13th Annual Oncology Grand Rounds

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

Gynecologic Cancers

Tuesday, April 27, 2021
5:00 PM – 6:30 PM ET

Medical Oncologists

Robert L Coleman, MD
Thomas J Herzog, MD
Krishnansu S Tewari, MD

Oncology Nurse Practitioners

Paula J Anastasia, MN, RN, AOCN
Courtney Arn, CNP
Kimberly A Spickes, MNSc, RN, APRN, OCN, ACNP-BC

Moderator

Neil Love, MD

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Medical Oncologists

Robert L Coleman, MD
Chief Scientific Officer
US Oncology Research
Gynecologic Oncology
The Woodlands, Texas

Thomas J Herzog, MD
Paul and Carolyn Flory Professor
Deputy Director, University of Cincinnati Cancer Center
Vice-Chair, Quality and Safety
Department of Obstetrics and Gynecology
University of Cincinnati Medical Center
Associate Director, GOG Partners
Cincinnati, Ohio

Krishnansu S Tewari, MD
Professor and Division Director
Division of Gynecologic Oncology
University of California, Irvine
Irvine, California

Oncology Nurse Practitioners

Paula J Anastasia, MN, RN, AOCN
GYN Oncology Advanced Practice Nurse
University of California, Los Angeles
Los Angeles, California

Courtney Arn, CNP
The James Cancer Hospital and Solove Research Institute
The Ohio State University
Columbus, Ohio

Kimberly A Spickes, MNSc, RN, APRN, OCN, ACNP-BC
Nurse Practitioner
UAMS Division of Gynecologic Oncology
University of Arkansas for Medical Sciences
Little Rock, Arkansas

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Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Eisai Inc, GlaxoSmithKline and Merck.

Dr Love — Disclosures

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Data and Safety Monitoring Board/Committee	AstraZeneca Pharmaceuticals LP, VBL Therapeutics

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Dr Tewari — Disclosures

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Contracted Research (to Institution)	Regeneron Pharmaceuticals Inc
Data and Safety Monitoring Board/Committee	Iovance Biotherapeutics
Speakers Bureau	AstraZeneca Pharmaceuticals LP, Clovis Oncology, Eisai Inc, Merck, Tesaro, A GSK Company

Ms Anastasia — Disclosures

No relevant conflicts of interest to disclose.

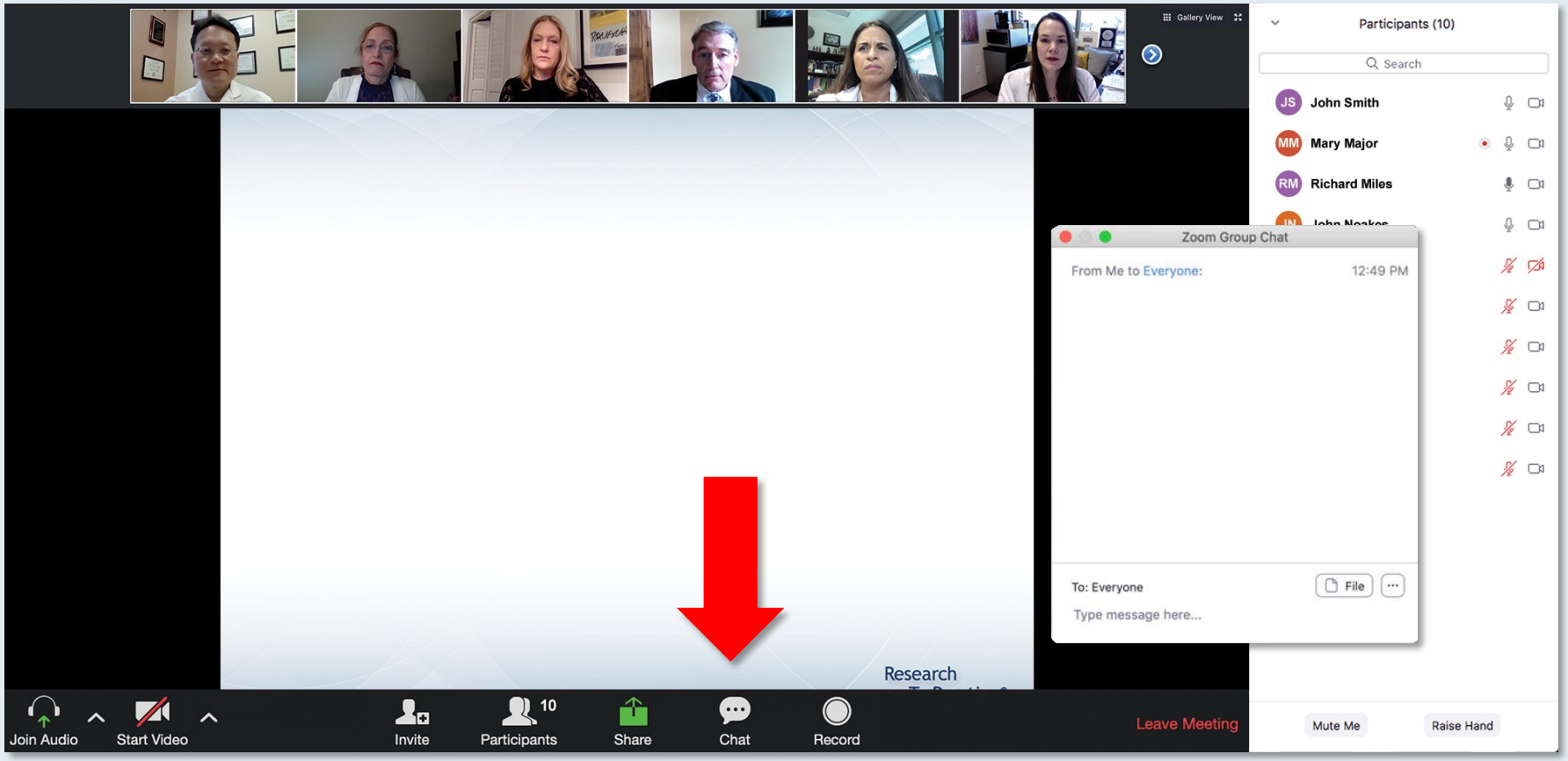
Ms Arn — Disclosures

No relevant conflicts of interest to disclose.

Ms Spickes — Disclosures

No relevant conflicts of interest to disclose.

We Encourage Clinicians in Practice to Submit Questions



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

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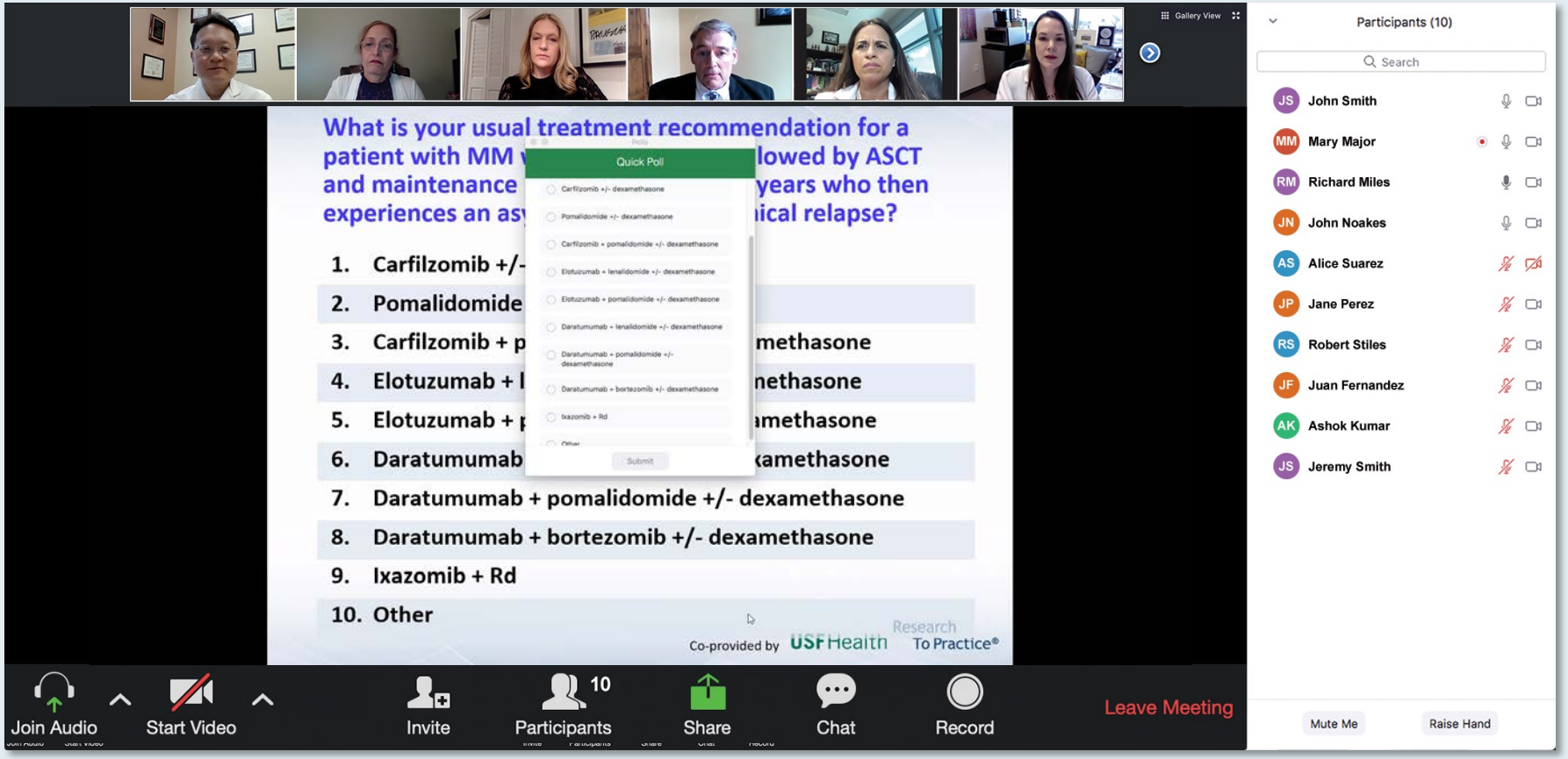
Familiarizing Yourself with the Zoom Interface

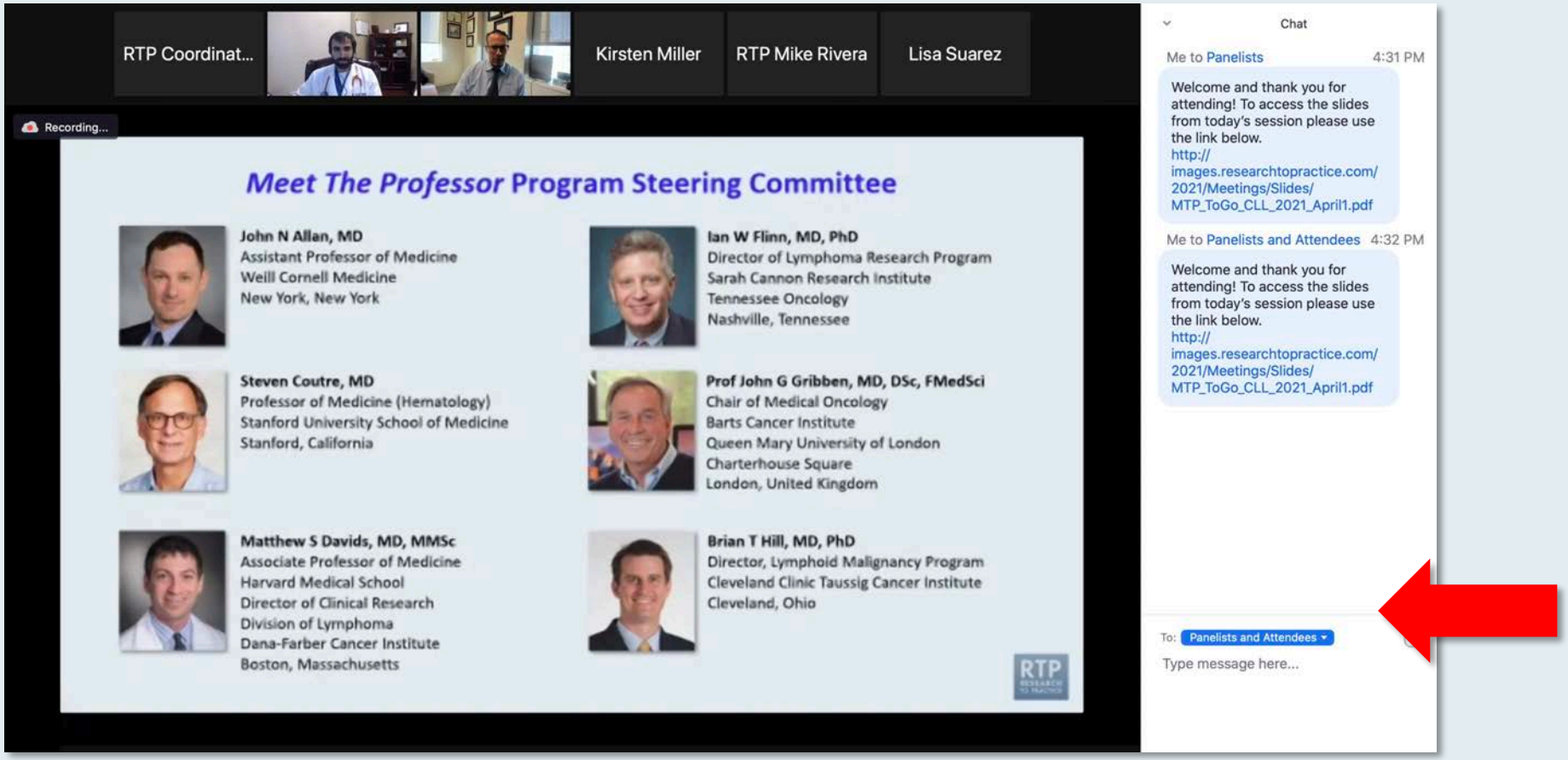
How to answer poll questions



When a poll question pops up, click your answer choice from the available options.

Familiarizing Yourself with the Zoom Interface

Expand chat submission box



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

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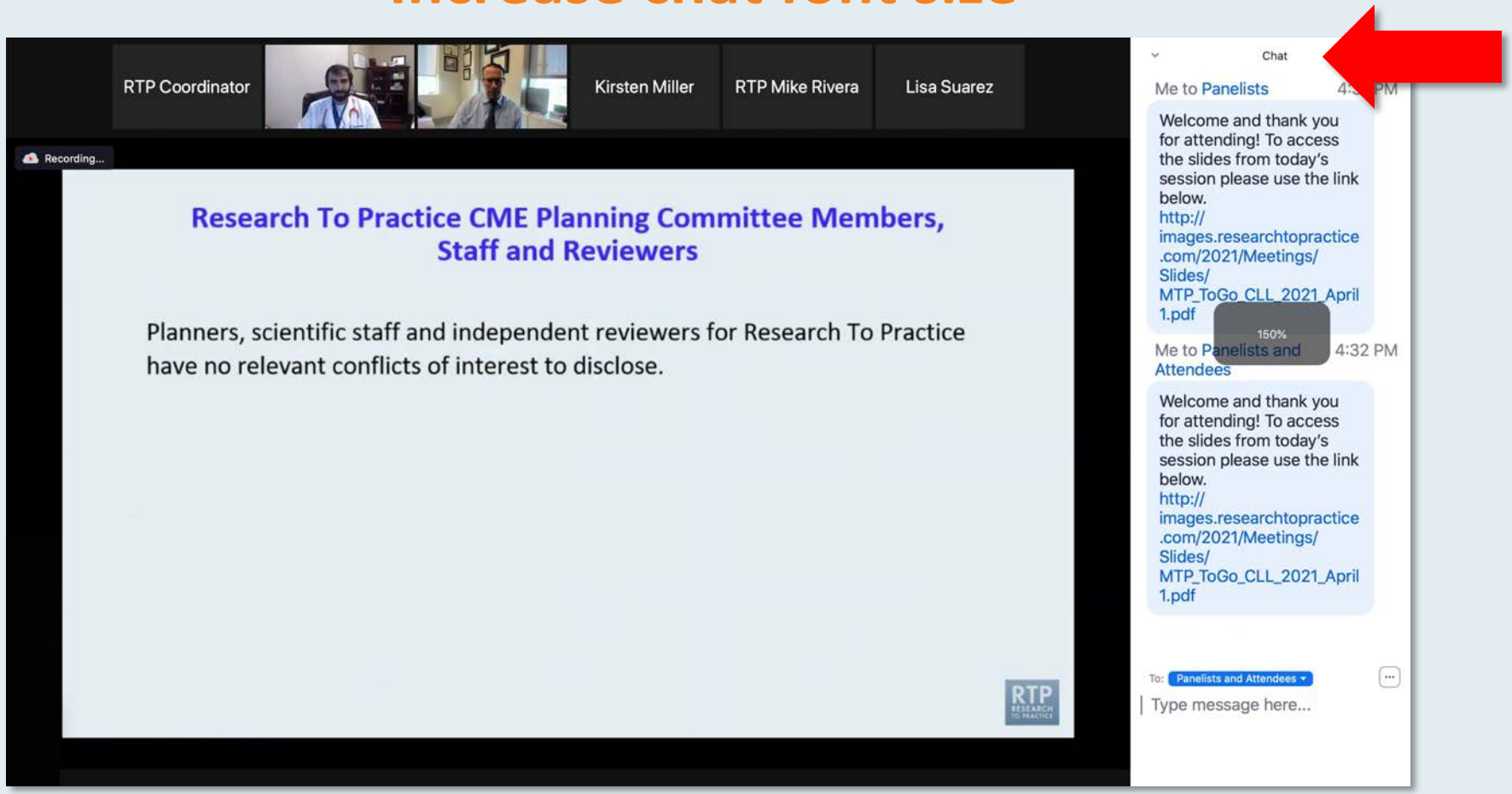
Familiarizing Yourself with the Zoom Interface

Increase chat font size



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

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WITH DR NEIL LOVE

PARP Inhibitors in Ovarian Cancer

DR ANTONIO GONZÁLEZ-MARTÍN
CLÍNICA UNIVERSIDAD DE NAVARRA

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

Non-Small Cell Lung Cancer
Tuesday, April 20, 2021
5:00 PM – 6:30 PM ET

Acute Myeloid Leukemia
Wednesday, April 21, 2021
12:00 PM – 1:00 PM ET

Colorectal and Gastroesophageal Cancers
Wednesday, April 21, 2021
4:45 PM – 5:45 PM ET

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

Hodgkin and Non-Hodgkin Lymphomas
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Urothelial Bladder Carcinoma
Wednesday, April 28, 2021
12:00 PM – 1:00 PM ET

Chronic Lymphocytic Lymphoma
Thursday, April 29, 2021
8:30 AM – 10:00 AM ET

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

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

In Partnership with Project Echo® and Florida Cancer Specialists

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

Faculty

Chung-Han Lee, MD, PhD

Moderator

Neil Love, MD

Current Concepts and Recent Advances in Oncology

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

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

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Saturday, May 15, 2021

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

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

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

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

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Saturday, May 15, 2021

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

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

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

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

A Daylong Multitumor Educational Webinar
in Partnership with Florida Cancer Specialists

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

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RESEARCH
TO PRACTICE

Saturday, May 22, 2021

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

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

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

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

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

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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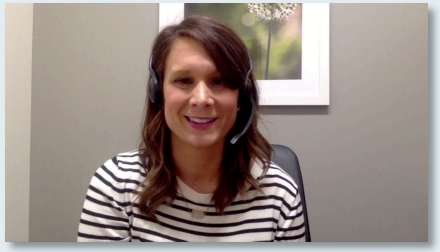

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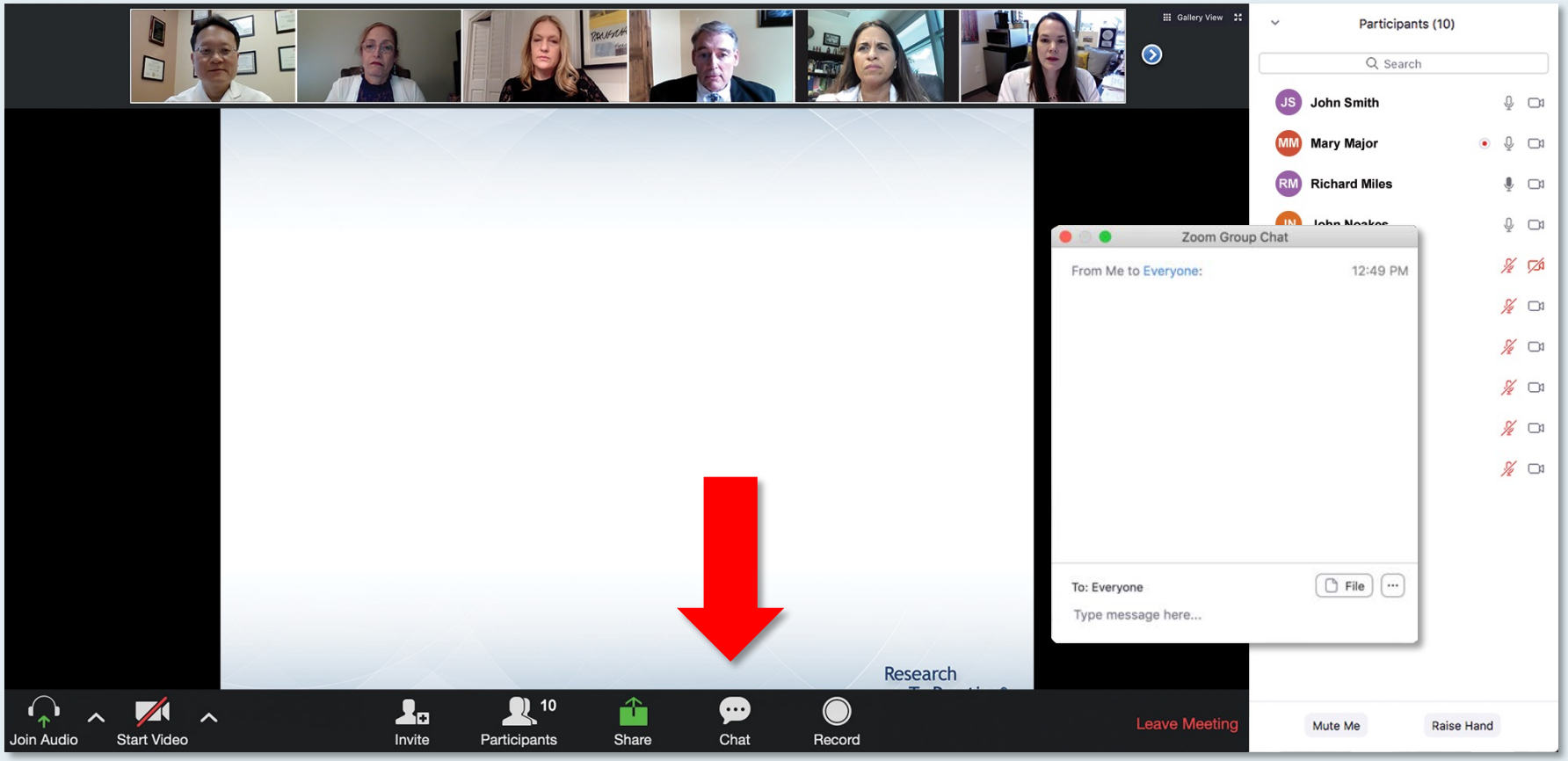

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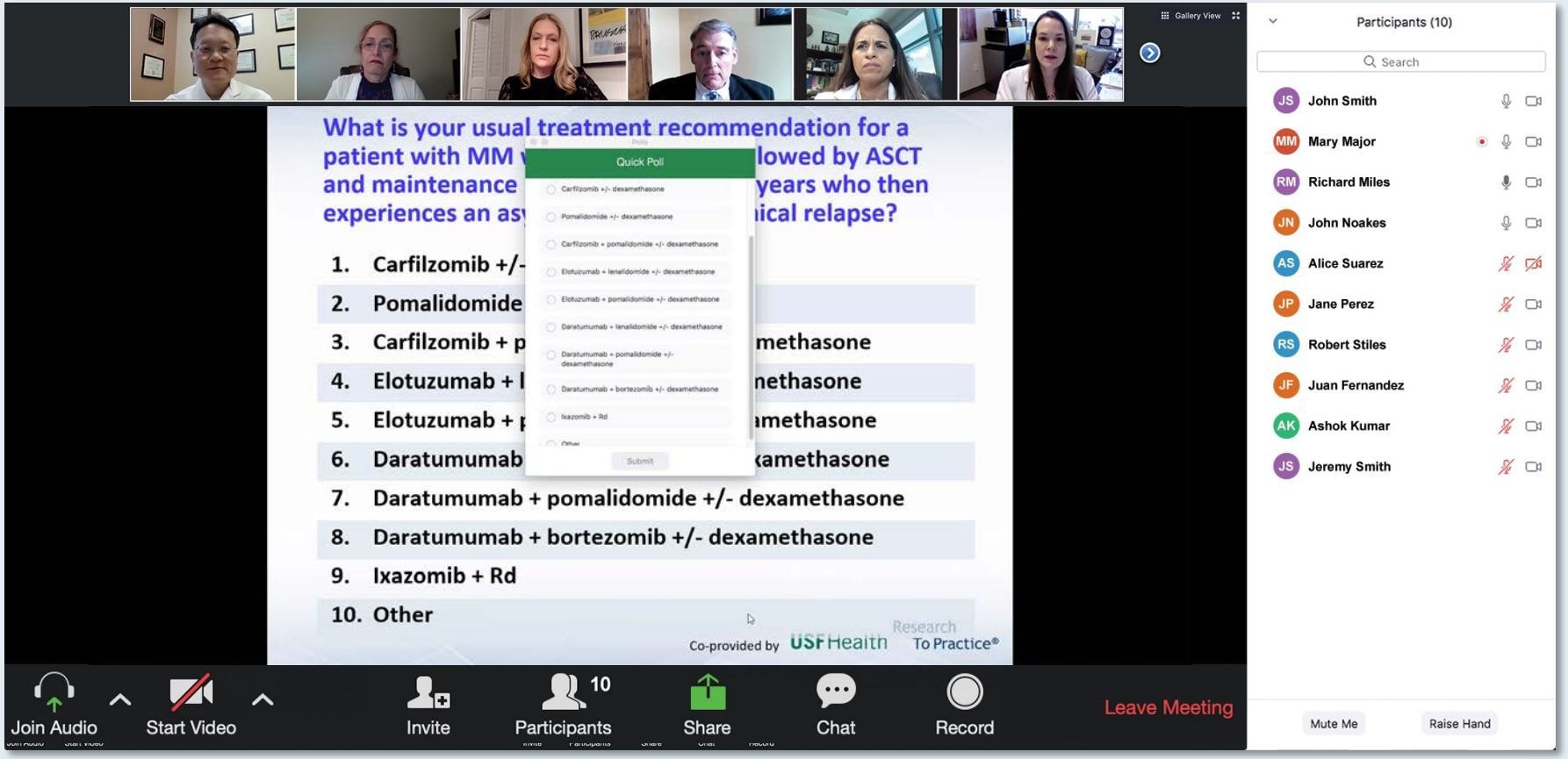

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Medical Oncologists

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Duke Cancer Institute
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Mayo Clinic
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Tennessee Oncology
Nashville, Tennessee

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Chair, Genitourinary Oncology Multidisciplinary Team
Professor of Oncology and Medicine
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Director, Prostate Cancer Research
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Thomas J Herzog, MD
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Deputy Director, University of Cincinnati Cancer Center
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Medical Oncologists

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Senior Physician
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Associate Professor of Medicine
Harvard Medical School
Boston, Massachusetts

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University of California, Los Angeles
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The Ohio State University
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Oncology Nurse Practitioners

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Assistant Professor of Medicine
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Mayo Clinic
Rochester, Minnesota

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Rochester, Minnesota

Mollie Moran, APRN-CNP, AOCNP
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The Ohio State University
Columbus, Ohio

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Cleveland, Ohio

Kimberly A Spickes, MNSc, RN, APRN, OCN, ACNP-BC
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MD Anderson Cancer Center
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Ronald Stein, JD, MSN, NP-C, AOCNP
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USC Norris Comprehensive Cancer Center
Los Angeles, California

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Perelman Center for Advanced Medicine
University of Pennsylvania Medical Center
Faculty, University of Pennsylvania School of Nursing
Philadelphia, Pennsylvania

Elizabeth Zerante, MS, AGACNP-BC
APN Inpatient Hematopoietic Cellular Therapy Service
University of Chicago Medicine
Chicago, Illinois

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Oncology Grand Rounds Nursing Webinar Series

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

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WITH DR NEIL LOVE

A Personal Experience with COVID-19

DR NOOPUR RAJE

MASSACHUSETTS GENERAL HOSPITAL

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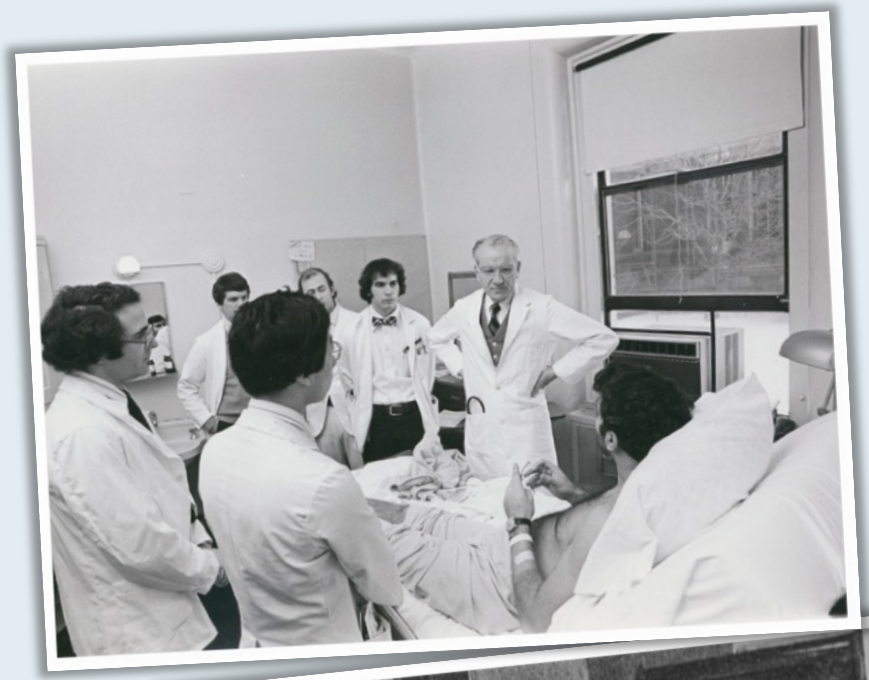

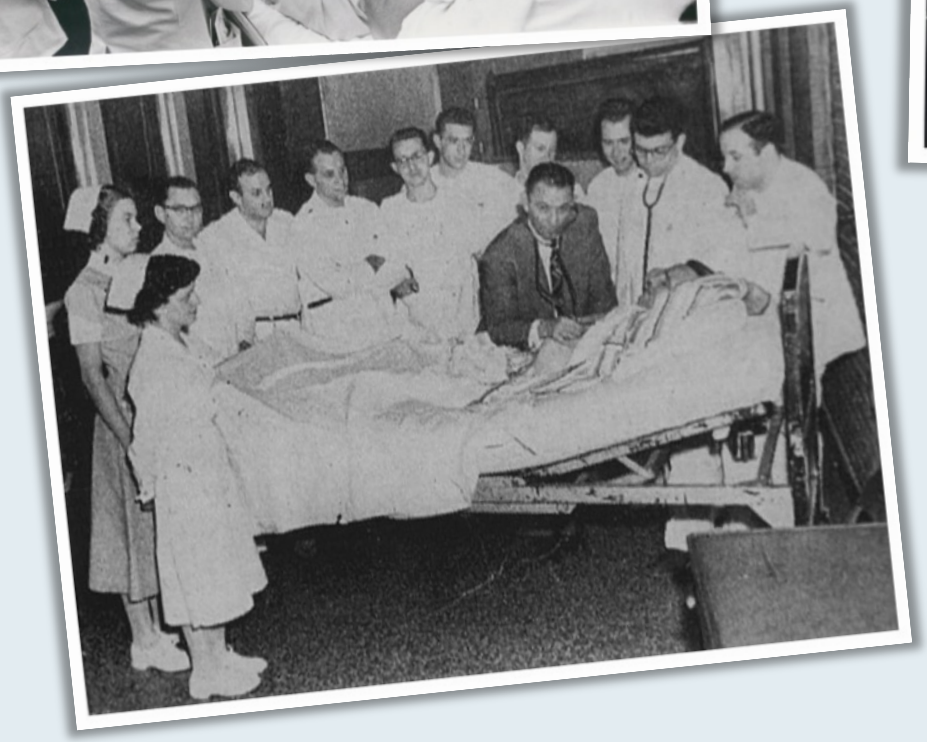


The Birmingham News

13th Annual Oncology Grand Rounds

Oncology Nurse Practitioners

Case Presentations

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

Clinical Investigators

Oncology Strategy

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

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RESEARCH
TO PRACTICE

13th Annual Oncology Grand Rounds

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

Gynecologic Cancers

Tuesday, April 27, 2021
5:00 PM – 6:30 PM ET

Medical Oncologists

Robert L Coleman, MD
Thomas J Herzog, MD
Krishnansu S Tewari, MD

Oncology Nurse Practitioners

Paula J Anastasia, MN, RN, AOCN
Courtney Arn, CNP
Kimberly A Spickes, MNSc, RN, APRN, OCN, ACNP-BC

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE


Paula J Anastasia, NP MN AOCN


Courtney R Arn, APRN-CNP


Kimberly A Spickes, MNSc, RN, APRN, OCN, ACNP-BC

Agenda

Module 1: Ovarian Cancer

- Case 1 (Ms Spickes): A 52-year-old woman with Stage IIIA2 ovarian cancer and a somatic BRCA2 mutation
- Case 2 (Ms Anastasia): A 59-year-old woman with BRCA wild-type, HRD-proficient ovarian cancer
- Case 3 (Ms Arn): A 51-year-old woman with Stage IIIC ovarian cancer and a germline BRCA1 mutation

Module 2: Endometrial Cancer

- Case 4 (Ms Spickes): A 68-year-old woman with recurrent endometrial cancer, MSI high
- Case 5 (Ms Arn): An 81-year-old woman with recurrent endometrial cancer, MMR proficient
- Case 6 (Ms Anastasia): A 60-year-old woman with recurrent endometrial cancer, MMR deficient
- Case 7 (Ms Anastasia): A 50-year-old woman with recurrent endometrial cancer, MMR proficient

Module 3: Cervical Cancer – Relapsed Disease

- Case 8 (Ms Arn): A 58-year-old woman with recurrent cervical cancer, PD-L1-positive
- Case 9 (Ms Arn): A 37-year-old woman with recurrent cervical cancer, PD-L1-negative

Ms Spickes: Connecting with patients in the age of COVID-19

Agenda

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At a minimum, all patients with ovarian cancer should have the following assay(s) conducted at diagnosis regardless of family history of cancer.

1. BRCA germline testing
2. BRCA somatic testing
3. Multiplex germline testing
4. Multiplex somatic testing
5. Both 1 and 2
6. Both 3 and 4
7. I don’t know

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Bevacizumab can be particularly effective in patients with ovarian cancer who have ascites and/or pleural effusion…

1. Agree
2. Disagree
3. I don’t know

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In general, postoperative, postchemotherapy primary maintenance therapy with a PARP inhibitor is considered standard for patients with a germline or somatic BRCA mutation.

1. Agree
2. Disagree
3. I don’t know

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Which of the following PARP inhibitors is approved for use as primary maintenance therapy for patients with BRCA wild-type ovarian cancer?

1. Olaparib
2. Niraparib
3. Rucaparib
4. Veliparib
5. Both 1 and 2
6. All of the above
7. I don’t know

Which of the following PARP inhibitors is approved in combination with bevacizumab for use as primary maintenance therapy after first-line platinum-based chemotherapy?

1. Olaparib
2. Niraparib
3. Rucaparib
4. Veliparib
5. Both 1 and 2
6. All of the above
7. I don’t know

What was the duration of treatment with olaparib and niraparib in the Phase III trials evaluating maintenance therapy with PARP inhibitors after debulking surgery and first-line platinum-based chemotherapy?

1. 2 years for both
2. 3 years for both
3. 2 years for olaparib, 3 years for niraparib
4. 2 years for niraparib, 3 years for olaparib
5. I don’t know

Case Presentation – A 52-year-old woman with Stage IIIA2 ovarian cancer and a somatic BRCA2 mutation

Ms Spickes

- Past medical history of cerebral palsy and stroke, presents to the emergency room with pain and is diagnosed with ovarian cancer
- Surgery → adjuvant chemotherapy x 6 cycles
- Maintenance olaparib
- Dose reduction to mitigate side effects

Ms Anastasia: Genetic testing and counseling; use of neoadjuvant therapy

Case Presentation – A 59-year-old woman with BRCA wild-type, HRD-proficient ovarian cancer

Ms Anastasia

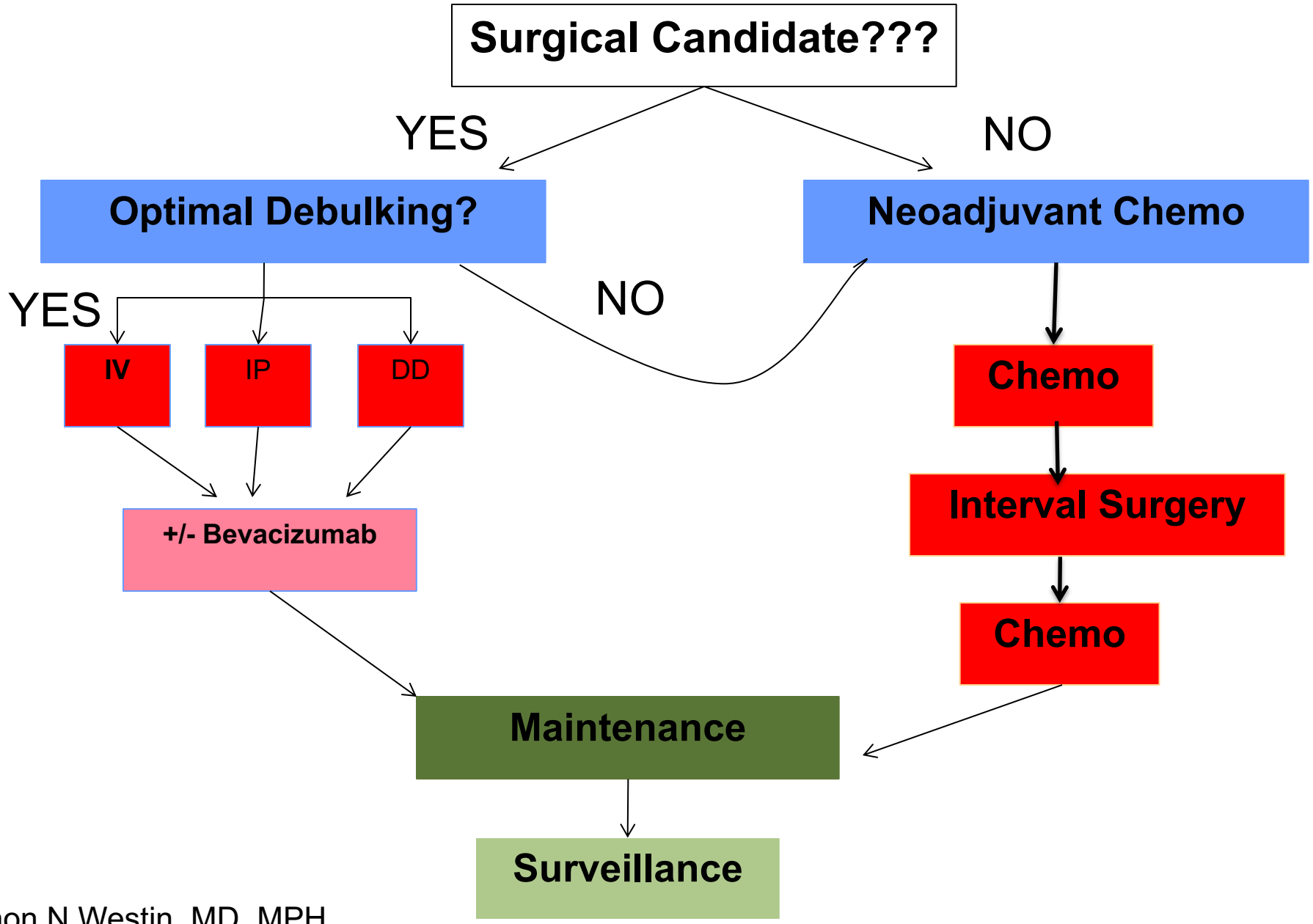
- Former pharmaceutical sales representative presents with ascites and is diagnosed with ovarian cancer
- Neoadjuvant carboplatin/docetaxel + bevacizumab
- Maintenance niraparib (200 mg QD)
- Patient remains NED after 6 months

Case Presentation – A 51-year-old woman with Stage IIIC ovarian cancer and a germline BRCA1 mutation

Ms Arn

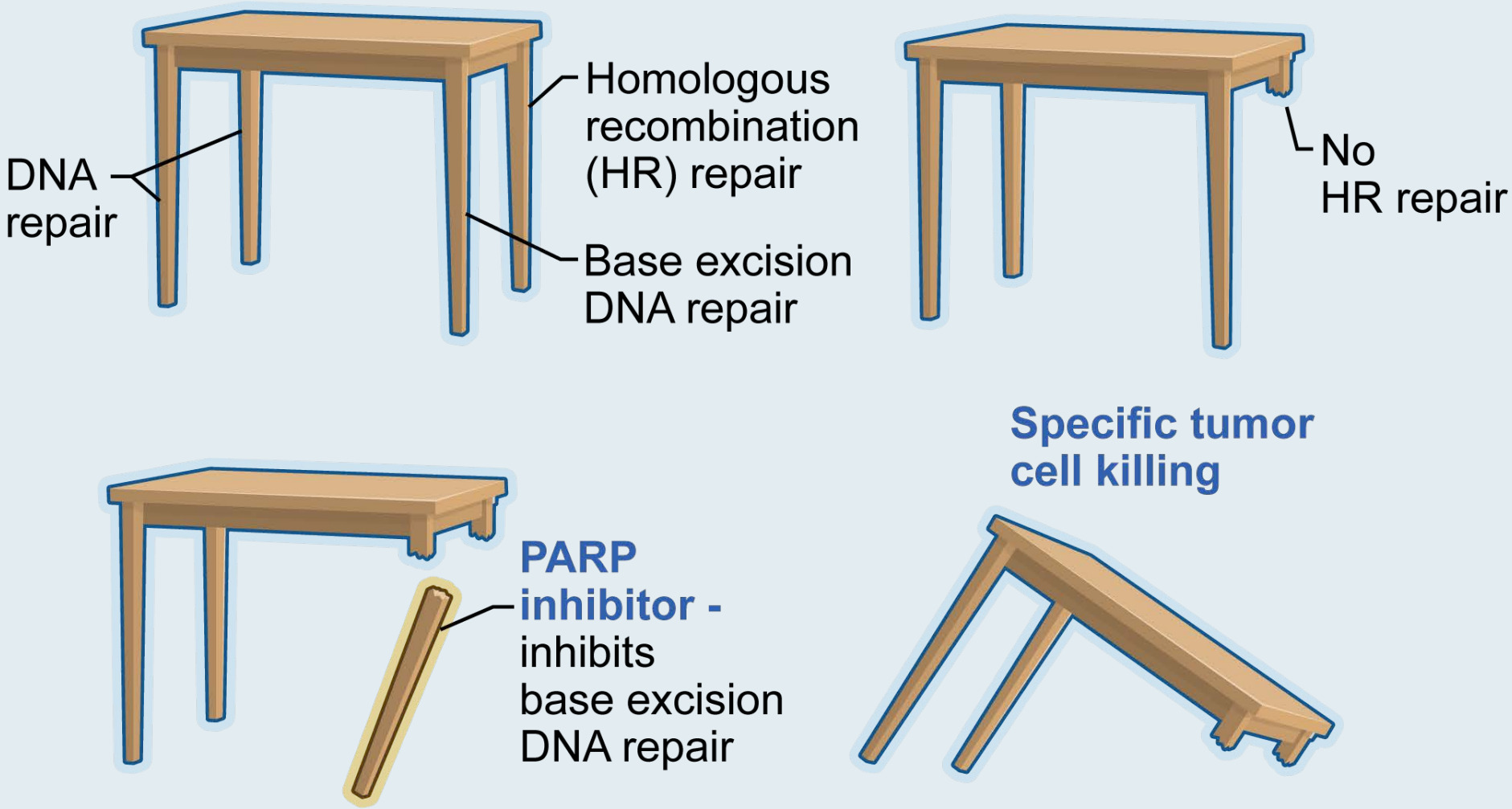
- Married social worker and mother of a 9-year-old son is diagnosed with high-grade adenocarcinoma of the ovary
- Neoadjuvant carboplatin/paclitaxel x 4 cycles → interval tumor reduction surgery → carboplatin/paclitaxel x 3 cycles
- Maintenance olaparib
- Risk of MDS and/or AML associated with PARP inhibitors

New Advanced Ovarian Cancer



Courtesy, Shannon N Westin, MD, MPH

Mechanism of Cell Death from Synthetic Lethality Induced by PARP Inhibition



Courtesy of Jenny C Chang, MD

Current FDA-Approved and Investigational PARP Inhibitors: Differences

PARP inhibitor	FDA approvals	PARP trapping potency	PARPi target selectivity (strength of binding)	Dose
Olaparib	Ovarian, breast, pancreatic, prostate	1	Potent PARP1 inhibitor, less selective	300 mg BID
Rucaparib	Ovarian, prostate	1	Potent PARP1 inhibitor, less selective	600 mg BID
Niraparib	Ovarian	~2	Selective inhibitor of PARP1 and 2	300 mg qd
Veliparib	None	<0.2	Potent PARP1 inhibitor, less selective	400 mg BID
Talazoparib	Breast	~100	Potent PARP1 inhibitor, less selective	1 mg qd

Lim JSJ, Tan DSP. *Cancers* 2017;9(8):pii:E109.

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Phase III First-Line PARPi Maintenance Trials

Study Design	SOLO-1 (N=451)	PAOLA-1 (N=612)	PRIMA (N=620)	VELIA (N=1140)
Treatment arms vs placebo	**Olaparib (n=260)**	**Bevacizumab ± Olaparib**	**Niraparib**	**Veliparib**
Patient Population	*BRCA* mutation	All comers	All comers	*All comers*
Treatment Duration	24 months	15 months for Bev 24 months for Olaparib	36 months or until PD	24 months

Burger RA, *N Engl J Med* 2011; Norquist B *Clin Cancer Res* 2018*; Bevacizumab* prescribing information; Moore K, NEJM 2018; Gonzalez-Martin NEJM 2019; Ray-Coquard NEJM 2019; Coleman NEJM 2019

Courtesy of Shannon N Westin, MD, MPH

RTP RESEARCH TO PRACTICE

Phase III Olympia Trial of Adjuvant Olaparib for High-Risk HER2-Negative Localized Breast Cancer with a BRCA Mutation Crossed the Superiority Boundary for Invasive Disease-Free Survival

Press Release – February 17, 2021

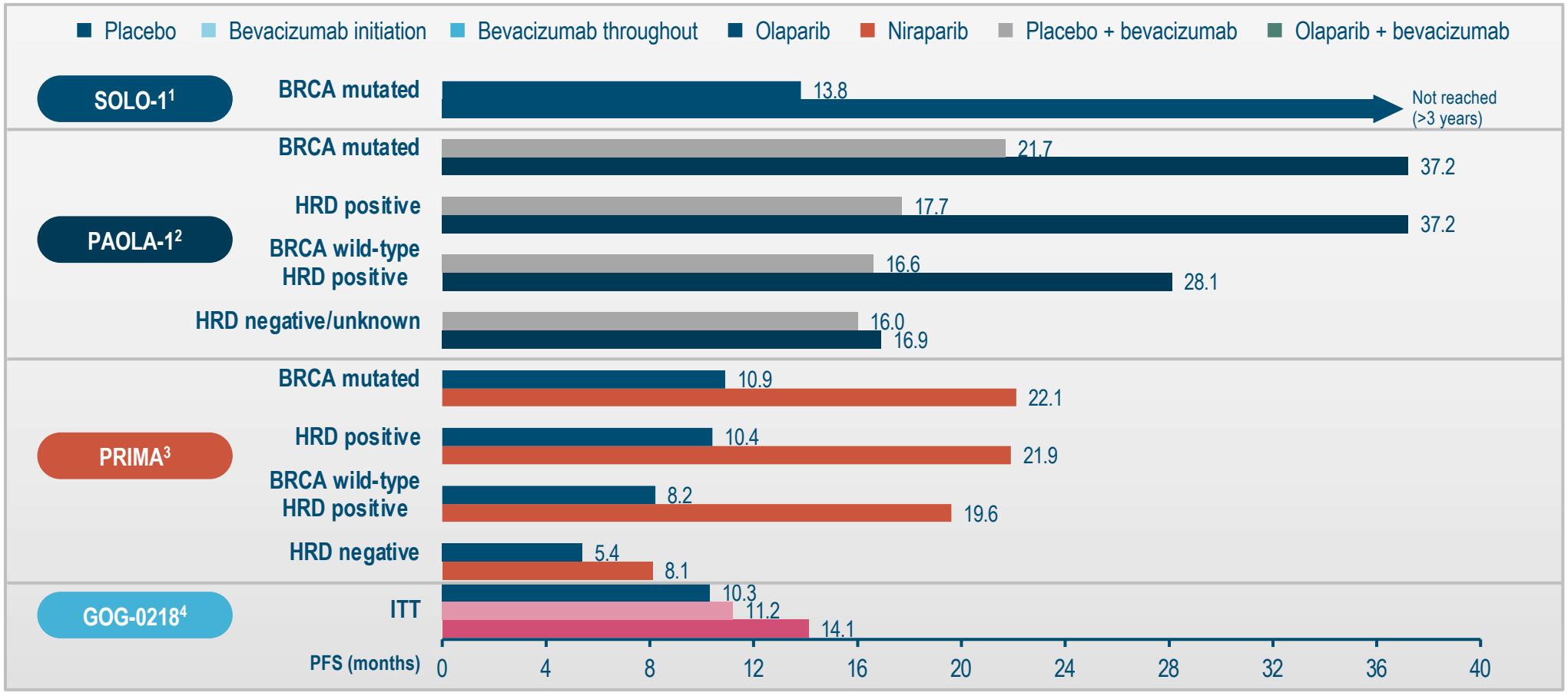
"The OlympiA Phase III trial of [olaparib] will move to early primary analysis and reporting following a recommendation from the Independent Data Monitoring Committee (IDMC).

Based on the planned interim analysis, the IDMC concluded that the trial crossed the superiority boundary for its primary endpoint of invasive disease-free survival (iDFS) and demonstrated a sustainable, clinically relevant treatment effect for olaparib versus placebo for patients with germline BRCA-mutated (gBRCAm) high-risk human epidermal growth factor receptor 2 (HER2)-negative early breast cancer, and recommend primary analysis now take place.

In its communication, the IDMC did not raise any new safety concerns. The trial will continue to assess the key secondary endpoints of overall survival and distant disease-free survival."

https://www.astrazeneca.com/media-centre/press-releases/2021/olympia-trial-of-lynparza-idmc-recommend-early-analysis.html

SUMMARY OF APPROVED MAINTENANCE STUDIES IN THE FIRST-LINE



Comparisons across trials should not be made as trials were not head-to-head.

BRCA, breast cancer gene; HRD, homologous recombination deficiency; ITT, intent-to-treat; PFS, progression-free survival

1. Moore K, et al. N Engl J Med 2018;379:2495–2505; 2. Ray-Coquard IL, et al. N Engl J Med 2019; 381:2416–2428; 3. Gonzalez-Martin A, et al. N Engl J Med 2019;381:2391–2402; 4. Burger RA, et al. N Engl J Med 2011;365:2473–2483

Courtesy of Robert L Coleman, MD

Which of the following PARP inhibitors is approved to treat recurrent ovarian cancer?

1. Olaparib
2. Niraparib
3. Rucaparib
4. All of the above
5. I don’t know

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Tolerability of PARP Inhibitors

- Fatigue: usually plateaus after two weeks
- Nausea: may require daily anti-emetics – have used transdermal patch in a few patients
- Hematologic: monitor monthly, may consider weekly for 1st month. Hold dose for grade 2 hematologic events, Reduce dose in half if dose delay
- AML/MDS: refer patient to hematologist if blood counts do not return within 4 weeks. 2% study subjects were diagnosed

Courtesy of Paula J Anastasia, MN, RN, AOCN

SOLO-1 Trial 5-Year Update: Safety Profile

n (%)	Olaparib (n=260)	Placebo (n=130)
Any AE	256 (98)	120 (92)
Grade ≥3 AE	103 (40)	25 (19)
Serious AE	55 (21)	17 (13)
AE leading to dose interruption	136 (52)	22 (17)
AE leading to dose reduction	75 (29)	4 (3)
AE leading to treatment discontinuation	30 (12)	4 (3)
MDS/AML	3 (1)	0 (0)
New primary malignancy	7 (3)	5 (4)

No additional cases of MDS/AML reported; incidence remained <1.5%

Follow-up for MDS/AML continued until death due to any cause

Banerjee S et al. ESMO 2020;Abstract 811MO.

Adverse Events: Class Effects and Specific Drug Differences

	Notes	Olaparib	Niraparib	Rucaparib	Talazoparib	Veliparib
Fatigue	50%-70%, mainly Gr1-2	✓	✓	✓	✓	✓
Hematologic AEs						
Anemia	40%-60%	✓	✓	✓	✓	✓--
Thrombocytopenia	Niraparib dose adjustment, based on platelet counts	✓	✓++	✓	✓	✓
Neutropenia	~20%	✓	✓	✓	✓	✓
Gastrointestinal AEs						
Nausea/vomiting	Moderately emetic >30%	✓	✓	✓	✓	✓
Diarrhea	~33%	✓	✓	✓	✓	✓
Laboratory abnormalities						
ALT/AST elevation	5%-10% olaparib, niraparib; 34% rucaparib	✓--	✓--	✓++	✓++	?
Creatinine elevation	10%-12%	✓	✓	✓	NR	NR

NR = not reported

Olaparib PI, rev 5/2020; Niraparib PI, rev 4/2020; Rucaparib PI, rev 5/2020; Talazoparib PI, rev 3/2020;
Madariaga A et al. *Int J Gyn Cancer* 2020 April 9;[Online ahead of print]; Litton JK et al. *NEJM* 2018;379:753-63.

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Adverse Events: Class Effects and Specific Drug Differences

	Notes	Olaparib	Niraparib	Rucaparib	Talazoparib	Veliparib
Respiratory disorders						
Dyspnea +/- cough	10%-20%, usually Gr 1-2	✓	✓	✓	✓	**NR**
Nasopharyngitis	~10%	✓	✓	✓	✓	**NR**
Nervous system and psychiatric disorders						
Insomnia/headache	10%-25%, usually Gr 1-2	✓	✓	✓	✓	✓
Dermatologic toxicity						
Rash, photosensitivity		**<1%**	✓	✓++	**NR**	**NR**
Cardiovascular toxicity						
Hypertension, tachycardia, palpitation		**1%**	✓++	**NR**	**NR**	**NR**
Rare AEs						
MDS/AML	~1% of pts	✓	✓	✓	✓	✓

NR = not reported

Olaparib PI, rev 5/2020; Niraparib PI, rev 4/2020; Rucaparib PI, rev 5/2020; Talazoparib PI, rev 3/2020; Madariaga A et al. *Int J Gyn Cancer* 2020 April 9;[Online ahead of print]; Litton JK et al. *NEJM* 2018;379:753-63.

Dose Adjustments for Adverse Events

Olaparib dose reductions	Dose (tablet)
Starting dose	300 mg BID
First dose reduction	250 mg BID
Second dose reduction	200 mg BID

Niraparib dose reductions	Dose
Starting dose	300 mg daily
First dose reduction	200 mg daily
Second dose reduction	100 mg daily

Rucaparib dose reductions	Dose
Starting dose	600 mg twice daily
First dose reduction	500 mg twice daily
Second dose reduction	400 mg twice daily
Third dose reduction	300 mg twice daily

Courtesy, Shannon N Westin, MD, MPH

FDA Prescribing Information.

Agenda

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Module 3: Cervical Cancer – Relapsed Disease

- Case 8 (Ms Arn): A 58-year-old woman with recurrent cervical cancer, PD-L1-positive
- Case 9 (Ms Arn): A 37-year-old woman with recurrent cervical cancer, PD-L1-negative

Checkpoint inhibitors are approved for and commonly used in cervical and endometrial cancer but not ovarian cancer.

1. Agree
2. Disagree
3. I don’t know

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What is the usual sequence of treatment for patients with MSI-high metastatic endometrial cancer?

1. Chemotherapy first line; pembrolizumab second line
2. Chemotherapy first line; pembrolizumab second line for increased PD-L1 levels
3. Chemotherapy first line; pembrolizumab/lenvatinib second line
4. Pembrolizumab first line; chemotherapy second line
5. I don’t know

What is the usual sequence of treatment for patients with MS-stable metastatic endometrial cancer?

1. Chemotherapy first line; pembrolizumab second line
2. Chemotherapy first line; pembrolizumab second line for increased PD-L1 levels
3. Chemotherapy first line; pembrolizumab/lenvatinib second line
4. Pembrolizumab first line; chemotherapy second line
5. I don’t know

The rapidity of onset and severity of hypertension associated with lenvatinib is greater than that with bevacizumab.

1. Agree
2. Disagree
3. I don’t know

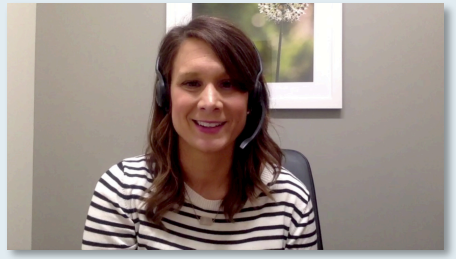
Case Presentation – A 68-year-old woman with recurrent endometrial cancer, MSI high

Ms Spickes

- Initially diagnosed with Stage IB, Grade I endometrial cancer and experienced disease recurrence 4 months after completing adjuvant brachytherapy

- Pembrolizumab x 33 cycles → complete response

Case Presentation – An 81-year-old woman with recurrent endometrial cancer, MMR proficient (Part 1)

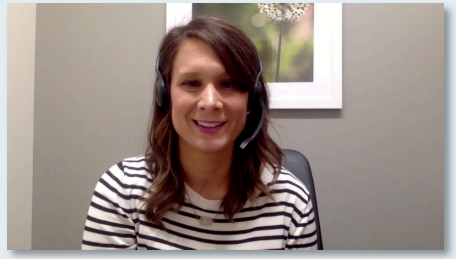


Ms Arn

- Divorced older woman s/p hysterectomy and adjuvant chemotherapy for Stage IA endometrial cancer experiences metastatic recurrence

- Lenvatinib/pembrolizumab

Case Presentation – An 81-year-old woman with recurrent endometrial cancer, MMR proficient (Part 2)



Ms Arn

- Divorced older woman s/p hysterectomy and adjuvant chemotherapy for Stage IA endometrial cancer experiences metastatic recurrence
- Lenvatinib/pembrolizumab
- ***Supportive care for patients and their ability to maintain independence***

Case Presentation – A 60-year-old woman with recurrent endometrial cancer, MMR deficient

Ms Anastasia

- Originally diagnosed in 2004 with Stage IIIC endometrial cancer and has experienced multiple disease recurrences after initial surgery and chemotherapy
  - Disease recurrences on carboplatin/paclitaxel, RT, tamoxifen and megestrol
- Pembrolizumab on KEYNOTE-158 trial with complete response after 3 cycles
  - Discontinued pembrolizumab in 2018 after 32 cycles
- Currently, 2 years later, she remains NED

Case Presentation – A 50-year-old woman with recurrent endometrial cancer, MMR proficient

Ms Anastasia

- Grade II endometrioid adenocarcinoma s/p LAVH/BSO/LND → surveillance
- 1 year later: Recurrent disease in lung, ER/PR-positive, MSS
  - Paclitaxel/carboplatin x 6
- 1 year later: Multiple new lung lesions, PD-L1-positive
- Pembrolizumab/lenvatinib
  - Grade 1-2 fatigue and diarrhea

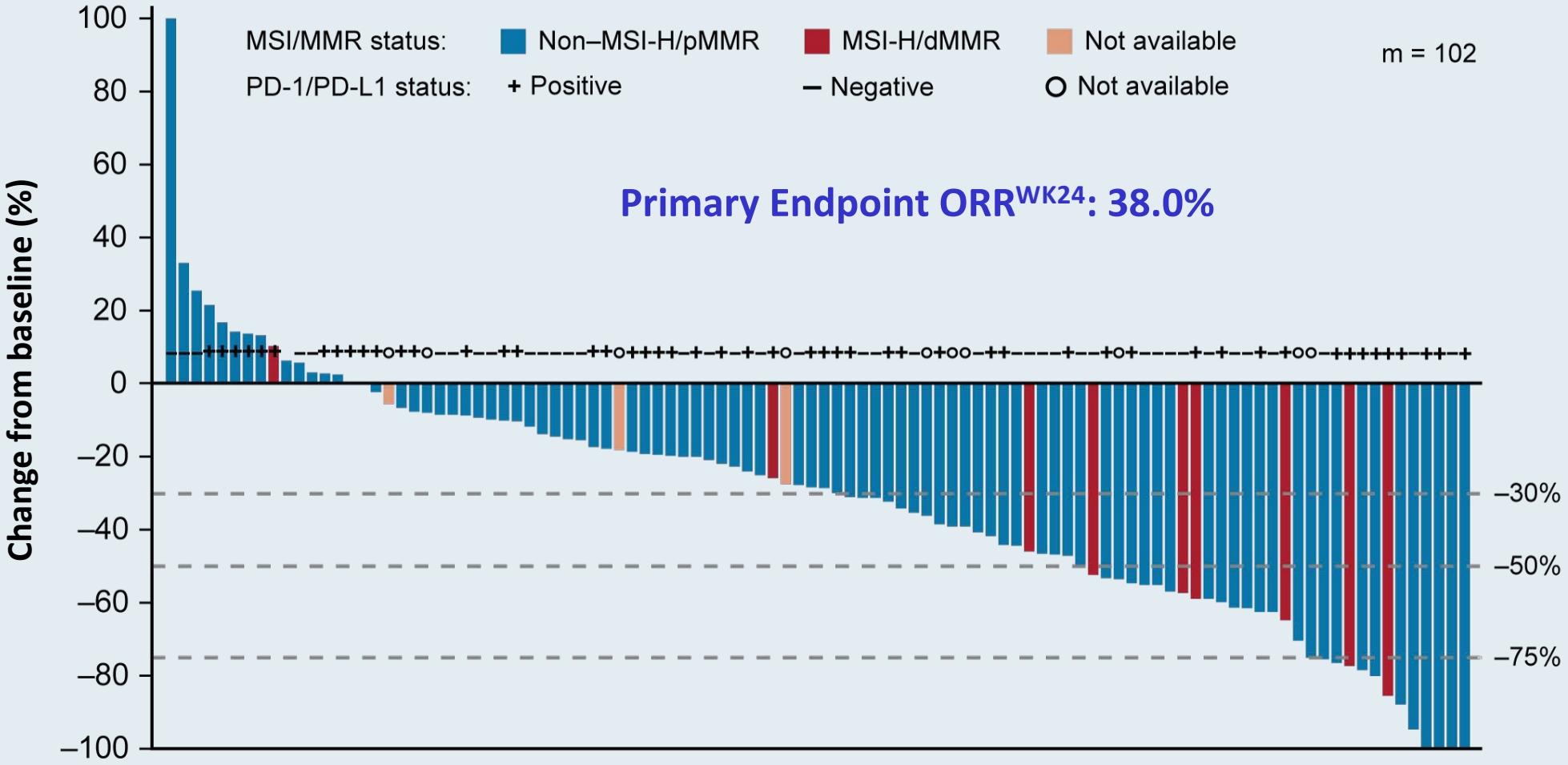
original reports

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.

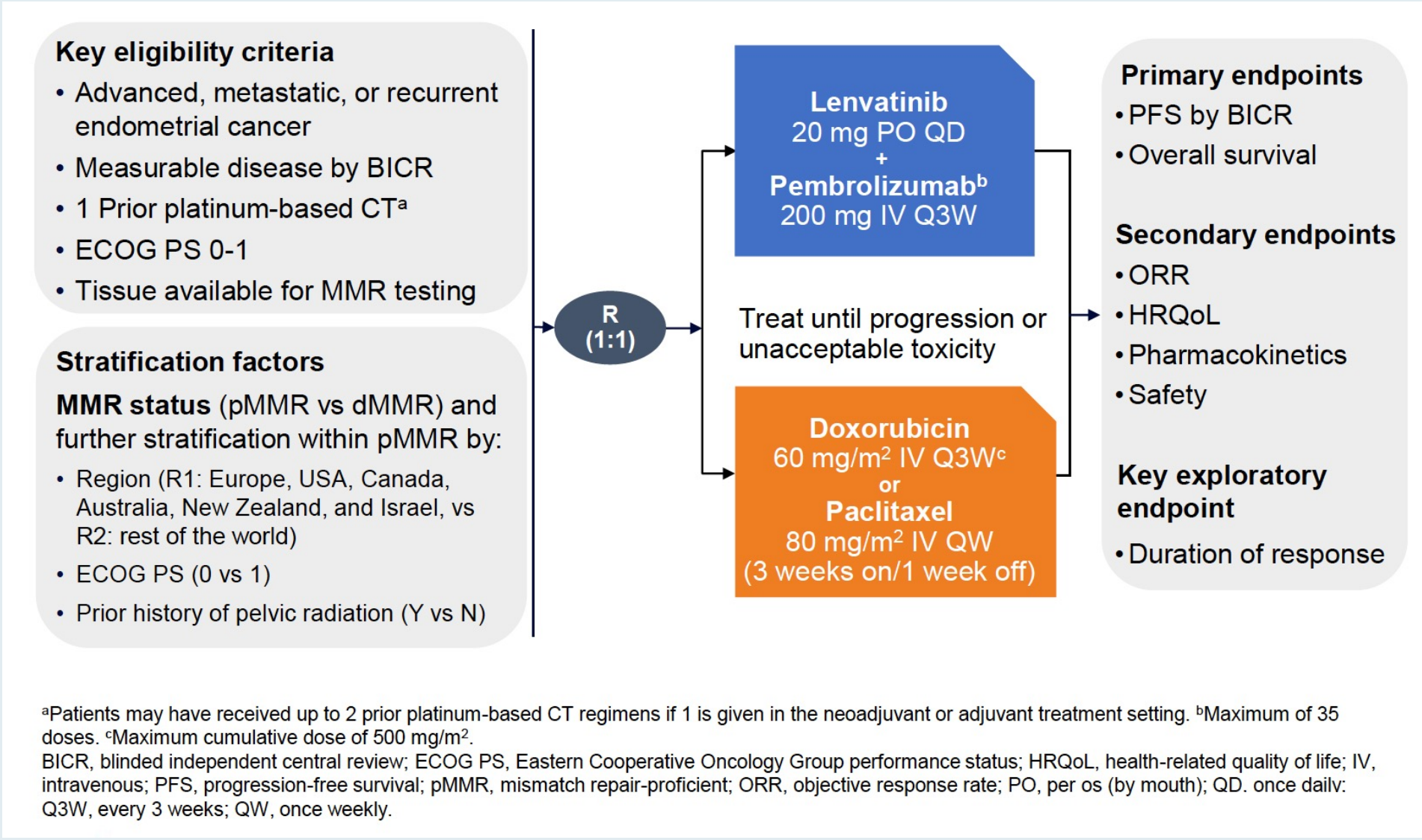
RTP RESEARCH TO PRACTICE

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.

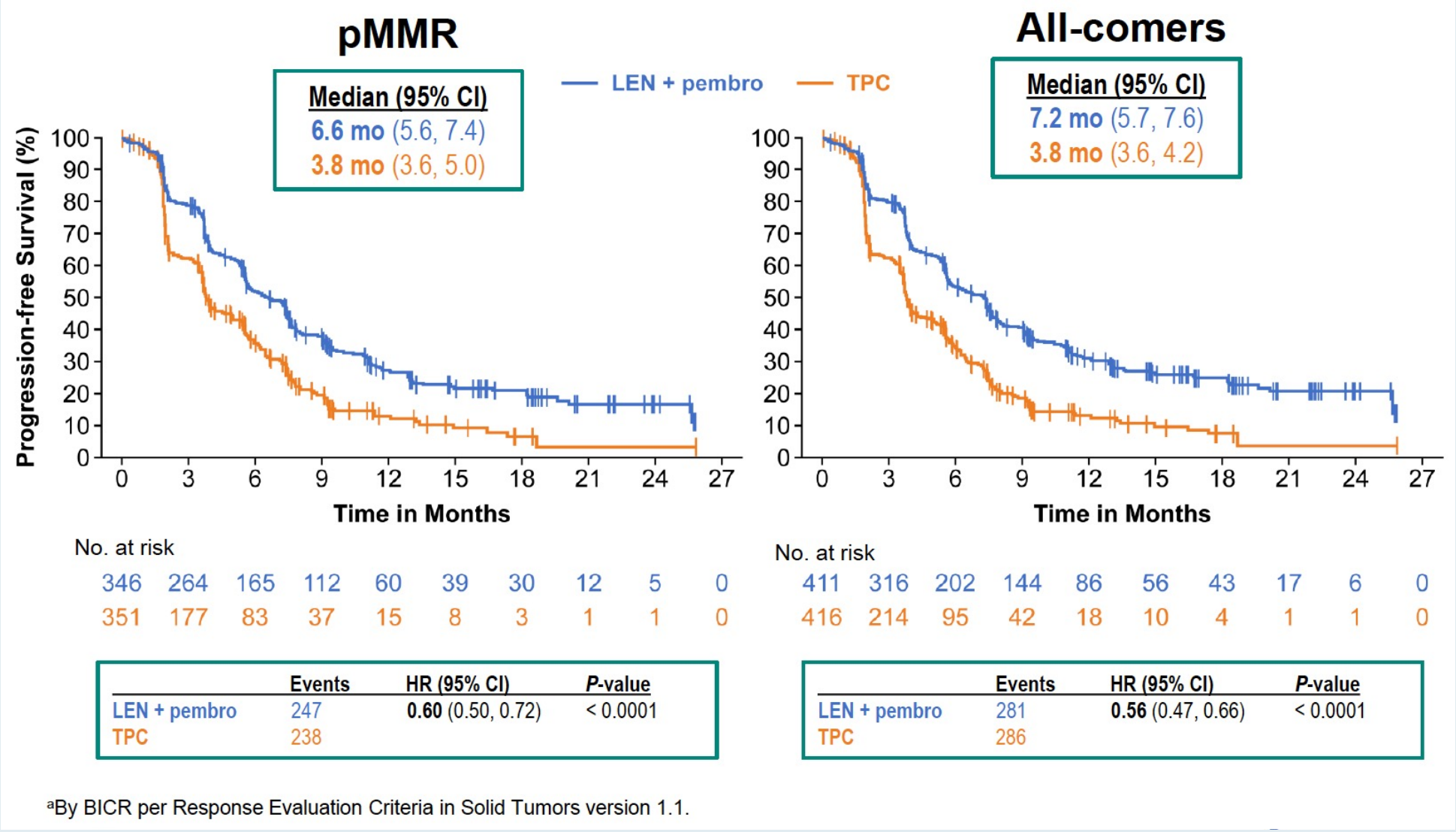
Study 309/KEYNOTE-775: Phase III Trial Schema



[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.

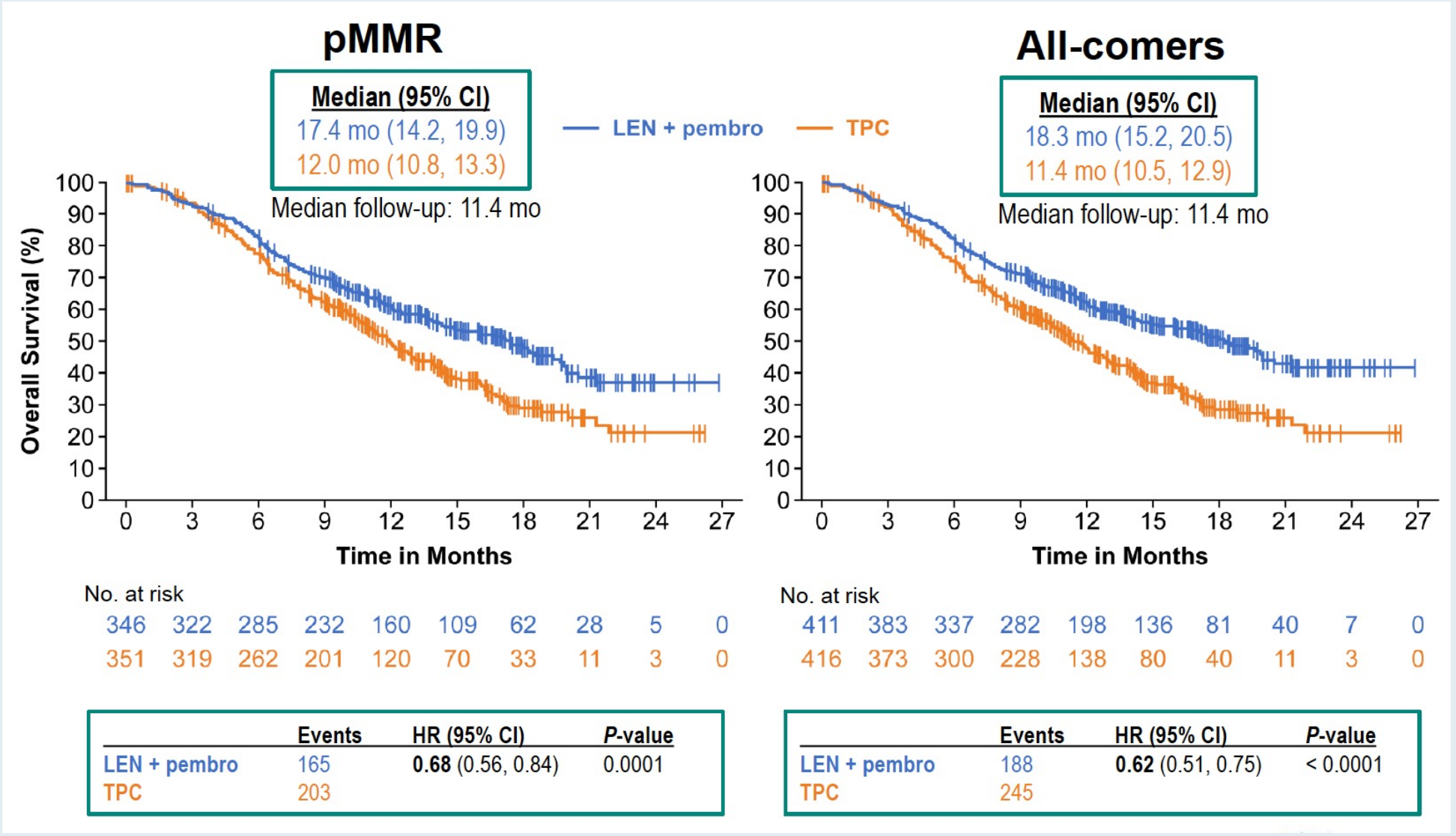
Makker V et al. SGO 2021;Abstract 11512.

Study 309/KEYNOTE-775: Progression-Free Survival



Makker V et al. SGO 2021;Abstract 11512.

Study 309/KEYNOTE-775: Overall Survival



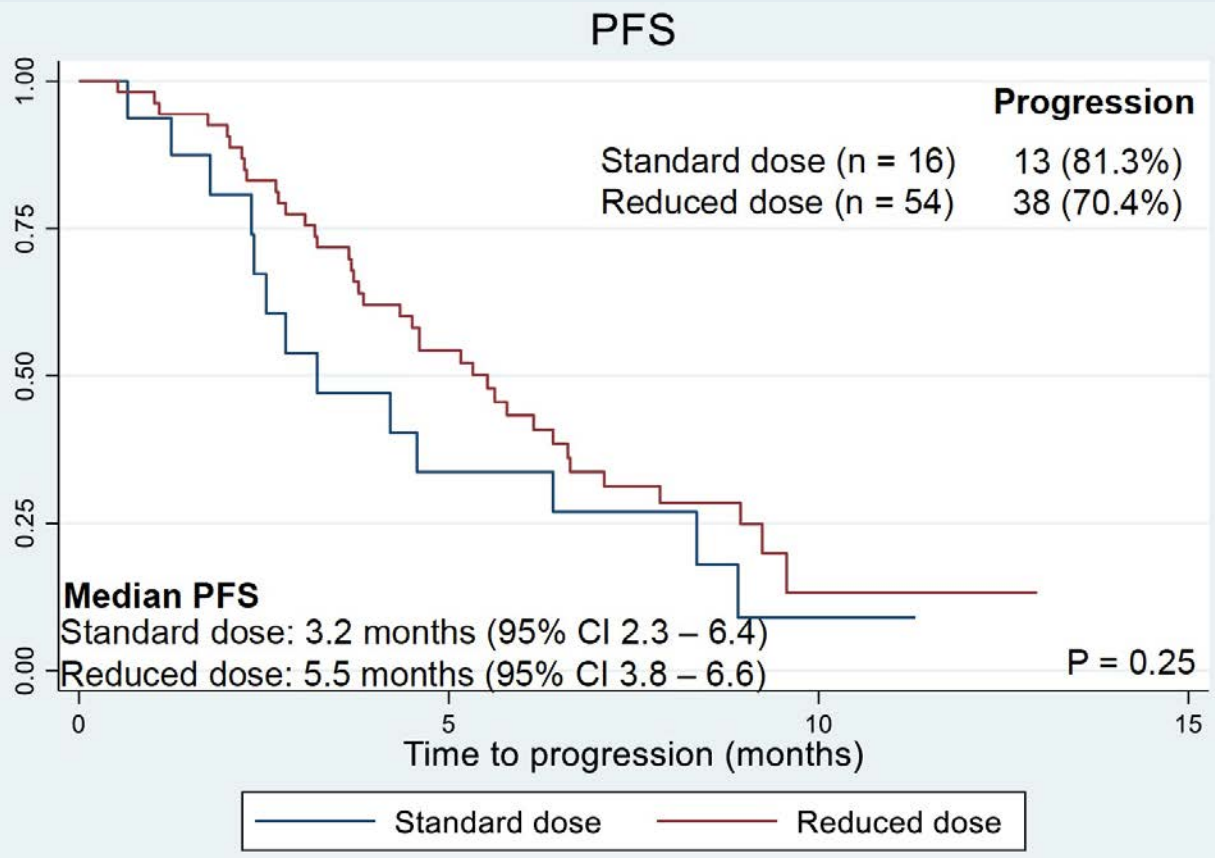
Makker V et al. SGO 2021;Abstract 11512.

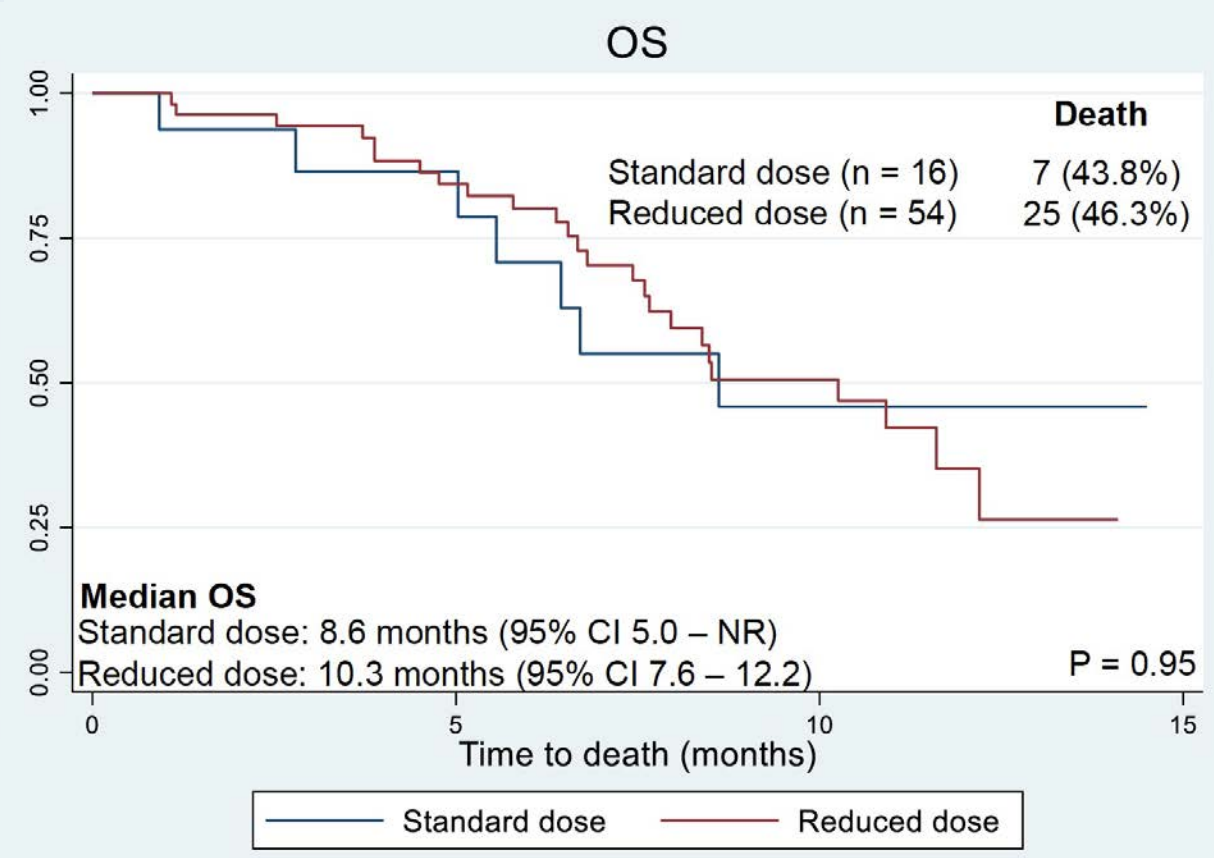
The Use of Pembrolizumab and Lenvatinib Combination Therapy in Endometrial Cancer: An Examination of Toxicity and Treatment Efficacy in Clinical Practice

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.

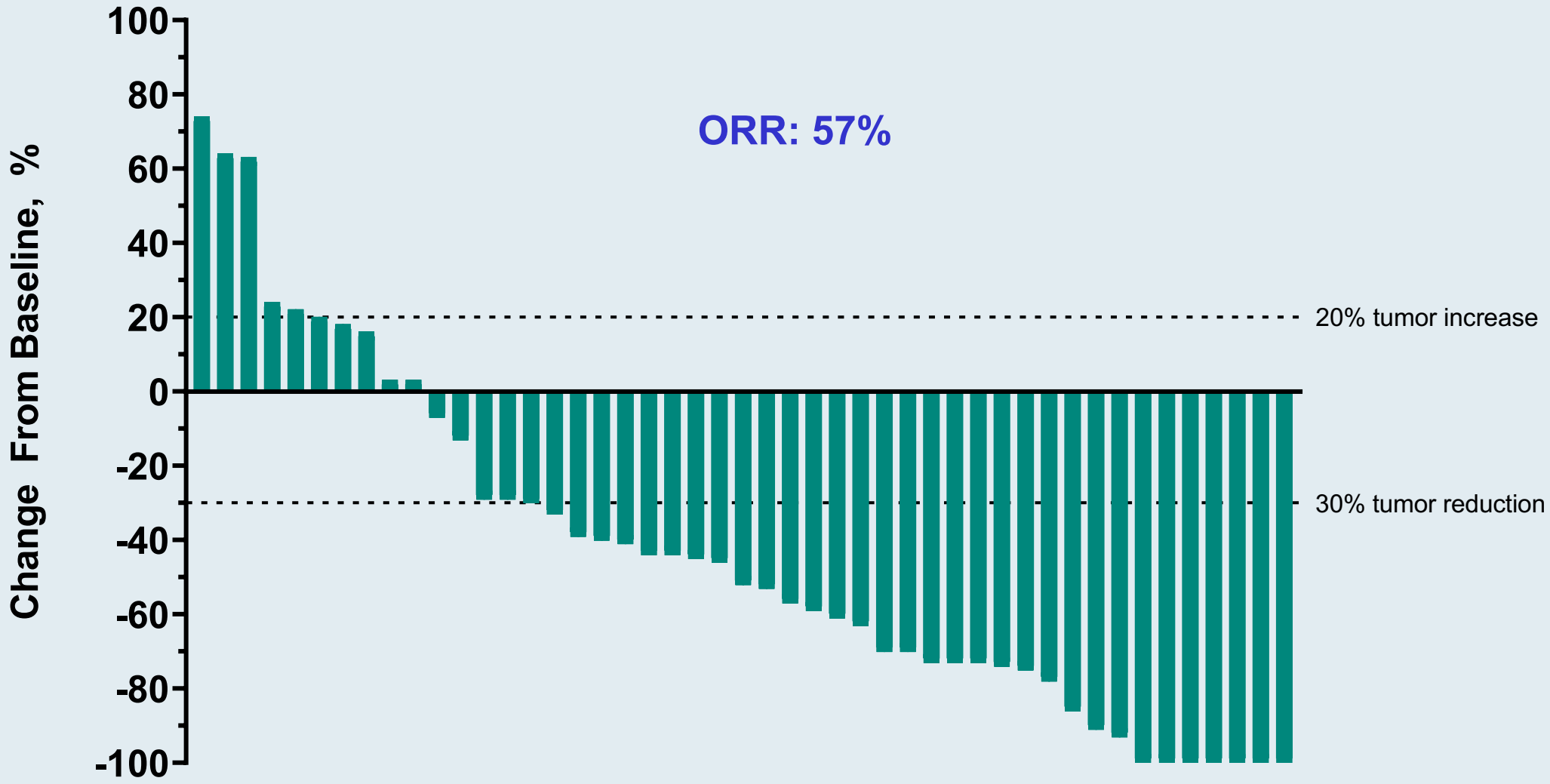
RTP RESEARCH TO PRACTICE

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?utm_medium=email&utm_source=govdelivery

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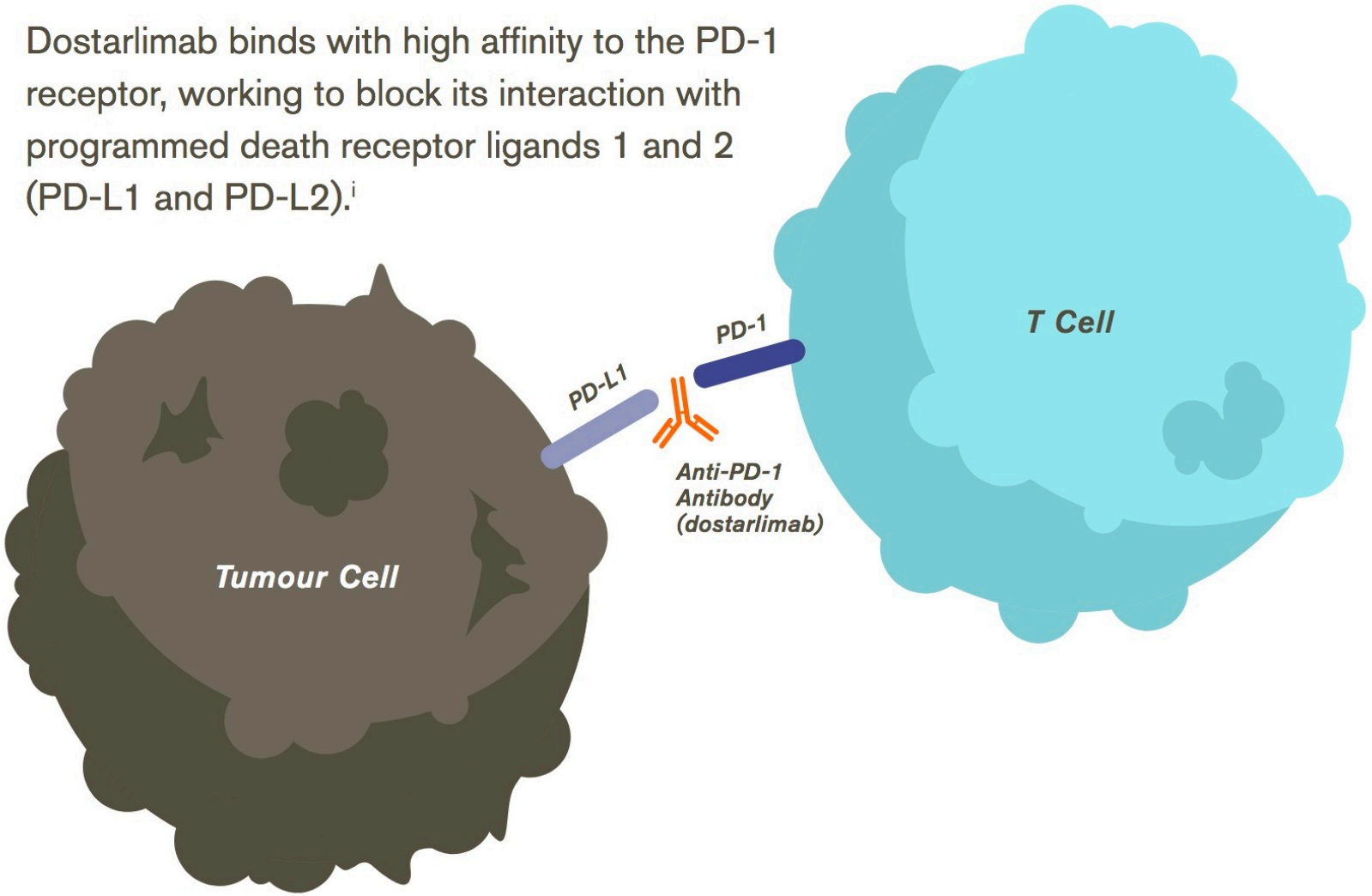
Dostarlimab Mechanism of Action

Dostarlimab binds with high affinity to the PD-1 receptor, working to block its interaction with programmed death receptor ligands 1 and 2 (PD-L1 and PD-L2).[i]



https://us.gsk.com/media/5875/dostarlimab-infographic_approved-0422.pdf

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Research

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

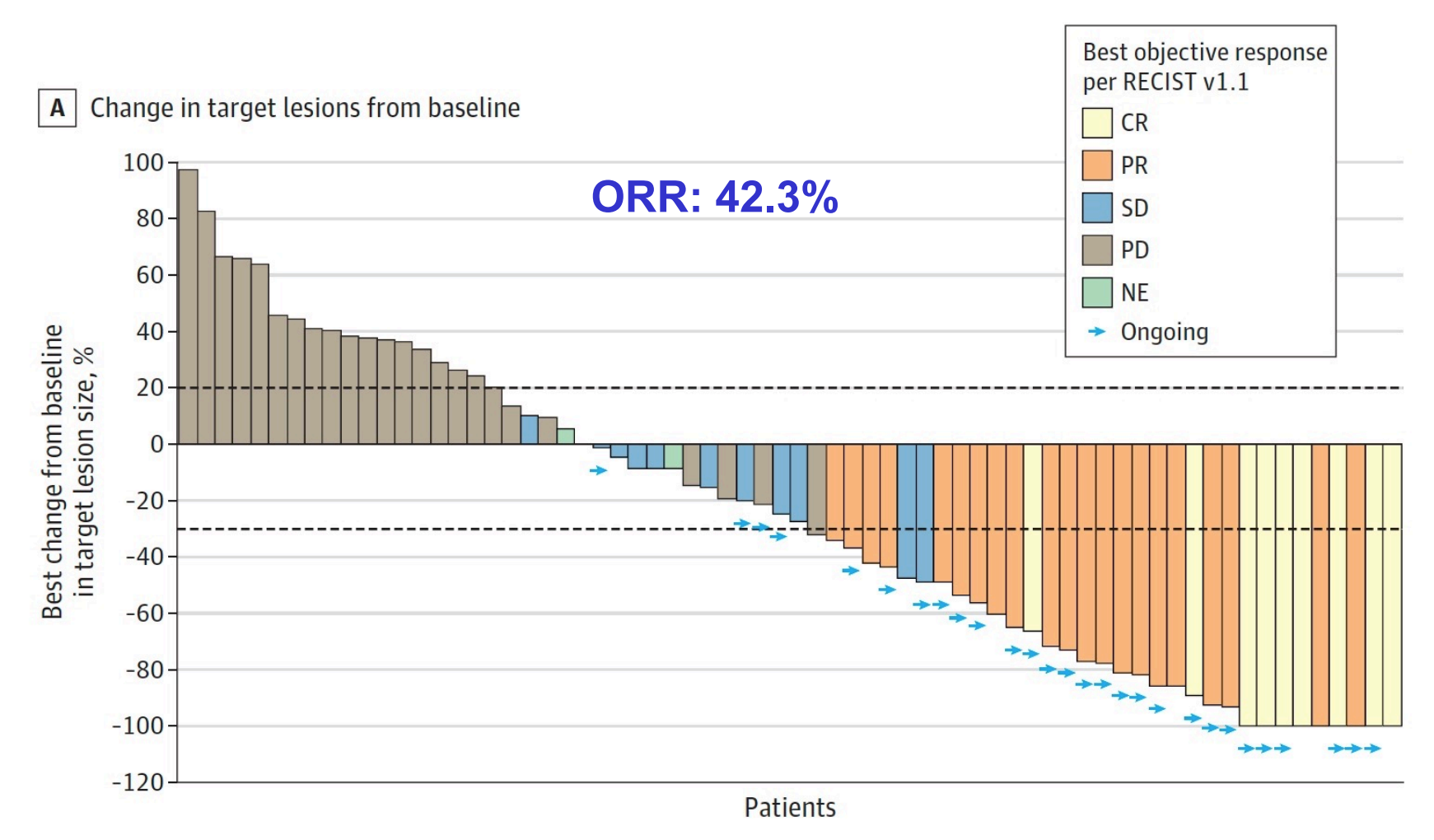
JAMA Oncology | Original Investigation

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.

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

Ana Oaknin,[1] Lucy Gilbert,[2] Anna V. Tinker,[3] Renaud Sabatier,[4] Valentina Boni,[5] David M. O'Malley,[6] Sharad Ghamande,[7] Linda Duska,[8] Prafull Ghatage,[9] Wei Guo,[10] Ellie Im,[10] **Bhavana Pothuri**[11]

[1]Vall d'Hebron Institute of Oncology (VHIO), Vall d'Hebron University Hospital, Barcelona, Spain; [2]McGill University Health Centre-RI, Montreal, Quebec, Canada; [3]BC Cancer, Vancouver, British Columbia, Canada; [4]Department of Medical Oncology, Institut Paoli Calmettes, Aix-Marseille University, Marseille, France; [5]Centro Integral Oncológico Clara Campal, Hospital Universitario HM Sanchinarro, Madrid, Spain; [6]James Comprehensive Cancer Center, The Ohio State University, Columbus, OH, USA; [7]Georgia Cancer Center, Augusta University, Augusta, GA, USA; [8]Emily Couric Clinical Cancer Center, University of Virginia, Charlottesville, VA, USA; [9]Department of Gynecological Oncology, University of Calgary, Calgary, Alberta, Canada; [10]GlaxoSmithKline, Waltham, MA, USA; [11]Department of Obstetrics and Gynecology, New York University, New York, NY, USA

Poster #10417

SGO 2021 VIRTUAL ANNUAL MEETING ON WOMEN'S CANCER®

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GARNET Study of Dostarlimab: 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.

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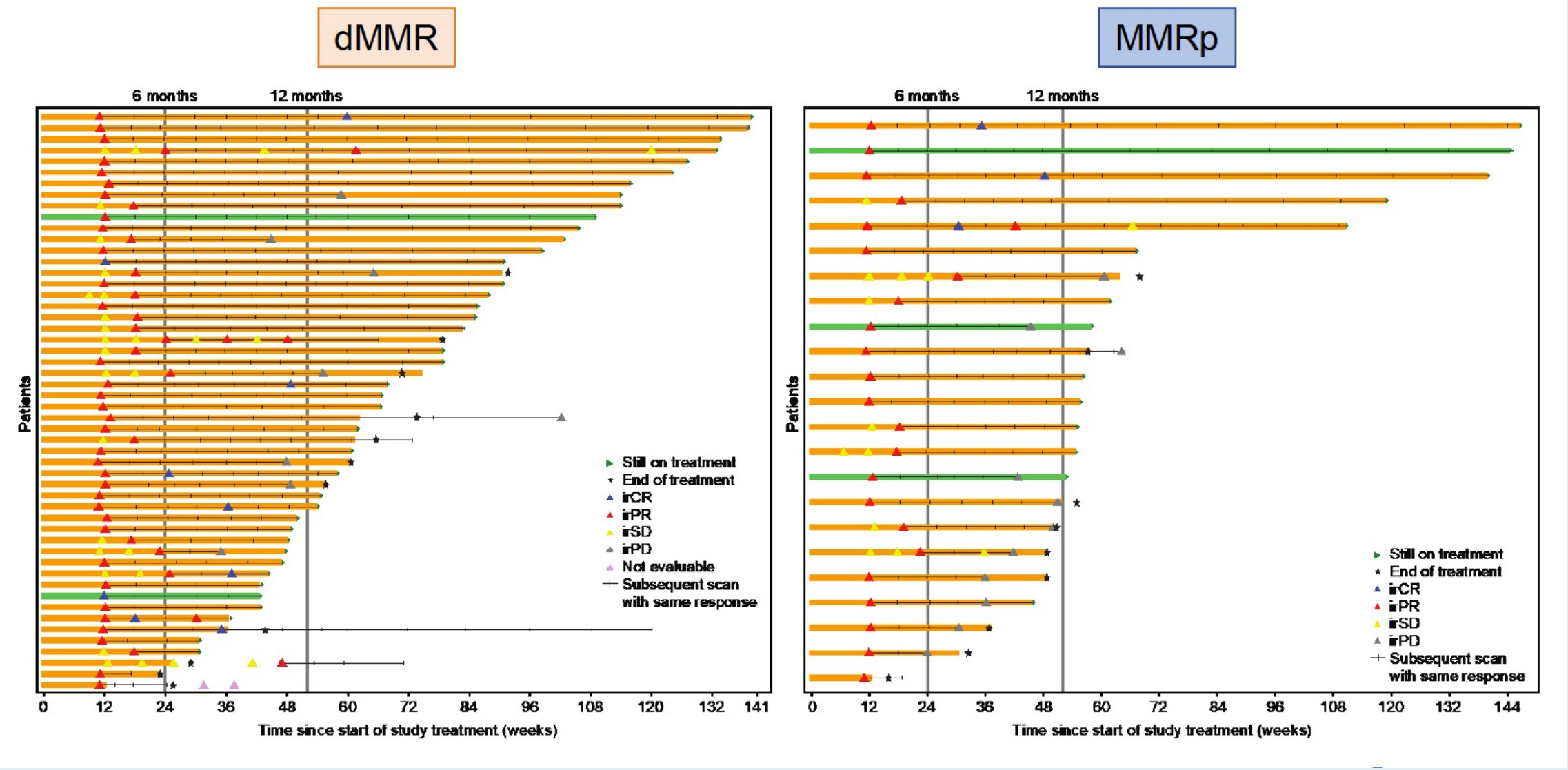
GARNET: Duration of Response with Dostarlimab



Pothuri B et al. SGO 2021;Abstract 10417.

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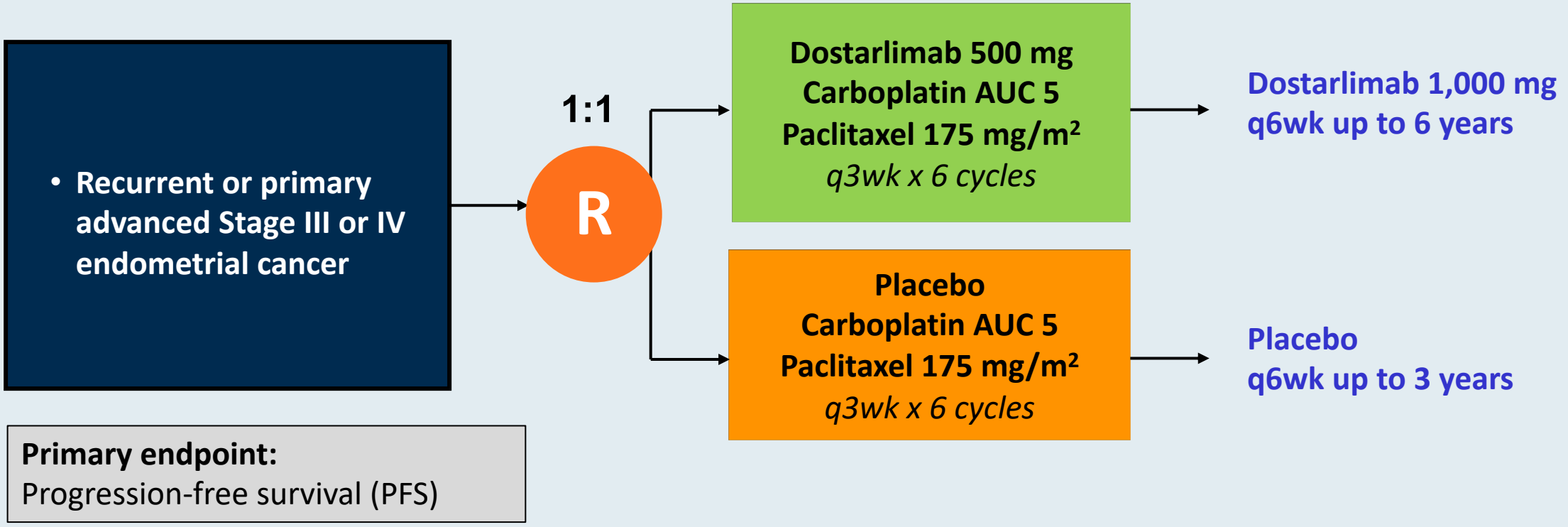
ENGOT-EN6/NSGO-RUBY Phase III Schema of Dostarlimab



Mirza MR et al. ASCO 2020;Abstract TPS6107.

Agenda

Module 1: Ovarian Cancer

- Case 1 (Ms Spickes): A 52-year-old woman with Stage IIIA2 ovarian cancer and a somatic BRCA2 mutation
- Case 2 (Ms Anastasia): A 59-year-old woman with BRCA wild-type, HRD-proficient ovarian cancer
- Case 3 (Ms Arn): A 51-year-old woman with Stage IIIC ovarian cancer and a germline BRCA1 mutation

Module 2: Endometrial Cancer

- Case 4 (Ms Spickes): A 68-year-old woman with recurrent endometrial cancer, MSI high
- Case 5 (Ms Arn): An 81-year-old woman with recurrent endometrial cancer, MMR proficient
- Case 6 (Ms Anastasia): A 60-year-old woman with recurrent endometrial cancer, MMR deficient
- Case 7 (Ms Anastasia): A 50-year-old woman with recurrent endometrial cancer, MMR proficient

Module 3: Cervical Cancer – Relapsed Disease

- Case 8 (Ms Arn): A 58-year-old woman with recurrent cervical cancer, PD-L1-positive
- Case 9 (Ms Arn): A 37-year-old woman with recurrent cervical cancer, PD-L1-negative

Pembrolizumab is approved as second-line treatment for metastatic cervical cancer…

1. In all patients
2. In patients with elevated PD-L1 levels
3. In combination with chemotherapy
4. All of the above
5. I don’t know

Checkpoint inhibitors frequently cause low-grade rash or other dermatologic side effects.

1. Agree
2. Disagree
3. I don’t know

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One of the most common autoimmune toxicities associated with checkpoint inhibitors is thyroid dysfunction.

1. Agree
2. Disagree
3. I don’t know

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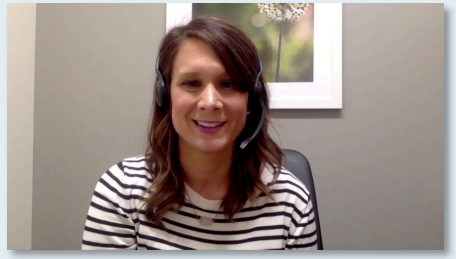
Case Presentation – A 58-year-old woman with recurrent cervical cancer, PD-L1-positive



Ms Arn

- Initially diagnosed with Stage IB2 cervical cancer and completed chemoradiation followed by 4 cycles of carboplatin/paclitaxel
- Disease recurrence 2 years later → gemcitabine/cisplatin → PD
- PD-L1-positive → pembrolizumab x 2 years with complete response

Ms Anastasia: Screening and early diagnosis of cervical cancer

Case Presentation – A 37-year-old woman with recurrent cervical cancer, PD-L1-negative

Ms Arn

- Young mother of 2 children initially diagnosed with PD-L1-negative, Stage IIIB cervical cancer who completed chemoradiation
- Multiple metastatic disease recurrences in the lung and spine treated with chemotherapy and radiation; poor performance status
- Enrolled in clinical trial of tisotumab vedotin with good response and symptom improvement

Pembrolizumab Treatment of Advanced Cervical Cancer: Updated Results from the Phase 2 KEYNOTE-158 Study

Hyun Cheol Chung[1], Jean-Pierre Delord[2], Ruth Perets[3], Antoine Italiano[4], Ronnie Shapira-Frommer[5], Lyudmila Manzuk[6], Sarina A. Piha-Paul[7], Lei Xu[8], Fan Jin[8], Kevin Norwood[8], Alexandra Leary[9]

[1]Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, South Korea; [2]Institut Claudius Regaud, Toulouse, France; [3]Rambam Health Care Campus, Haifa, Israel; [4]Institut Bergonie, Bordeaux, France; [5]Sheba Medical Center, Ramat-Gan, Israel; [6]N.N. Blokhin NMRCO, Moscow, Russia; [7]MD Anderson Cancer Center, Houston, TX, USA; [8]Merck & Co., Inc., Kenilworth, NJ, USA; [9]Gustave Roussy, Villejuif, France

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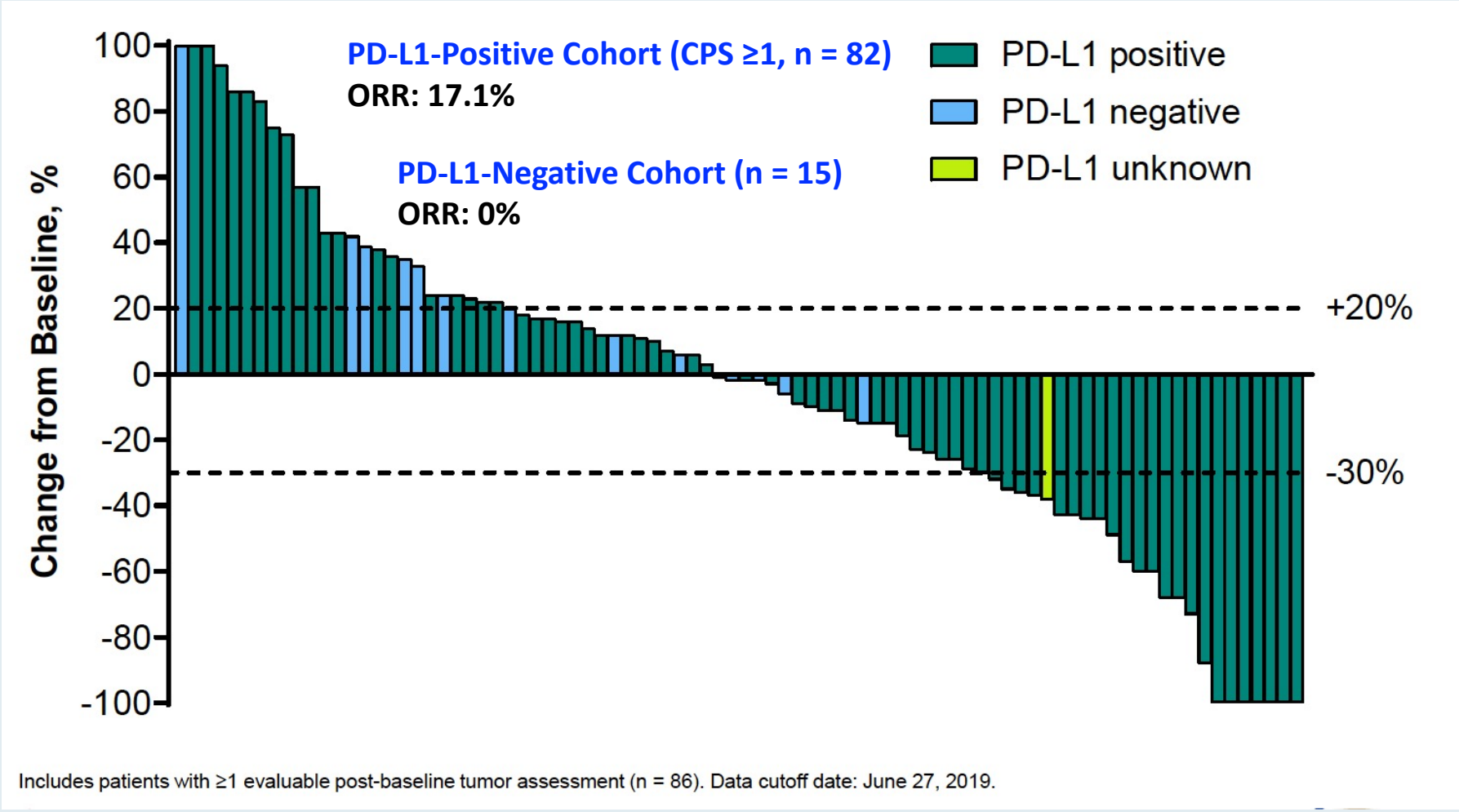
Phase II KEYNOTE-158: Updated Results with Pembrolizumab for Previously Treated Advanced Cervical Cancer



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.

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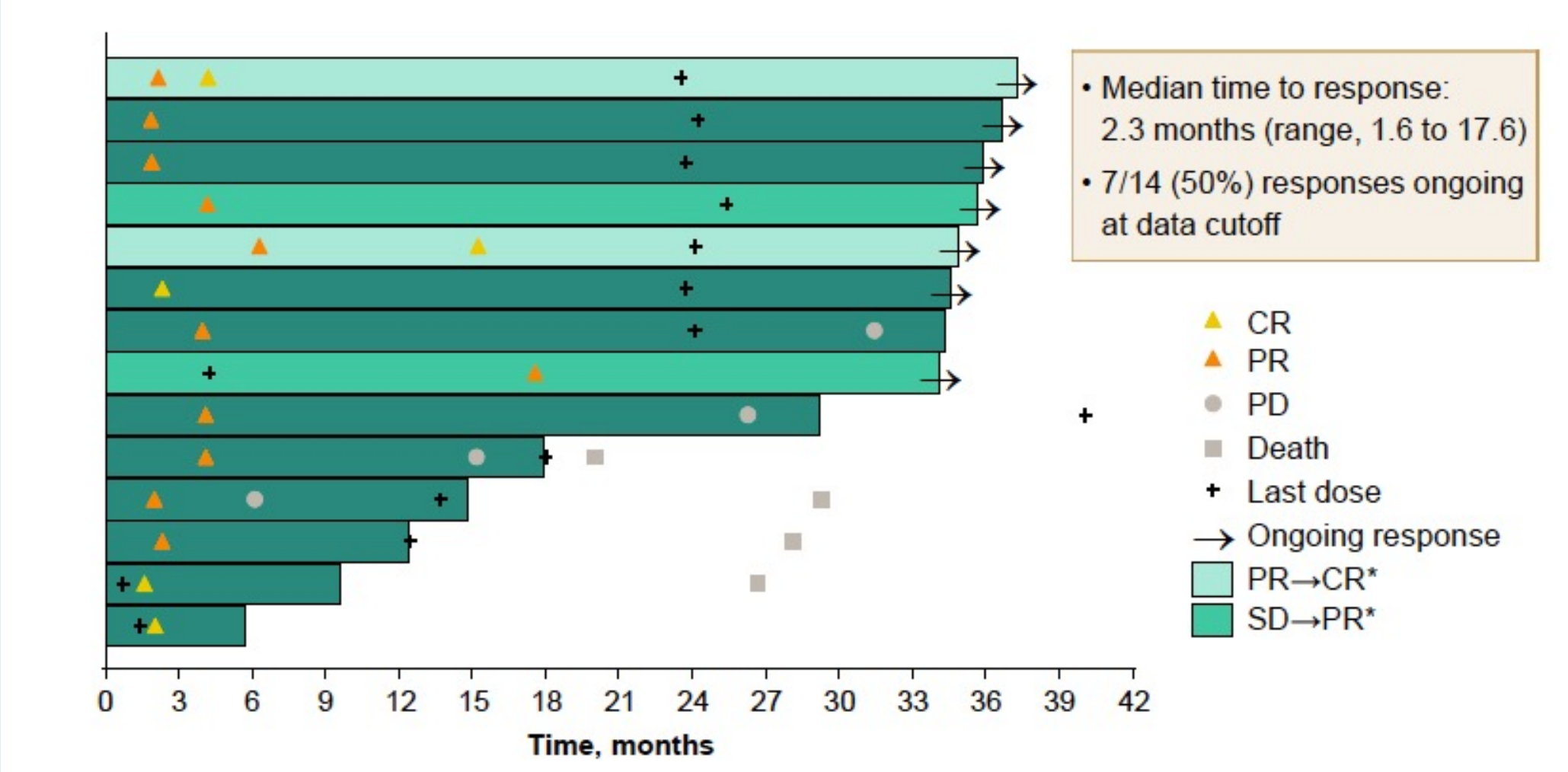
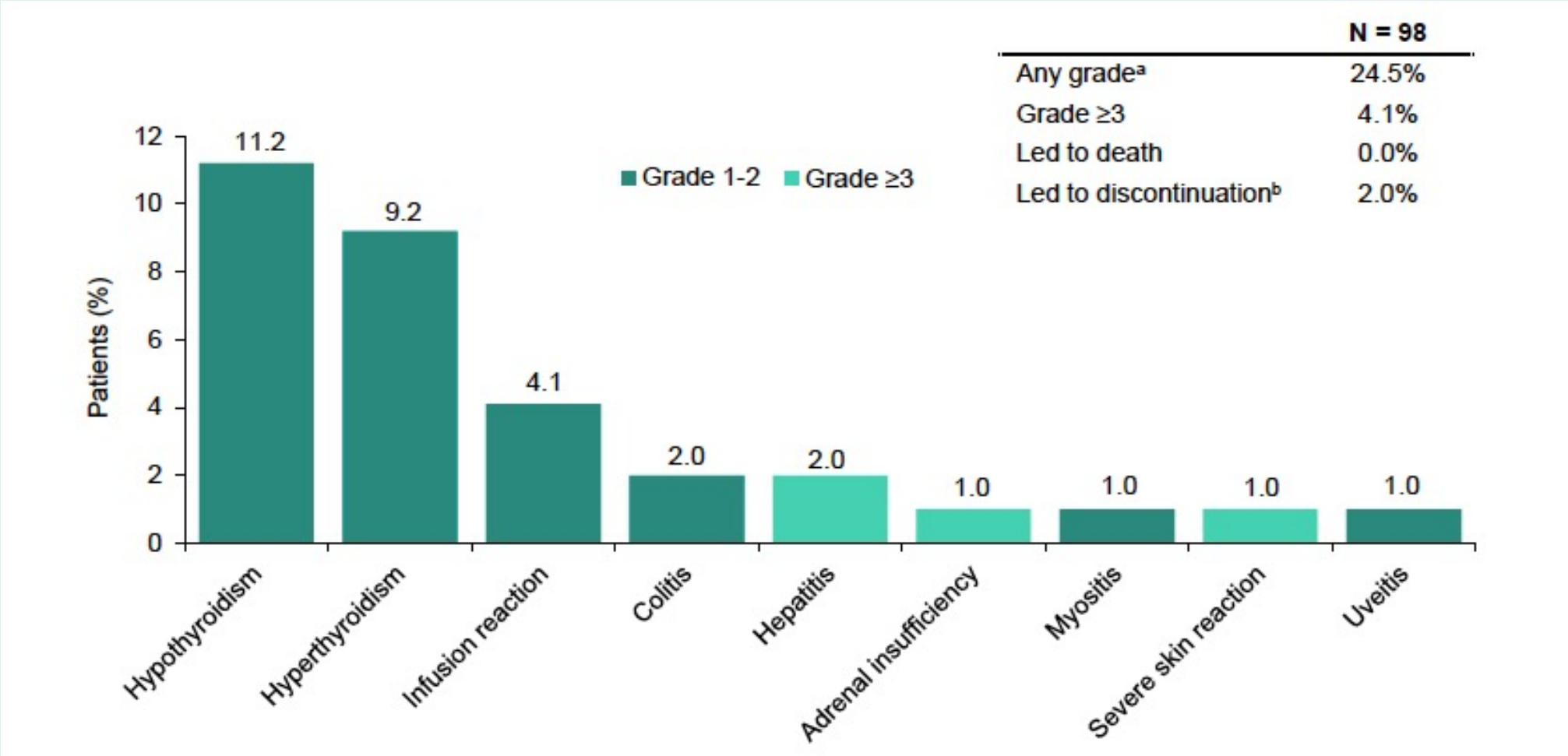
Phase II KEYNOTE-158: Time to Response and Duration of Response with Pembrolizumab



Chung HC et al. SGO 2021;Abstract 10440.

Phase II KEYNOTE-158: Immune-Mediated Adverse Events and Infusion Reactions



Includes events of any grade that occurred in ≥1 patient

Chung HC et al. SGO 2021;Abstract 10440.

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

Press Release – March 15, 2021

"Positive results demonstrating an overall survival (OS) benefit from the Phase 3 trial investigating the PD-1 inhibitor cemiplimab as monotherapy compared to chemotherapy in patients previously treated with chemotherapy whose cervical cancer is recurrent or metastatic, were announced today. 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 three weeks) or an investigator's choice of commonly used chemotherapy (pemetrexed, vinorelbine, topotecan, irinotecan or gemcitabine)."

https://www.sanofi.com/en/media-room/press-releases/2021/2021-03-15-07-00-00-2192446

Phase III Trial of Cemiplimab Monotherapy in Advanced Cervical Cancer Halted Early for Positive Overall Survival Result (Continued)

Press Release – March 15, 2021

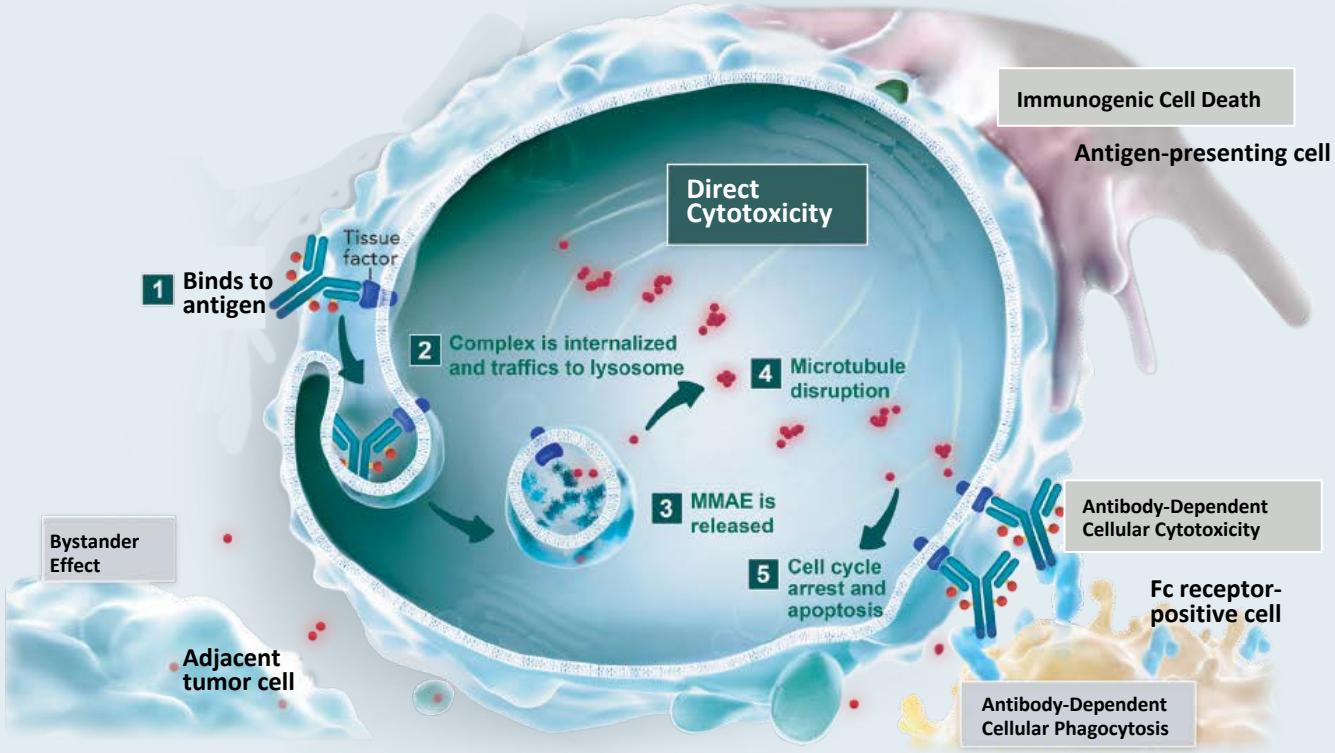
"Compared to chemotherapy, patients receiving cemiplimab experienced:

- **Total population:** 31% reduced risk of death
  - Median 12.0 months survival for cemiplimab (n=304) compared to 8.5 months for chemotherapy (n=304) (HR: 0.69; p<0.001)
- **Squamous cell carcinoma:** 27% reduced risk of death
  - Median 11.1 months survival for cemiplimab (n=239) compared to 8.8 months for chemotherapy (n=238) (HR: 0.73; p=0.003)
- **Adenocarcinoma:** 44% reduced risk of death
  - Median 13.3 months survival for cemiplimab (n=65) compared to 7.0 months for chemotherapy (n=66) (HR: 0.56; p<0.005)"

https://www.sanofi.com/en/media-room/press-releases/2021/2021-03-15-07-00-00-2192446

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

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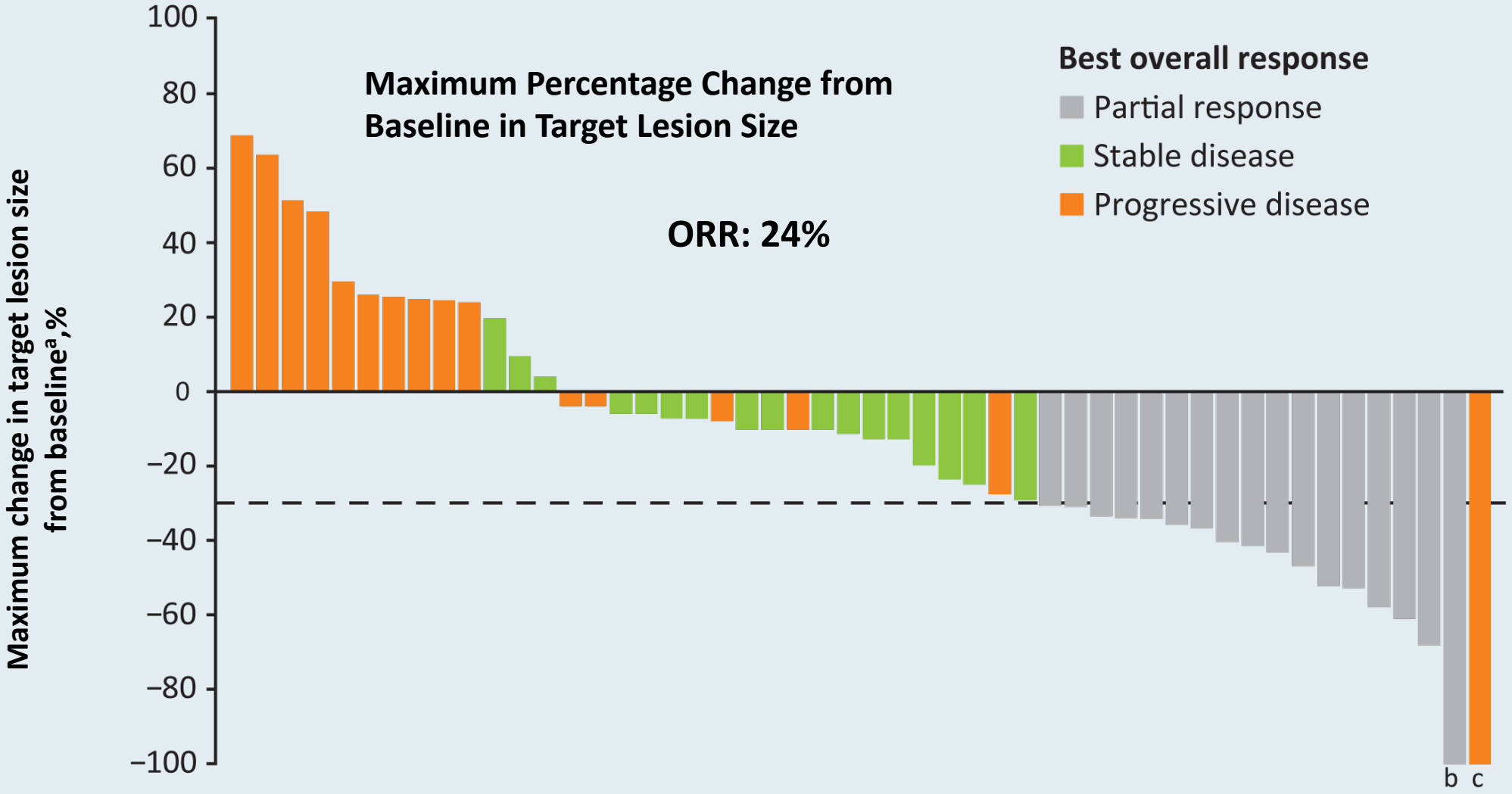
innovaTV 201: Best Overall Response to TV



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

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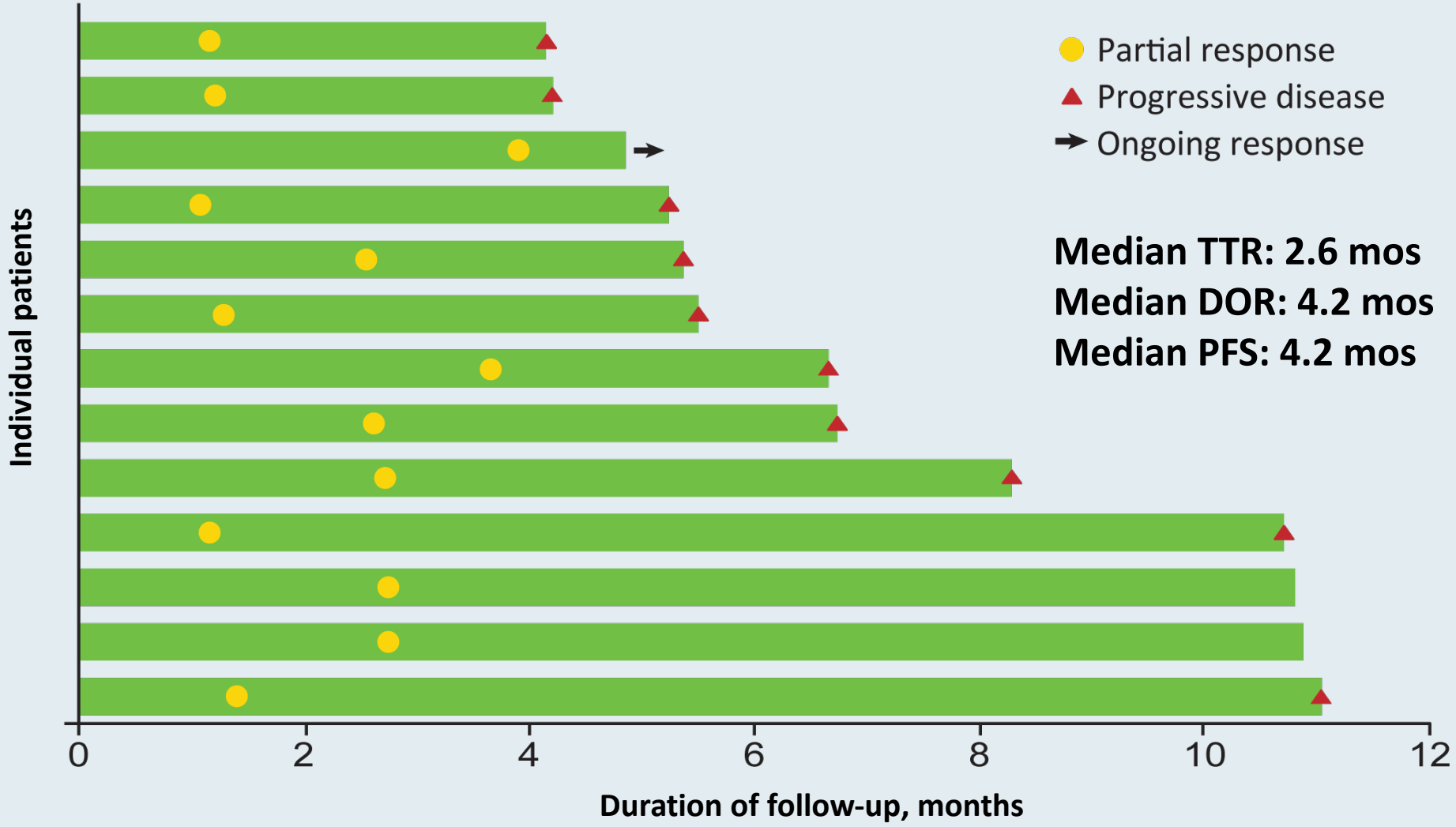
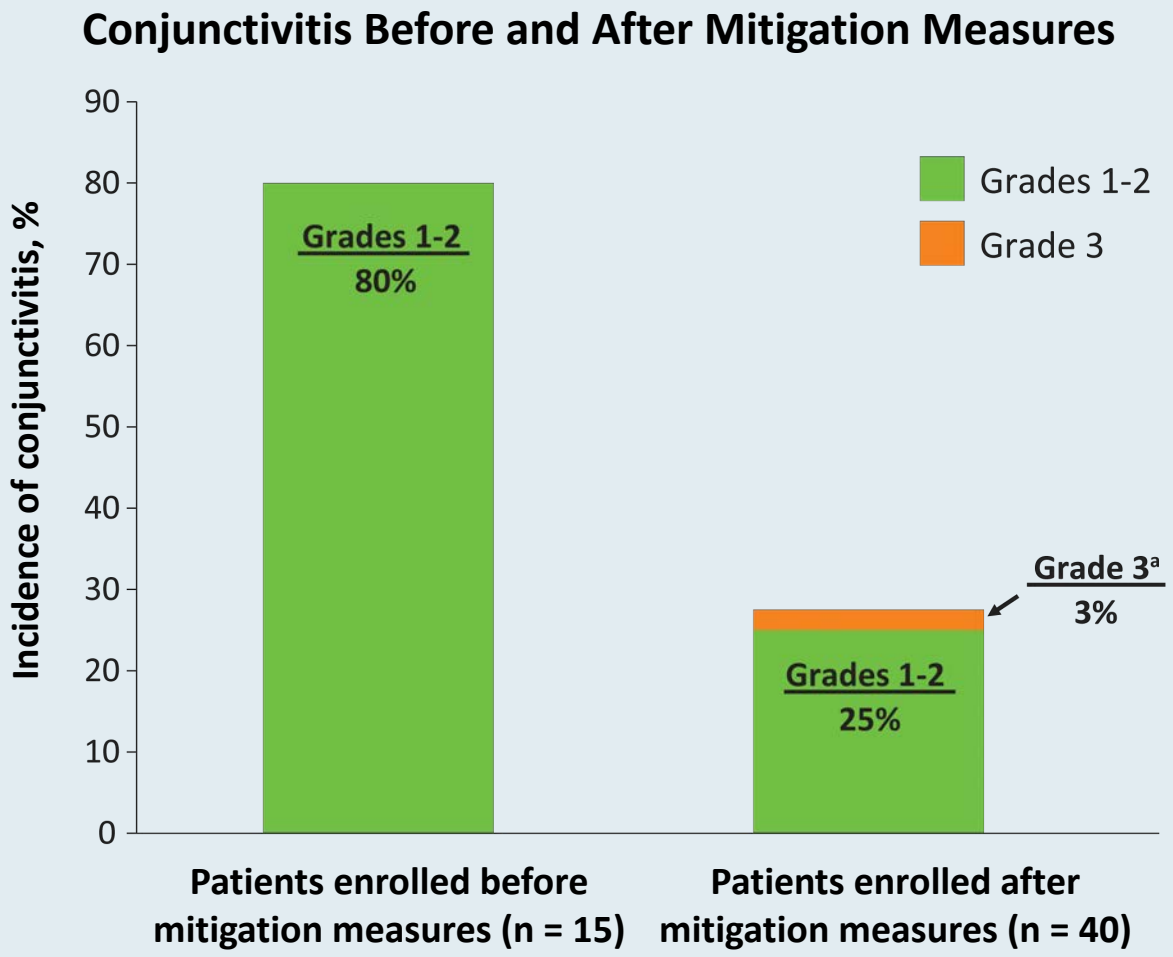
innovaTV 201: Time to Response and Duration of Response in Patients with a Confirmed PR to TV



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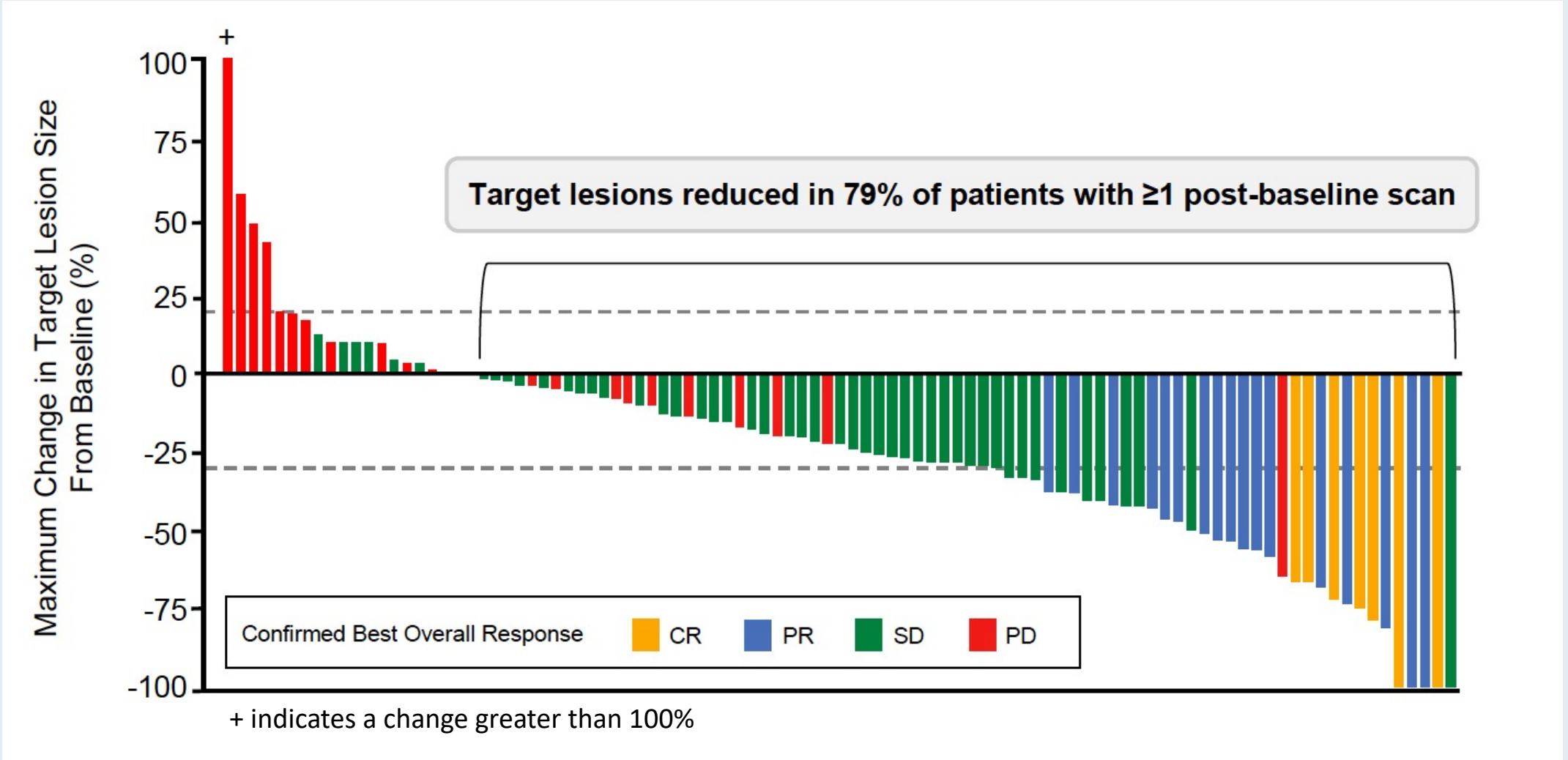
Tisotumab Vedotin in Previously Treated Recurrent or Metastatic Cervical Cancer: Results from the Phase II innovaTV 204/GOG-3023/ENGOT-cx6 Study

Coleman RL et al.

ESMO 2020;Abstract LBA32.

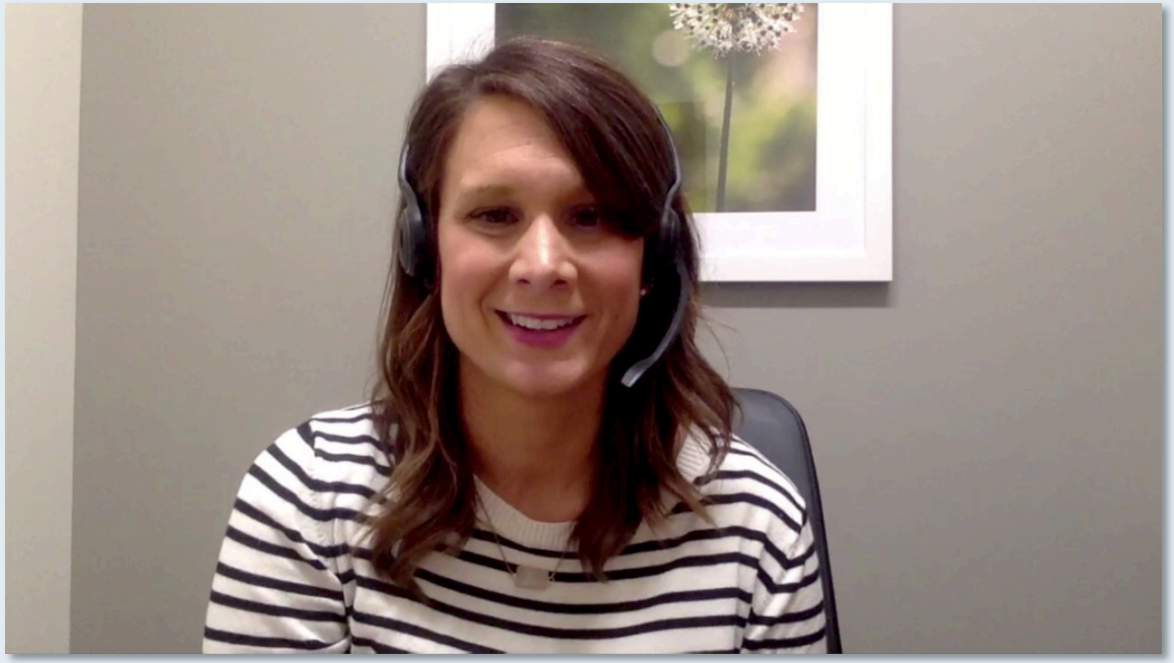
innovaTV 204: Maximum Change in Target Lesion Size by IRC Assessment



+ indicates a change greater than 100%

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

Reflections on patient care in oncology



Ms Arn

Ms Spickes

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Paula J Anastasia, NP MN AOCN


Courtney R Arn, APRN-CNP


Kimberly A Spickes, MNSc, RN, APRN, OCN, ACNP-BC

13th Annual Oncology Grand Rounds

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

Urothelial Bladder Carcinoma

Wednesday, April 28, 2021
12:00 PM – 1:00 PM ET

Medical Oncologists

Elisabeth I Heath, MD
Daniel P Petrylak, MD

Oncology Nurse Practitioners

Monica Averia, MSN, AOCNP, NP-C
Kathy D Burns, RN, MSN, AGACNP-BC, OCN

Moderator

Neil Love, MD

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Thank you for joining us!

NCPD credit information will be emailed to each participant shortly.

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