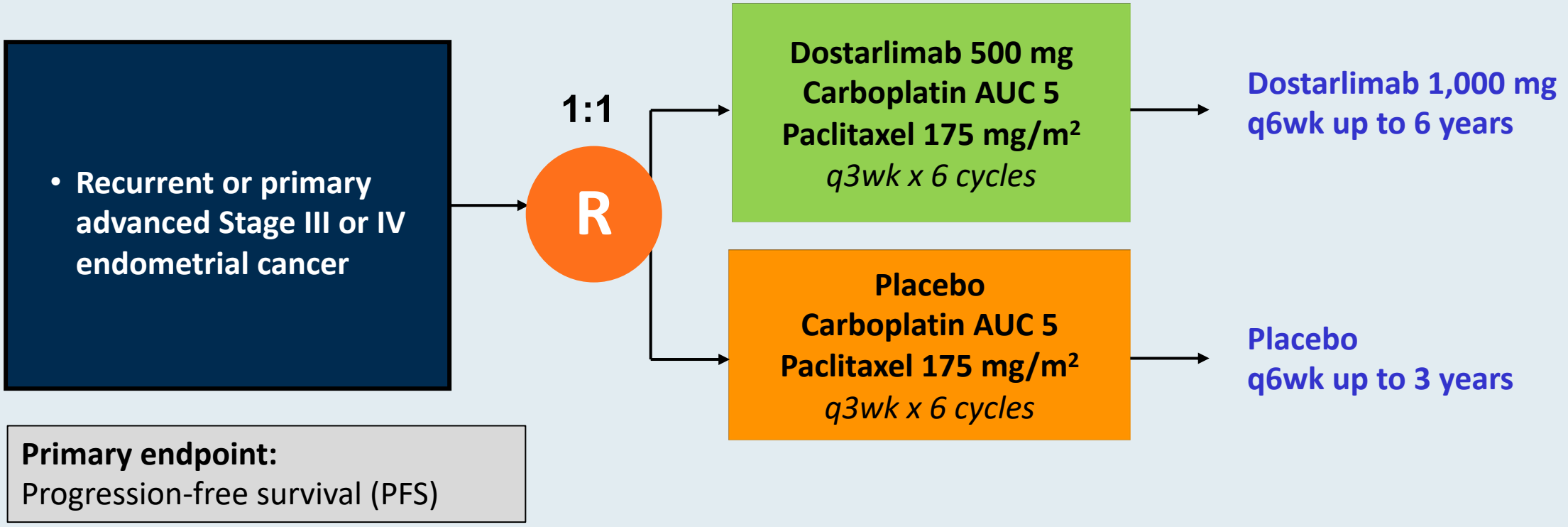
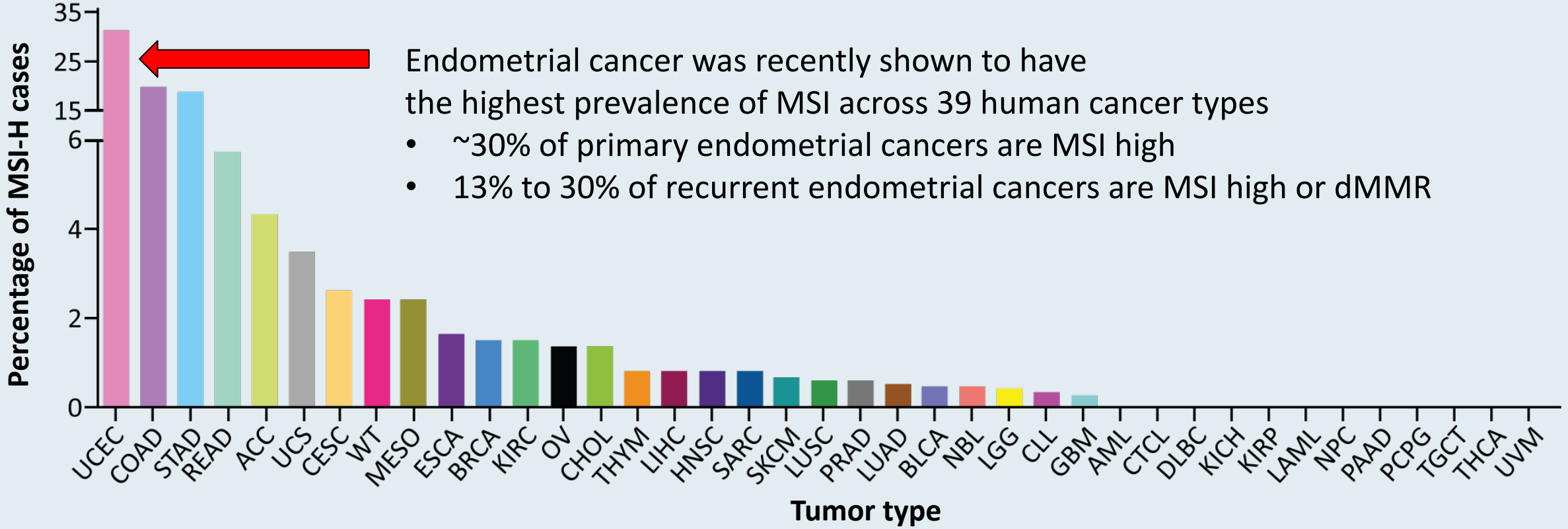
ENGOT-EN6/NSGO-RUBY Phase III Schema



Mirza MR et al. ASCO 2020;Abstract TPS6107.

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.

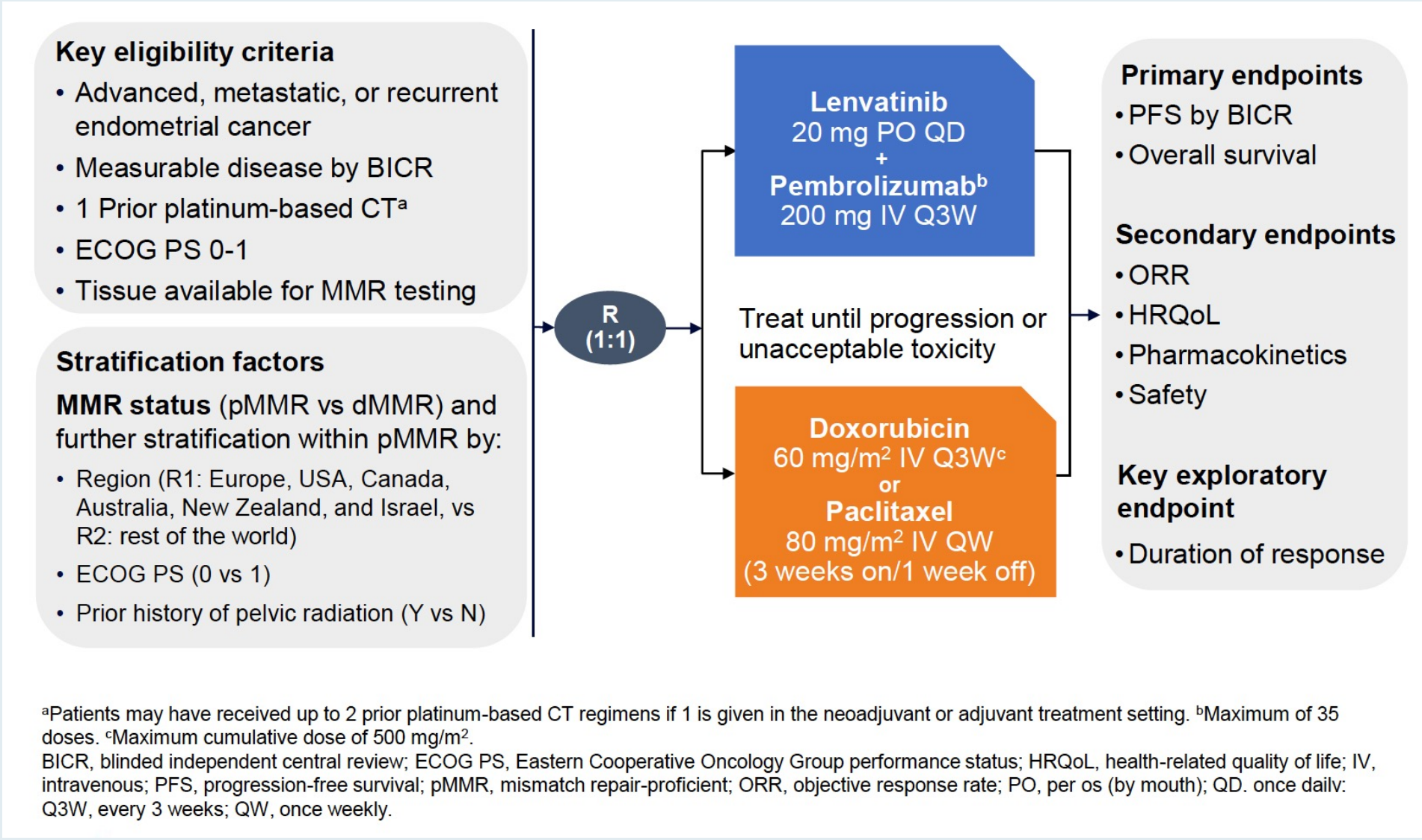
RTP RESEARCH TO PRACTICE

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.

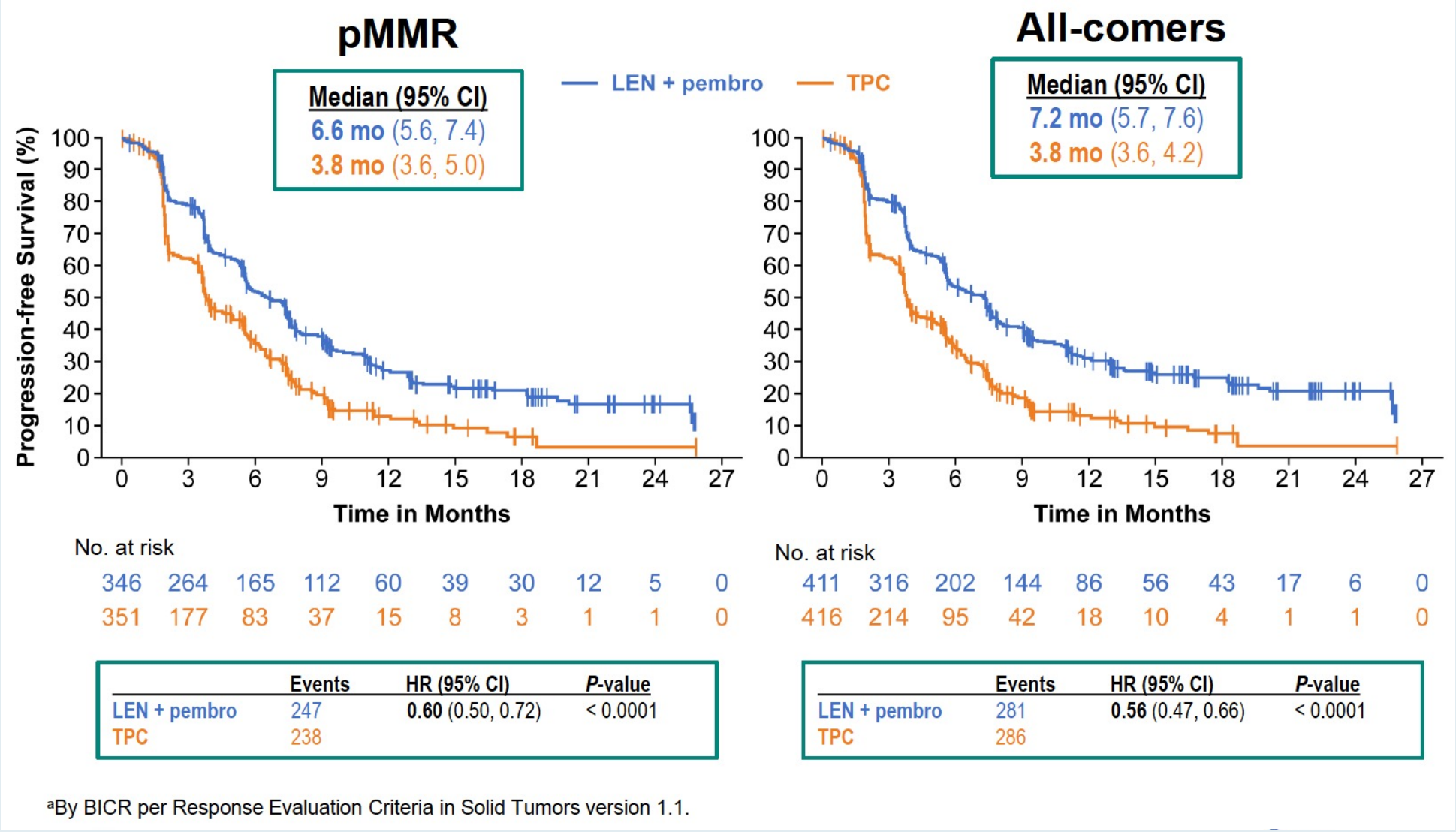
Study 309/KEYNOTE-775: Phase III Trial Schema



[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/m².
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 dailv: Q3W, every 3 weeks; QW, once weekly.

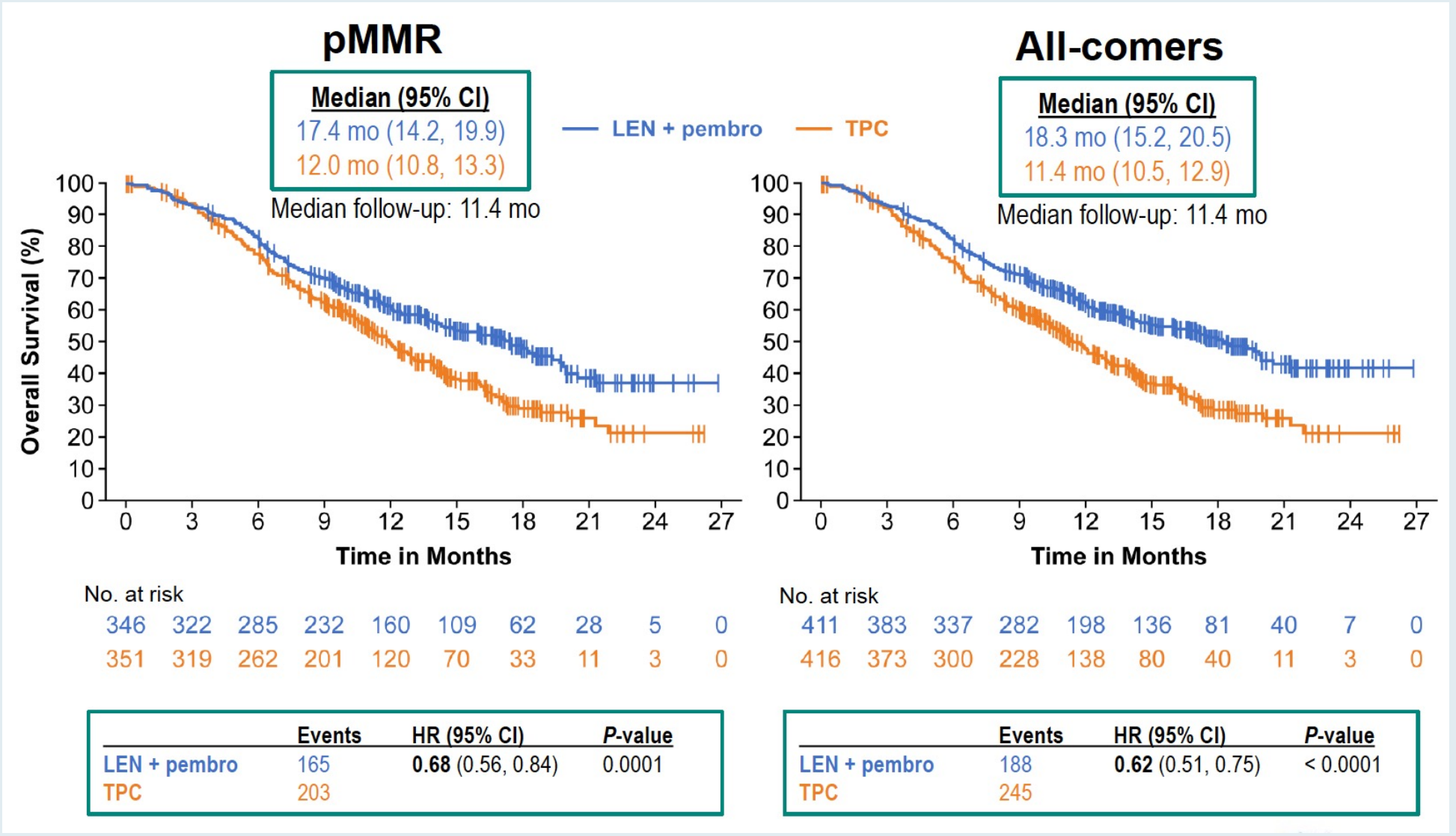
Makker V et al. SGO 2021;Abstract 11512.

Study 309/KEYNOTE-775: Progression-Free Survival



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 Cervical Cancer

Phase III Trial of Cemiplimab Monotherapy in Advanced Cervical Cancer Stopped Early for Positive Result on Overall Survival

Press Release – March 15, 2021

"Regeneron Pharmaceuticals, Inc. and Sanofi today announced positive results demonstrating an overall survival (OS) benefit from the Phase 3 trial investigating the PD-1 inhibitor cemiplimab monotherapy compared to chemotherapy, in patients previously treated with chemotherapy whose cervical cancer is recurrent or metastatic. The trial will be stopped early based on a unanimous recommendation by the Independent Data Monitoring Committee (IDMC), and the data will form the basis of regulatory submissions in 2021 ...

"This is the largest Phase 3 randomized clinical trial in advanced cervical cancer and included women (median age: 51 years) with either squamous cell carcinoma or adenocarcinoma. Patients were randomized to receive cemiplimab monotherapy (350 mg every 3 weeks) or an investigator's choice of commonly used chemotherapy (pemetrexed, vinorelbine, topotecan, irinotecan or gemcitabine). Compared to chemotherapy, patients receiving cemiplimab experienced: Total population: 31% reduced risk of death; Squamous cell carcinoma: 27% reduced risk of death; Adenocarcinoma: 44% reduced risk of death. The primary endpoint for the trial was OS, analyzed first among patients with squamous cell carcinoma, then in the total population…

"Detailed results will be presented at an upcoming medical meeting."

https://finance.yahoo.com/news/phase-3-trial-libtayo-cemiplimab-060000401.html?guccounter=1

RTP RESEARCH TO PRACTICE

ESMO VIRTUAL PLENARY

12 & 13 May 2021

Krishnansu Tewari

ESMO VIRTUAL PLENARY

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

12 May 2021

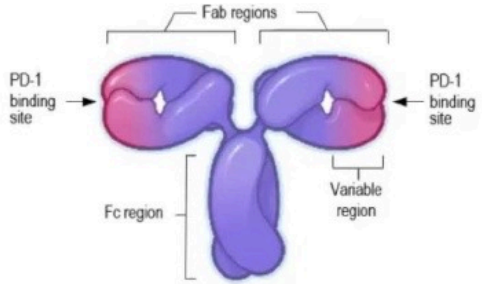
*Contributed equally to this presentation.

This study (NCT03257267) was sponsored by Regeneron Pharmaceuticals, Inc. and Sanofi.

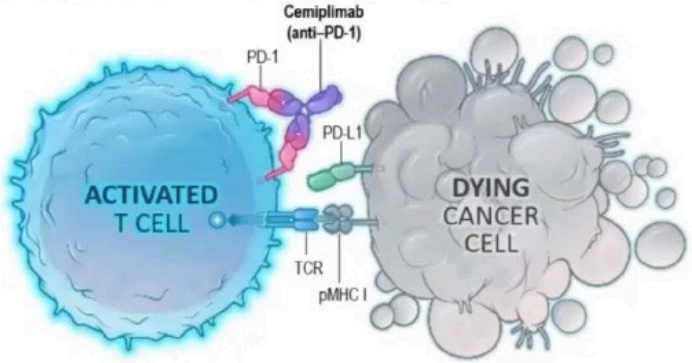
Krishnansu Tewari

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]

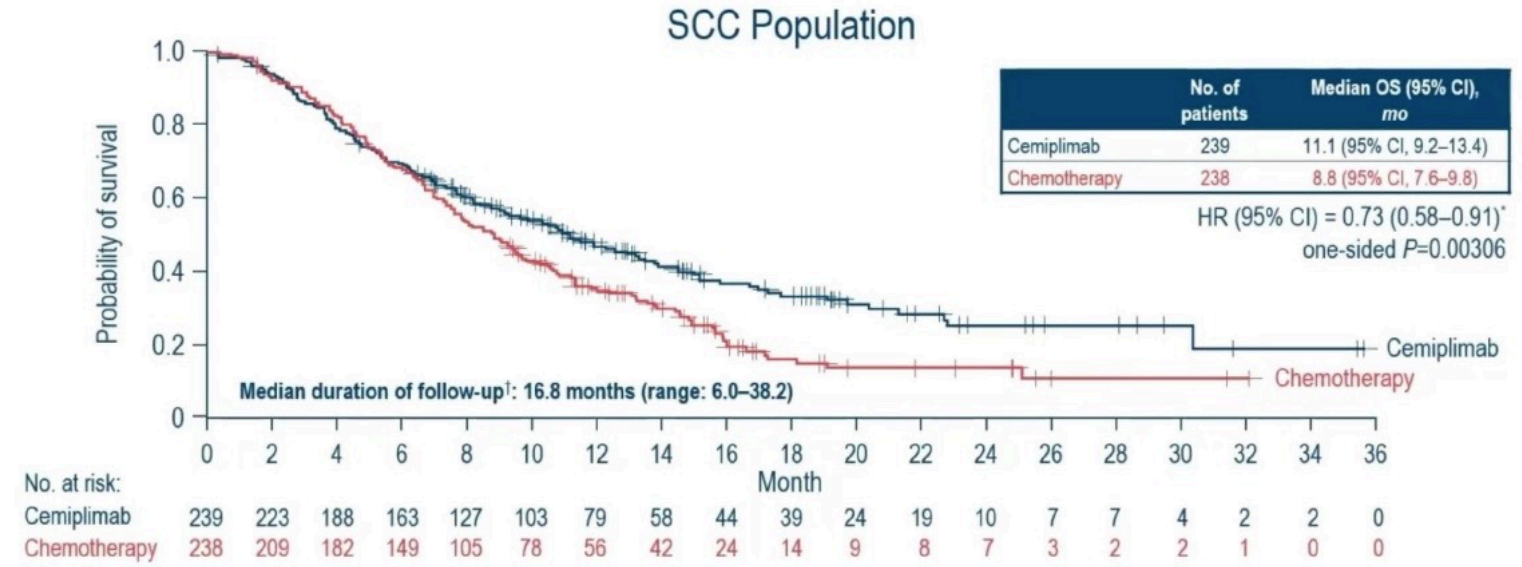
Ig, immunoglobin; Fc, fragment crystallizable; ORR, objective response rate; PD-1, programmed cell death-1; PD-L1, PD-ligand 1; pMHC I, peptide-bound major histocompatibility complex I; R/M, recurrent or metastatic; TCR, T-cell receptor.

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

Krishnansu Tewari

OVERALL SURVIVAL

- 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.
CI, confidence interval; HR, hazard ratio; IDMC, Independent Data Monitoring Committee; mo, month; OS, overall survival; ROW, rest of world; SCC, squamous cell carcinoma.

Data cutoff date: 4 Jan 2021

Krishnansu Tewari

OVERALL SURVIVAL

	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.
AC, adenocarcinoma or adenosquamous carcinoma; CI, confidence interval; HR, hazard ratio; mo, month; OS, overall survival; ROW, rest of world; SCC, squamous cell carcinoma..

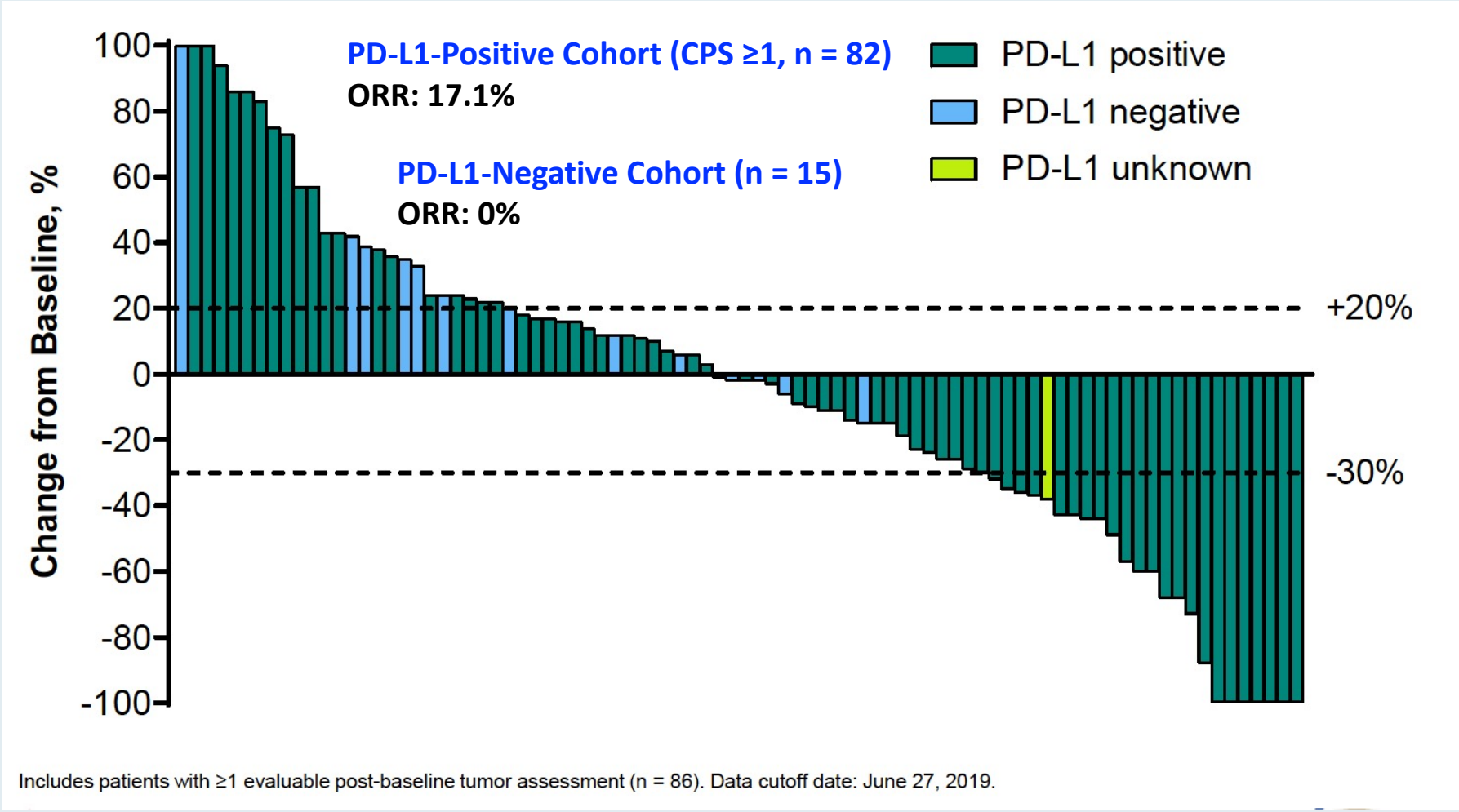
Data cutoff date: 4 Jan 2021

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.

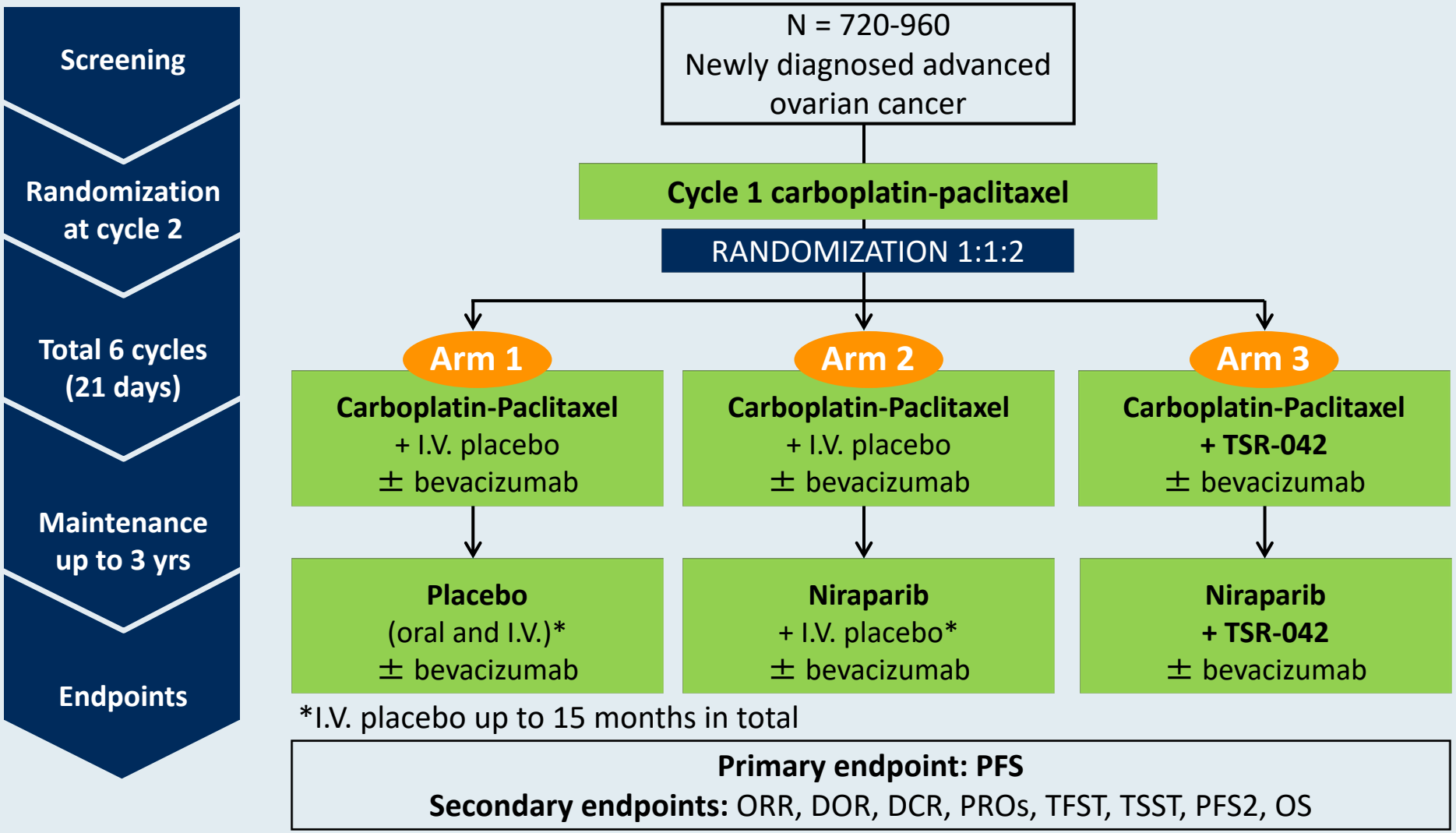
Combined Positive Score (CPS) = PD-L1+ cells (tumor cells, lymphocytes, macrophages) / Total number of tumor cells x 100

Chung HC et al. SGO 2021;Abstract 10440.

RTP RESEARCH TO PRACTICE

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

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

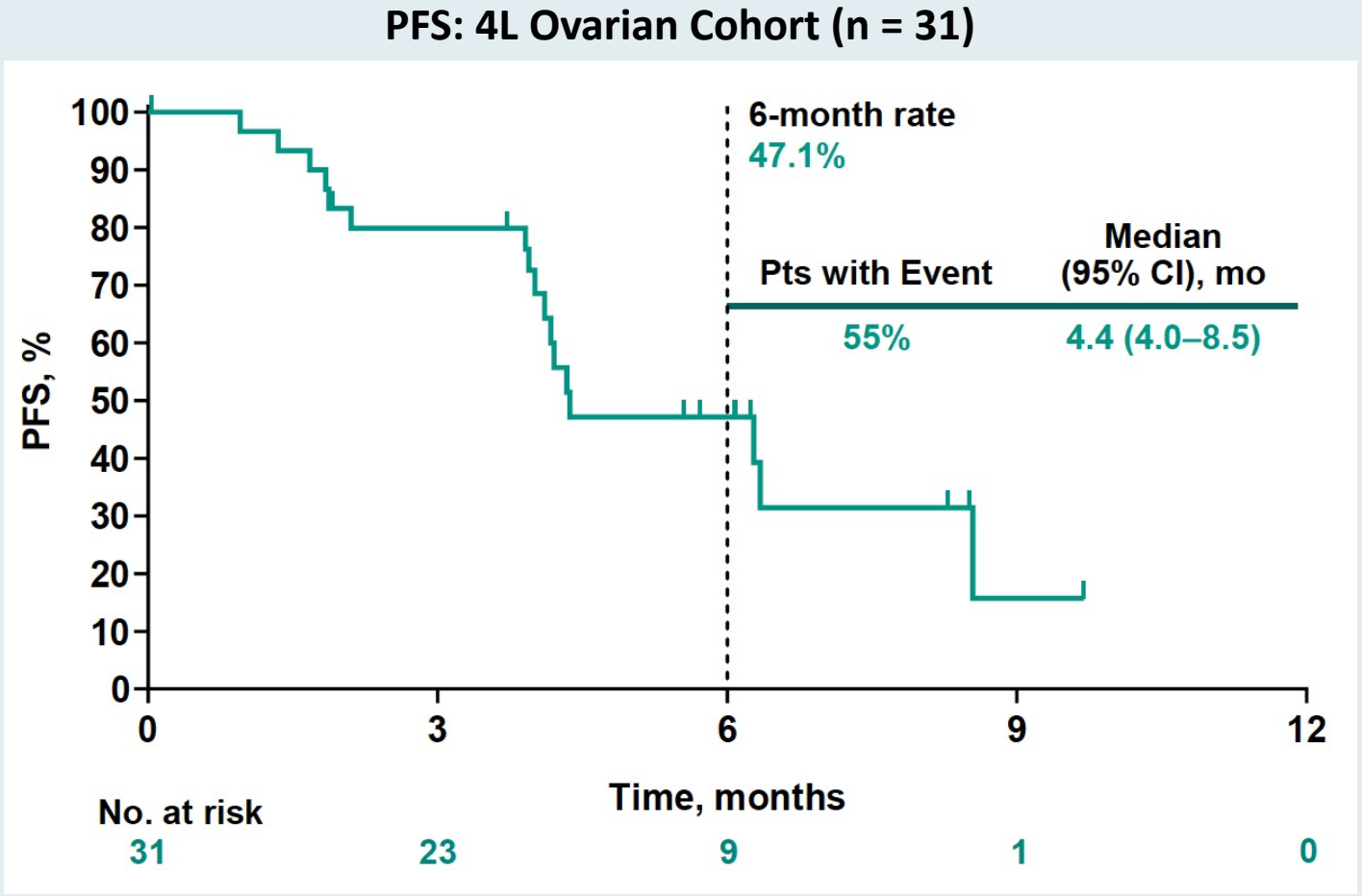
LEAP-005: Phase II Study of Lenvatinib (Len) plus Pembrolizumab (Pembro) in Patients (Pts) with Previously Treated Advanced Solid Tumours

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

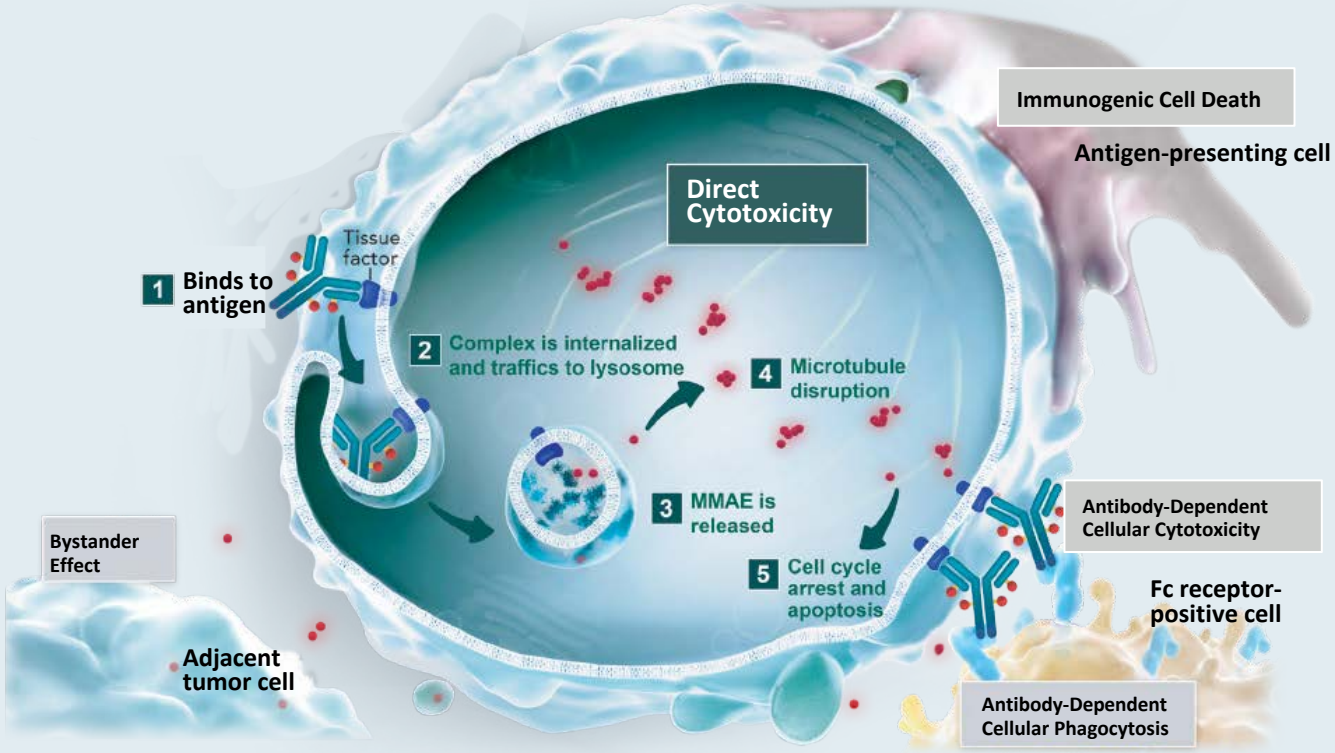


Lwin Z et al. *ESMO* 2020;Abstract LBA41.

Tisotumab Vedotin and Other Novel Agents in Gynecologic Cancers

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

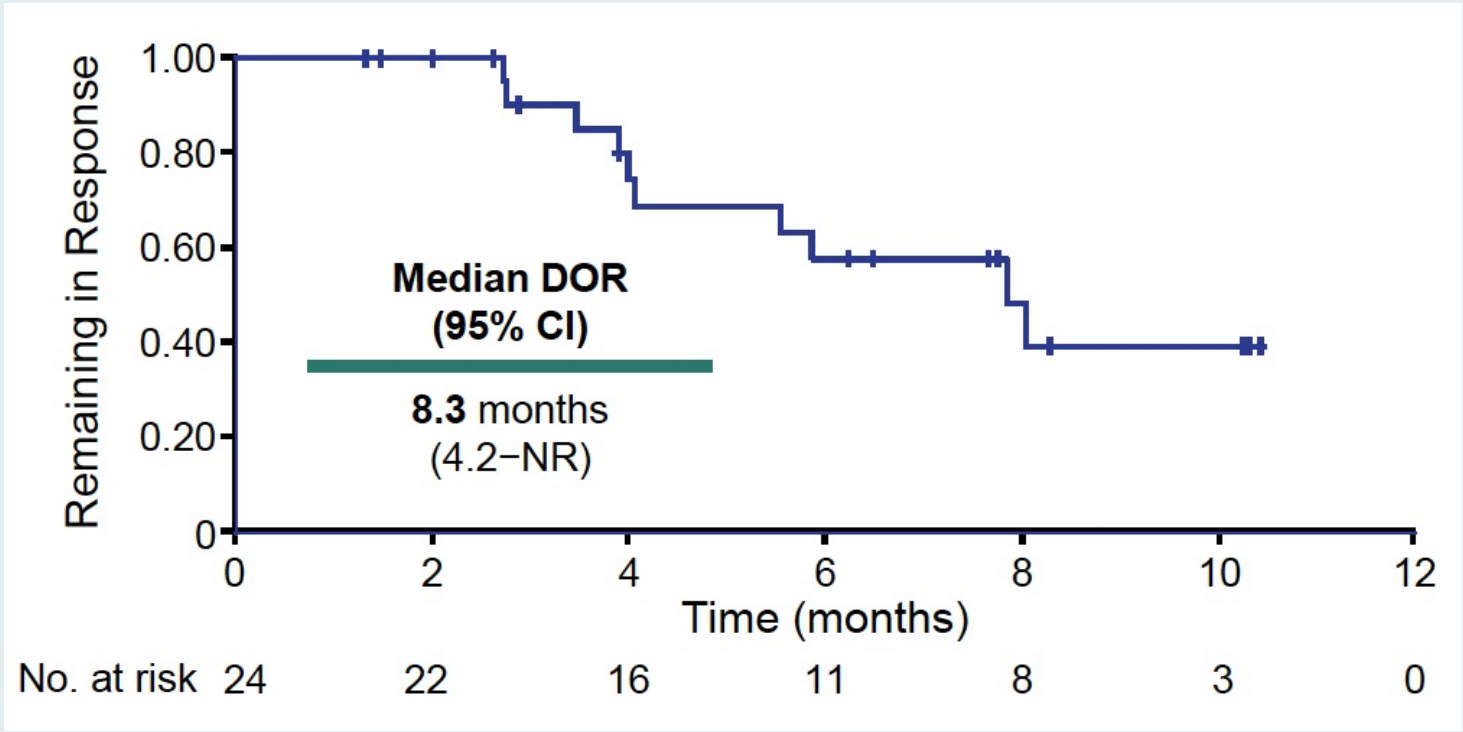
Coleman RL et al.

ESMO 2020;Abstract LBA32.

innovaTV 204: Antitumor Activity by IRC Assessment

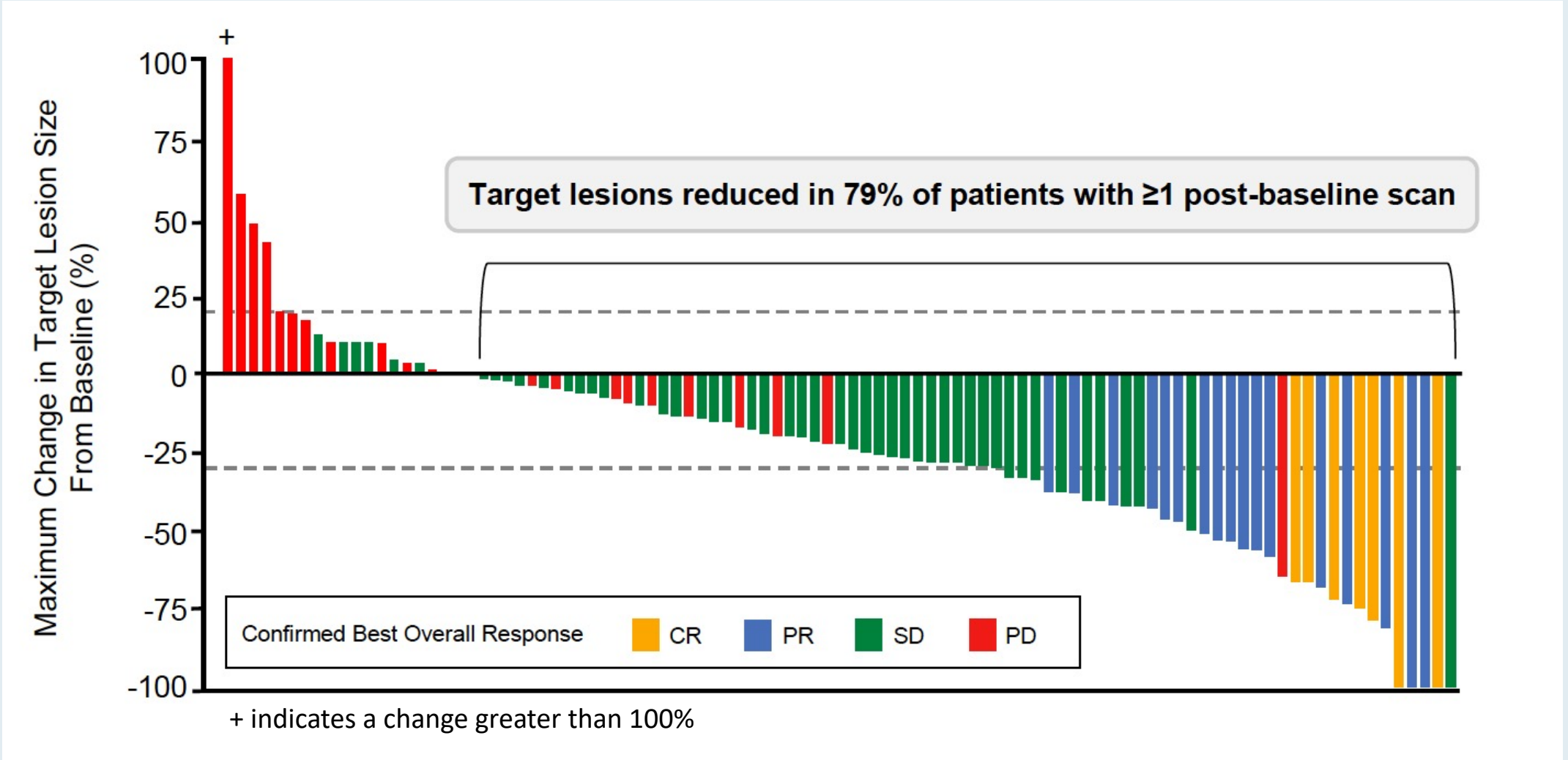
Clinical Variable	N = 101
Confirmed ORR	24%
CR	7%
PR	17%
SD	49%
PD	24%
Not evaluable	4%

Duration of Response



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

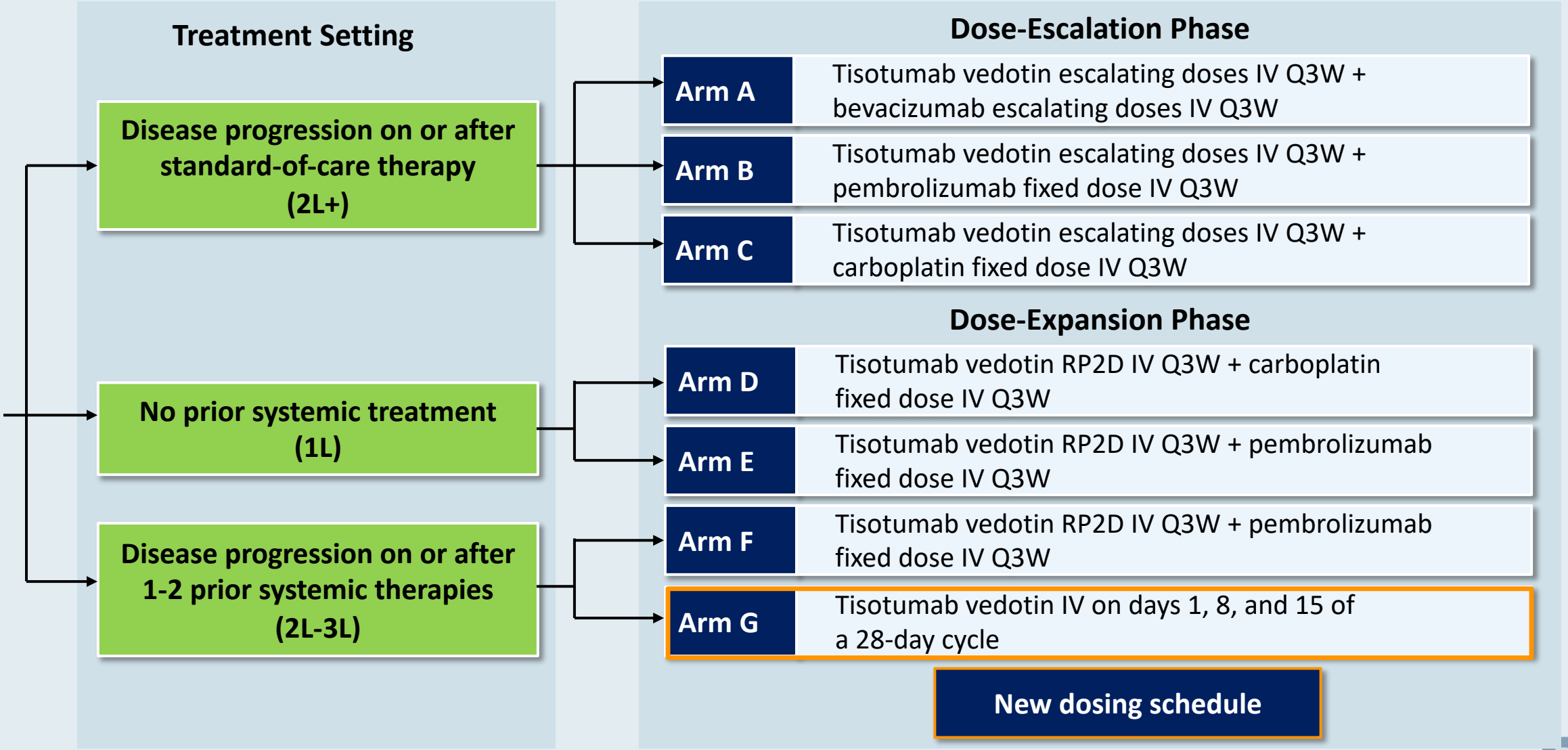
innovaTV 204: Maximum Change in Target Lesion Size by IRC Assessment



+ indicates a change greater than 100%

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

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



Courtesy of David M O'Malley, MD

Meet The Professor with Dr Armstrong

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MODULE 3: Key Recent Data Sets

MODULE 4: Appendix

RTP RESEARCH TO PRACTICE

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

RTP
RESEARCH
TO PRACTICE

Research

JAMA Oncol 2020;6(11):1766-72

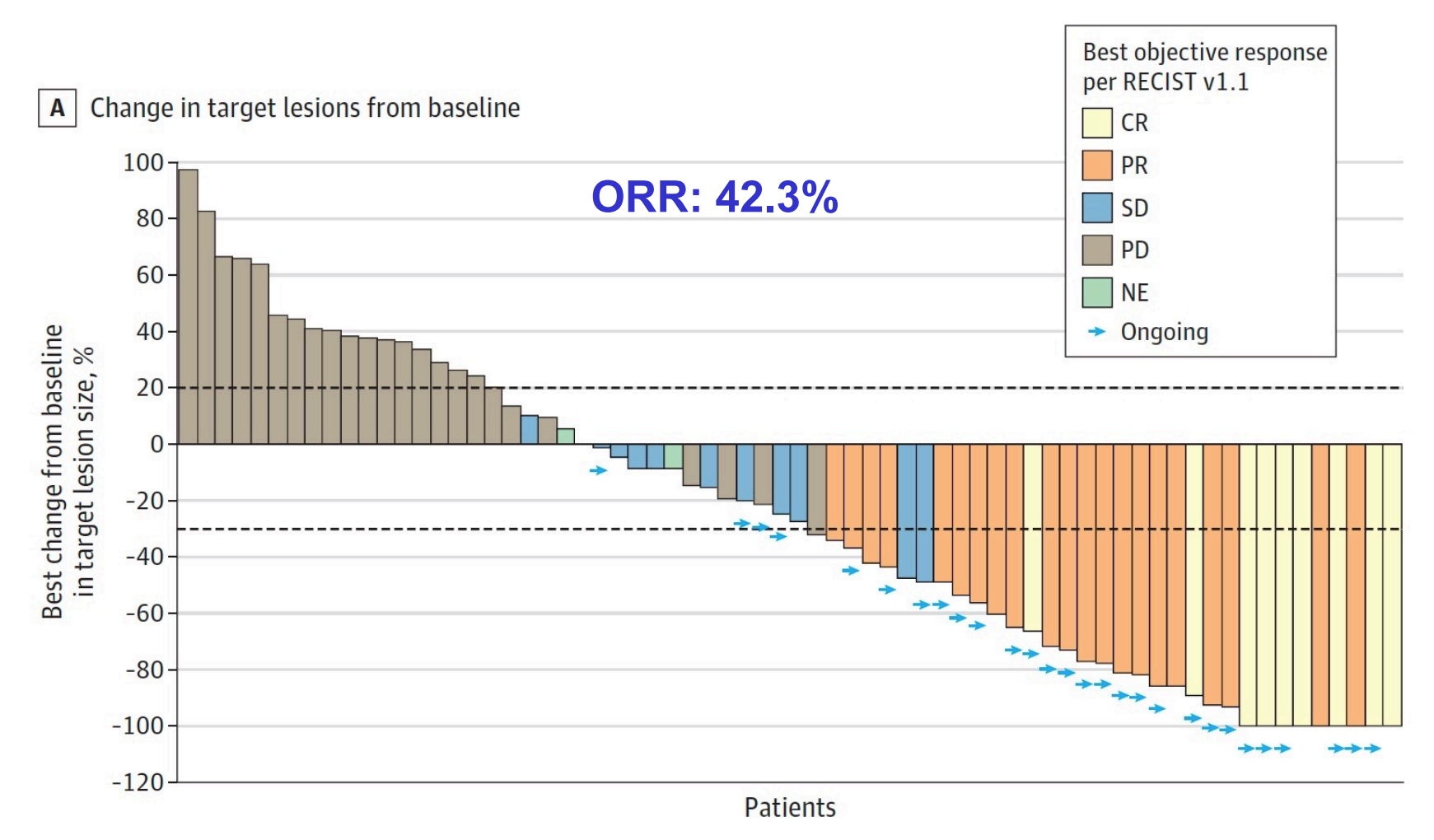
JAMA Oncology | Original Investigation

Clinical Activity and Safety of the Anti–Programmed Death 1 Monoclonal Antibody Dostarlimab for Patients With Recurrent or Advanced Mismatch Repair–Deficient Endometrial Cancer

A Nonrandomized Phase 1 Clinical Trial

Ana Oaknin, MD, PhD; Anna V. Tinker, MD; Lucy Gilbert, MD; Vanessa Samouëlian, MD; Cara Mathews, MD; Jubilee Brown, MD; Maria-Pilar Barretina-Ginesta, MD; Victor Moreno, MD; Adriano Gravina, MD; Cyril Abdeddaim, MD; Susana Banerjee, MD; Wei Guo, PhD; Hadi Danaee, ScD; Ellie Im, MD; Renaud Sabatier, MD

GARNET: Dostarlimab for Recurrent or Advanced dMMR Endometrial Cancer — Best Percentage Change in Lesion Size



Oaknin A et al. *JAMA Oncol* 2020;6(11):1766-72.

RTP RESEARCH TO PRACTICE

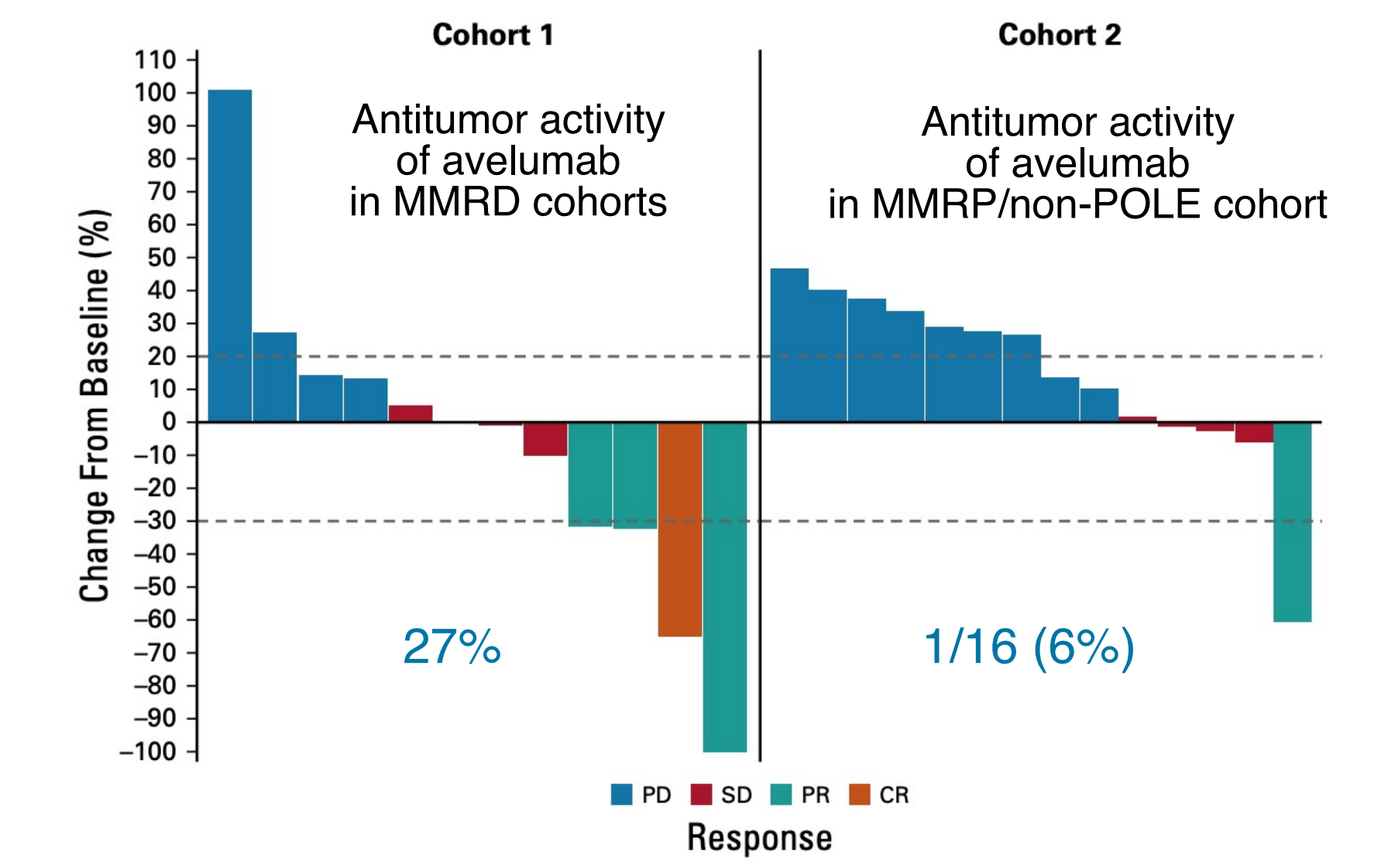
original report

Phase II Study of Avelumab in Patients With Mismatch Repair Deficient and Mismatch Repair Proficient Recurrent/Persistent Endometrial Cancer

Panagiotis A. Konstantinopoulos, MD, PhD[1]; Weixiu Luo, MS[1]; Joyce F. Liu, MD[1]; Doga C. Gulhan, PhD[2]; Carolyn Krasner, MD[1]; Jeffrey J. Ishizuka, MD, DPhil[1]; Allison A. Gockley, MD[3]; Mary Buss, MD, MPH[4]; Whitfield B. Growdon, MD[5]; Heather Crowe[5]; Susana Campos, MD, MPH[1]; Neal I. Lindeman, MD[3]; Sarah Hill, MD, PhD[3]; Elizabeth Stover, MD, PhD[1]; Susan Schumer, MD[1]; Alexi A. Wright, MD, MPH[1]; Jennifer Curtis, MS[1]; Roxanne Quinn[1]; Christin Whalen, RN[1]; Kathryn P. Gray, PhD[1]; Richard T. Penson, MD[5]; Stephen A. Cannistra, MD[4]; Gini F. Fleming, MD[6]; and Ursula A. Matulonis, MD[1]

J Clin Oncol 2019;37(30):2786-94

Objective Response Rate: Avelumab



Konstantinopoulos PA, et al. *J Clin Oncol* 2019;37(30):2786-94.

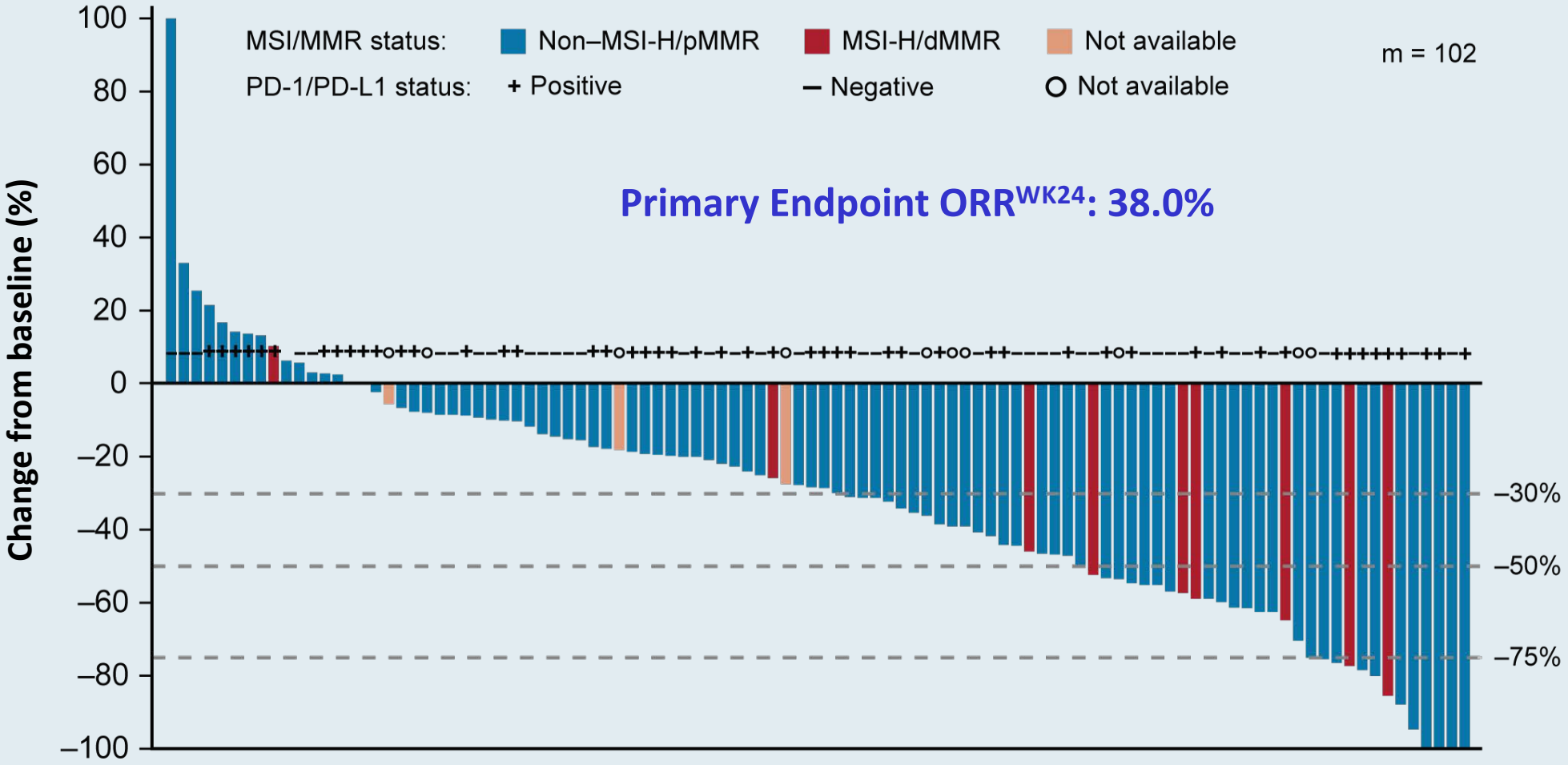
original reports

Lenvatinib Plus Pembrolizumab in Patients With Advanced Endometrial Cancer

Vicky Makker, MD[1]; Matthew H. Taylor, MD[2]; Carol Aghajanian, MD[1]; Ana Oaknin, MD, PhD[3]; James Mier, MD[4]; Allen L. Cohn, MD[5]; Margarita Romeo, MD, PhD[6]; Raquel Bratos, MD[7]; Marcia S. Brose, MD, PhD[8]; Christopher DiSimone, MD[9]; Mark Messing, MD[10]; Daniel E. Stepan, MD[11]; Corina E. Dutcus, MD[12]; Jane Wu, PhD[12]; Emmett V. Schmidt, MD, PhD[13]; Robert Orlowski, MD[13]; Pallavi Sachdev, PhD[12]; Robert Shumaker, PhD[11]; and Antonio Casado Herraez, MD, PhD[14]

J Clin Oncol 2020;38(26):2981-92

KEYNOTE-146: Pembrolizumab/Lenvatinib in Advanced Endometrial Cancer That Is *Not* MSI High or dMMR After Disease Progression on Prior Systemic Therapy



Makker V et al. *J Clin Oncol* 2020;38(26):2981-92.

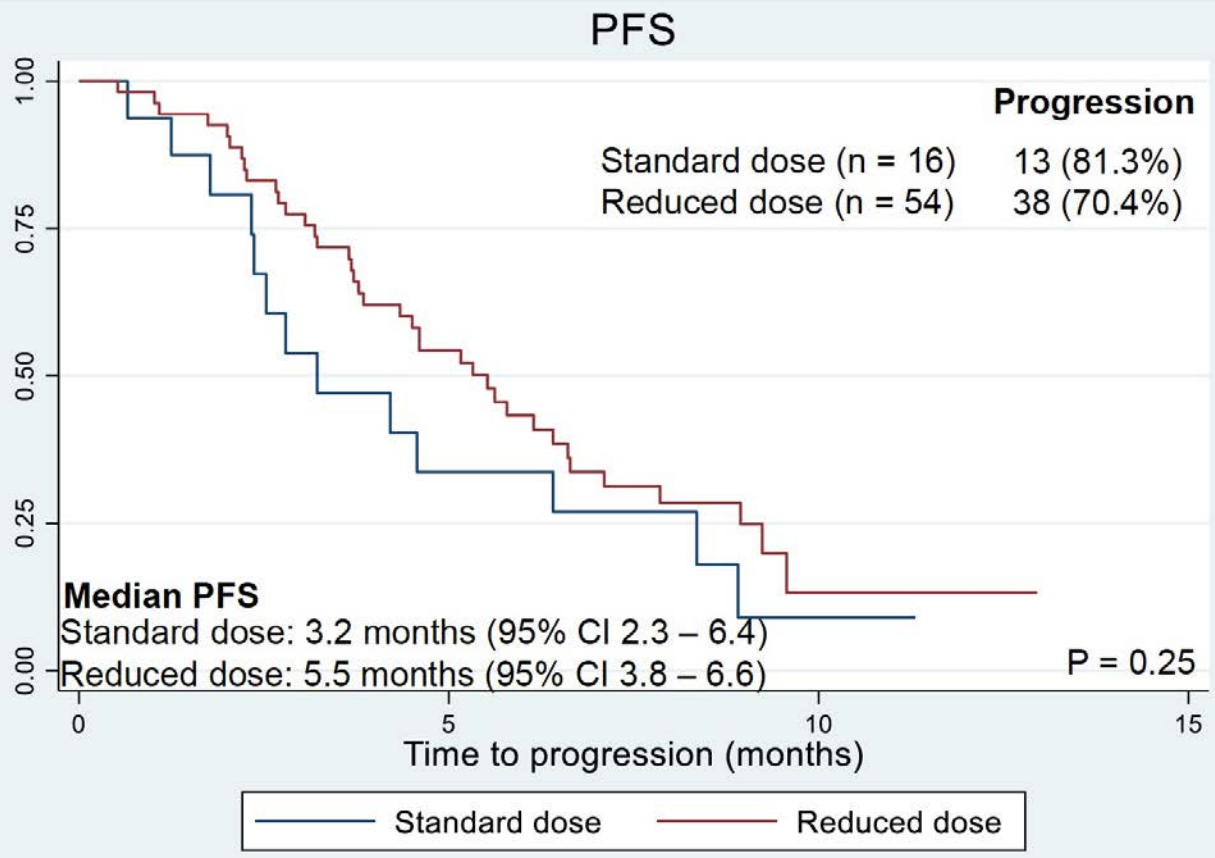
RTP RESEARCH TO PRACTICE

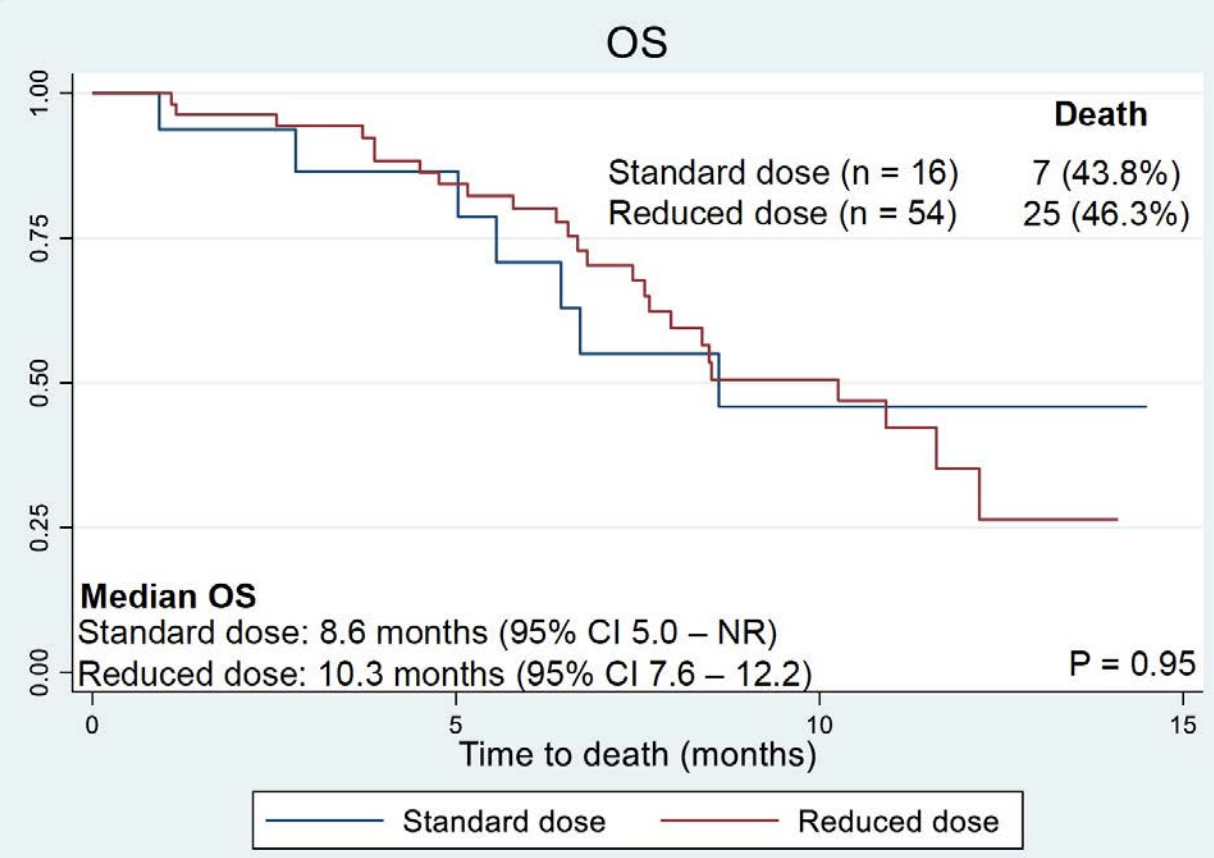
The Use of Pembrolizumab and Lenvatinib Combination Therapy in Endometrial Cancer: An Examination of Toxicity and Treatment Efficacy in Clinical Practice

How JA et al.

SGO 2021;Abstract 10775.

Retrospective Analysis of Reduced-Dose Lenvatinib (<20 mg) with Pembrolizumab at MD Anderson Cancer Center





- Reduced starting dose of lenvatinib was associated with longer time to treatment toxicity and fewer dose de-escalations.
- "Published studies and these results may support using lenvatinib at a starting dose of 14 mg daily in clinical practice."

How JA et al. SGO 2021;Abstract 10775.

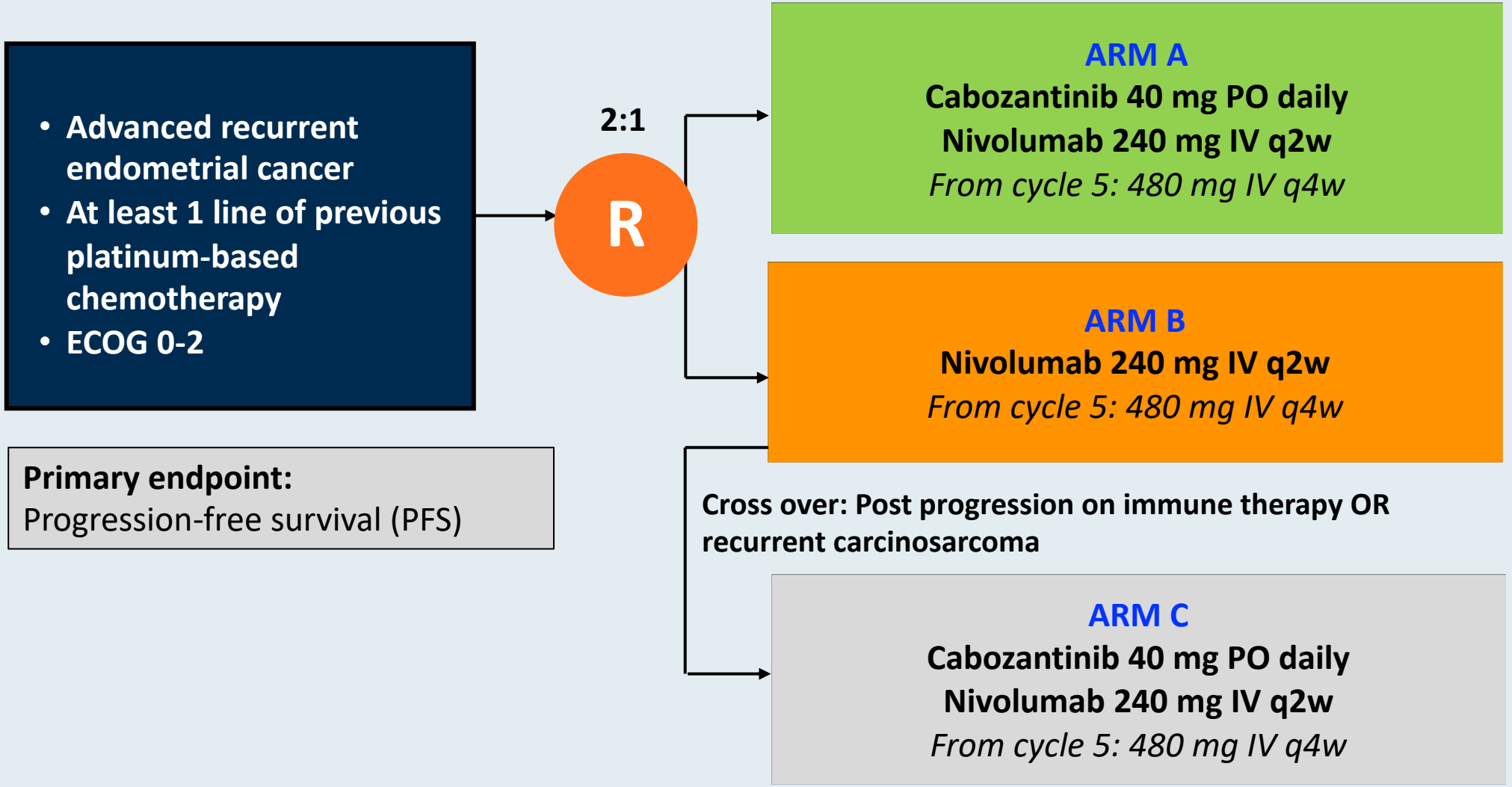
RTP RESEARCH TO PRACTICE

NCI 10104: A Randomized Phase 2 Study of Cabozantinib in Combination with Nivolumab in Advanced, Recurrent Metastatic Endometrial Cancer

Lheureux S et al.

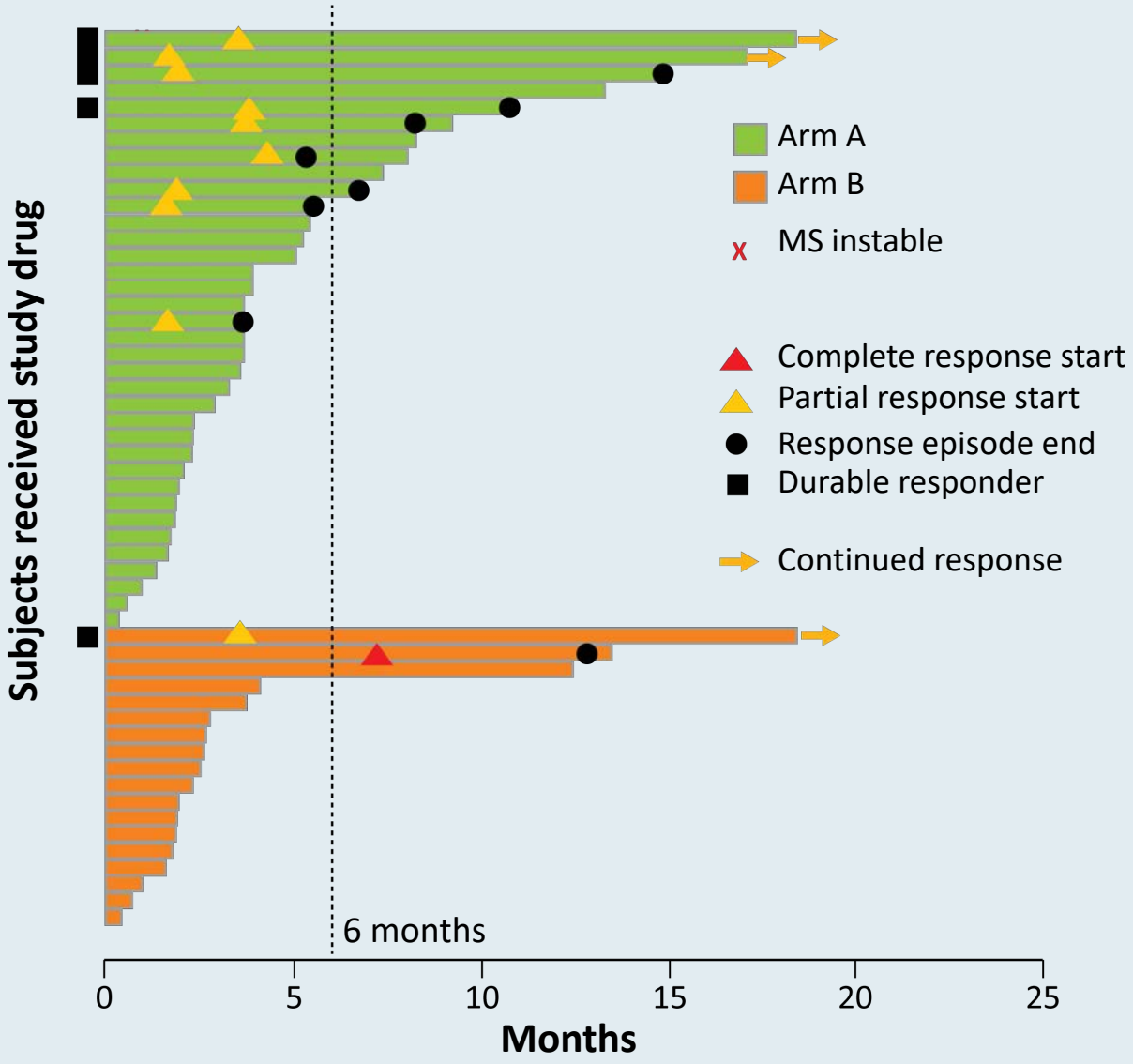
ASCO 2020;Abstract 6010.

NCI 10104 Phase II Study Schema



Lheureux S et al. ASCO 2020;Abstract 6010.

NCI 10104: Response Rate and Duration and Survival Analyses



	Arm A Cabo/nivolumab (n = 36)	Arm B Nivolumab (n = 18)
ORR	25%	11%
SD as best response	44%	11%
CBR	69%	22%
Median PFS*	5.3 mo	1.9 mo
Median OS†	13.0 mo	7.9 mo

* HR: 0.59, significant

† Immature, 55% events

Lheureux S et al. ASCO 2020;Abstract 6010.

Select Ongoing Phase III Immune Checkpoint Inhibitor Combination Studies

Trial	N	Eligibility	Randomization
KEYNOTE-775	780	• Advanced, recurrent or metastatic EC • PD after 1 prior platinum-based chemo regimen	• Pembro + lenvatinib • Paclitaxel + carboplatin
LEAP-001	720	• Stage III, IV or recurrent EC • May have received 1 prior line of platinum-based adjuvant or neoadjuvant chemo	• Pembro + lenvatinib • Paclitaxel + carboplatin
NRG-GY018	810	• Stage III, IVA or IVB or recurrent EC • No prior chemo for EC, except adjuvant	• Pembro + paclitaxel + carboplatin → Pembro • Placebo + paclitaxel + carboplatin → Placebo
RUBY	470	• Stage III, IV or first recurrent EC	• Dostarlimab + paclitaxel + carboplatin • Placebo + paclitaxel + carboplatin
AtTEnd	550	• Newly dx with residual disease after surgery, OR inoperable Stage III-IV naïve to first-line systemic treatment	• Atezolizumab + paclitaxel + carboplatin • Placebo + paclitaxel + carboplatin

Clinicaltrials.gov. Accessed August 18, 2020; Green AK et al. *ASCO Ed Book* 2020.

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

Krishnansu Tewari

EMPOWER-CERVICAL 1/GOG-3016/ENGOT-CX9 STUDY DESIGN* (NCT03257267)

Recurrent and metastatic cervical cancer resistant to platinum-based chemotherapy ≥2nd line
ECOG PS ≤1

N=608: 477 SCC, 131 AC
Randomised 1:1
Stratified by:
- Histology (SCC/AC)
- Geographic region
- Prior bevacizumab (Y/N)
- ECOG PS (0 vs 1)

Patients were enrolled regardless of PD-L1 expression

Cemiplimab 350 mg Q3W IV

IC chemotherapy

Options:
- Pemetrexed 500 mg/m² Q3W IV
- Gemcitabine 1,000 mg/m² IV on Days 1 and 8 and every 21 days
- Topotecan 1 mg/m² daily IV for 5 days, every 21 days
- Irinotecan 100 mg/m² IV weekly x 4, followed by 10–14 days rest
- Vinorelbine 30 mg/m² IV on Days 1 and 8 and every 21 days

Treat up to 96 weeks with option for re-treatment

Tumour imaging conducted on Day 42 (±7 days) of cycles† 1–4, 6, 8, 10, 12, 14, and 16

Primary endpoint: OS

Secondary endpoints: PFS, ORR, DOR, safety, QoL

Exploratory endpoints: PK, immunogenicity, biomarkers, PD

- Two interim analyses were prespecified per protocol
- At first interim analysis, IDMC recommended trial to continue
- At second interim analysis (85% of total OS events), IDMC recommended trial be stopped early for efficacy; presented here

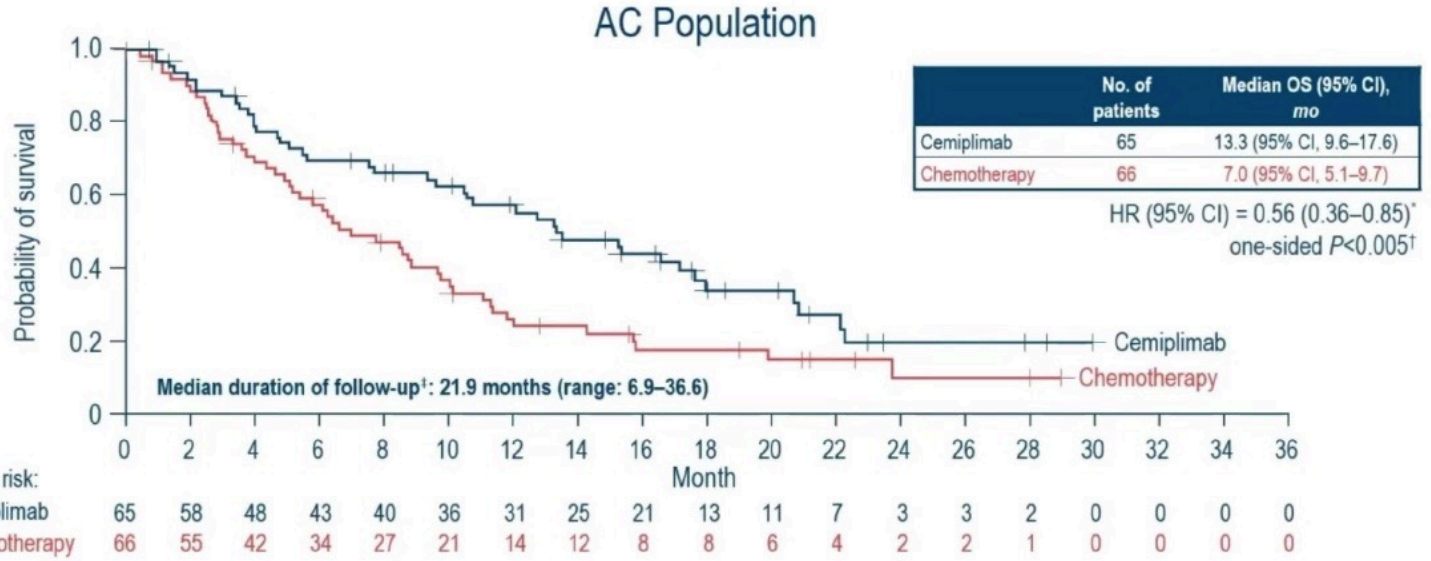
*Performed according to ENGOT Model C.† To account for differences in drug administration schedules, one cycle is defined as 6 weeks.
AC, adenocarcinoma or adenosquamous carcinoma; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IC, investigator's choice; IDMC, Independent Data Monitoring Committee; IV, intravenously; ORR, objective response rate; OS, overall survival; PD, pharmacodynamics; PD-L1, programmed cell death ligand 1; PFS, progression-free survival; PK, pharmacokinetics; Q3W, every 3 weeks; QoL, quality of life; SCC, squamous cell carcinoma.

1. Vergote I et al. *Int J Gynecol Cancer*. 2019;0:1–4.

Data cutoff date: 4 Jan 2021

Krishnansu Tewari

OVERALL SURVIVAL



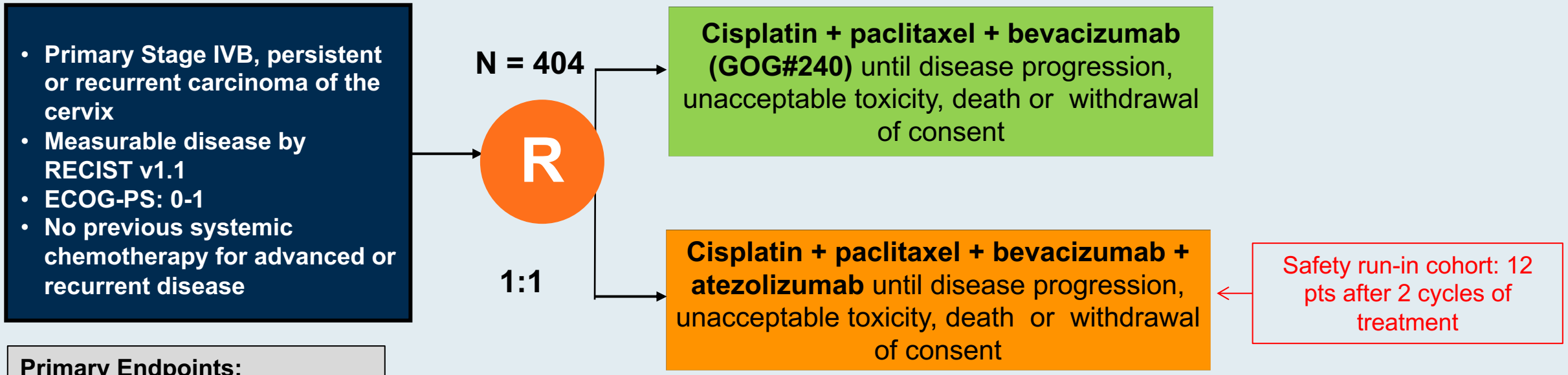
	No. of patients	Median OS (95% CI), *mo*
Cemiplimab	65	13.3 (95% CI, 9.6–17.6)
Chemotherapy	66	7.0 (95% CI, 5.1–9.7)

HR (95% CI) = 0.56 (0.36–0.85)*
one-sided $P<0.005^{\dagger}$

*Stratified by geographic region (North America vs Asia vs ROW) according to interactive web response system. †One-sided nominal *P* value, not adjusted for multiplicity.
‡From randomisation to data cutoff date.
AC, adenocarcinoma or adenosquamous carcinoma; CI, confidence interval; HR, hazard ratio; mo, month; OS, overall survival; ROW, rest of world; SCC, squamous cell carcinoma.

Data cutoff date: 4 Jan 2021

BEATcc Phase III Randomized Front-Line Trial of Atezolizumab



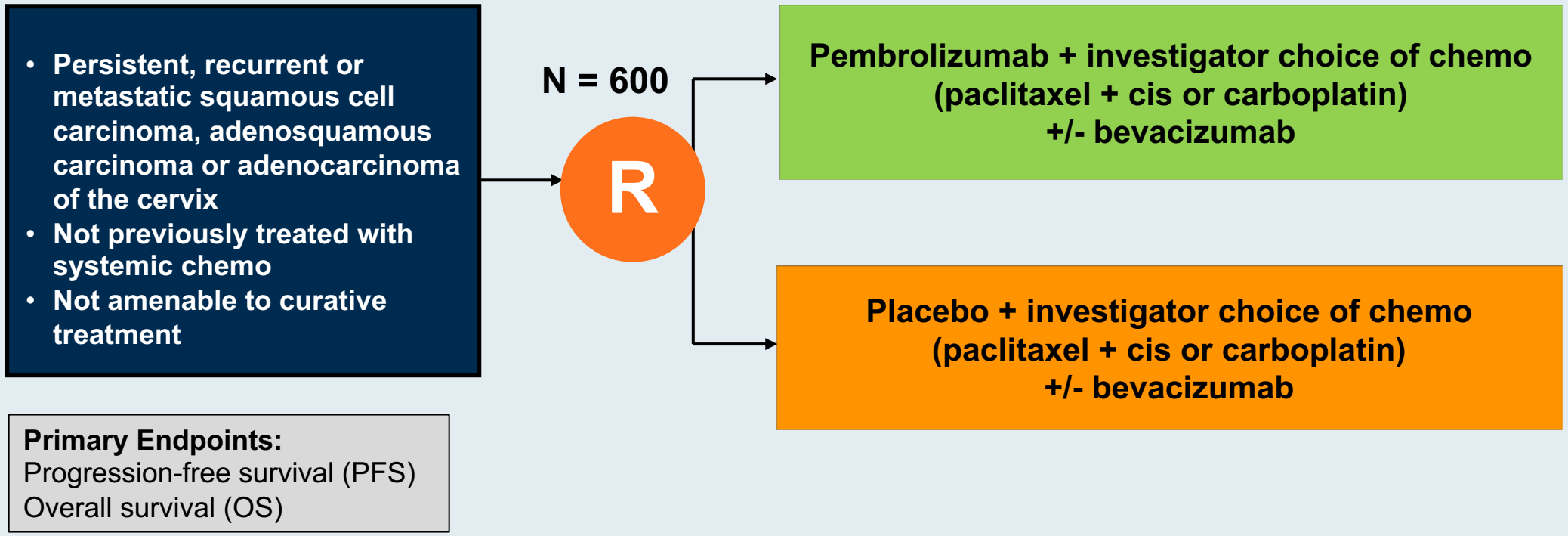
Primary Endpoints:
Overall survival (OS)
Secondary Endpoints:
- PFS
- ORR
- DOR
- Safety
- HR-QOL

Stratification Factors:
- Prior concurrent Cisplatin-RDT
- Histology: SCC vs ADK (including AdenoSquamous)
- Chemotherapy Backbone: Cisplatin vs Carboplatin

ClinicalTrials.gov Identifier: NCT03556839

Courtesy of Krishnansu S Tewari, MD

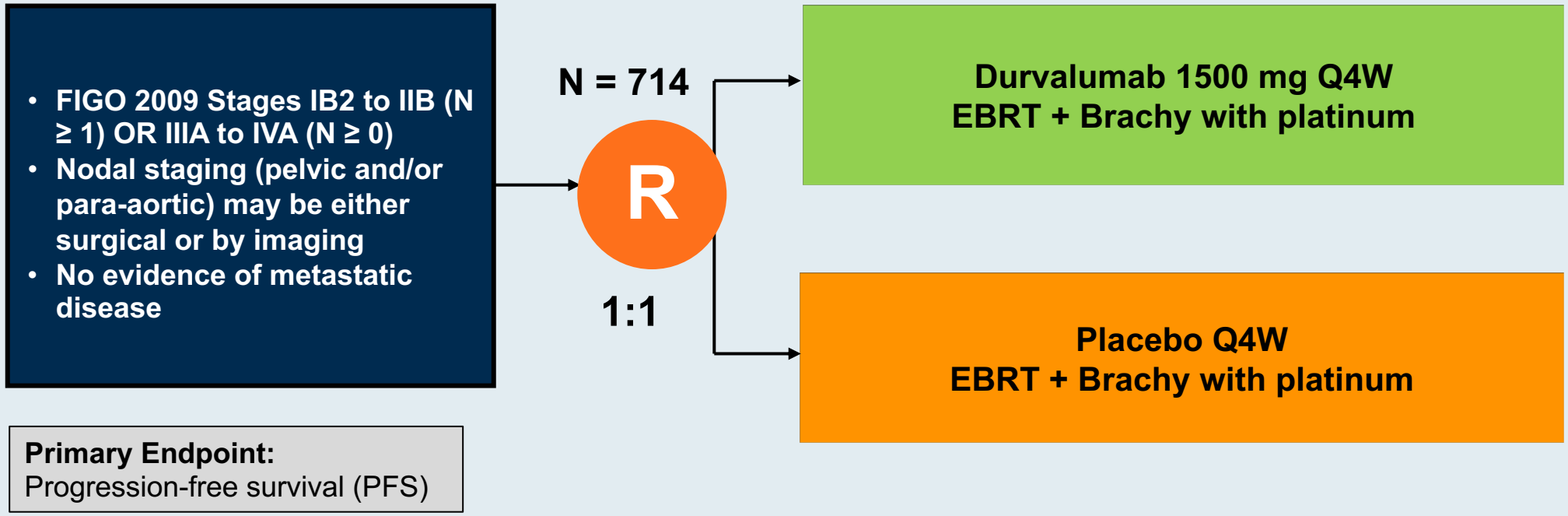
KEYNOTE-826 Phase III Schema



Primary Endpoints:
Progression-free survival (PFS)
Overall survival (OS)

ClinicalTrials.gov Identifier: NCT03635567, Accessed August 18, 2020

CALLA Phase III Schema



Primary Endpoint:
Progression-free survival (PFS)

Mayadev J et al. *Int J Gynecol Cancer* 2020;30:1065-1070.

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

FDA-Approved Indications for Immunotherapy in Ovarian Cancer

Pembrolizumab: 2017 FDA approval for MSI-high/MMR deficient cancers

- The incidence of germline MMR gene mutations in high grade serous cancers is 1-8%
- MMR deficiency is more common in non-serous ovarian cancer

2020 ASCO ovarian cancer genetics guidelines re MMR testing:

- Women diagnosed with clear cell, endometrioid, or mucinous ovarian cancer should be offered somatic tumor testing for mismatch repair deficiency
- Testing for MMR deficiency may be offered to women diagnosed with other histologic types of epithelial ovarian cancer

Xiao X, et al. *Gynecol Oncol.* 2014.; Morice P, et al. *N Engl J Med.* 2019.; Konstantinopoulos PA, et al. *J Clin Oncol.* 2020; Murphy MA Cancer 2011

Courtesy of Ursula Matulonis, MD

Avelumab Alone or in Combination with Pegylated Liposomal Doxorubicin versus Pegylated Liposomal Doxorubicin Alone in Platinum-Resistant or Refractory Epithelial Ovarian Cancer: Primary and Biomarker Analysis of the Phase III JAVELIN Ovarian 200 Trial

Pujade-Lauraine E et al.

SGO 2019;Abstract LBA1.

JAVELIN Ovarian 200: Avelumab Alone or in Combination with Pegylated Liposomal Doxorubicin (PLD) versus PLD Alone in Platinum-Resistant or Refractory OC

	Avelumab (n = 188)		Avelumab + PLD (n = 188)		PLD (n = 190)	
All patients						
Median OS	11.8 mo		15.7 mo		13.1 mo	
	HR: 1.14, *p* = 0.83		HR: 0.80, *p* = 0.21		Reference	
Median PFS	1.9 mo		3.7 mo		3.5 mo	
	HR: 1.68, *p* > 0.99		HR: 0.78, *p* = 0.03		Reference	
PD-L1 evaluable	**PD-L1+ (n = 91)**	**PD-L1- (n = 62)**	**PD-L1+ (n = 92)**	**PD-L1- (n = 58)**	**PD-L1+ (n = 73)**	**PD-L1- (n = 66)**
Median OS	13.7 mo	10.5 mo	18.4 mo	12.7 mo	13.8 mo	13.1 mo
	HR: 0.80	HR: 1.4	HR: 0.72	HR: 1.1	Ref	Ref
Median PFS	1.9 mo	1.8 mo	3.7 mo	3.9 mo	1.9 mo	3.7 mo
	HR: 1.3	HR: 1.8	HR: 0.59	HR: 0.92	Ref	Ref

Pujade-Lauraine E et al. SGO 2019;Abstract LBA1.

Final Results from the KEYNOTE-100 Trial of Pembrolizumab in Patients with Advanced Recurrent Ovarian Cancer

Matulonis UA et al.

ASCO 2020;Abstract 6005.

KEYNOTE-100 Phase II, 2-Cohort Study Schema

Patients (N = 376)

- Recurrent, advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer
- ECOG PS 0 or 1
- Provision of a tumor sample for biomarker analysis

Key exclusion criteria

- Mucinous histology
- No bowel obstruction within 3 months
- No active autoimmune disease
- No active CNS metastases and/or carcinomatous meningitis

Cohort A
1-3 prior lines
PFI or TFI of 3-12 months

Total enrollment: n = 285

Pembrolizumab 200 mg IV q3wk until PD, prohibitive toxicity, death, or completion of 2 years

Cohort B
4-6 prior lines
PFI or TFI of ≥3 months

Total enrollment: n = 91

PFI = platinum-free interval; TFI = treatment-free interval

Matulonis UA et al. ASCO 2020;Abstract 6005.

KEYNOTE-100: Summary of Efficacy, Including by PD-L1 Status

Endpoint	Cohort A 1-3 prior lines PFI/TFI 3-12 months			Cohort B 4-6 prior lines PFI/TFI ≥3 months			Cohorts A + B All comers		
	All n = 285	CPS ≥1 n = 101	CPS ≥10 n =43	All n = 91	CPS ≥1 n = 49	CPS ≥10 n = 22	All n = 376	CPS ≥1 n = 150	CPS ≥10 n = 65
ORR	8.1%	6.9%	11.6%	9.9%	10.2%	18.2%	8.5%	8.0%	13.8%
DoR	8.3 mo	Not reported	Not reported	23.6 mo	Not reported	Not reported	10.2 mo	Not reported	Not reported
OS	18.7 mo	20.6 mo	21.9 mo	17.6 mo	20.7 mo	24.0 mo	Not reported	Not reported	Not reported

Matulonis UA et al. ASCO 2020;Abstract 6005.

Research

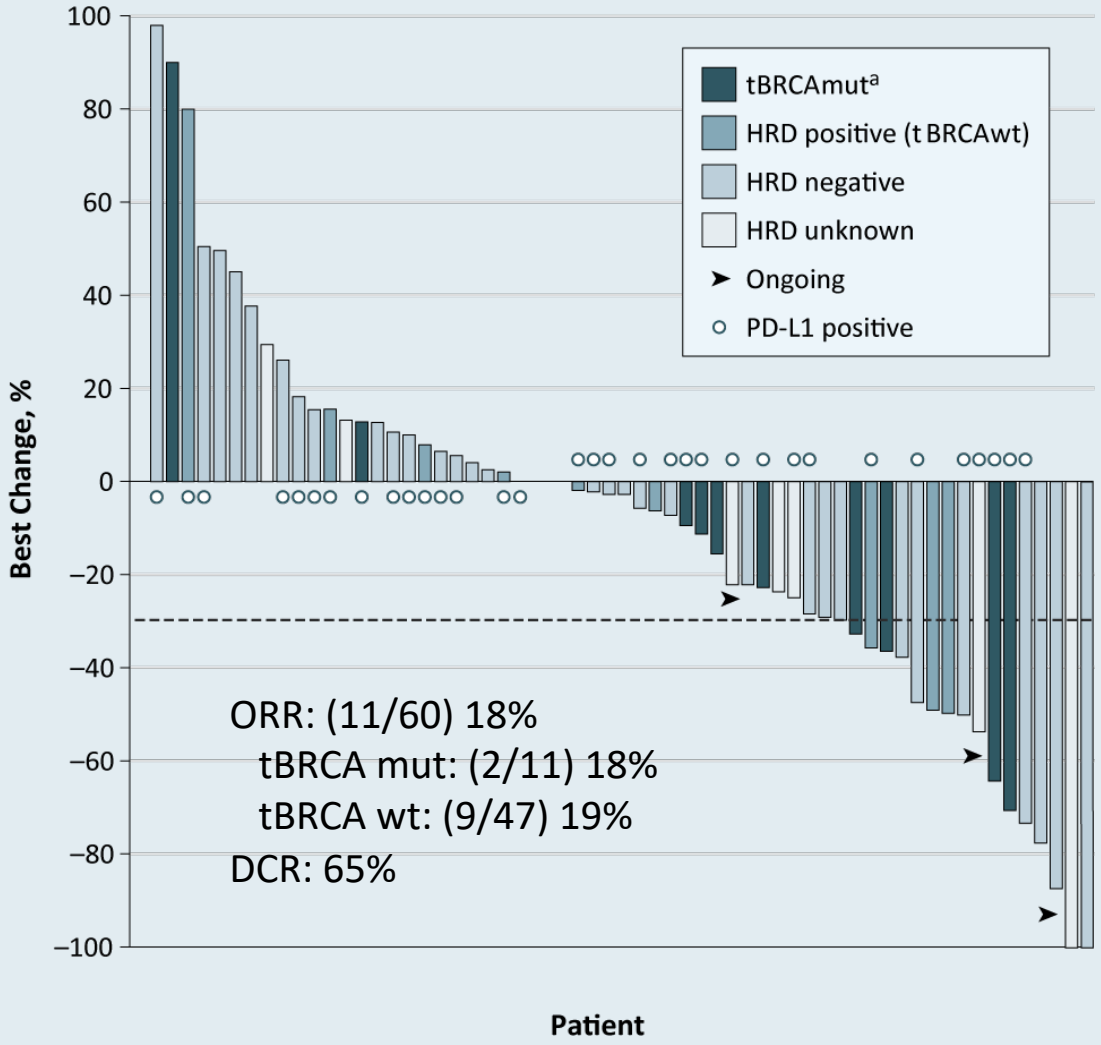
JAMA Oncol 2019;5(8):1141-9

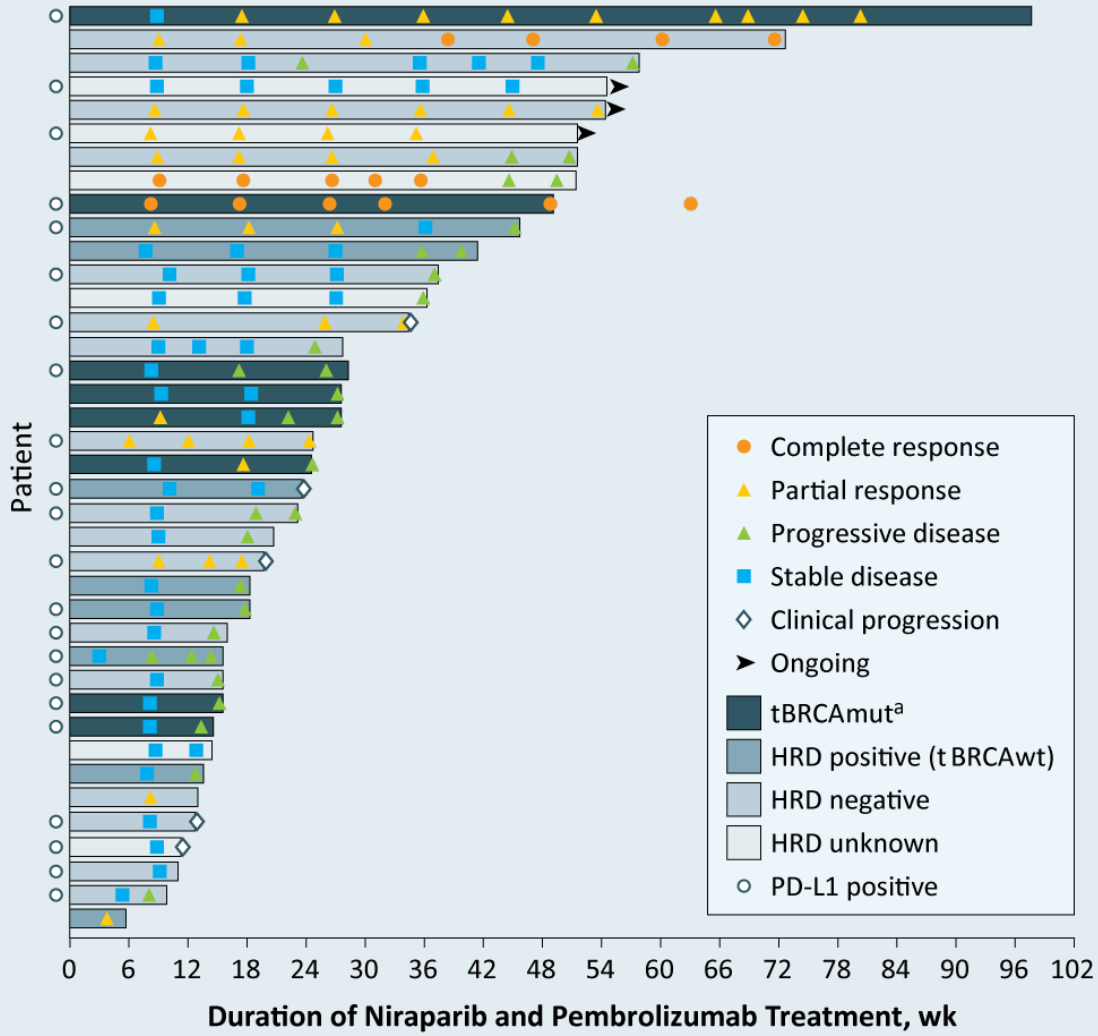
JAMA Oncology | Original Investigation

Single-Arm Phases 1 and 2 Trial of Niraparib in Combination With Pembrolizumab in Patients With Recurrent Platinum-Resistant Ovarian Carcinoma

Panagiotis A. Konstantinopoulos, MD, PhD; Steven Waggoner, MD; Gregory A. Vidal, MD; Monica Mita, MD; John W. Moroney, MD; Robert Holloway, MD; Linda Van Le, MD; Jasgit C. Sachdev, MD; Eloise Chapman-Davis, MD; Gerardo Colon-Otero, MD; Richard T. Penson, MD; Ursula A. Matulonis, MD; Young Bae Kim, MD; Kathleen N. Moore, MD; Elizabeth M. Swisher, MD; Anniina Färkkilä, MD; Alan D'Andrea, MD; Erica Stringer-Reasor, MD; Jing Wang, PhD; Nathan Buerstatte, MPH; Sujata Arora, MS; Julie R. Graham, PhD; Dmitri Bobilev, MD; Bruce J. Dezube, MD; Pamela Munster, MD

TOPACIO/KEYNOTE-162: Niraparib and Pembrolizumab in Recurrent Platinum-Resistant Ovarian Cancer





Konstantinopoulos PA, et al. *JAMA Oncol* 2019;5(8):1141-9.

RTP RESEARCH TO PRACTICE

Phase II Study of Olaparib (O) plus Durvalumab (D) and Bevacizumab (B) (MEDIOLA): Initial Results in Patients (pts) with Non-Germline BRCA-Mutated (Non-gBRCAm) Platinum Sensitive Relapsed (PSR) Ovarian Cancer (OC)

Drew Y et al.

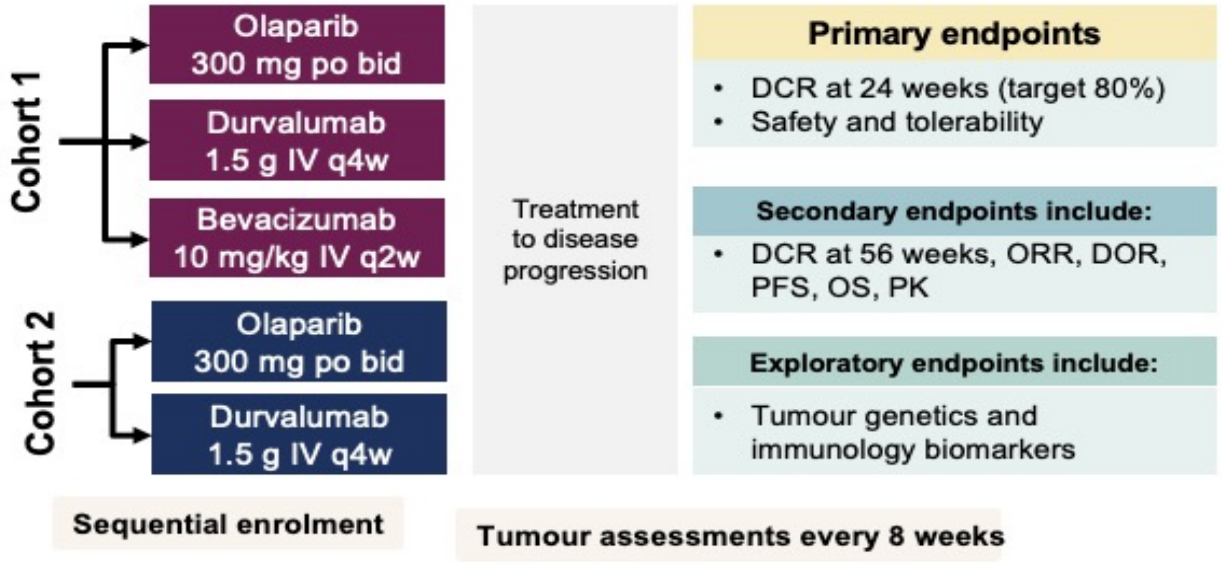
ESMO 2020;Abstract 814MO.

MEDIOLA: gBRCAwt Cohorts

Study Design

Patient population

- gBRCAwt
- PSR ovarian cancer
- ≤2 prior lines of chemotherapy
- PARP inhibitor and IO agent naïve



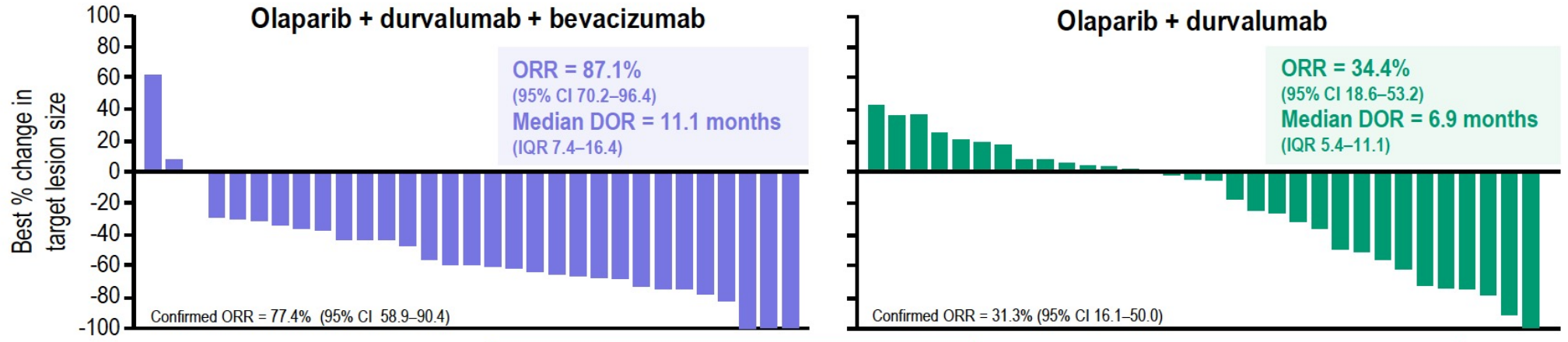
Patient Characteristics

	Olap + durva + bev (N=31)	Olap + durva (N=32)
Median age, years	64.0	68.5
Age group (years), n (%)		
<50	3 (9.7)	4 (12.5)
≥50–<65	14 (45.2)	8 (25.0)
≥65	14 (45.2)	20 (62.5)
Race, n (%)		
White	20 (64.5)	24 (75.0)
Asian	10 (32.3)	3 (9.4)
Other	1 (3.2)	5 (15.6)
Platinum sensitivity, n (%)		
>6–12 months	18 (58.1)	14 (43.8)
>12 months	13 (41.9)	18 (56.3)
Number of prior lines of chemotherapy, n (%)		
1 prior line	20 (64.5)	23 (71.9)
2 prior lines	11 (35.5)	9 (28.1)
Enrolment completed	January 2019	February 2019
Patients on study treatment at DCO, n (%) (13 February 2020)		
Olap; durva; bev	13 (41.9); 13 (41.9); 12 (38.7)	7 (21.9); 6 (18.8); NA

Drew Y et al. ESMO 2020;Abstract 814MO.

MEDIOLA: A Phase II Study of Olaparib and Durvalumab with or without Bevacizumab for Platinum-Sensitive Relapsed OC: No Germline BRCA Mutation Cohort

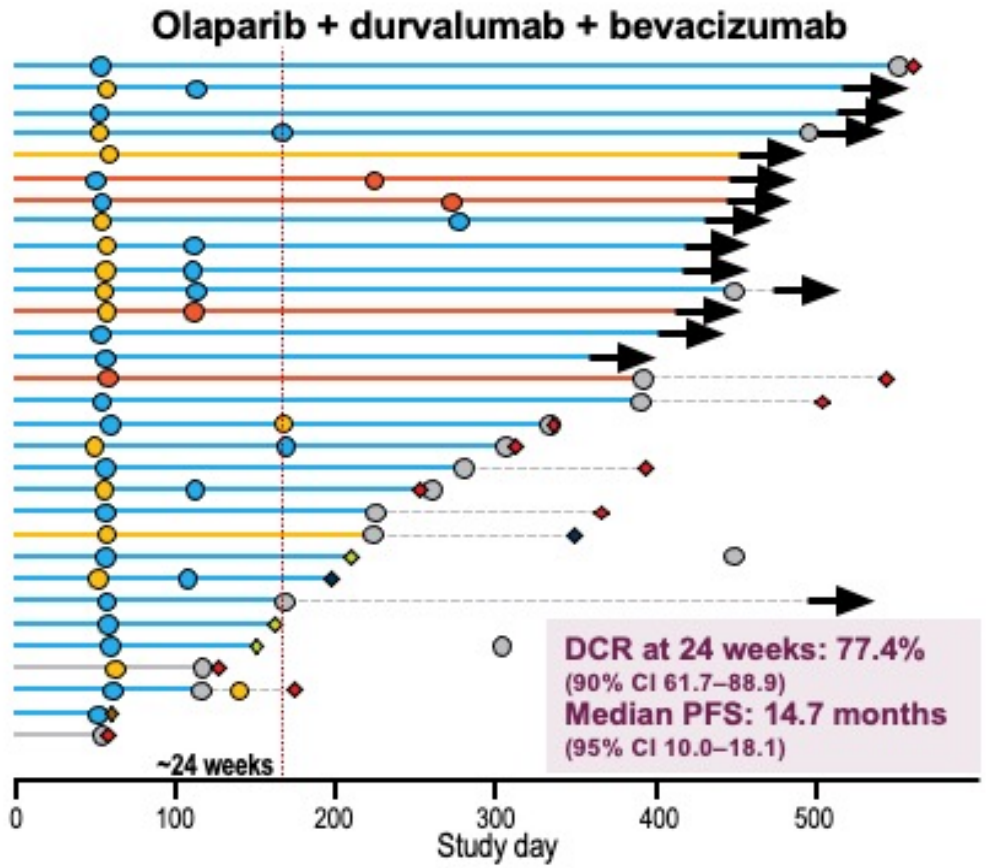
Exploratory analysis suggests ORR with triplet cohort is not dependent on genomic instability status (GIS)

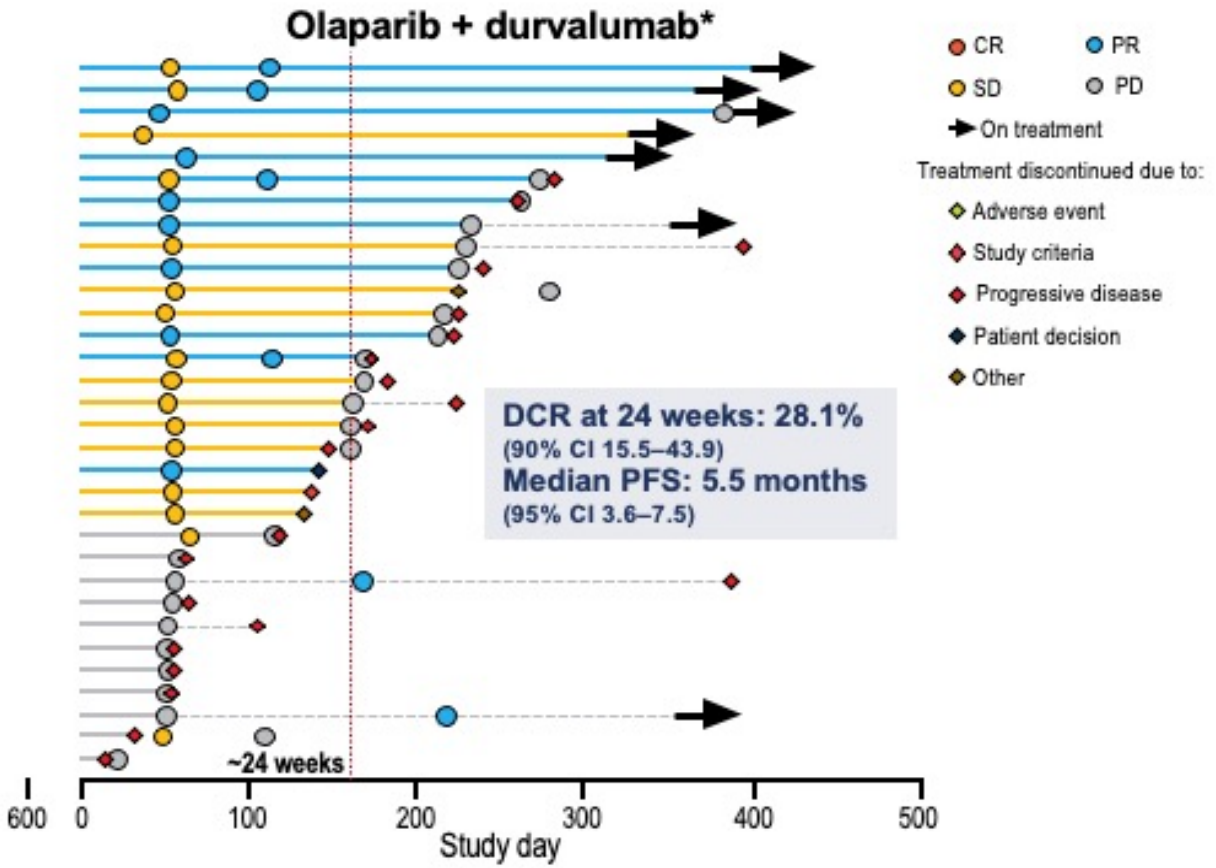


Genomic instability status* subgroup	Olaparib + durvalumab + bevacizumab		Olaparib + durvalumab	
	ORR (95% CI), %	n/N patients	ORR (95% CI), %	n/N patients
GIS-positive	100.0 (69.2–100.0)	10/10	50.0 (18.7–81.3)	5/10
GIS-negative	75.0 (34.9–96.8)	6/8	16.7 (0.4–64.1)	1/6
GIS-unknown	84.6 (54.6–98.1)	11/13	31.3 (11.0–58.7)	5/16

Drew Y et al. ESMO 2020;Abstract 814MO.

MEDIOLA: TTP or Treatment Discontinuation





- **Triplet cohort showed high DCT at 24 weeks and a long median PFS**

Drew Y et al. ESMO 2020;Abstract 814MO.

RTP RESEARCH TO PRACTICE

original reports

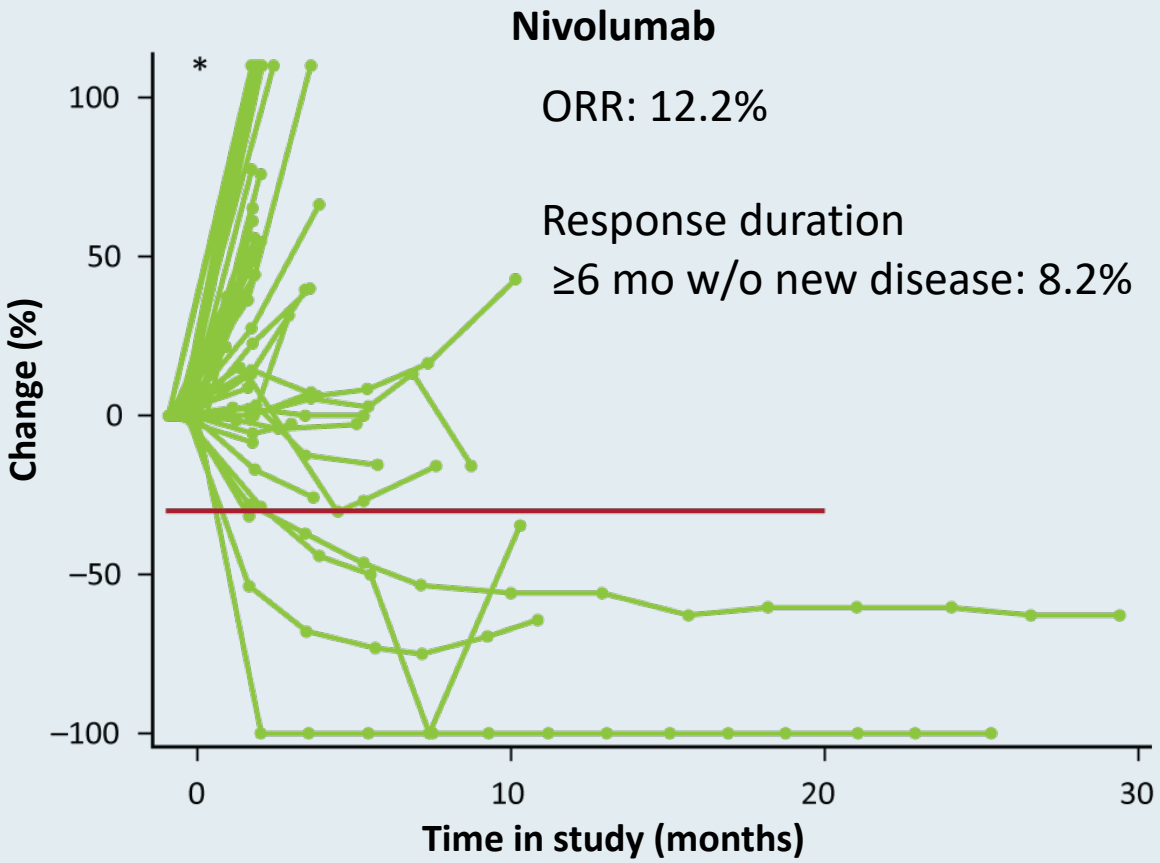
Randomized Phase II Trial of Nivolumab Versus Nivolumab and Ipilimumab for Recurrent or Persistent Ovarian Cancer: An NRG Oncology Study

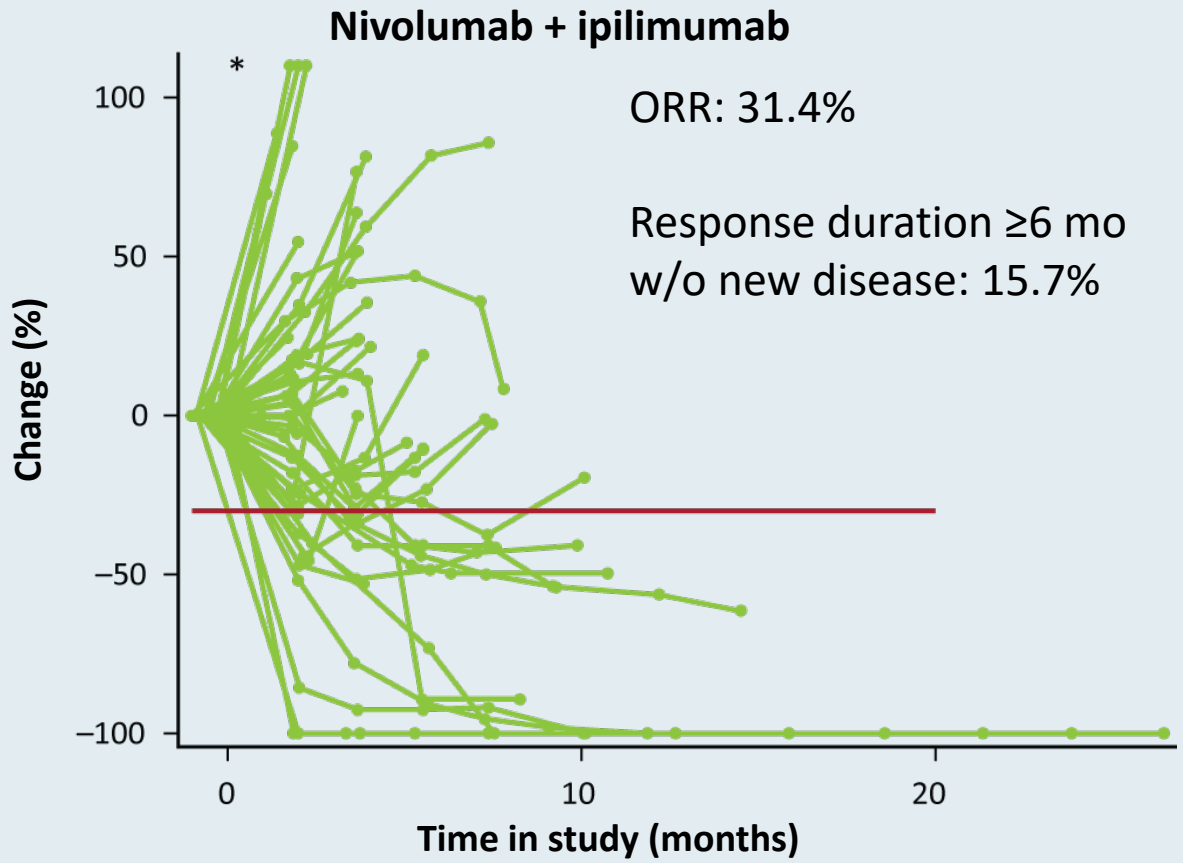
Dmitriy Zamarin, MD, PhD[1]; Robert A. Burger, MD[2]; Michael W. Sill, PhD[3]; Daniel J. Powell Jr, PhD[4]; Heather A. Lankes, PhD, MPH[5]; Michael D. Feldman, MD, PhD[4]; Oliver Zivanovic, MD, PhD[1]; Camille Gunderson, MD[6]; Emily Ko, MD, MSCR[2]; Cara Mathews, MD[7]; Sudarshan Sharma, MD[8]; Andrea R. Hagemann, MD[9]; Samir Khleif, MD[10]; and Carol Aghajanian, MD[1]

J Clin Oncol 2020;38:1814-23

NRG GY003 Phase II Study of Nivolumab with or without Ipilimumab in Recurrent or Persistent OC

(PFI <6 months: 62%, ≥2 prior cytotoxic regimens: 70%+ of patients)





PD-L1 expression was not significantly associated with response in either treatment group

Zamarin D et al. *J Clin Oncol* 2020;38:1814-23.

Select Ongoing Phase III Trials of Immunotherapy in Combination with PARP Inhibitors

Trial name (Trial identifier)	N	Setting	Treatment arms
ATHENA (NCT03522246)	1,012	Maintenance therapy after 1L platinum-based chemo	• Rucaparib + nivolumab • Rucaparib + placebo • Nivolumab + placebo • Placebo
DUO-O (NCT03737643)	1,056	Maintenance therapy after 1L platinum-based chemo/bev ± durvalumab	• Bevacizumab • Bevacizumab + durvalumab • Bevacizumab + durvalumab + olaparib

www.clinicaltrials.gov. Accessed August 2020.

HER2-Positive Endometrial Cancer

HER2 Testing in Endometrial Serous Carcinoma

Current Criteria (Approved or Proposed) for HER2 Positivity by Immunohistochemistry (IHC) and Fluorescence In Situ Hybridization (FISH) in Different Tumor Types

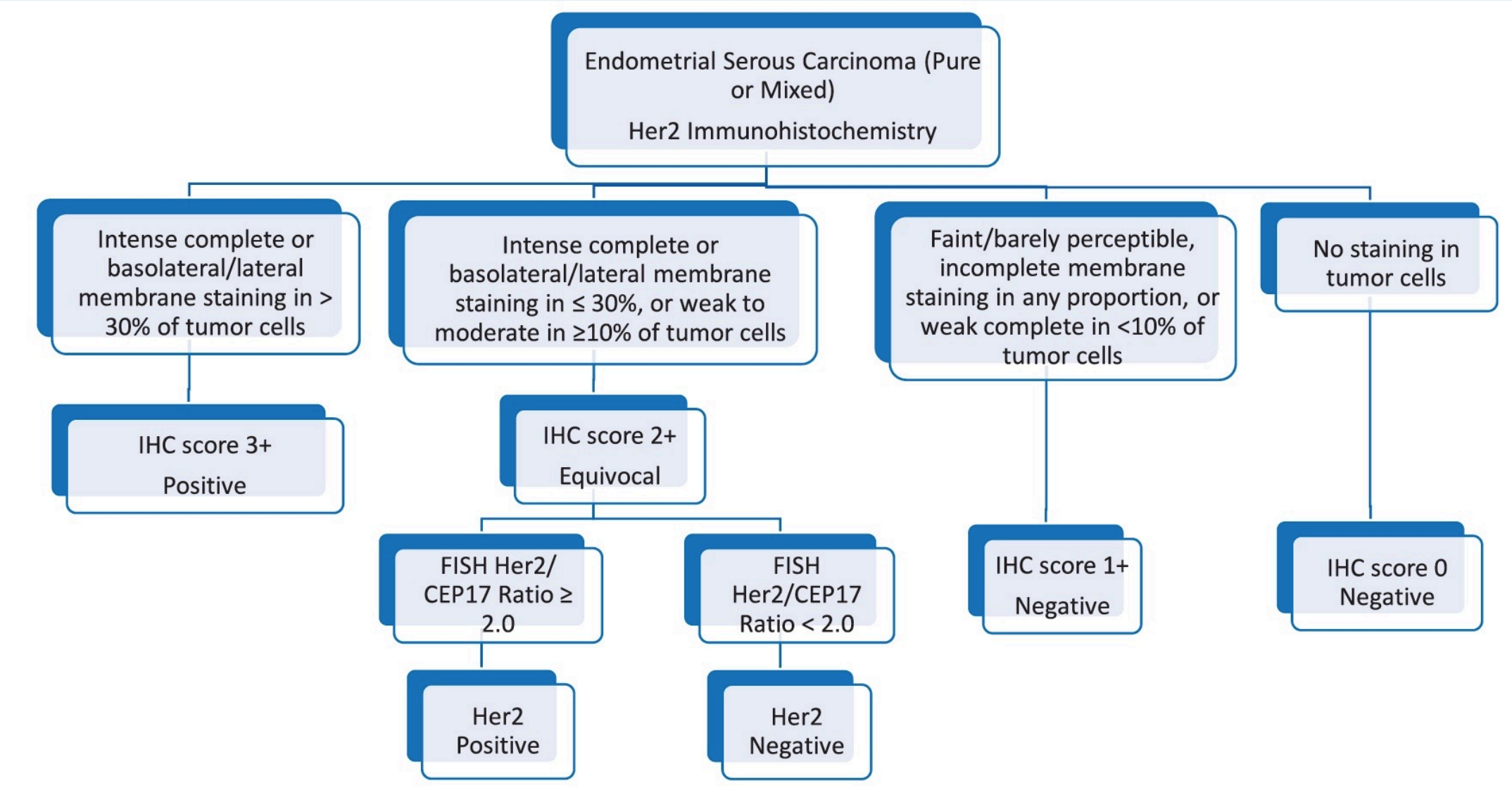
	Breast (ASCO/CAP 2018)[23]	Gastric (ASCO/CAP 2016)[36]	Colorectal (HERACLES Trial)[39]	Endometrial Serous (Fader et al Clinical Trial)[21]
HER2 IHC 3+	>10% circumferential, strong, complete	≥10%, strong complete, or basolateral/lateral	≥50% strong complete, or basolateral/lateral	>30% strong complete or basolateral/lateral
HER2 FISH amplification	*HER2*/CEP17 ratio ≥2.0 and *HER2* signal ≥4.0 per nucleus OR ratio <2.0 and *HER2* signal ≥6.0 per nucleus (if IHC score 2+ or 3+)	*HER2*/CEP17 ratio ≥2.0 OR ratio <2.0 and *HER2* signal >6.0 per nucleus	*HER2*/CEP17 ratio ≥2.0 in ≥50% of cells	*HER2*/CEP17 ratio ≥2.0

Abbreviations: ASCO, American Society of Clinical Oncology; CAP, College of American Pathologists.

Buza N. *Arch Pathol Lab Med* 2020;[Online ahead of print].

RTP RESEARCH TO PRACTICE

Proposed HER2 Testing Algorithm for Endometrial Serous Carcinoma



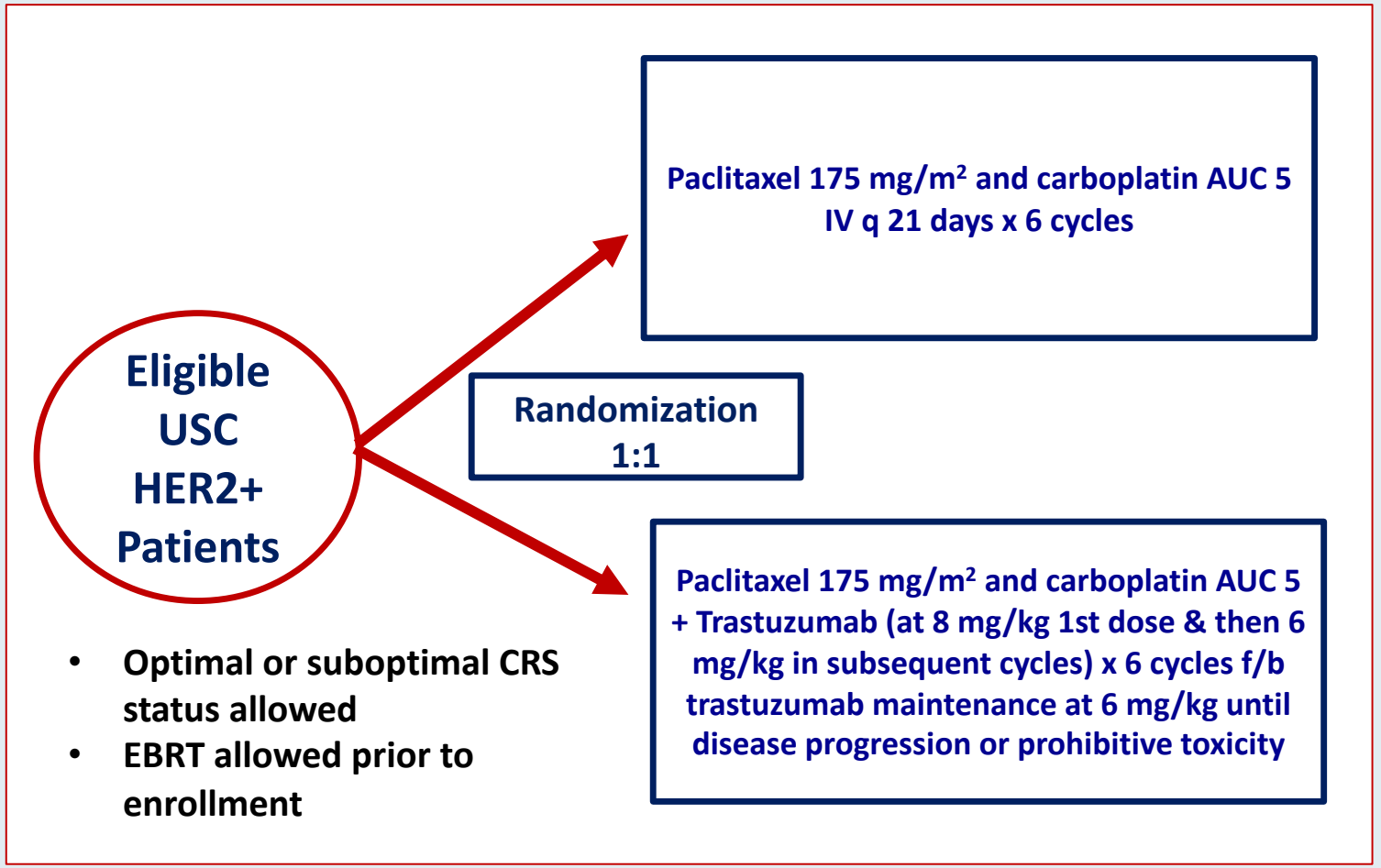
Buza N. *Arch Pathol Lab Med* 2020;[Online ahead of print].

RTP RESEARCH TO PRACTICE

Randomized Phase II Trial of Carboplatin/Paclitaxel versus Carboplatin/Paclitaxel/Trastuzumab for Uterine Serous Carcinoma That Overexpresses HER2/Neu: Updated Survival Analysis

Eligibility

- FIGO Stage III-IV USC or recurrent USC
- HER2/neu+ USC as defined by IHC score of 3+ (ASCO/CAP 2007 criteria) or 2+ with gene amplification confirmed by FISH
- Patients diagnosed with recurrence were required to have measurable disease, defined as at least one target lesion per RECIST 1.1
- Patients with recurrent disease may not have received >3 prior chemotherapies for treatment of their EC, and a treatment-free interval of >6 months from last C/T was required for patients with recurrent disease

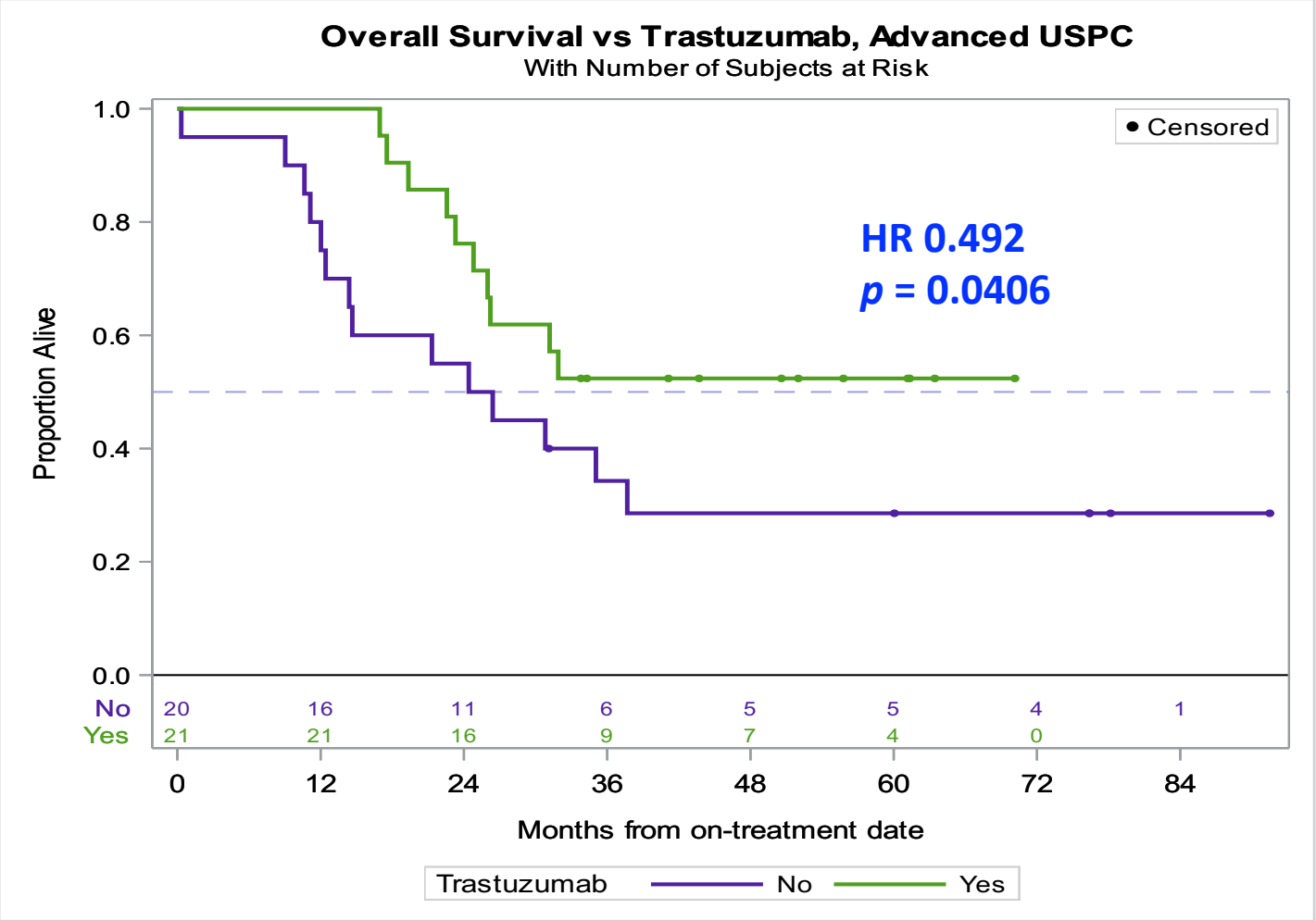


Fader AN et al. *Clin Cancer Res* 2020;26:3928-35.

Courtesy of David M O'Malley, MD

Overall Survival with the Addition of Trastuzumab to Carboplatin/ Paclitaxel for Advanced Uterine Serous Papillary Carcinoma (USPC)

- Benefit was particularly striking in the Stage III-IV pts, with a median OS of 25.4 mo (control) compared with an unreached median OS (experimental; *p* = 0.0406, HR 0.492)



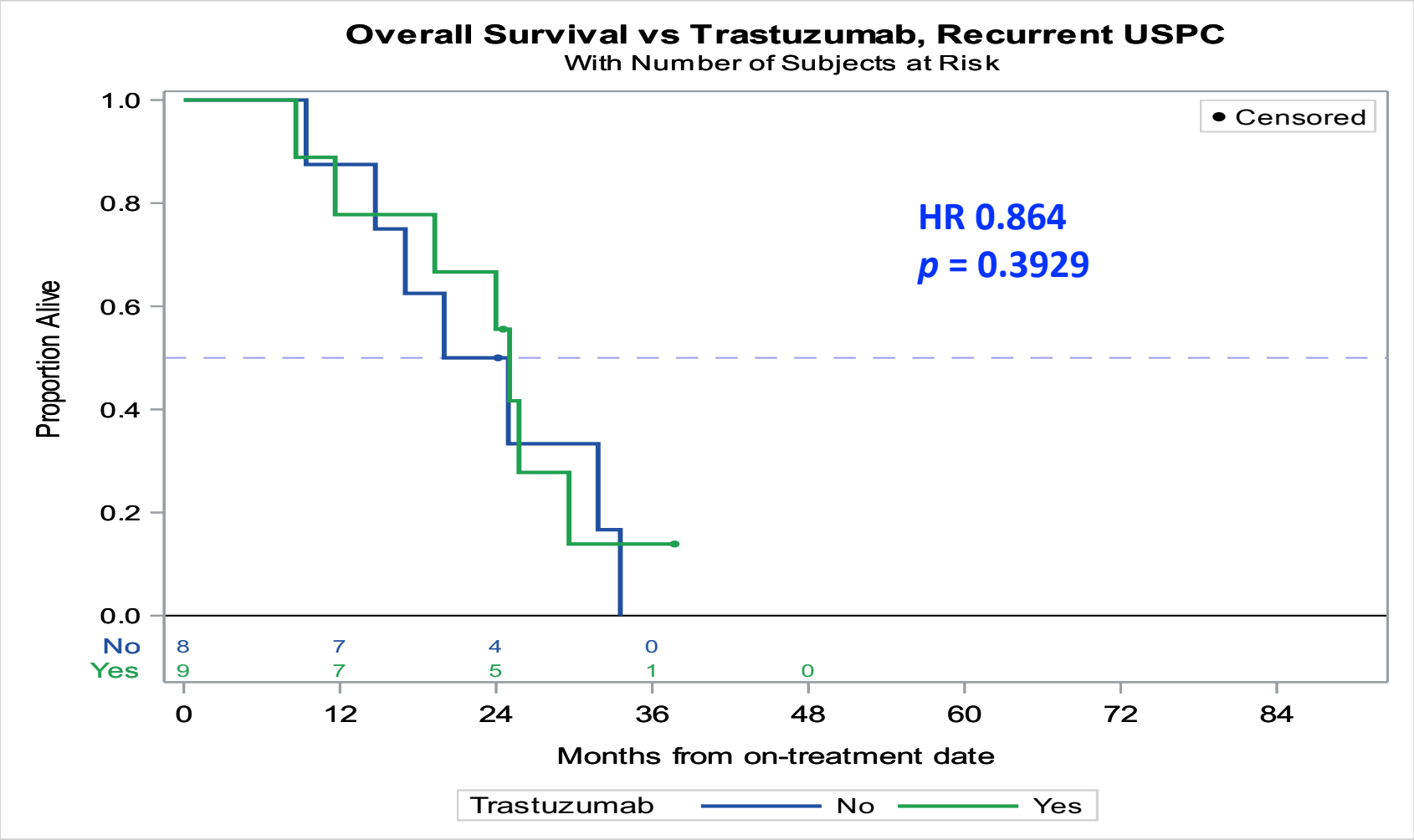
Fader AN et al. *Clin Cancer Res* 2020;26:3928-35.

Courtesy of David M O'Malley, MD

RTP RESEARCH TO PRACTICE

Overall Survival with the Addition of Trastuzumab to Carboplatin/Paclitaxel for Recurrent USPC

- No significant OS benefit was observed in the recurrence cohort



Fader AN et al. *Clin Cancer Res* 2020;26:3928-35.

Courtesy of David M O'Malley, MD

Carboplatin/Paclitaxel/Trastuzumab: Summary

- First trial of targeted therapy in USC ONLY patients
- Demonstration that HER2 is an important prognostic and actionable target in USC
- NCCN designation of C/T/Trastuzumab as a preferred regimen in HER2+ USC (Level IIA)

Fader AN et al. SGO 2020

Courtesy of David M O'Malley, MD

Phase II DESTINY-PanTumor02 Study Design

Trial Identifier: NCT04482309 (Not yet recruiting)
Estimated Enrollment: 280

Eligibility

- Locally advanced, unresectable or metastatic disease
- Disease progression after prior treatment or no satisfactory alternative treatment option
- Prior HER2-targeted therapy allowed
- HER2 expression may be based on local or central assessment

Trastuzumab deruxtecan

7 cohorts will be evaluated:
Endometrial cancer, cervical cancer, ovarian cancer, bladder cancer, biliary tract cancer, pancreatic cancer and rare tumors

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

https://www.clinicaltrials.gov/ct2/show/NCT04482309.

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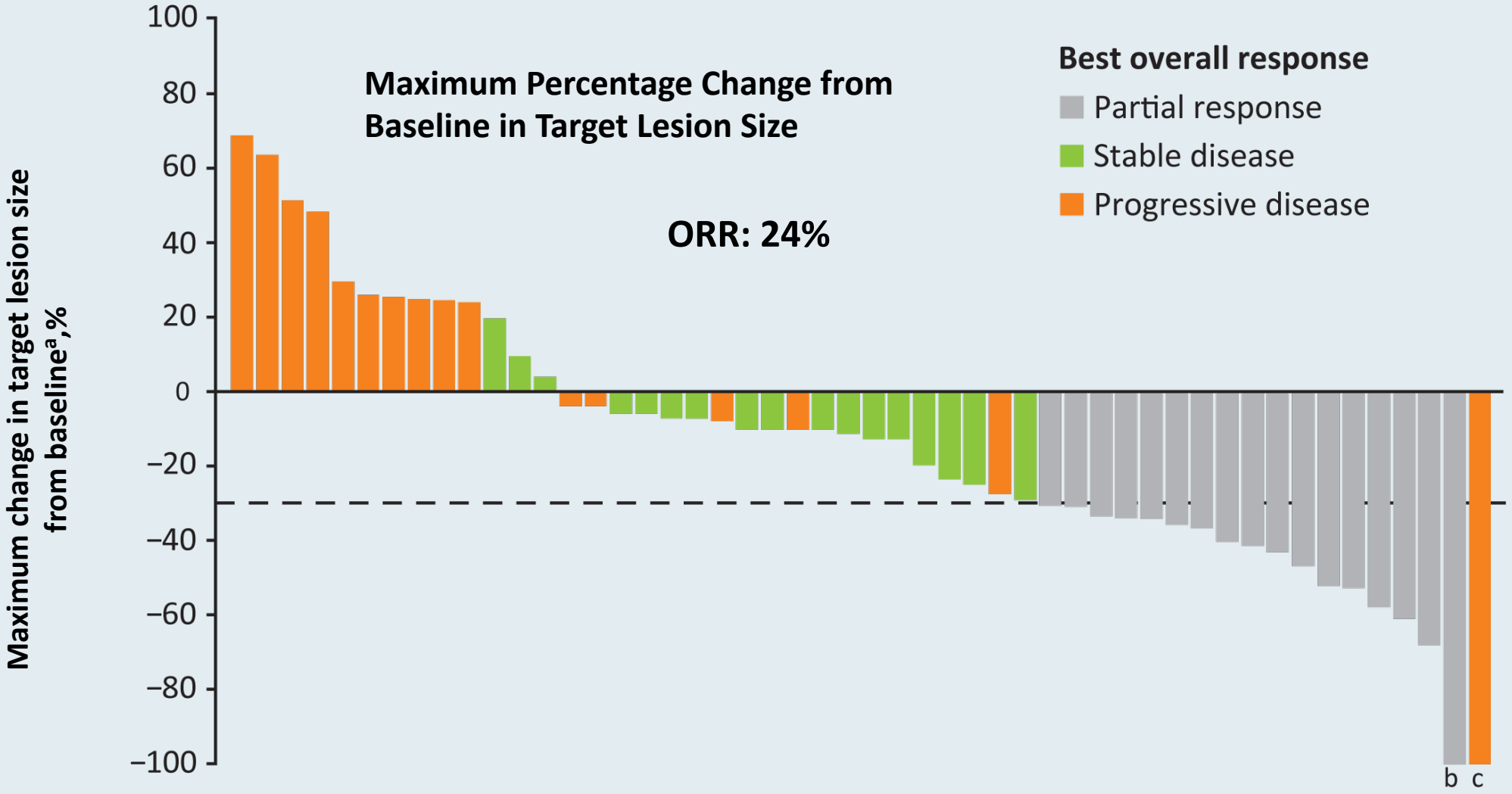
Tisotumab Vedotin and Other Novel Agents in Gynecologic Cancers

innovaTV 201: Best Overall Response to TV



Hong DS et al. *Clin Cancer Res* 2020;26:1220-8.

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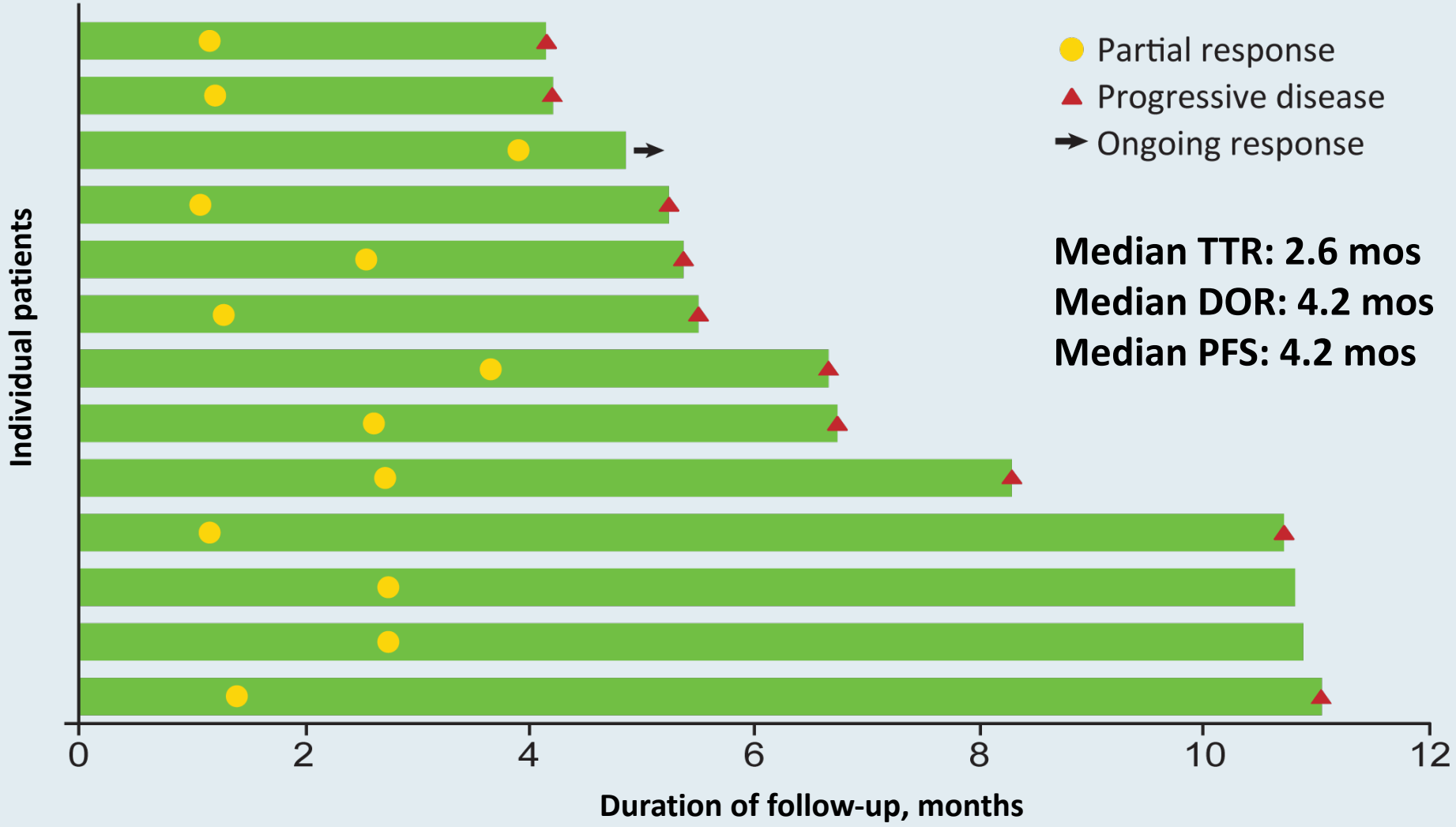
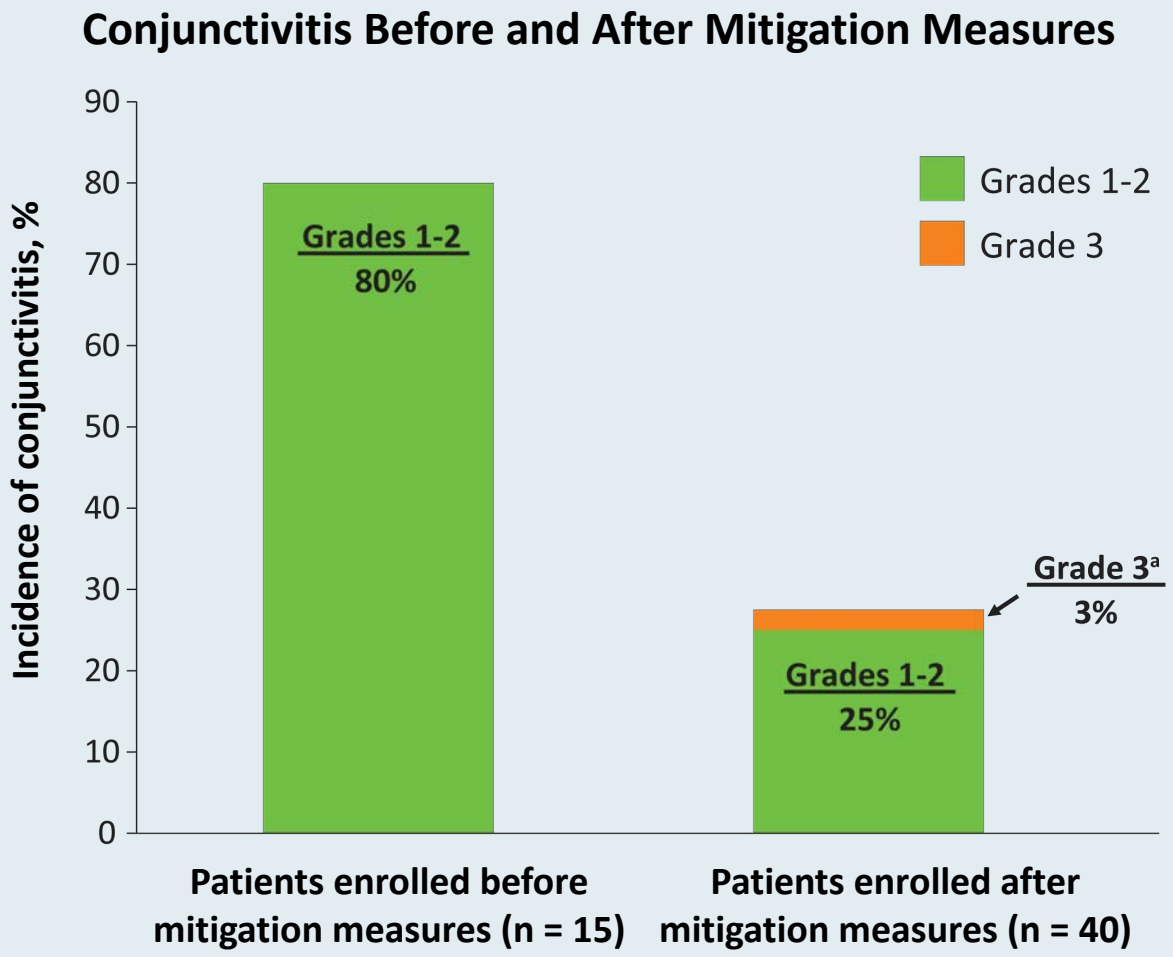
innovaTV 201: Time to Response and Duration of Response in Patients with a Confirmed PR to TV



Hong DS et al. *Clin Cancer Res* 2020;26:1220-8.

innovaTV 201: Treatment-Emergent Adverse Events

Adverse events	N = 55	
	All grade	Grade ≥3
Fatigue	51%	9%
Nausea	49%	5%
Neuropathy	55%	11%
Bleeding-related AEs	73%	5%
Ocular AEs	65%	2%
Conjunctivitis	42%	2%
Dry eye	24%	0
Ulcerative keratitis	7%	0
Blepharitis	5%	0
Keratitis	5%	0



Hong DS et al. *Clin Cancer Res* 2020;26:1220-8.

[a] One patient with grade 3 conjunctivitis after mitigation measures were implemented. No grade 3 events were observed before mitigation measures were implemented.

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

In Partnership with Project Echo® and Florida Cancer Specialists

Wednesday, June 2, 2021
5:00 PM – 6:00 PM ET

Faculty

Walter Stadler, 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.

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