Meet The Professor

Optimizing the Management of Ovarian Cancer

Thursday, September 14, 2023
5:00 PM – 6:00 PM ET

Faculty

Kathleen N Moore, MD, MS

Moderator

Neil Love, MD

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Commercial Support

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

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Dr Love — Disclosures

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

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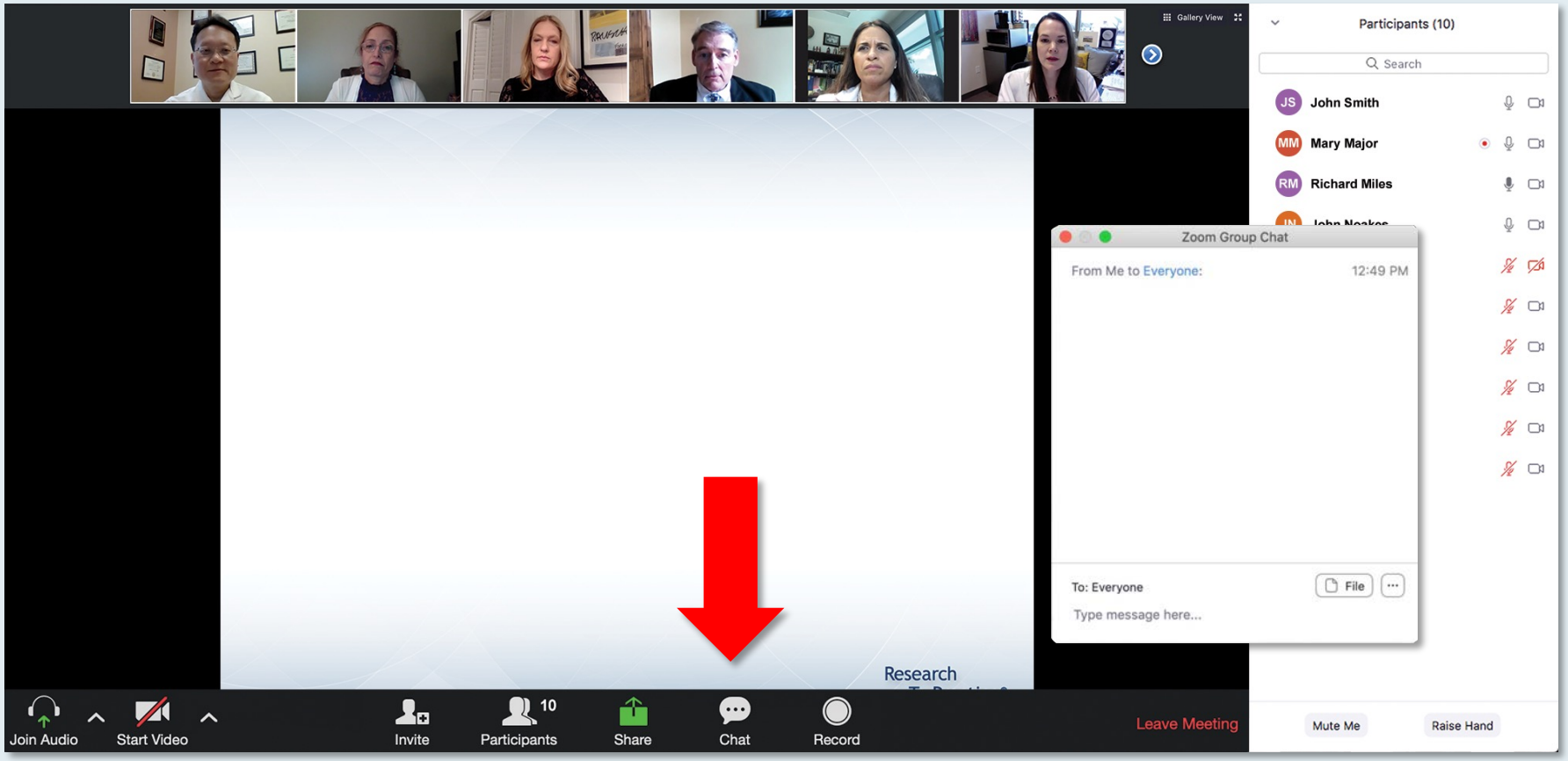
We Encourage Clinicians in Practice to Submit Questions



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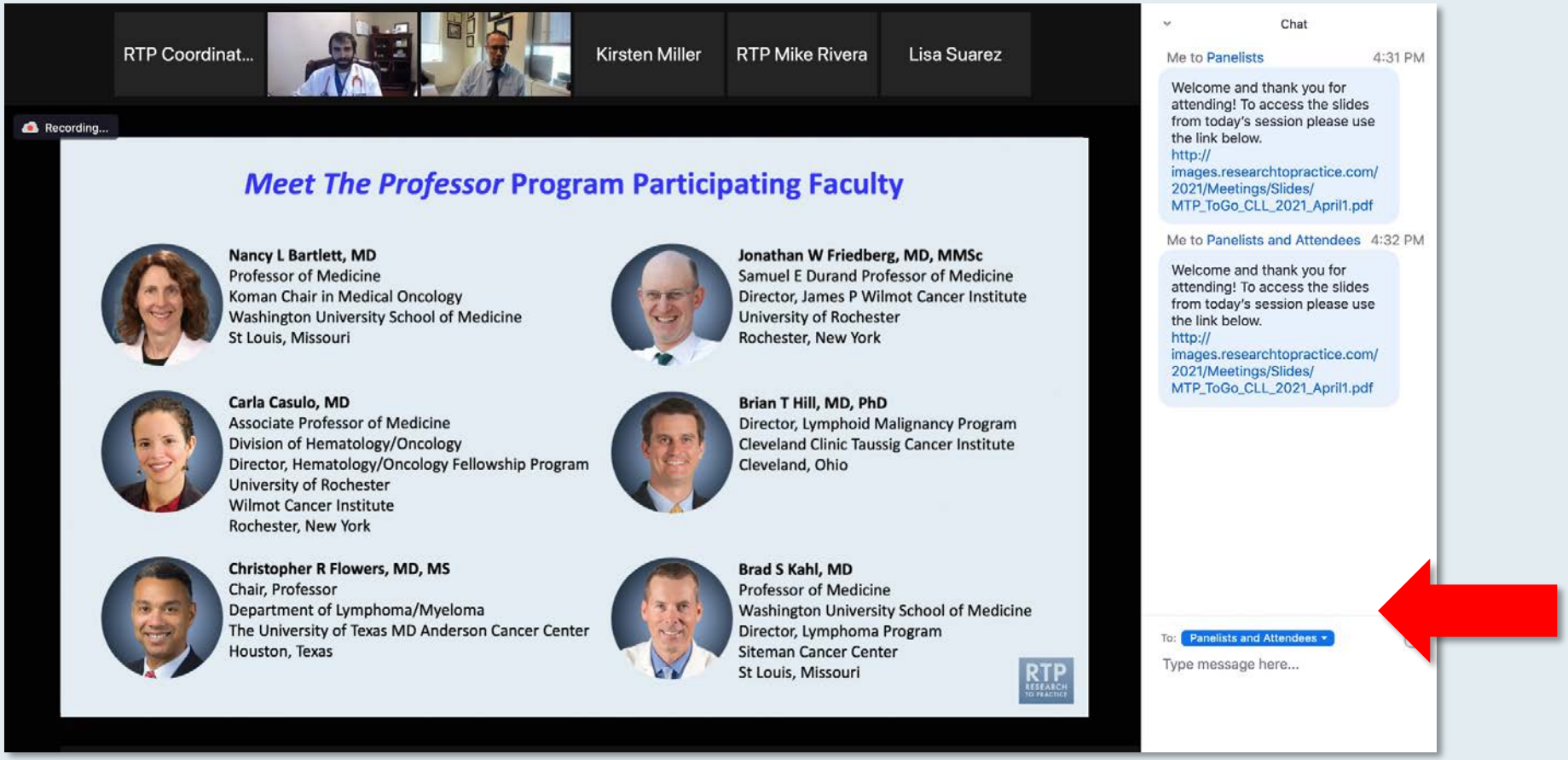

Drag the white line above the submission box up to create more space for your message.

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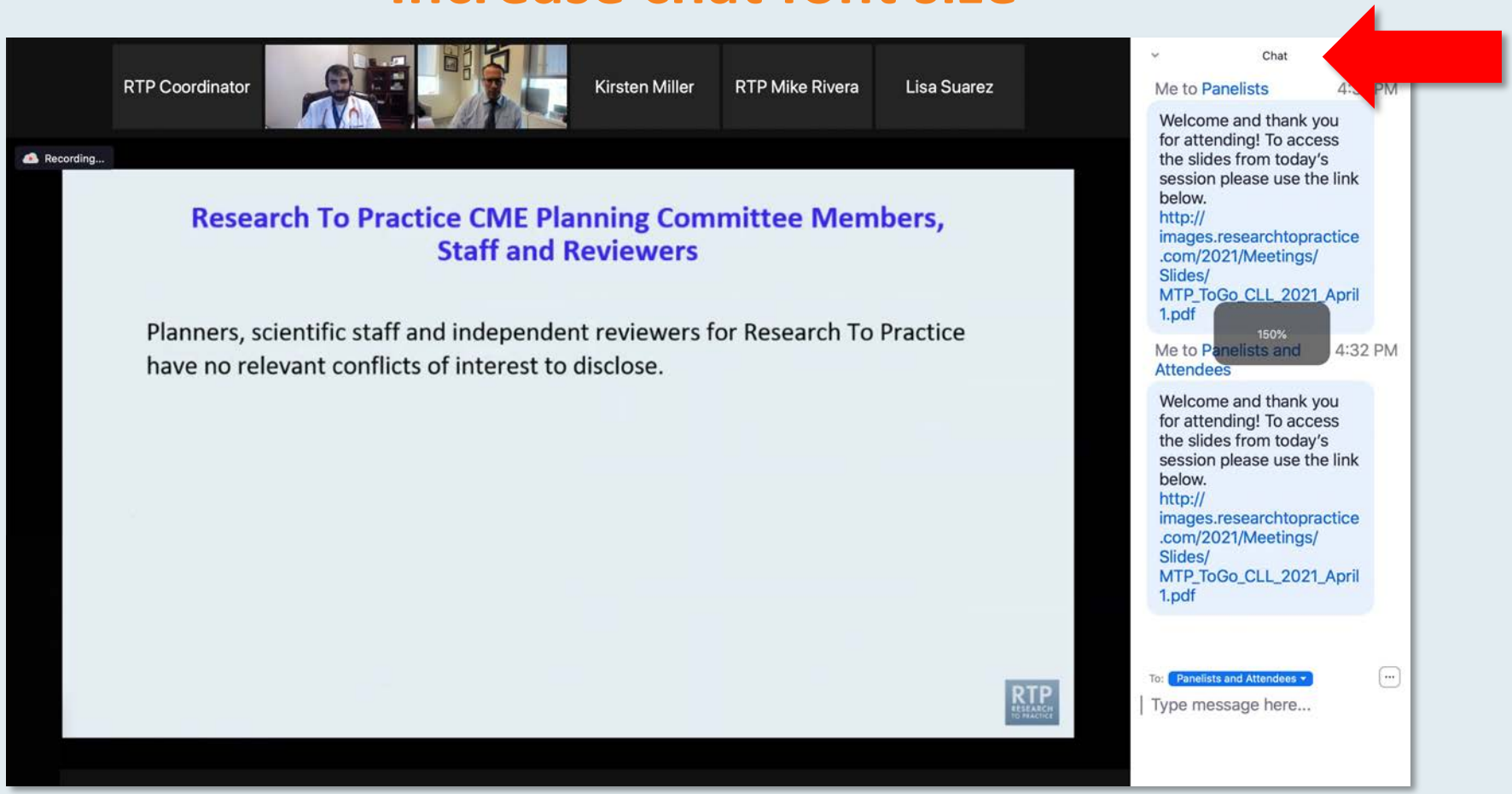

Press Command (for Mac) or Control (for PC) and the + symbol.
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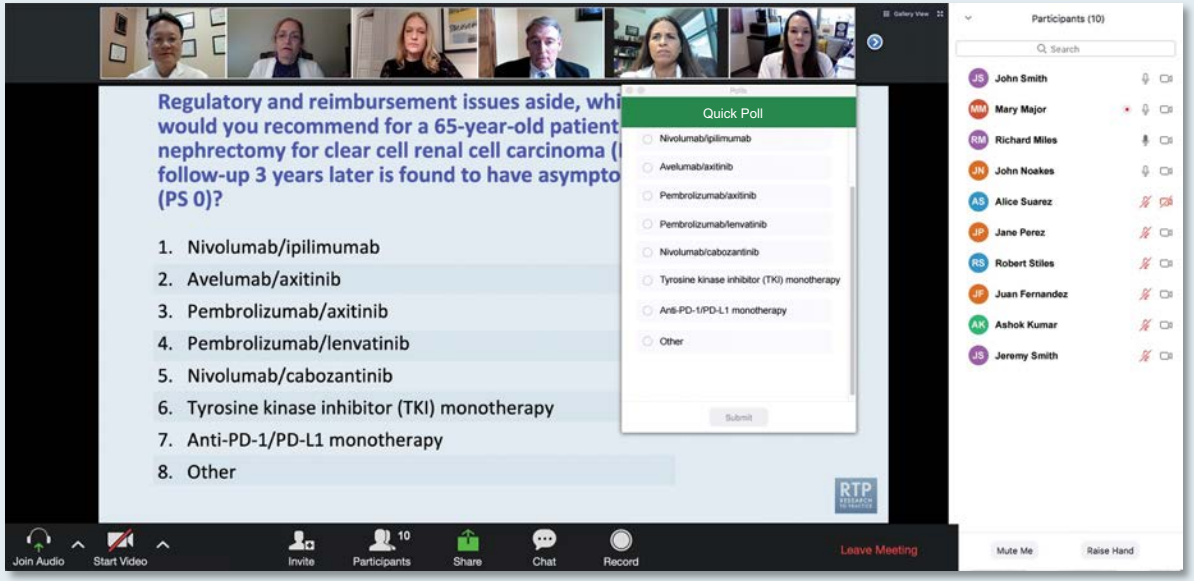

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WITH DR NEIL LOVE

Special Edition — Key Presentations from the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, Ovarian Cancer Issue

DR DAVID O'MALLEY
THE OHIO STATE UNIVERSITY AND
THE JAMES CANCER CENTER

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Meet The Professor

Optimizing the Management of Acute Myeloid Leukemia and Myelodysplastic Syndromes

Tuesday, September 19, 2023
5:00 PM – 6:00 PM ET

Faculty

Naval Daver, MD

Moderator

Neil Love, MD

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Practical Perspectives: Investigators Discuss Current Management and Actual Cases of Relapsed/Refractory Metastatic Colorectal Cancer

A CME/MOC-Accredited Virtual Event

Wednesday, September 20, 2023
5:00 PM – 6:00 PM ET

Faculty

Kristen K Ciombor, MD, MSCI
J Randolph Hecht, MD

Moderator

Neil Love, MD

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RESEARCH TO PRACTICE

Inside the Issue: Integrating Targeted and Immunotherapy into the Management of Localized Non-Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Thursday, September 21, 2023
5:00 PM – 6:00 PM ET

Faculty

Jamie E Chaft, MD
John V Heymach, MD, PhD

Moderator

Neil Love, MD

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RESEARCH
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What Clinicians Want to Know About the Management of Relapsed/Refractory Mantle Cell Lymphoma

A CME/MOC-Accredited Virtual Event

Tuesday, September 26, 2023
5:00 PM – 6:00 PM ET

Faculty

Toby A Eyre, MBChB, DipMedEd, MRCP, MD
Brad S Kahl, MD

Moderator

Neil Love, MD

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Meet The Professor
Optimizing the Management of Gastroesophageal Cancers

Thursday, September 28, 2023
5:00 PM – 6:00 PM ET

Faculty

Peter C Enzinger, MD

Moderator

Neil Love, MD

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RESEARCH TO PRACTICE

Inside the Issue: Optimizing the Management of Nonmelanoma Skin Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, October 3, 2023
5:00 PM – 6:00 PM ET

Faculty

Nikhil I Khushalani, MD
Anna C Pavlick, DO, MBA

Moderator

Neil Love, MD

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Thank you for joining us!

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

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Meet The Professor
Optimizing the Management of Ovarian Cancer

Kathleen N Moore, MD, MS
Associate Director, Clinical Research
Virginia Kerley Cade Chair in Developmental Therapeutics
Director, TSET Phase I Drug Unit
Co-Director, Cancer Therapeutics Program
Stephenson Cancer Center at the University of Oklahoma HSC
Associate Director, GOG Partners
Board of Directors, GOG Foundation
Oklahoma City, Oklahoma

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Meet The Professor Program Participating Faculty

Antonio González-Martín, MD, PhD
Director, Medical Oncology Department
Cancer Center Director
Clínica Universidad de Navarra
Madrid, Spain

Lainie Martin, MD
Division of Hematology/Oncology
Abramson Cancer Center
University of Pennsylvania
Philadelphia, Pennsylvania

Bradley J Monk, MD
Professor
Division of Gynecologic Oncology
University of Arizona College of Medicine
Creighton University School of Medicine
Phoenix, Arizona

Kathleen N Moore, MD, MS
Associate Director, Clinical Research
Virginia Kerley Cade Chair in Developmental Therapeutics
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Co-Director, Cancer Therapeutics Program
Stephenson Cancer Center at the University of Oklahoma HSC
Associate Director, GOG Partners
Board of Directors, GOG Foundation
Oklahoma City, Oklahoma

David M O'Malley, MD
Professor
Division Director, Gynecologic Oncology
The Ohio State University and The James
Cancer Center
Columbus, Ohio

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

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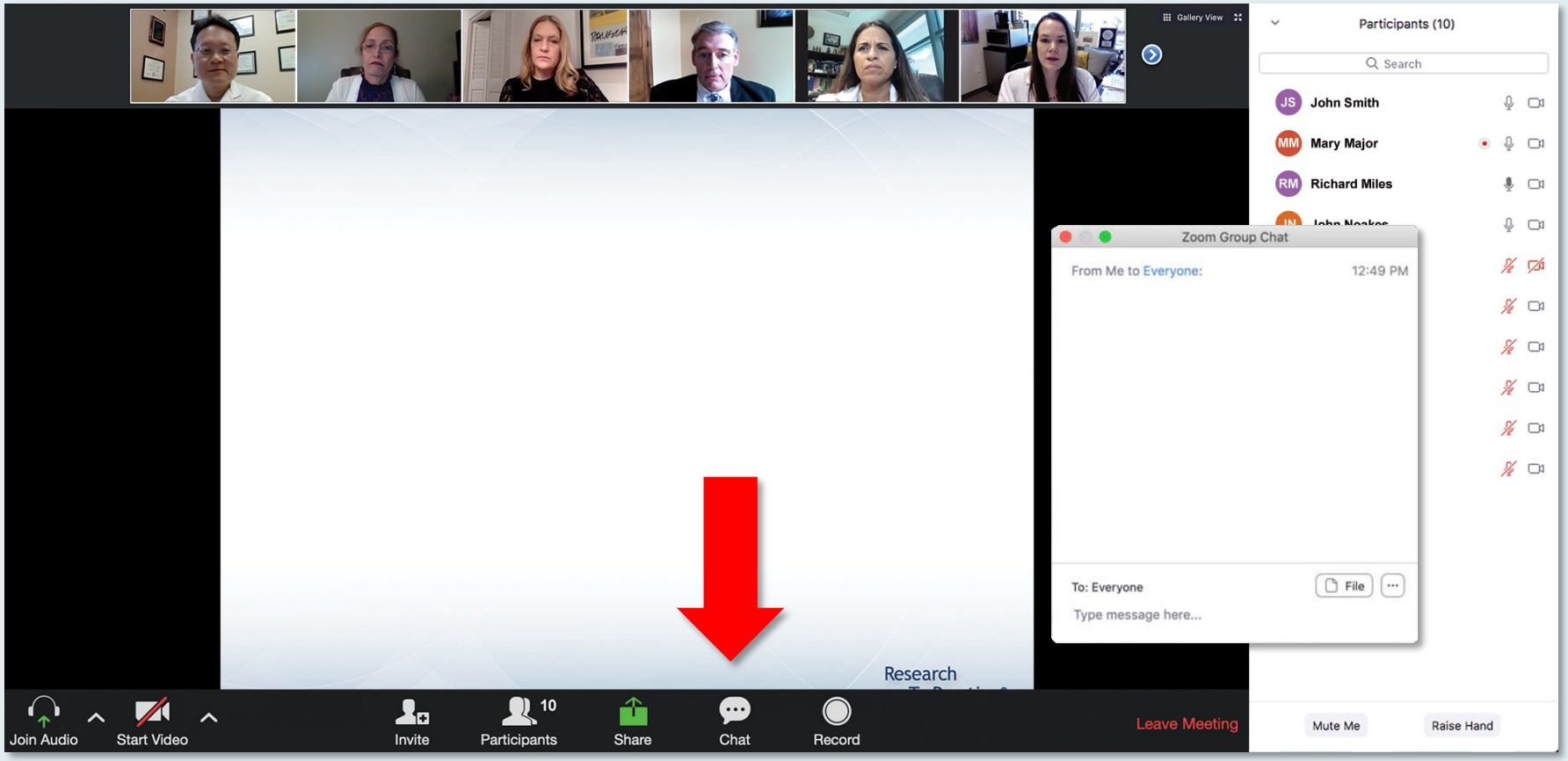
We Encourage Clinicians in Practice to Submit Questions



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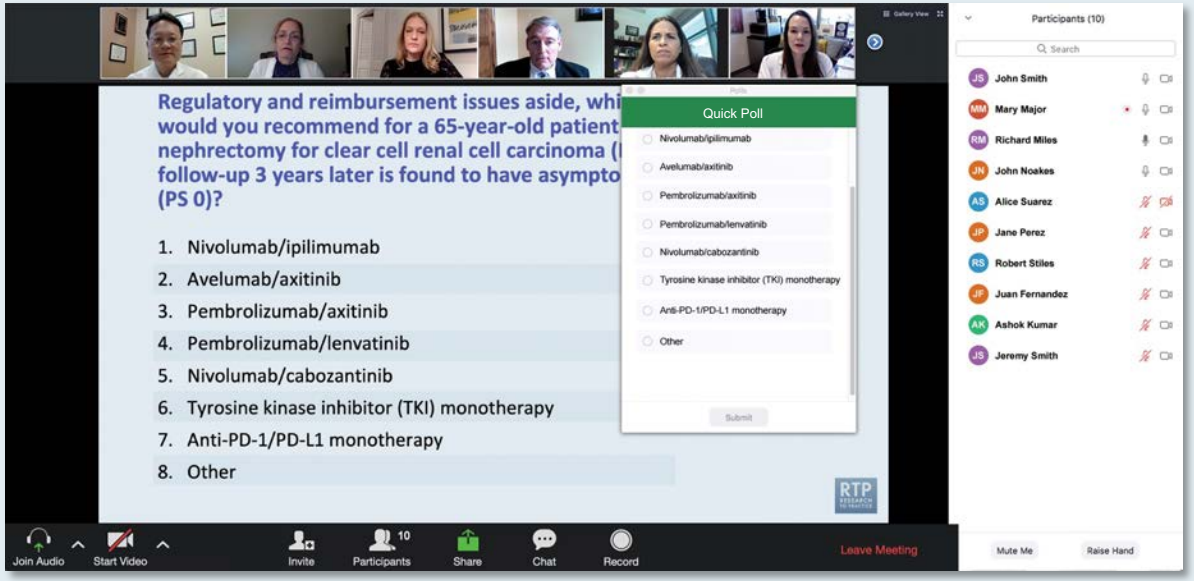

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John K Chan, MD
Sutter Cancer Research Consortium
San Francisco, California

Priya Rudolph, MD
Georgia Cancer Specialists
Athens, Georgia

Dana M Chase, MD
David Geffen School of Medicine
at UCLA
Los Angeles, California

Kellie E Schneider, MD
Novant Health Cancer Institute
Charlotte, North Carolina

Karim ElSahwi, MD
Hackensack Meridian Health
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Lyndsay J Willmott, MD
Virginia G Piper Cancer Care
Network
Phoenix, Arizona

Neil Morganstein, MD
Atlantic Health System
Summit, New Jersey

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Meet The Professor with Dr Moore

INTRODUCTION: SOLO-1 Trial

MODULE 1: Case Presentations

MODULE 2: Investigator Survey

MODULE 3: Journal Club with Dr Moore

MODULE 4: Appendix

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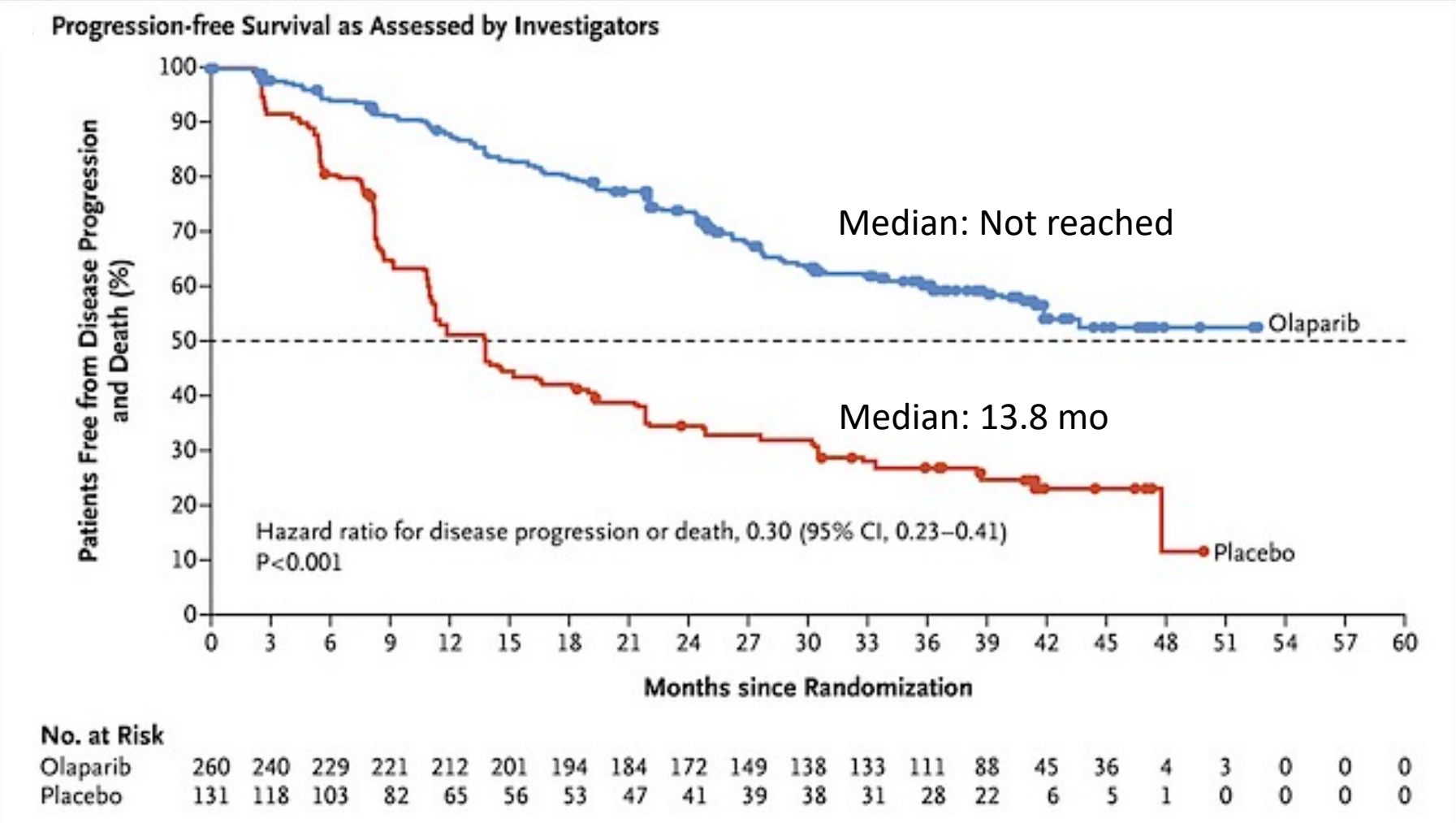
SOLO-1: Initial Results 2018



- Interim OS analysis: 3-Year OS rate was 84% in olaparib group, 80% in placebo group (HR 0.95)

Moore KN et al. *N Engl J Med* 2018;379:2495-505.

RTP RESEARCH TO PRACTICE

original reports

Overall Survival With Maintenance Olaparib at a 7-Year Follow-Up in Patients With Newly Diagnosed Advanced Ovarian Cancer and a BRCA Mutation: The SOLO1/GOG 3004 Trial

Paul DiSilvestro, MD[1]; Susana Banerjee, MD, PhD[2]; Nicoletta Colombo, MD, PhD[3]; Giovanni Scambia, MD[4]; Byoung-Gie Kim, MD, PhD[5]; Ana Oaknin, MD, PhD[6]; Michael Friedlander, MD[7]; Alla Lisyanskaya, MD[8]; Anne Floquet, MD[9,10]; Alexandra Leary, MD[10,11]; Gabe S. Sonke, MD, PhD[12]; Charlie Gourley, MD, PhD[13]; Amit Oza, MD[14]; Antonio González-Martín, MD, PhD[15,16]; Carol Aghajanian, MD[17]; William Bradley, MD[18]; Cara Mathews, MD[1]; Joyce Liu, MD[19]; John McNamara, MSc[20]; Elizabeth S. Lowe, MD[21]; Mei-Lin Ah-See, MB BChir, MD[22]; and Kathleen N. Moore, MD[23]; on behalf of the SOLO1 Investigators

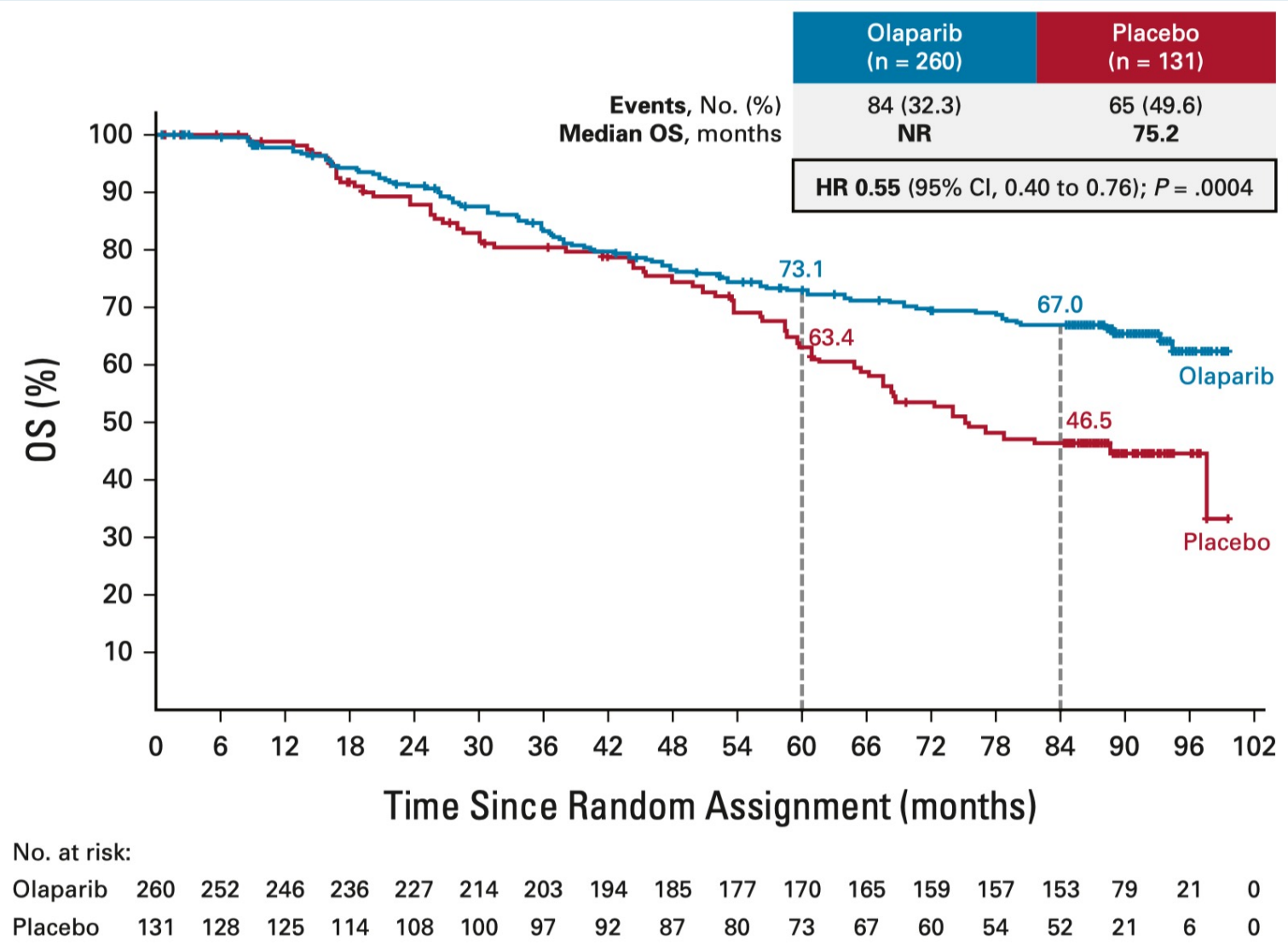
J Clin Oncol 2023;41(3):609-17.

SOLO-1: Subsequent PARP Inhibitor Therapy

Patients Receiving PARP Inhibitor	Olaparib (n = 260), No. (%)	Placebo (n = 131), No. (%)
Subsequent PARP inhibitor (any line)	38 (14.6)	58 (44.3)
First subsequent therapy	15 (5.8)	32 (24.4)
Second subsequent therapy	14 (5.4)	17 (13.0)
Third subsequent therapy	7 (2.7)	5 (3.8)
Fourth subsequent therapy	0	3 (2.3)
Fifth subsequent therapy	2 (0.8)	1 (0.8)

DiSilvestro P et al. *J Clin Oncol* 2023;41(3):609-17.

SOLO-1: Seven-Year Overall Survival



DiSilvestro P et al. *J Clin Oncol* 2023;41(3):609-17.

SOLO-1: Seven-Year Summary of Select Adverse Events (AEs)

	Olaparib (n = 260), No. (%)		Placebo (n = 130), No. (%)	
Patient With AE	Any Grade	Grade ≥ 3	Any Grade	Grade ≥ 3
Any	256 (98.5)	103 (39.6)	120 (92.3)	26 (20.0)
Nausea	202 (77.7)	2 (0.8)	49 (37.7)	0.0
Fatigue or asthenia	167 (64.2)	10 (3.8)	54 (41.5)	2 (1.5)
Vomiting	104 (40.0)	1 (0.4)	19 (14.6)	1 (0.8)
Anemia[b]	104 (40.0)	57 (21.9)	13 (10.0)	2 (1.5)
Diarrhea	90 (34.6)	8 (3.1)	32 (24.6)	0.0

- The most common Grade ≥3 AE was anemia.
- Serious AEs occurred in 21.2% of olaparib patients and 13.8% of placebo patients.
- The most commonly reported serious AEs were anemia (7.3% of olaparib patients versus 0.0% of placebo patients) and neutropenia (1.5% versus 0.0%).
- In total, 4 (1.5%) cases of MDS/AML were reported in the olaparib group and 1 (0.8%) case was reported in the placebo group.

DiSilvestro P et al. *J Clin Oncol* 2023;41(3):609-17.

PRIMA/ENGOT-OV26/GOG-3012 Study: Updated Long-term PFS and Safety

Antonio González-Martín,[1] Bhavana Pothuri,[2] Ignace Vergote,[3] Whitney Graybill,[4] Mansoor R. Mirza,[5] Colleen C. McCormick,[6] Domenica Lorusso,[7] Gilles Freyer,[8] Floor Backes,[9] Klaus Baumann,[10] Andrés Redondo,[11] Richard G. Moore,[12] Christof Vulsteke,[13] Roisin E. O'Cearbhaill,[14] Izabela A. Malinowska,[15] Luda Shtessel,[15]

[1]Medical Oncology Department, Clínica Universidad de Navarra, Madrid, Program in Solid Tumours, CIMA, Pamplona, and (GOG), Department of Obstetrics/Gynecology, Perlmutter Cancer Center, NYU Langone Health, New York, NY, USA; [3]Belg Division of Gynaecologic Oncology, University Hospitals Leuven, Leuven Cancer Institute, Leuven, Belgium; [4]GOG, Gynecolo University Hospital, Copenhagen, Denmark; [6]GOG, Legacy Medical Group Gynecologic Oncology, Portland, OR, USA; [7]Mult IRCCS and Catholic University of Sacred Heart, Rome, Italy; [8]Groupe d'Investigateurs Nationaux pour l'Etude des Cancers [9]Division of Gynecologic Oncology, Ohio State University, Columbus, OH, USA; [10]Arbeitsgemeinschaft Gynäkologische On Germany; [11]GEICO, Hospital Universitario La Paz-IdiPAZ, Madrid, Spain; [12]US Oncology Research, Division of Gynecolo Rochester, NY, USA; [13]BGOG, Department of Medical Oncology and Hematology, AZ Maria Middelares, Gent, and De Antwerp University, Antwerp, Belgium; [14]GOG, Gynecologic Medical Oncology, Memorial Medical College, New York, NY, USA; [15]GSK, Middlesex, UK; [16]HonorHealth Phoenix Creighton University, P

IGCS 2022;Abstract S005/1753.

Progression-free survival and safety at 3.5 years of follow-up: results from the randomised phase 3 PRIMA/ENGOT-OV26/GOG-3012 trial of niraparib maintenance treatment in patients with newly diagnosed ovarian cancer

Antonio González-Martín [a,*], Bhavana Pothuri [b], Ignace Vergote [c], Whitney Graybill [d], Domenica Lorusso [e], Colleen C. McCormick [f], Gilles Freyer [g], Floor Backes [h], Florian Heitz [i,q], Andrés Redondo [j], Richard G. Moore [k], Christof Vulsteke [l,r], Roisin E. O'Cearbhaill [m], Izabela A. Malinowska [n], Luda Shtessel [n], Natalie Compton [n], Mansoor R. Mirza [o], Bradley J. Monk [p]

Eur J Cancer 2023 August;189:112908.

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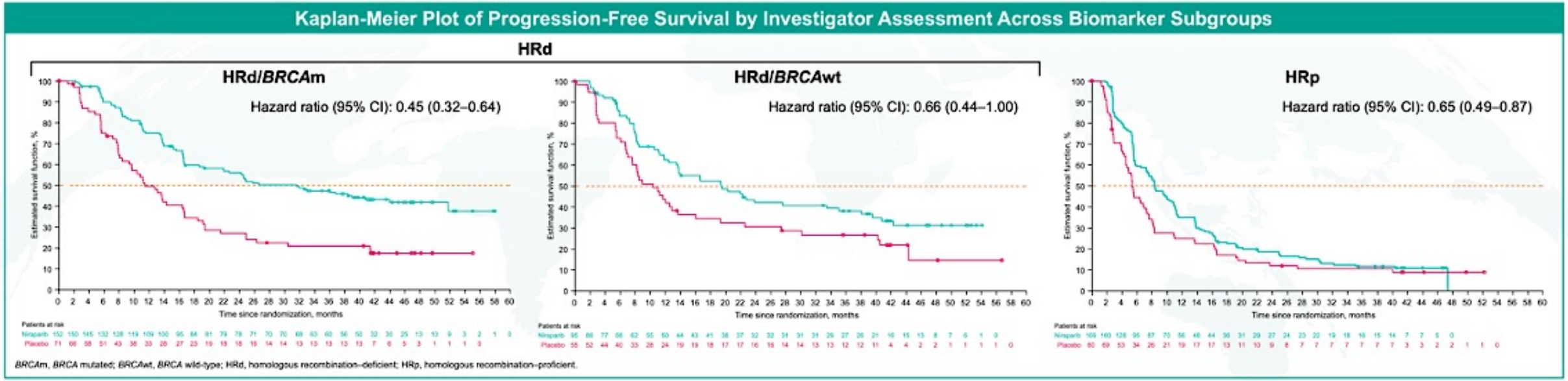
PRIMA: PFS Across Biomarker Subgroups (Investigator-Assessed)

November 17, 2021, Clinical Cutoff Date



- Niraparib treatment increased PFS duration compared with placebo treatment across biomarker subgroups
- The greatest treatment benefit was seen in patients with HRd tumors that were *BRCA*m

IGCS 2022 ANNUAL GLOBAL MEETING

González-Martín A et al. IGCS 2022;Abstract S005/1753. González-Martín A et al. *Eur J Cancer* 2023;189:112908.

RTP RESEARCH TO PRACTICE

original reports

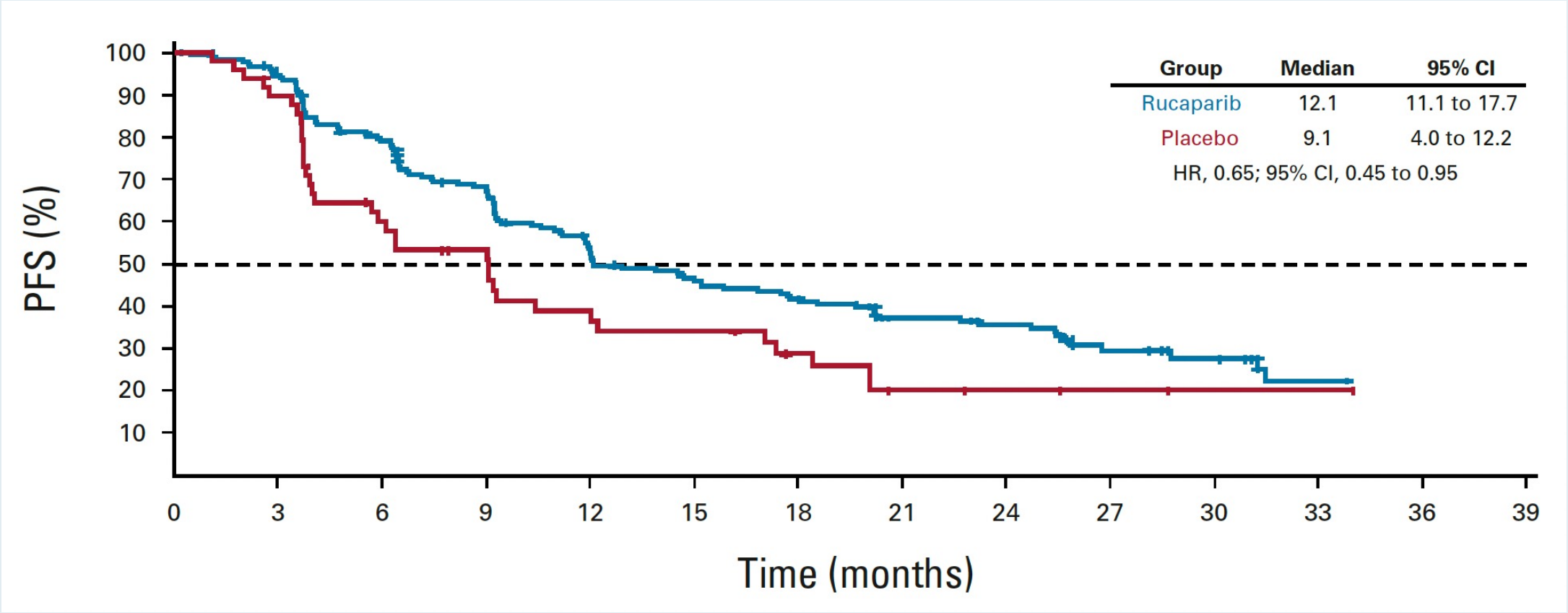
A Randomized, Phase III Trial to Evaluate Rucaparib Monotherapy as Maintenance Treatment in Patients With Newly Diagnosed Ovarian Cancer (ATHENA–MONO/GOG-3020/ENGOT-ov45)

Bradley J. Monk, MD[1]; Christine Parkinson, MD[2]; Myong Cheol Lim, MD, PhD[3]; David M. O'Malley, MD[4]; Ana Oaknin, MD, PhD[5]; Michelle K. Wilson, MD[6]; Robert L. Coleman, MD[7]; Domenica Lorusso, MD, PhD[8]; Paul Bessette, MD[9]; Sharad Ghamande, MD[10]; Athina Christopoulou, MD, PhD[11]; Diane Provencher, MD[12]; Emily Prendergast, MD[13]; Fuat Demirkiran, MD[14]; Olga Mikheeva, MD[15]; Oladapo Yeku, MD, PhD[16]; Anita Chudecka-Glaz, MD, PhD[17]; Michael Schenker, MD, PhD[18]; Ramey D. Littell, MD[19]; Tamar Safra, MD[20]; Hung-Hsueh Chou, MD[21,22]; Mark A. Morgan, MD[23]; Vít Drochýtek, MD[24]; Joyce N. Barlin, MD[25]; Toon Van Gorp, MD[26]; Fred Ueland, MD[27]; Gabriel Lindahl, MD[28,29]; Charles Anderson, MD[30]; Dearbhaile C. Collins, MBBCh, MA, PhD[31]; Kathleen Moore, MD[32]; Frederik Marme, MD, PhD[33]; Shannon N. Westin, MD, MPH[34]; Iain A. McNeish, MD, PhD[35]; Danny Shih, BA[36]; Kevin K. Lin, PhD[37]; Sandra Goble, MS[38]; Stephanie Hume, PhD[39]; Keiichi Fujiwara, MD, PhD[40]; and Rebecca S. Kristeleit, MD, PhD[41]

J Clin Oncol 2022;40(34):3952-64.

JC JOURNAL CLUB RTP RESEARCH TO PRACTICE

ATHENA-MONO: Investigator-Assessed Progression-Free Survival (PFS) in HRD-Negative Patient Group (BRCA Wild Type, LOH Low)



Monk BJ et al. *J Clin Oncol* 2022;40(34):3952-64.

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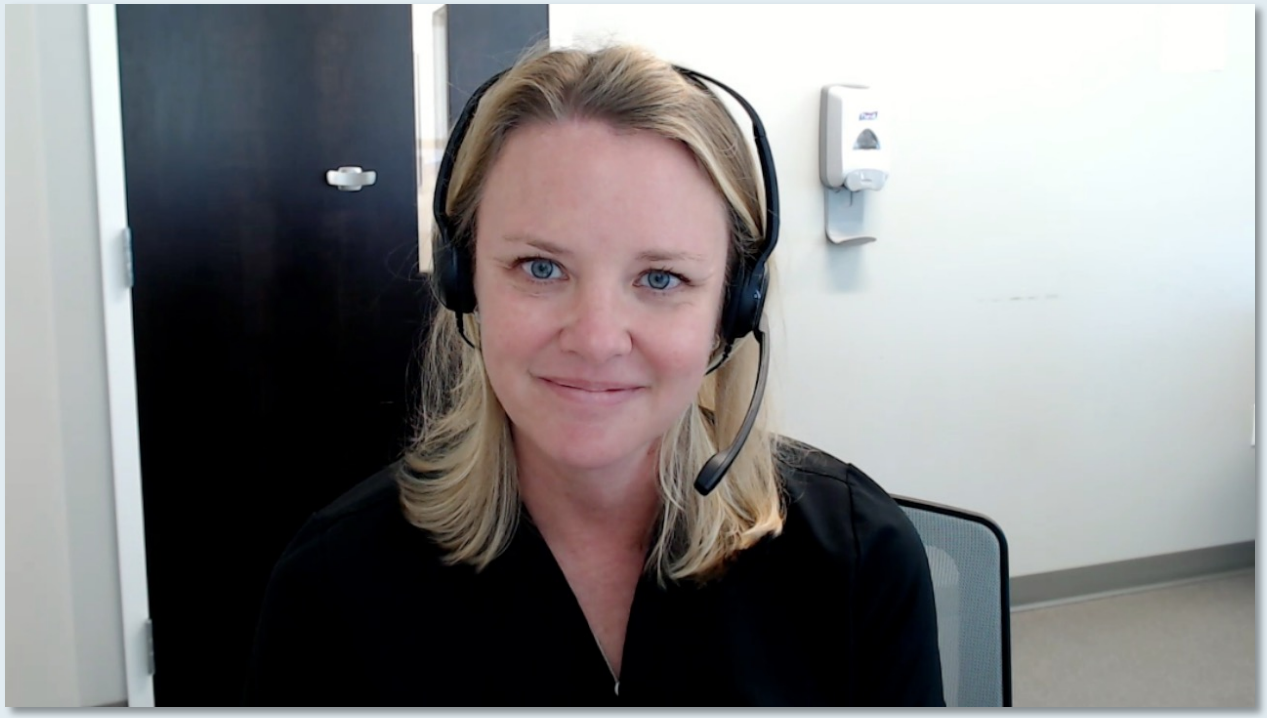
Case Presentation: 54-year-old woman, gBRCA1, s/p IV/IP chemotherapy → olaparib maintenance, now with recurrence

Dr Neil Morganstein (Summit, New Jersey)

Case Presentation: 57-year-old woman, gBRCA2, s/p surgery, chemotherapy, Stage II HGSOC



Dr Kellie Schneider (Charlotte, North Carolina)

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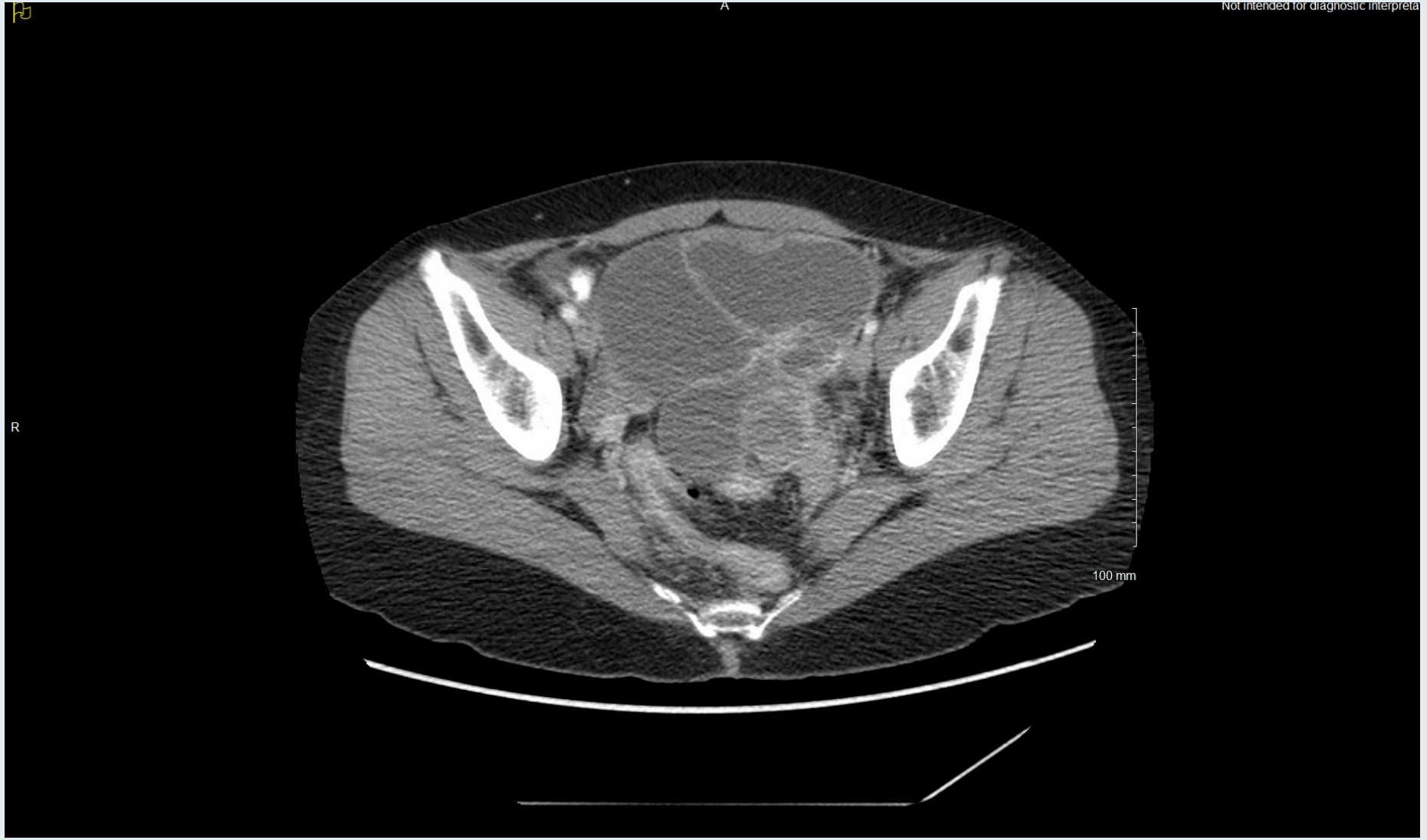
TO PRACTICE



Case Presentation: 77-year-old woman, sBRCA2 Stage IVB HGSOC, PD on the PRIMA trial (placebo). Recurrence 2019 → liposomal doxorubicin/carboplatin → maintenance niraparib

Dr Karim ElSahwi (Neptune City, New Jersey)

RTP RESEARCH TO PRACTICE

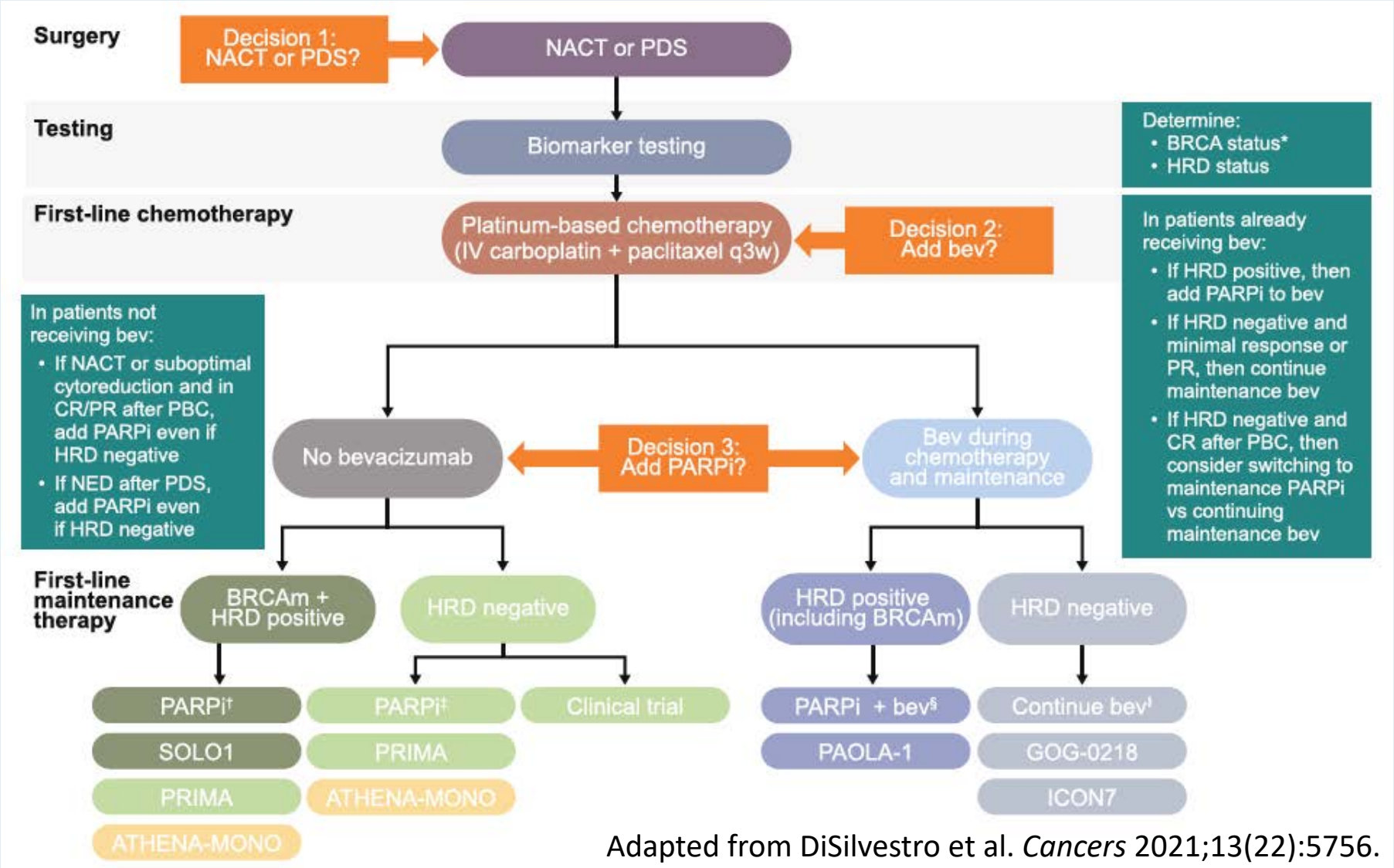
Targeted Oncology (2023) 18:471–503
https://doi.org/10.1007/s11523-023-00970-w

REVIEW ARTICLE

PARP Inhibitors in Ovarian Cancer: A Review

David M. O'Malley[1] · Thomas C. Krivak[2] · Nashwa Kabil[3] · Jiefen Munley[4] · Kathleen N. Moore[5]

Proposed Treatment Algorithm for Newly Diagnosed Ovarian Cancer



Adapted from DiSilvestro et al. *Cancers* 2021;13(22):5756.

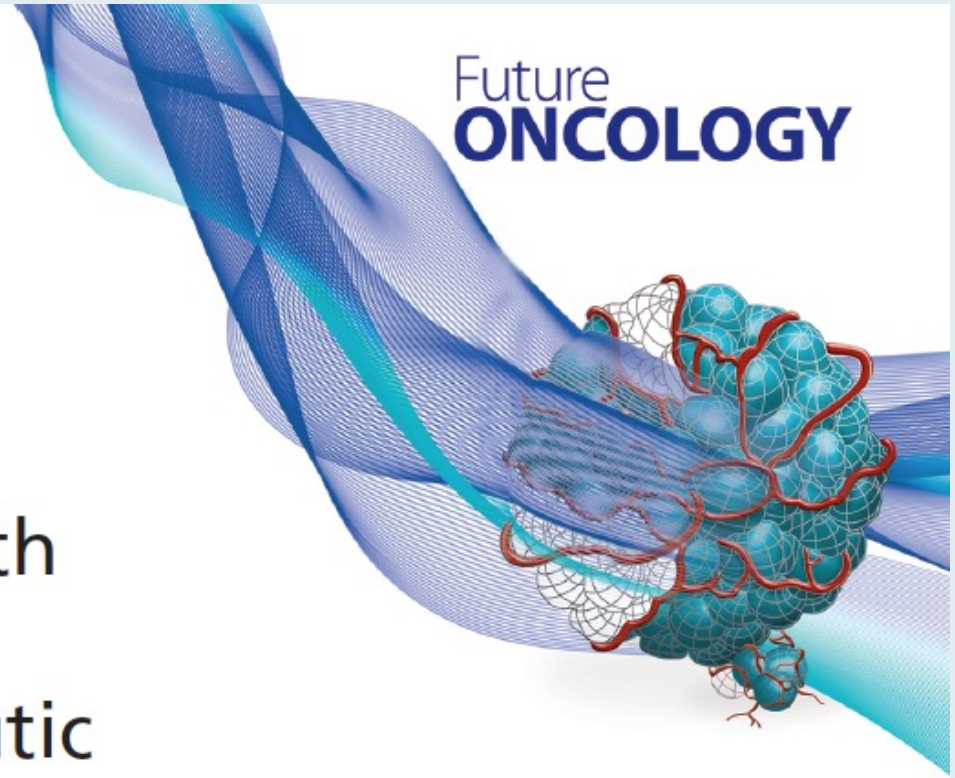
NACT = neoadjuvant chemotherapy; PDS = primary debulking surgery; HRD = homologous recombination deficiency

O'Malley DM et al. *Target Oncol* 2023;18(4):471-503.

2022;18(23):2505-36

Drug Evaluation

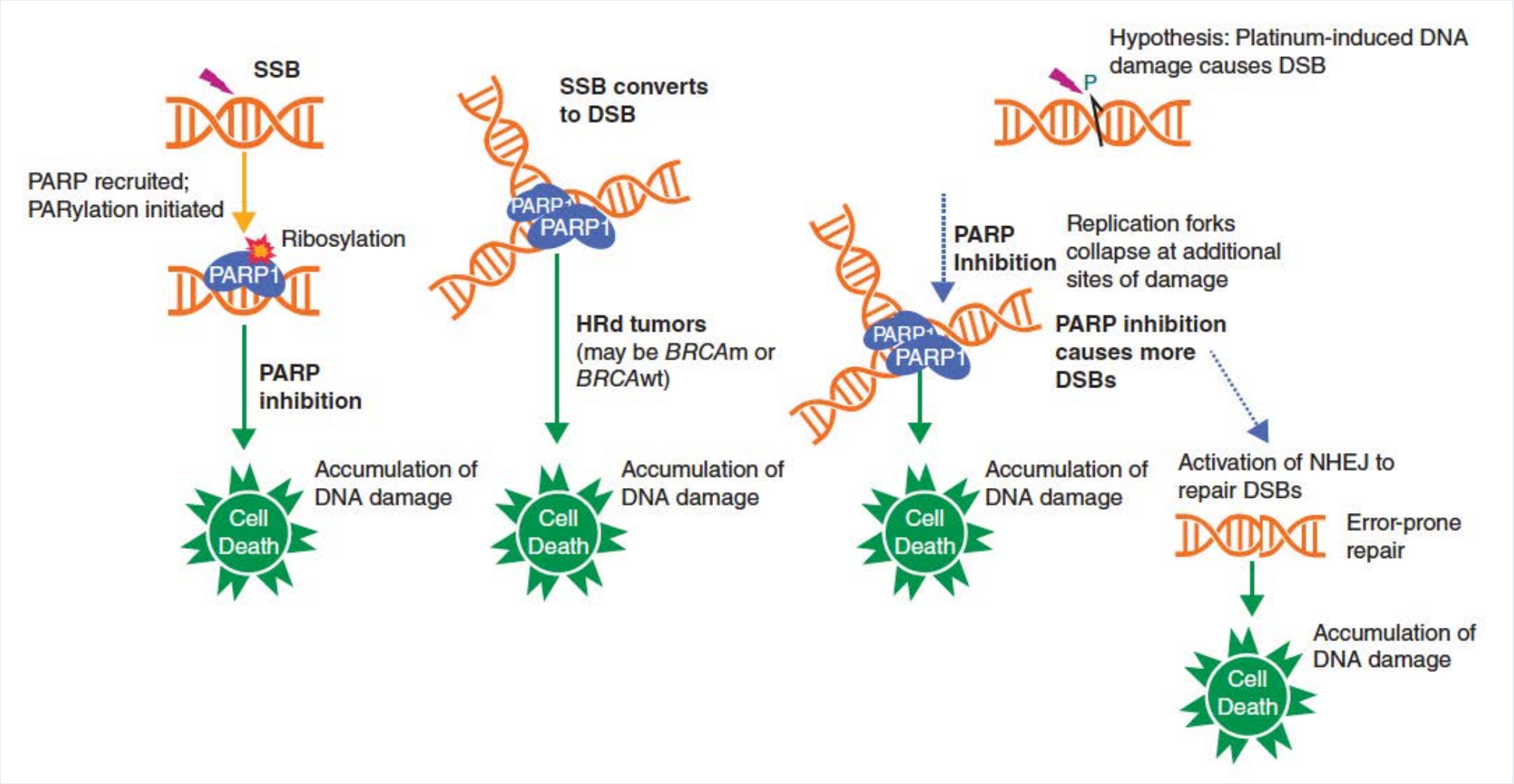
Future ONCOLOGY



Niraparib treatment for patients with *BRCA*-mutated ovarian cancer: review of clinical data and therapeutic context

Antonio González-Martín[1], Ursula A Matulonis[2], Jacob Korach[3], Mansoor R Mirza[4], Kathleen N Moore[5], Xiaohua Wu[6], Whitney York[7], Divya Gupta[8], Stanislav Lechpammer[‡,8] & Bradley J Monk[*,9]

Poly(ADP-Ribose) Polymerase (PARP) and PARP Inhibitor Mechanisms of Action



SSB = single-stand break; DSB = double-strand break

González-Martín A et al. *Future Oncol* 2022;18(23):2505-36.

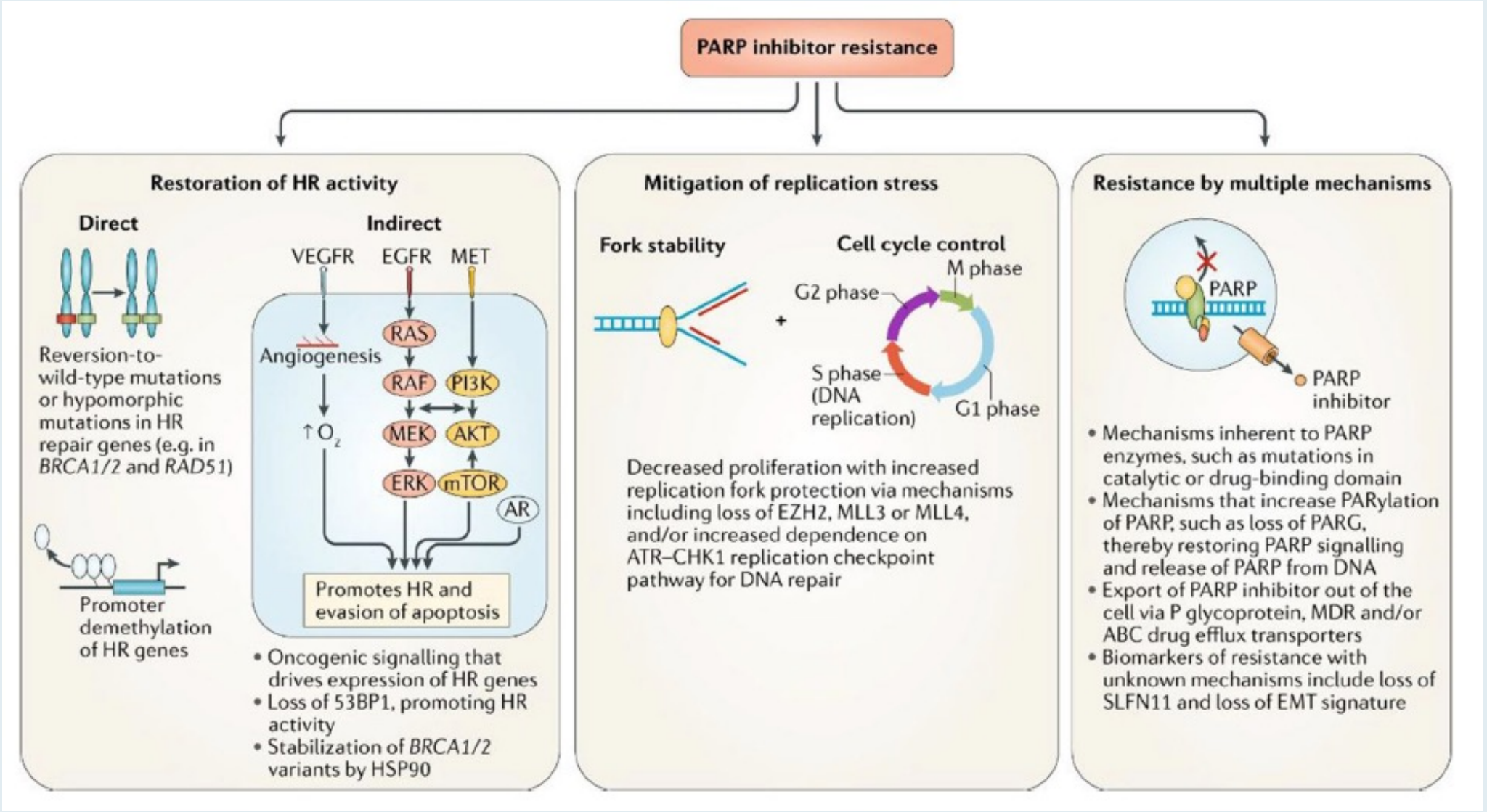
Current Oncology Reports (2022) 24:1685–1693
https://doi.org/10.1007/s11912-022-01337-6

GYNECOLOGIC CANCERS (NS REED, SECTION EDITOR)

Resistance to Poly (ADP-Ribose) Polymerase Inhibitors (PARPi): Mechanisms and Potential to Reverse

Christina R. Washington[1] · Kathleen N. Moore[1]

Mechanisms of Resistance to PARP Inhibitors



HR = homologous recombination

Washington CR, Moore KN. *Curr Oncol Rep* 2022;24(12):1685-93.

Case Presentation: 52-year-old woman with recurrent BRCA WT, HRD-negative clear cell OC after interval debulking surgery

Dr Dana Chase (Los Angeles, California)

RTP RESEARCH TO PRACTICE

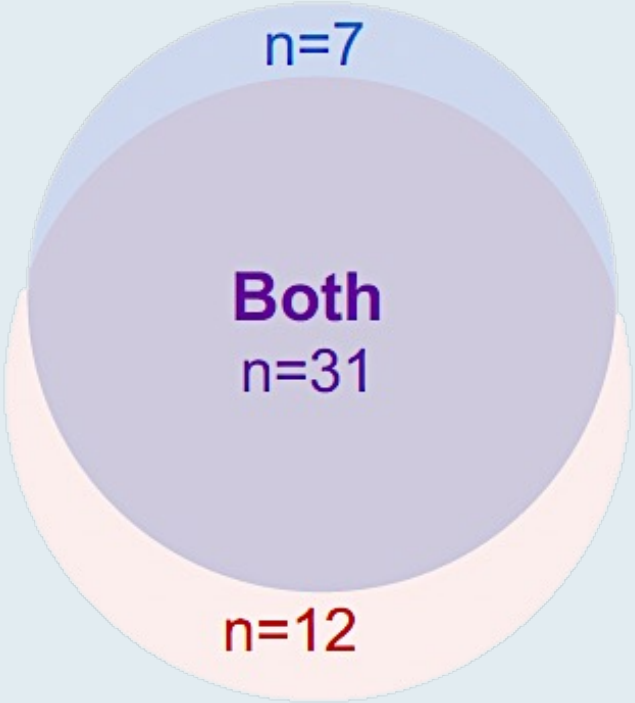
Case Presentation: 61-year-old woman with BRCA WT, HRD-negative OC, primary progression on neoadjuvant carboplatin/paclitaxel. Folate receptor alpha-positive: now on mirvetuximab sorvatansine

Dr Priya Rudolph (Athens, Georgia)

RTP RESEARCH TO PRACTICE

Unique Events Associated with Mirvetuximab Soravtansine: Keratopathy and Blurred Vision

Events developed in 50/106 (47%) patients: Mostly low grade



Proactive supportive care
– Lubricating artificial tears
– Corticosteroid eye drops

Predictable
– Median time to onset: Cycle 2 (~1.5 months)

Manageable with dose modifications, if needed
– 22% of patients (23/106) had dose delay and/or reduction

Reversible
– At data cutoff: >80% of patients with Grade 2-3 events had resolved to Grade 0-1
– Nine patients still receiving MIRV or being followed up for resolution

<1% discontinuation due to ocular events
– One of 106 patients discontinued due to Grade 4 keratopathy, which resolved within 15 days

Matulonis UA et al. SGO 2022;Abstract LBA4.

Updated Results From the Phase 1b Expansion Study of Upifitamab Rilsodotin (UpRi; XMT-1536), a NaPi2b-directed Dolaflexin Antibody Drug Conjugate (ADC) in Ovarian Cancer

Richardson, Debra L[1]; Hamilton, Erika P[2]; Barve, Minal[3]; Anderson, Charles K[4]; Taylor, Sara K[5]; Lakhani, Nehal[6]; Buscema, Joseph[7]; Tolcher, Anthony W[8]; Zarwan, Corrine[9]; Werner, Theresa L[10]; Hays, John L[11]; Richards, Paul[12]; Arend, Rebecca[13]; Edenfield, Jeffery[14]; Putiri, Emily[15]; Bernardo, Patricia[15]; Burger, Robert A[15]; Matulonis, Ursula A[16]

[1]Stephenson Cancer Center, University of Oklahoma Health Sciences Center and the Sarah Cannon Research Institute, Oklahoma City, OK; [2]Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN; [3]Mary Crowley Cancer Research, Dallas, TX; [4]Willamette Valley Cancer Institute and Research Center, Eugene, OR; [5]BC Cancer - Kelowna, Kelowna BC, Canada; [6]START Midwest, Grand Rapids, MI; [7]Arizona Oncology, Tucson, AZ; [8]NEXT Oncology, San Antonio, TX; [9]Lahey Clinic, Burlington, MA; [10]Huntsman Cancer Institute, University of Utah, Salt Lake City, UT; [11]Arthur James Cancer Hospital, Ohio State University, Columbus, OH; [12]US Oncology, Oncology and Hematology Assoc. of Southwest VA, Salem, VA; [13]University of Alabama at Birmingham, Birmingham, AL; [14]Prisma Health Cancer Institute, Greenville, SC; [15]Mersana Therapeutics, Inc, Cambridge, MA; [16]Dana-Farber Cancer Institute, Boston, MA

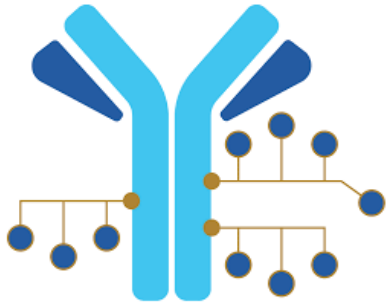
Abstract 76

ANNUAL MEETING ON WOMENS' CANCER®
BUILDING BRIDGES // BREAKING BARRIERS
SGO // PHOENIX, ARIZONA // MARCH 18 - 21, 2022

SGO 2022

Society of Gynecologic Oncology

Upifitamab Rilsodotin (UpRi): First-in-Class ADC Targeting NaPi2b



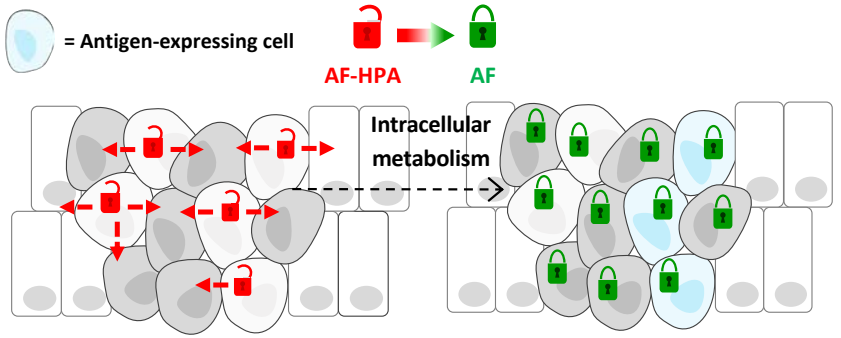
UpRi

Antibody: Humanized monoclonal anti-NaPi2b[1]

Linker: Polymer scaffold; cleavable ester linker[2]

Payload: AF-HPA (DolaLock-controlled bystander effect)[1]

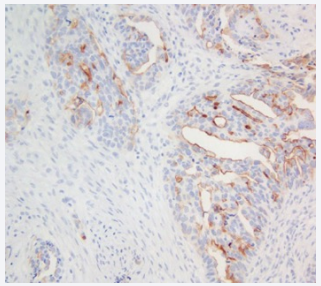
Drug-to-Antibody Ratio: ~10



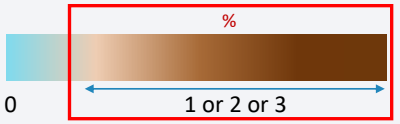
Upon ADC internalization into tumor cells and efficient release of payload, AF-HPA payload is metabolized to AF that remains highly potent but loses the ability to cross the cell membrane, locking it in the tumor, controlling the bystander effect, and consequently limiting impact on adjacent healthy cells[2,3]

NaPi2b Is a Sodium-Dependent Phosphate Transporter Broadly Expressed in Ovarian Cancer With Limited Expression in Healthy Tissues[4]

- NaPi2b expressed by tumor cells in two-thirds of patients with high-grade serous ovarian cancer[2]
- NaPi2b is a lineage antigen (not an oncogene)[1]



NaPi2b IHC assay in development *– an optimal diagnostic assay would be robust, predictive, reproducible, easily able to distinguish a wide range of expression using* ***TPS scoring method***[2]



ADC, antibody drug conjugate; AF, Auristatin F; AF-HPA, auristatin F-hydroxypropylamide; IHC, immunohistochemistry; NaPi2b, sodium-dependent phosphate transport protein 2B; TPS, tumor proportion score; UpRi, upifitamab rilsodotin.

1. Bodyak ND et al. *Mol Cancer Ther.* 2021;20(5):885–895. 2. Mersana. Data on File. 2022. 3. Tolcher AW et al. ASCO Annual Meeting 2019; Abstract 3010.
4. Lin K et al. *Clin Cancer Res*. 2015;21(22):5139–5150.

Richardson DL et al. SGO 2022;Abstract 76.

FDA Issues Partial Clinical Hold on Enrollment Based on Safety Data from UP-NEXT and UPGRADE-A Trials Evaluating UpRi

Press Release: June 15, 2023

"June 15, 2023 (GLOBE NEWSWIRE) — A clinical-stage biopharmaceutical company focused on discovering and developing a pipeline of antibody-drug conjugates (ADCs) targeting cancers in areas of high unmet medical need, today announced that the US Food and Drug Administration (FDA) has issued a partial clinical hold pausing new patient enrollment in UP-NEXT and UPGRADE-A, the company's ongoing clinical trials of UpRi in platinum-sensitive ovarian cancer. UPLIFT, [the] ongoing clinical trial of UpRi in platinum-resistant ovarian cancer, completed enrollment in October 2022. Patients who are already enrolled in these trials may continue receiving UpRi. [The company] expects to lock its UPLIFT clinical trial database and disclose UPLIFT top-line data by early August.

The partial clinical hold follows a submission by [the manufacturer] of a recent aggregate safety report of all patients dosed with UpRi (approximately 560 patients) evaluating bleeding events. As noted in FDA guidance, aggregate analyses generally become more informative as a drug progresses through development and accumulates data. Detection of a clinically meaningful risk, particularly in single-arm clinical trials, typically requires a large safety database to detect differences in rates of adverse events compared to those that are expected in the population being studied.

Although data on the background rate of bleeding in platinum-resistant ovarian cancer are limited, [the company's] recent assessment determined that serious bleeding events appear to occur at a higher rate than background. **While most bleeding cases in this aggregate safety analysis were low-grade, five (<1%) Grade 5 (fatal) bleeding events were observed among the approximately 560 patients dosed to date.** The causes of bleeding events remain under investigation."

https://ir.mersana.com/news-releases/news-release-details/mersana-therapeutics-announces-partial-clinical-hold-next-and

RTP RESEARCH TO PRACTICE

Case Presentation: 64-year-old woman with recurrent BRCA WT HGSOC, TTFields discontinued due to skin toxicity

Dr Lyndsay Willmott (Phoenix, Arizona)

RTP
RESEARCH
TO PRACTICE

Tumor Treating Fields (TTFields) Mechanism of Action

TTFields therapy mechanism of action

1

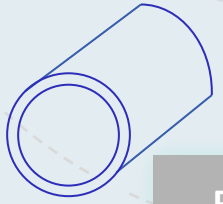
DDR DOWNREGULATION

R-loop formation disruption
Red. replication fork speed
Chromatid aberrations
Downregulation of the FA-BRCA pathway

2

INTERFERENCE IN CELL MOBILITY AND MIGRATION

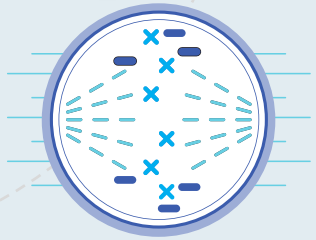
Actin bundling and formation of focal adhesions
Loss of cytoskeletal directionality



3

PERMEABILITY

Tight junction protein delocalisation in endothelial cells



4

DISRUPTION OF MITOSIS

Diminished microtubule abundance
Red. mitotic spindle assembly
Septin disruption and cytoplasmic blebbing
Organelle migration to cleavage furrow

5

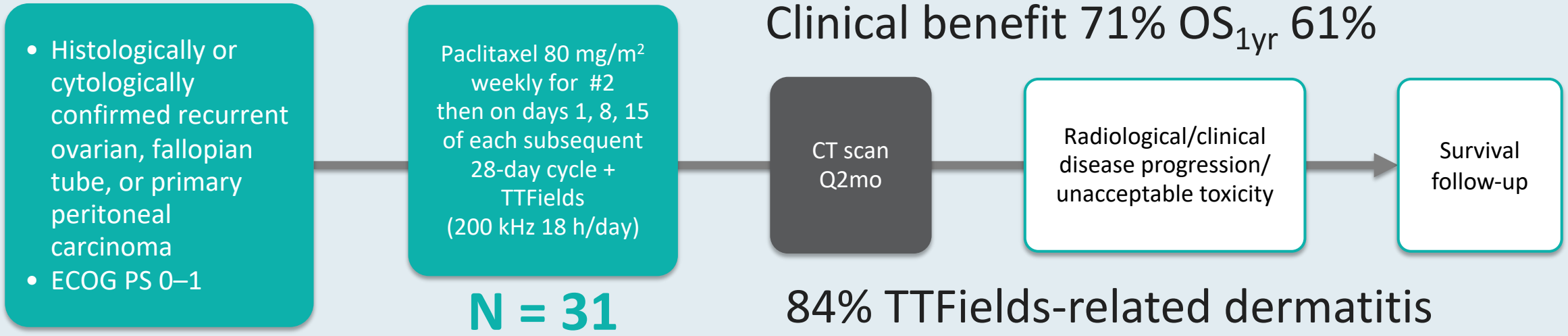
ENHANCEMENT OF ANTITUMOR IMMUNITY

Activation of immunogenic cell death
Recruitment and infiltration of tumor leukocytes
Activation of downstream adaptive immunity

Kirson ED et al. *Cancer Res* 2004;64(9):3288-95;
Mun EJ et al. *Clin Cancer Res* 2018;24(2):266-75.

Courtesy of Richard T Penson, MD

INNOVATE: Phase II Trial Design



Start date: September 2014
Primary completion date: December 2016
Study sites: 5 (Europe)

Primary endpoints:
- AE severity and frequency, No. prematurely DCing TTFields due to skin toxicity

Secondary endpoints:
- PFS, OS, OS_{1yr}, ORR and DOR, CA-125 response and DOR, TTFields usage

Vergote I et al. *Gynecol Oncol* 2018;150(3):471-77.

Courtesy of Richard T Penson, MD

Phase III Pivotal INNOVATE-3 Study of Tumor Treating Fields for Ovarian Cancer Does Not Meet Primary Endpoint

Press Release — August 28, 2023

"[It was announced] that the phase 3 ENGOT-ov50/GOG-3029/INNOVATE-3 clinical trial of Tumor Treating Fields (TTFields) together with paclitaxel in patients with platinum-resistant ovarian cancer did not meet its primary endpoint of overall survival (OS) at the final analysis. Patients randomized to receive TTFields therapy plus paclitaxel (n=280) demonstrated a median OS of 12.2 months versus a median OS of 11.9 months in patients treated with paclitaxel alone (n=278) (HR: 1.008). Consistent with previously reported studies, TTFields therapy was well-tolerated with no added systemic toxicities.

The ENGOT-ov50/GOG-3029/INNOVATE-3 trial enrolled patients with a maximum of five total prior lines of systemic therapy. An analysis of exploratory subgroups suggests a potential survival benefit in patients who received only one prior line of therapy. This signal could merit further exploration given the unmet need for the ~20% of ovarian cancer patients who have a limited response to frontline platinum-based treatment. Full evaluation of the data from the ENGOT-ov50/GOG-3029/INNOVATE-3 trial, including subgroup analyses, is ongoing."

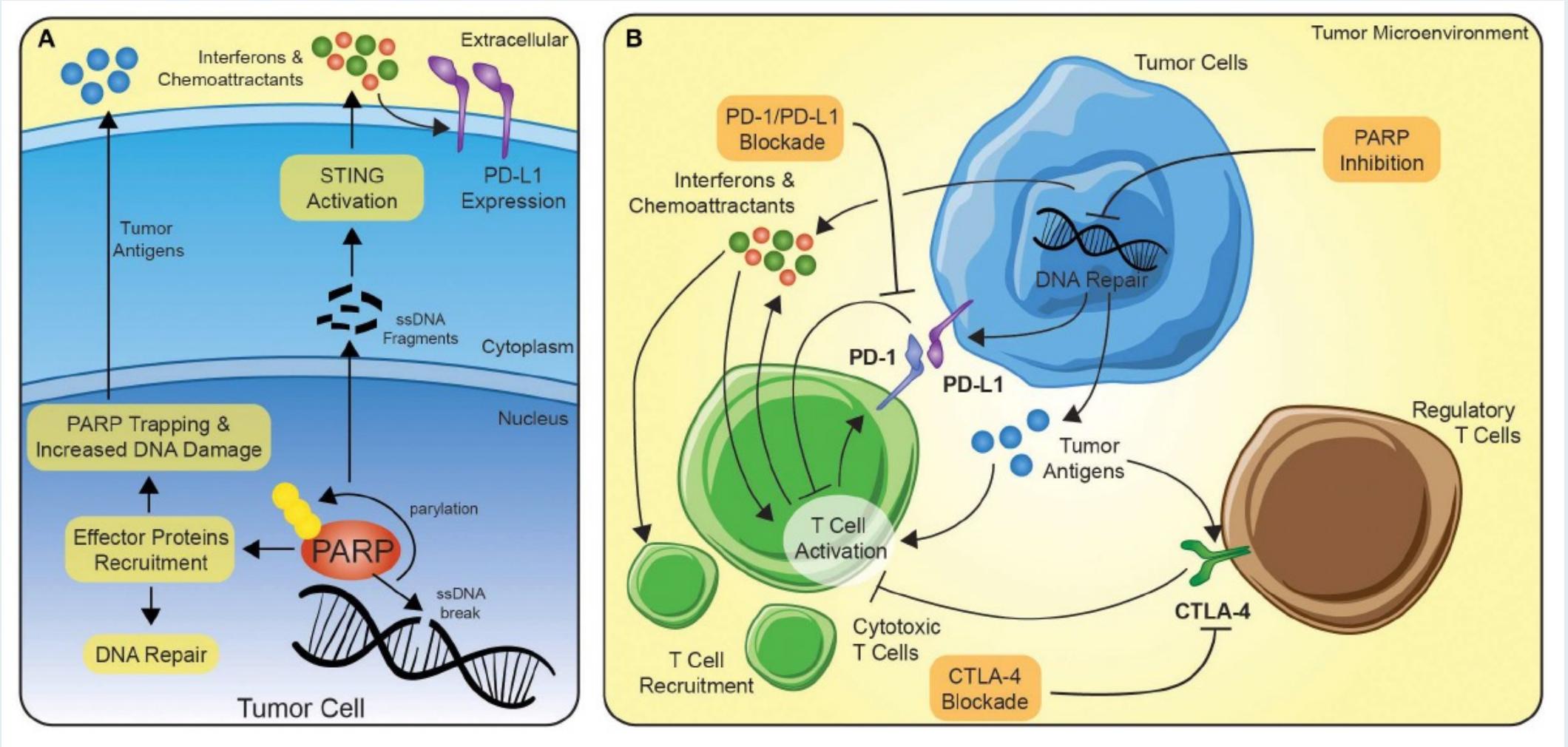
https://www.novocure.com/novocure-provides-update-on-phase-3-engot-ov50-gog-3029-innovate-3-trial-evaluating-tumor-treating-fields-therapy-in-platinum-resistant-ovarian-cancer/

Case Presentation: 59-year-old woman, gBRCA1, PMH of breast cancer and prophylactic BSO, now recurrent peritoneal cancer. Responds for 10 months to olaparib followed by chemotherapy followed by rucaparib. Nivolumab on TAPUR trial

Dr John Chan (San Francisco, California)

RTP RESEARCH TO PRACTICE

Potential Synergy Between PARP Inhibition and Immune Checkpoint Blockade



Vikas P et al. *Front Oncol* 2020;10:570.

2023 ASCO ANNUAL MEETING

Abstract LBA5506

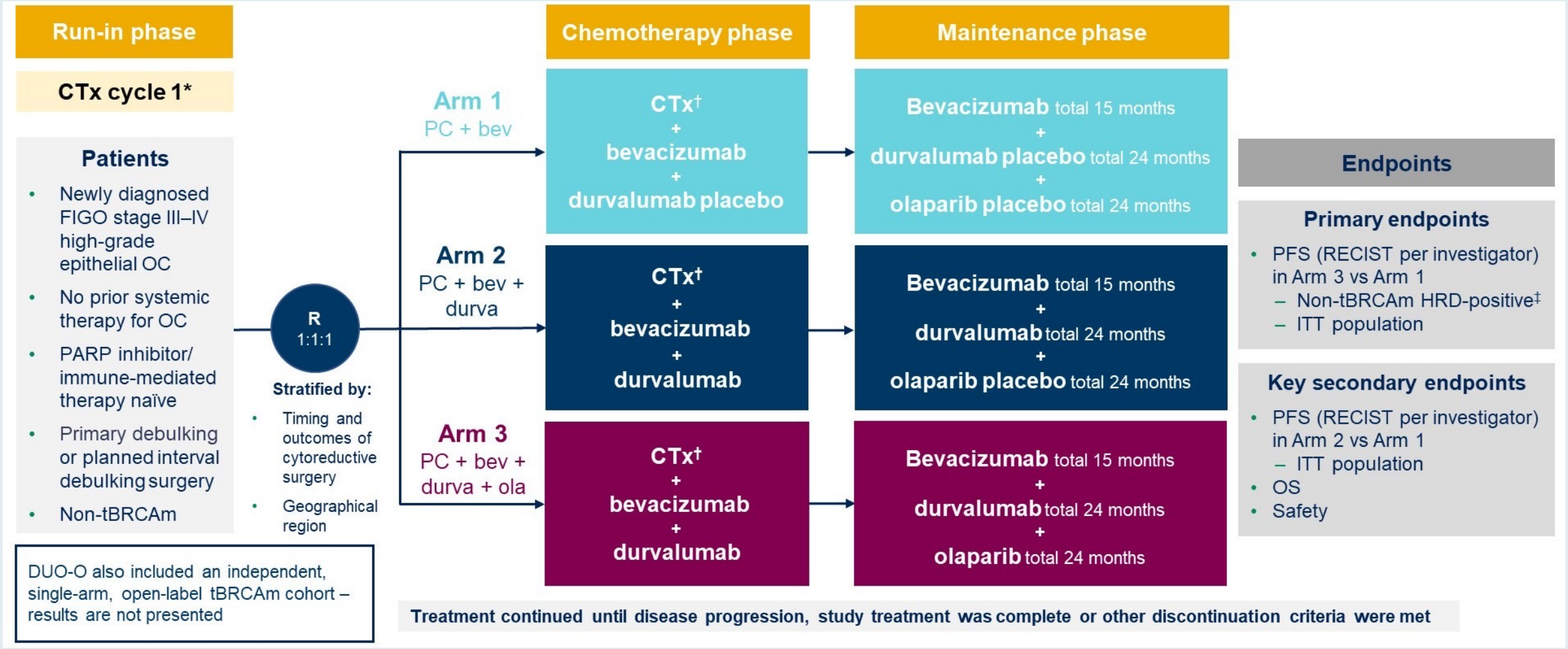
Durvalumab with paclitaxel/carboplatin and bevacizumab followed by maintenance durvalumab, bevacizumab and olaparib in patients with newly diagnosed advanced ovarian cancer without a tumor *BRCA1/BRCA2* mutation: results from the randomized, placebo-controlled Phase III DUO-O/ENGOT-ov46/AGO-OVAR 23/GOG-3025 trial

Philipp Harter,[1] Fabian Trillsch,[2] Aikou Okamoto,[3] Alexander Reuss,[4] Jae-Weon Kim,[5] Maria Jesús Rubio-Pérez,[6] Mehmet Ali Vardar,[7] Giovanni Scambia,[8] Olivier Trédan,[9] Gitte-Bettina Nyvang,[10] Nicoletta Colombo,[11] Anita Chudecka-Głaz,[12] Christoph Grimm,[13] Stephanie Lheureux,[14] Els Van Nieuwenhuysen,[15] Florian Heitz,[16] Robert M. Wenham,[17] Kimio Ushijima,[18] Emily Day,[19] Carol Aghajanian[20]

[1]Kliniken Essen-Mitte, Essen, and AGO, Germany; [2]University Hospital, LMU Munich, Munich, and AGO, Germany; [3]The Jikei University School of Medicine, Tokyo, and JGOG, Japan; [4]Coordinating Center for Clinical Trials of the Philipps-University of Marburg, Marburg, and ENGOT, Germany; [5] Seoul National University Hospital, Seoul, and KGOG, South Korea; [6]Reina Sofia University Hospital, Cordoba, and GEICO, Spain; [7]Medical Faculty, University of Cukurova, and Balcalı Hospital, Adana, and TRSGO, Turkey; [8]Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, and MITO, Italy; [9]Centre Léon Bérard, Centre de Recherche en Cancérologie de Lyon, Lyon, and GINECO, France; [10] Odense Universitetshospital, Odense, and NSGO, Denmark; [11]University of Milan-Bicocca and Istituto Europeo di Oncologia IRCCS, Milan, and MANGO, Italy; [12]SPSK Nr 2, Pomeranian Medical University, Szczecin, and PGOG, Poland; [13]Gynecologic Cancer Unit, Medical University Vienna, and AGO-Au, Austria; [14]Princess Margaret Hospital, Toronto, ON, and PMHC, Canada; [15]UZ Leuven, Leuven, and BGOG, Belgium, [16]Ev. Kliniken Essen-Mitte, Essen, and Charité Campus Virchow-Klinikum, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, Berlin Institute of Health, Berlin, and AGO, Germany; [17]Moffitt Cancer Center, Tampa, FL, and GOG-F, USA; [18]Kurume University School of Medicine, Kurume, and JGOG, Japan; [19]Oncology Biometrics, AstraZeneca, Cambridge, UK; [20]Memorial Sloan Kettering Cancer Center, New York, NY, and GOG-F, USA

ClinicalTrials.gov identifier: NCT03737643

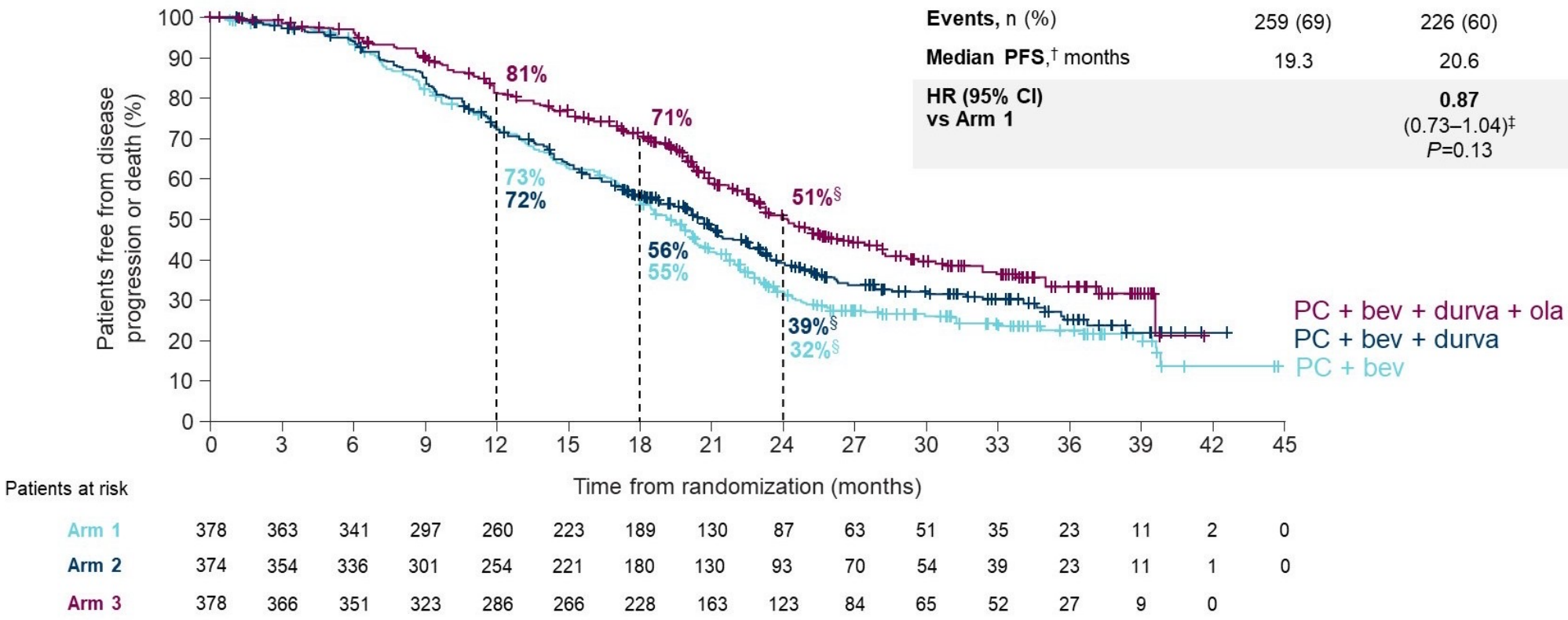
DUO-O: Study Design



Harter P et al. ASCO 2023;Abstract LBA5506.

DUO-O: PFS in the ITT Population

	Arm 1 PC + bev N=378	Arm 2 PC + bev + durva N=374	Arm 3 PC + bev + durva + ola N=378
Median follow-up,* months	25.5	23.1	23.3
Events, n (%)	259 (69)	226 (60)	193 (51)
Median PFS,† months	19.3	20.6	24.2
HR (95% CI) vs Arm 1		**0.87** (0.73–1.04)‡ *P*=0.13	**0.63** (0.52–0.76)‡ *P*<0.0001



Patients at risk

Arm 1	378	363	341	297	260	223	189	130	87	63	51	35	23	11	2	0
Arm 2	374	354	336	301	254	221	180	130	93	70	54	39	23	11	1	0
Arm 3	378	366	351	323	286	266	228	163	123	84	65	52	27	9	0	

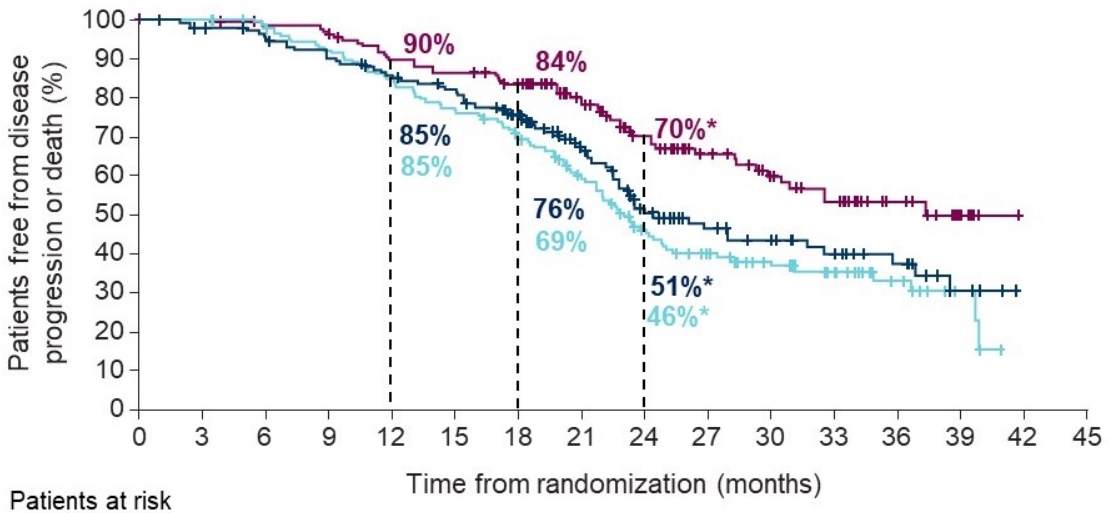
*In censored patients; †Medians and rates were estimated by KM method; ‡HR and CI were estimated from a stratified Cox proportional hazards model. Model stratified by timing and outcome of cytoreductive surgery and geographical region. *P* value from a stratified log rank text; §24-month PFS rates unstable.

PFS = progression-free survival; ITT = intent to treat

Harter P et al. ASCO 2023;Abstract LBA5506.

DUO-O: Subgroup Analysis of PFS by HRD status

Non-tBRCAm HRD-positive

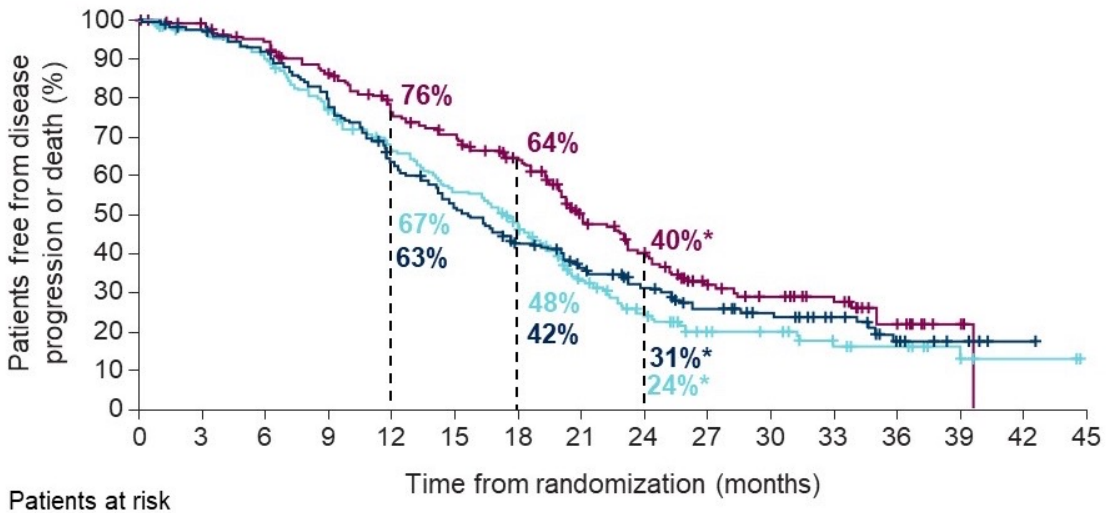


Patients at risk

Arm 1	143	141	136	126	116	105	93	73	52	41	31	22	13	6	0
Arm 2	148	142	137	128	118	112	94	66	45	34	28	21	15	7	0
Arm 3	140	138	135	131	120	116	107	84	63	49	39	32	17	6	0

	Arm 1 PC + bev N=143	Arm 2 PC + bev + durva N=148	Arm 3 PC + bev + durva + ola N=140
Events, n (%)	86 (60)	69 (47)	49 (35)
Median PFS, months†	23.0	24.4‡	37.3‡
HR (95% CI) vs Arm 1		**0.82** (0.60–1.12)§	**0.51** (0.36–0.72)§

HRD-negative



Patients at risk

Arm 1	216	203	188	159	135	112	92	55	34	21	19	12	9	5	2	0
Arm 2	199	189	177	153	120	97	76	59	45	33	25	17	8	4	1	0
Arm 3	211	202	190	169	145	132	111	75	57	33	26	20	10	3	0	

	Arm 1 PC + bev N=216	Arm 2 PC + bev + durva N=199	Arm 3 PC + bev + durva + ola N=211
Events, n (%)	157 (73)	142 (71)	127 (60)
Median PFS, months†	17.4	15.4	20.9
HR (95% CI) vs Arm 1		**0.94** (0.75–1.18)§	**0.68** (0.54–0.86)§

Harter P et al. ASCO 2023;Abstract LBA5506.

Meet The Professor with Dr Moore

INTRODUCTION: SOLO-1 Trial

MODULE 1: Case Presentations

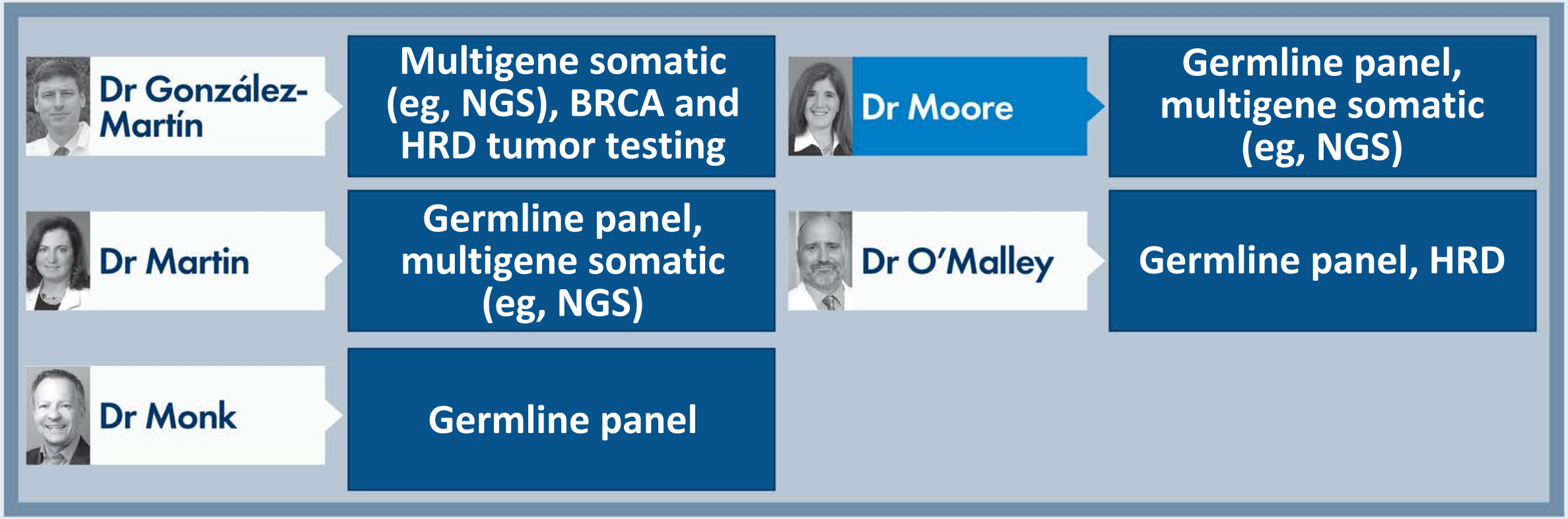
MODULE 2: Investigator Survey

MODULE 3: Journal Club with Dr Moore

MODULE 4: Appendix

RTP
RESEARCH
TO PRACTICE

Which specific assays or genetic testing platforms do you typically order for your patients with newly diagnosed advanced ovarian cancer (OC)?



NGS = next-generation sequencing; HRD = homologous recombination deficiency

A 65-year-old woman with no comorbidities with OC (Stage IIIC, extensive intra-abdominal disease and ascites) receives neoadjuvant carboplatin/paclitaxel/bev (good response) → R0 resection. Regulatory and reimbursement issues aside, what would you most likely recommend as maintenance therapy if genetic testing revealed the patient's tumor was positive for a BRCA1/2 or PALB2 mutation?

	Maintenance therapy	Duration
 Dr González-Martín	Bevacizumab with olaparib	Bevacizumab: 15 months Olaparib: 2 years
 Dr Martin	Bevacizumab with olaparib	Bevacizumab: 1 year Olaparib: 2 years
 Dr Monk	Bevacizumab with olaparib	2 years
 Dr Moore	Bevacizumab with olaparib	Bevacizumab: 15 months Olaparib: 2 years
 Dr O'Malley	Bevacizumab with olaparib	Bevacizumab: 1 year Olaparib: 2 years

PARPi = PARP inhibitor

A 65-year-old woman with no comorbidities with OC (Stage IIIC, extensive intra-abdominal disease and ascites) receives neoadjuvant carboplatin/paclitaxel/bev (good response) → R0 resection. Regulatory and reimbursement issues aside, what would you most likely recommend as maintenance therapy if genetic testing revealed the patient's tumor was BRCA wild type, HR deficient (LOH high)?

	Maintenance therapy	Duration
 Dr González-Martín	Bevacizumab with olaparib	Bevacizumab: 15 months Olaparib: 2 years
 Dr Martin	Bevacizumab with olaparib	Bevacizumab: 1 year Olaparib: 2 years
 Dr Monk	Bevacizumab with olaparib	2 years
 Dr Moore	Bevacizumab with olaparib	Bevacizumab: 15 months Olaparib: 2 years
 Dr O'Malley	Bevacizumab with olaparib	Bevacizumab: 1 year Olaparib: 2 years

A 65-year-old woman with no comorbidities with OC undergoes R0 resection and receives adjuvant carboplatin/paclitaxel (good response). Regulatory and reimbursement issues aside, what would you most likely recommend as maintenance therapy if genetic testing revealed the patient's tumor was positive for a BRCA1/2 or PALB2 mutation?

	Maintenance therapy	Duration
 Dr González-Martín	Olaparib	2 years
 Dr Martin	Olaparib or niraparib	2-3 years depending on choice of PARPi
 Dr Monk	Olaparib	2 years
 Dr Moore	Bevacizumab with olaparib	Bevacizumab: 15 months Olaparib: 2 years
 Dr O'Malley	Bevacizumab with olaparib	Bevacizumab: 1 year Olaparib: 2 years

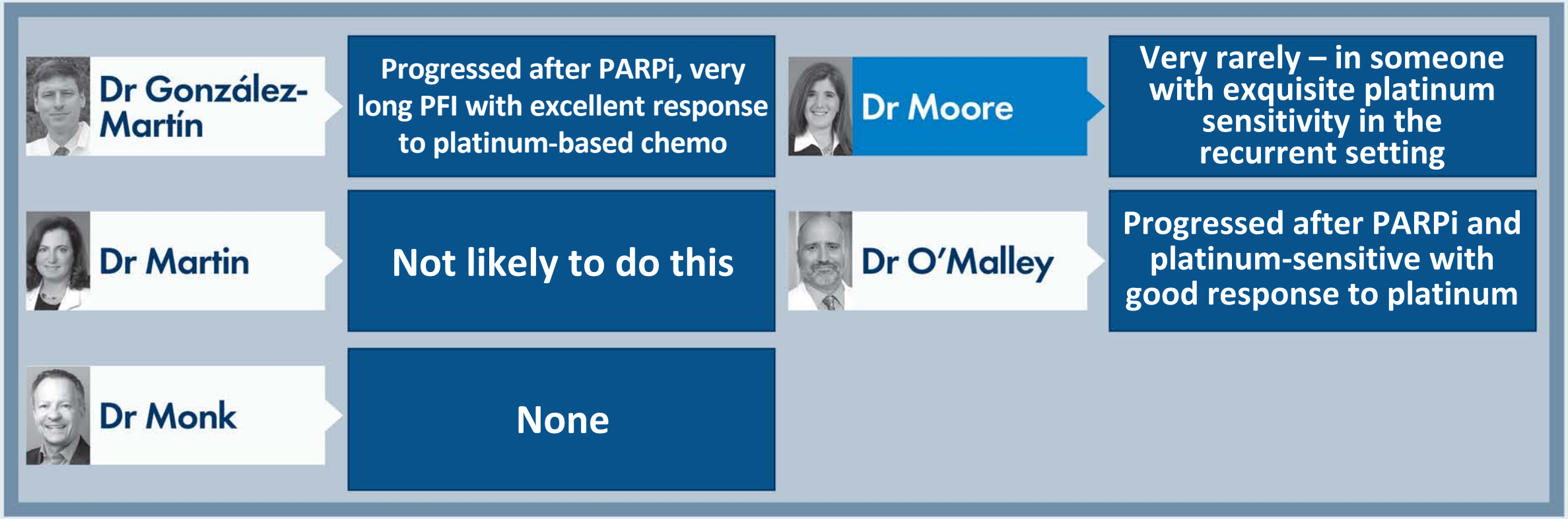
A 65-year-old woman with no comorbidities with OC undergoes R0 resection and receives adjuvant carboplatin/paclitaxel (good response). Regulatory and reimbursement issues aside, what would you most likely recommend as maintenance therapy if genetic testing revealed the patient's tumor was BRCA wild type, HR deficient (LOH high)?

	Maintenance therapy	Duration
 Dr González-Martín	Niraparib	3 years
 Dr Martin	Olaparib or niraparib	2-3 years depending on choice of PARPi
 Dr Monk	Niraparib	2 years
 Dr Moore	Bevacizumab with olaparib	Bevacizumab: 15 months Olaparib: 2 years
 Dr O'Malley	Bevacizumab with olaparib	Bevacizumab: 1 year Olaparib: 2 years

A 65-year-old woman with no comorbidities with OC undergoes R0 resection and receives adjuvant carboplatin/paclitaxel (good response). Regulatory and reimbursement issues aside, what would you most likely recommend as maintenance therapy if genetic testing revealed the patient's tumor was BRCA wild type, HR proficient (LOH low)?

	Maintenance therapy	Duration
 Dr González-Martín	Niraparib	3 years
 Dr Martin	None	Not applicable
 Dr Monk	Niraparib	2 years
 Dr Moore	Bevacizumab	15 months
 Dr O'Malley	Bevacizumab	1 year

Outside of a protocol setting, in what situations, if any, would you administer a PARP inhibitor as a component of later-line treatment for a patient whose disease had progressed on or after first-line maintenance with a PARP inhibitor?



PFI = platinum-free interval

Outside of a protocol setting, in what clinical situations would you administer a PARP inhibitor to a patient with relapsed advanced OC?

CR/PR = complete response/partial response

To approximately how many patients with advanced OC have you administered tumor treating fields (TTFields) on protocol?

 Dr González-Martín	5	 Dr Moore	0
 Dr Martin	0	 Dr O'Malley	5
 Dr Monk	2		

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Based on your personal clinical experience and knowledge of available data, how feasible are TTFields from the perspective of administration and patient compliance?

RTP RESEARCH TO PRACTICE

Which other novel agents and strategies in clinical development for patients with advanced recurrent OC do you find most promising?
Have you had patients experience meaningful clinical benefit with any of these novel investigational agents, and if so, which agent or agents?

	Promising novel agent/strategy	Meaningful clinical benefit
 Dr González-Martín	ADCs with novel targets (trastuzumab deruxtecan, DS-600) and ATR inhibitors	Trastuzumab deruxtecan is outstanding
 Dr Martin	Angioimmunotherapy; trastuzumab deruxtecan and other novel ADCs, small molecule inhibitors of CCNE1 amplification	Yes, all of them
 Dr Monk	ADCs, pembrolizumab, relacorilant, nemvaleukin, afuresertib, novel CTLA-4 Ab	Yes, all of them
 Dr Moore	DS-6000, engineered T-cells, novel FRalpha ADC with deruxtecan payload, avotumetinib + defactinib in LGSOC	Yes, all of them
 Dr O'Malley	DS-6000, nemvaleukin, azenosertib, ADP-A2M4CD8, STRO-002, ubamatamab	STRO-002, ubamatamab

ADC = antibody-drug conjugate

How would you rate your enthusiasm for enrolling a patient on the Phase II randomized ENGOT-OV56/NSGO-CTU-DOVACC trial of olaparib, durvalumab and cancer vaccine UV1 for patients with BRCA wild-type recurrent OC?

	Enthusiasm*	Comments
 Dr González-Martín	2	Not convinced that PARPi + IO will be practice-changing combo
 Dr Martin	2	No comment
 Dr Monk	1	Phase 2 IIT in EU of telomerase vaccine UV1, low performance index
 Dr Moore	1	Dubious PARPi + IO synergistic; Question potential efficacy in pts with prior PARPi
 Dr O'Malley	1	No comment

* 1 = not at all enthusiastic, 4 = very enthusiastic

IO = immunotherapy; IIT = investigator-initiated trial

Meet The Professor with Dr Moore

INTRODUCTION: SOLO-1 Trial

MODULE 1: Case Presentations

MODULE 2: Investigator Survey

MODULE 3: Journal Club with Dr Moore

MODULE 4: Appendix

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ENGOT-EN20/GOG-3083/xport-EC-042: A Phase 3, Randomized, Placebo-Controlled, Double-Blind, Multicenter Trial of Selinexor in Maintenance Therapy After Systemic Therapy for Patients with P53 Wild-Type, Advanced or Recurrent Endometrial Carcinoma

Vergote I et al.

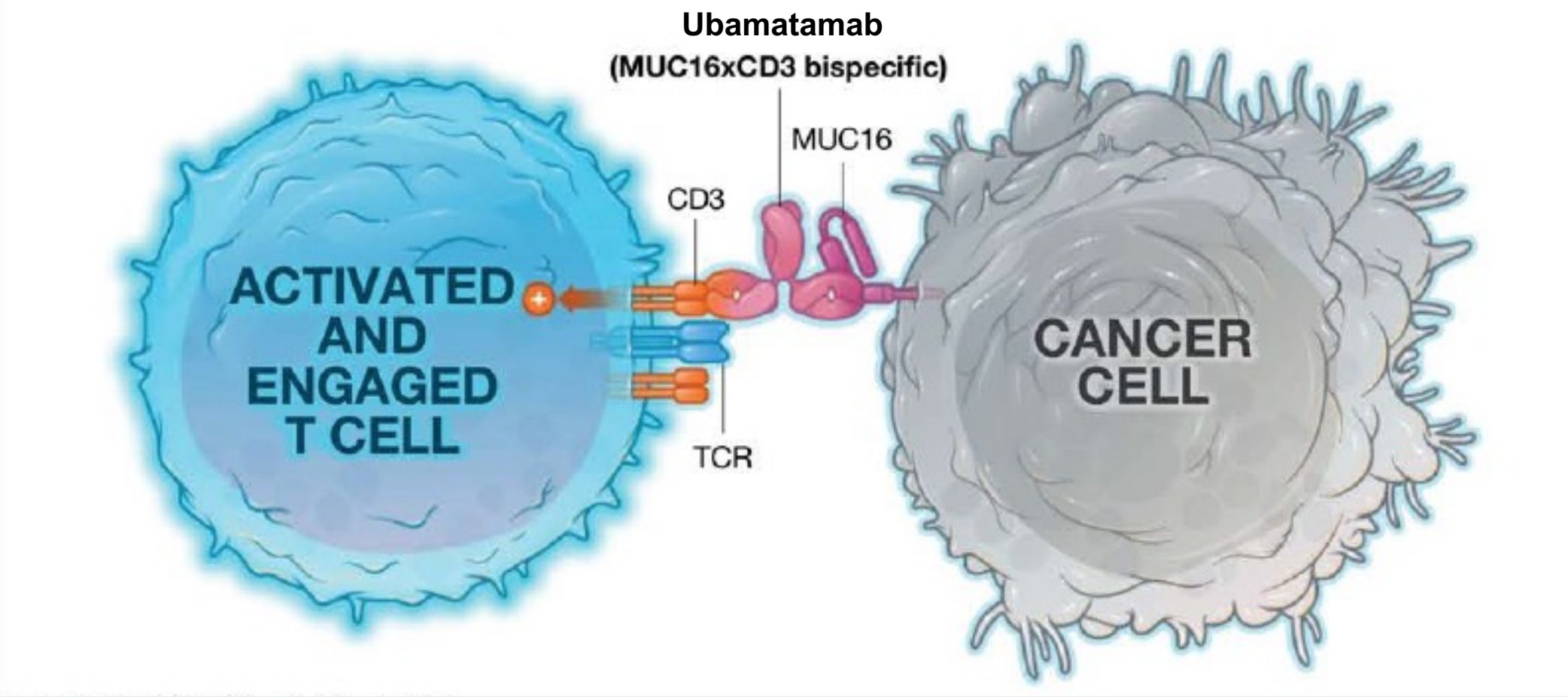
ASCO 2023;Abstract TPS5627.

First-in-Human Phase 1/2 Study of Ubamatamab, a MUC16xCD3 Bispecific Antibody, Administered Alone or in Combination with Cemiplimab in Patients with Recurrent Ovarian Cancer

Moore KN et al.

ASCO 2023;Abstract TPS5624.

Mechanism of Action of Ubamatamab



Moore KN et al. ASCO 2023;Abstract TPS5624.

Raludotatug Deruxtecan (R-DXd; DS-6000) Monotherapy in Patients with Previously Treated Ovarian Cancer (OVC): Subgroup Analysis of a First-in-Human Phase 1 Study

Moore KN et al.

ESMO 2023;Abstract 745MO.

2023;33(9):1458-63

Clinical trial

A phase III, multicenter, randomized study of olvimulogene nanivacirepvec followed by platinum-doublet chemotherapy and bevacizumab compared with platinum-doublet chemotherapy and bevacizumab in women with platinum-resistant/refractory ovarian cancer

Robert W Holloway ,[1] Premal Thaker,[2] Alberto A Mendivil,[3] Sarfraz Ahmad ,[1] Ahmed N Al-Niaimi,[4] James Barter,[5] Tiffany Beck,[3] Setsuko K Chambers,[6] Robert L Coleman,[7] Sarah M Crafton,[8] Erin Crane,[9] Eskander Ramez,[10] Sharad Ghamande,[11] Whitney Graybill,[12] Thomas Herzog,[13] Megan Dr Indermaur,[14] Veena S John,[15] Lisa Landrum,[16] Peter C Lim,[17] Joseph A Lucci,[18] Michael McHale,[19] Bradley J Monk ,[20] Kathleen Nadine Moore,[21] Robert Morris,[22] David M O'Malley,[23] Thomas J Reid,[24] Debra Richardson ,[25] Peter G Rose,[26] Jennifer M Scalici,[27] Dan-Arin Silasi,[28] Krishnansu Tewari,[29] Edward W Wang[30]

2023 September 4;33(9):1331-44

Consensus statement

Low-grade serous ovarian cancer: expert consensus report on the state of the science

Rachel N Grisham [1], Brian M Slomovitz [2,3], Nicole Andrews,[4] Susana Banerjee [5], Jubilee Brown,[6] Mark S Carey,[7] Herman Chui,[8] Robert L Coleman,[9] Amanda N Fader,[10] Stephanie Gaillard,[10] Charlie Gourley,[11] Anil K Sood [12], Bradley J Monk [13], Kathleen N Moore,[14] Isabelle Ray-Coquard [15,16], Ie-Ming Shih,[10] Shannon N Westin [12], Kwong-Kwok Wong,[12] David M Gershenson [12]

JC JOURNAL CLUB RTP RESEARCH TO PRACTICE

2022 ASCO ANNUAL MEETING

Abstract 5501

A PHASE I/II STUDY OF RUXOLITINIB WITH FRONT-LINE NEOADJUVANT AND POST-SURGICAL THERAPY IN PATIENTS WITH ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER

NRG-GY007 (NCT #02713386)

Charles "Chip" Landen, Jr, MD, MS on behalf of NRG and co-authors

University of Virginia, Charlottesville, VA

Ronald J. Buckanovich*, Mike Sill, Robert Mannel, Joan Walker, Paul DiSilvestro, Cara Mathews, David Mutch, Marcia Hernandez, Lainie Martin, Erin Bishop, Brian Chang, Sarah Gill, Mary Gordinier, Robert Burger, Carol Aghajanian, Joyce Liu, Kathleen Moore, and Michael Bookman

Recommended Phase 2 Dose (RP2D) Selection and Pharmacodynamic (PD) Data of the First-in-Human Immune-Stimulating Antibody Conjugate (ISAC) BDC-1001 in Patients (pts) with Advanced HER2-Expressing Solid Tumors

Li BTet al.

ESMO 2023;Abstract 657MO.

Meet The Professor with Dr Moore

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Up-Front Treatment for Advanced Ovarian Cancer

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Select Phase III First-Line PARP Inhibitor Maintenance Trials

Study design	SOLO-1[1] (N = 391)	PAOLA-1[2] (N = 806)	PRIMA[3] (N = 733)	PRIME[4] (N = 384)
Treatment arms vs placebo	**Olaparib**	**Bevacizumab ± olaparib**	**Niraparib**	**Niraparib**
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	36 months
Median PFS	56 vs 13.8 months HR: 0.33	22.1 vs 16.6 months HR: 0.59	22.1 vs 10.9 months HR 0.40	24.8 vs 8.3 months HR: 045

bev = bevacizumab; PD = disease progression; PFS = progression-free survival

[1] Banerjee S et al. *Lancet Oncol* 2021;22:1721-31. [2] Ray-Coquard I et al. *Ann Oncol* 2023;34(8):681-92. [3] González-Martín A et al. *Eur J Cancer* 2023;189:112908. [4] Li N et al. *JAMA Oncol*. 2023;[Online ahead of print].

PRIMA/ENGOT-OV26/GOG-3012 Study: Updated Long-term PFS and Safety

Antonio González-Martín,[1] Bhavana Pothuri,[2] Ignace Vergote,[3] Whitney Graybill,[4] Mansoor R. Mirza,[5] Colleen C. McCormick,[6] Domenica Lorusso,[7] Gilles Freyer,[8] Floor Backes,[9] Klaus Baumann,[10] Andrés Redondo,[11] Richard G. Moore,[12] Christof Vulsteke,[13] Roisin E. O'Cearbhaill,[14] Izabela A. Malinowska,[15] Luda Shtessel,[15]

[1]Medical Oncology Department, Clínica Universidad de Navarra, Madrid, Program in Solid Tumours, CIMA, Pamplona, and (GOG), Department of Obstetrics/Gynecology, Perlmutter Cancer Center, NYU Langone Health, New York, NY, USA; [3]Belg Division of Gynaecologic Oncology, University Hospitals Leuven, Leuven Cancer Institute, Leuven, Belgium; [4]GOG, Gynecolo University Hospital, Copenhagen, Denmark; [6]GOG, Legacy Medical Group Gynecologic Oncology, Portland, OR, USA; [7]Mult IRCCS and Catholic University of Sacred Heart, Rome, Italy; [8]Groupe d'Investigateurs Nationaux pour l'Etude des Cancers [9]Division of Gynecologic Oncology, Ohio State University, Columbus, OH, USA; [10]Arbeitsgemeinschaft Gynäkologische On Germany; [11]GEICO, Hospital Universitario La Paz-IdiPAZ, Madrid, Spain; [12]US Oncology Research, Division of Gynecolo Rochester, NY, USA; [13]BGOG, Department of Medical Oncology and Hematology, AZ Maria Middelares, Gent, and De Antwerp University, Antwerp, Belgium; [14]GOG, Gynecologic Medical Oncology, Memorial Medical College, New York, NY, USA; [15]GSK, Middlesex, UK; [16]HonorHealth Phoenix Creighton University, P

IGCS 2022;Abstract S005/1753.

Progression-free survival and safety at 3.5 years of follow-up: results from the randomised phase 3 PRIMA/ENGOT-OV26/GOG-3012 trial of niraparib maintenance treatment in patients with newly diagnosed ovarian cancer

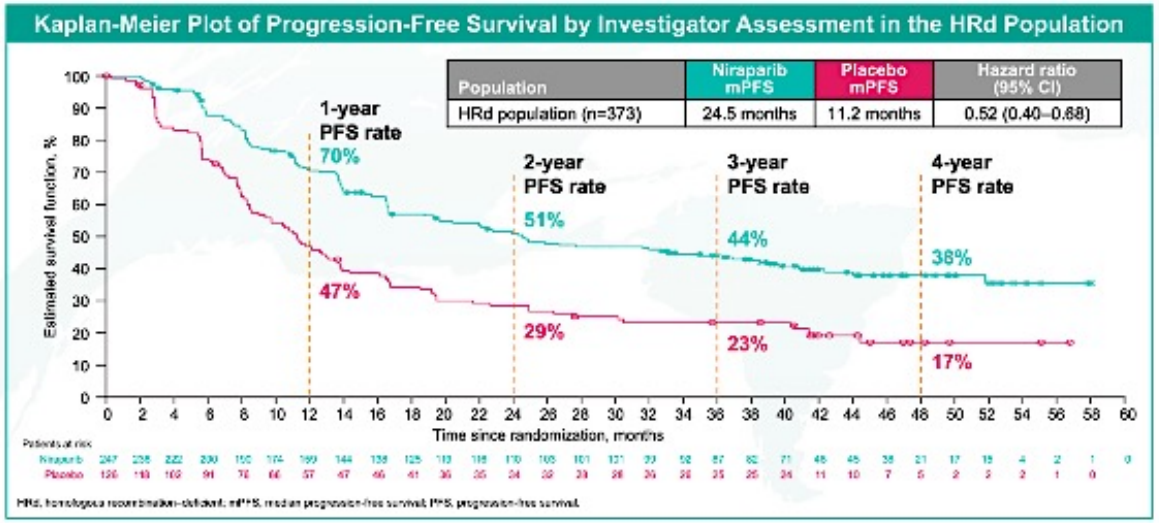
Antonio González-Martín [a,*], Bhavana Pothuri [b], Ignace Vergote [c], Whitney Graybill [d], Domenica Lorusso [e], Colleen C. McCormick [f], Gilles Freyer [g], Floor Backes [h], Florian Heitz [i,q], Andrés Redondo [j], Richard G. Moore [k], Christof Vulsteke [l,r], Roisin E. O'Cearbhaill [m], Izabela A. Malinowska [n], Luda Shtessel [n], Natalie Compton [n], Mansoor R. Mirza [o], Bradley J. Monk [p]

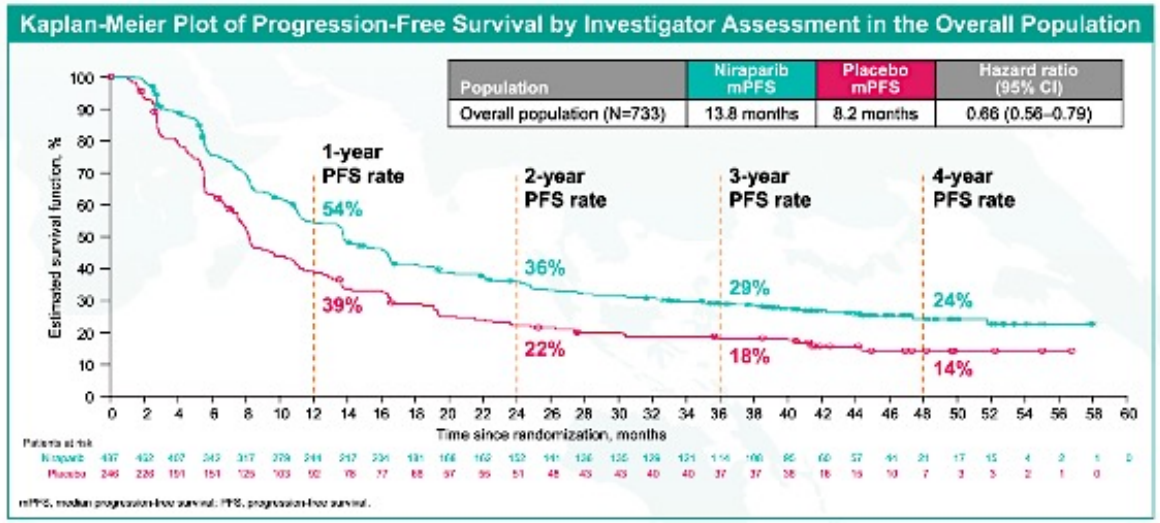
Eur J Cancer 2023 August;189:112908.

RTP RESEARCH TO PRACTICE

PRIMA: Updated Long-Term PFS (Investigator-Assessed)

November 17, 2021, Clinical Cutoff Date





- At the time of the updated clinical cutoff date, 16.3% and 11.1% of patients were receiving niraparib or placebo, respectively
- Niraparib treatment significantly extended IA PFS compared with placebo in both the HRd and overall populations
- Updated long-term IA PFS results were also consistent with BICR PFS results from the primary analysis
- OS remains immature at 41.2% for the overall population

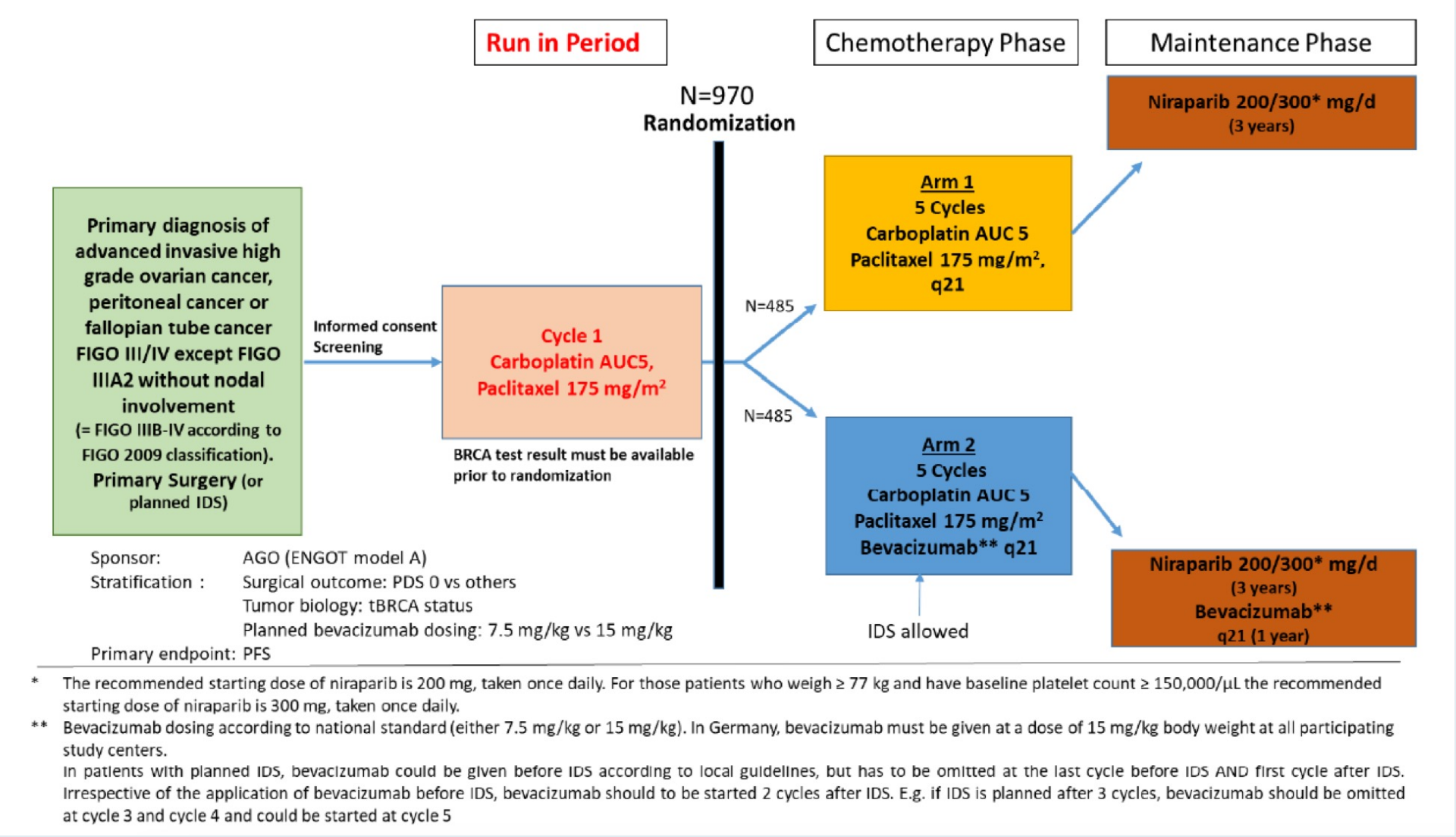
IGCS 2022 ANNUAL GLOBAL MEETING

BICR, blinded independent central review; HRd, homologous recombination–deficient; IA, investigator assessed; mPFS, median progression-free survival; OS, overall survival; PFS, progression-free survival.

González-Martín A et al. IGCS 2022;Abstract S005/1753. González-Martín A et al. *Eur J Cancer* 2023;189:112908.

RTP RESEARCH TO PRACTICE

AGO-OVAR 28/ENGOT-OV57: Phase III Trial Comparing Niraparib to Niraparib with Bevacizumab for Advanced Ovarian Cancer



* The recommended starting dose of niraparib is 200 mg, taken once daily. For those patients who weigh ≥ 77 kg and have baseline platelet count ≥ 150,000/µL the recommended starting dose of niraparib is 300 mg, taken once daily.

** Bevacizumab dosing according to national standard (either 7.5 mg/kg or 15 mg/kg). In Germany, bevacizumab must be given at a dose of 15 mg/kg body weight at all participating study centers.
In patients with planned IDS, bevacizumab could be given before IDS according to local guidelines, but has to be omitted at the last cycle before IDS AND first cycle after IDS. Irrespective of the application of bevacizumab before IDS, bevacizumab should to be started 2 cycles after IDS. E.g. if IDS is planned after 3 cycles, bevacizumab should be omitted at cycle 3 and cycle 4 and could be started at cycle 5

Heitz F et al. ASCO 2022;Abstract TPS5612.

Emerging Novel Approaches to Up-Front Treatment for Ovarian Cancer

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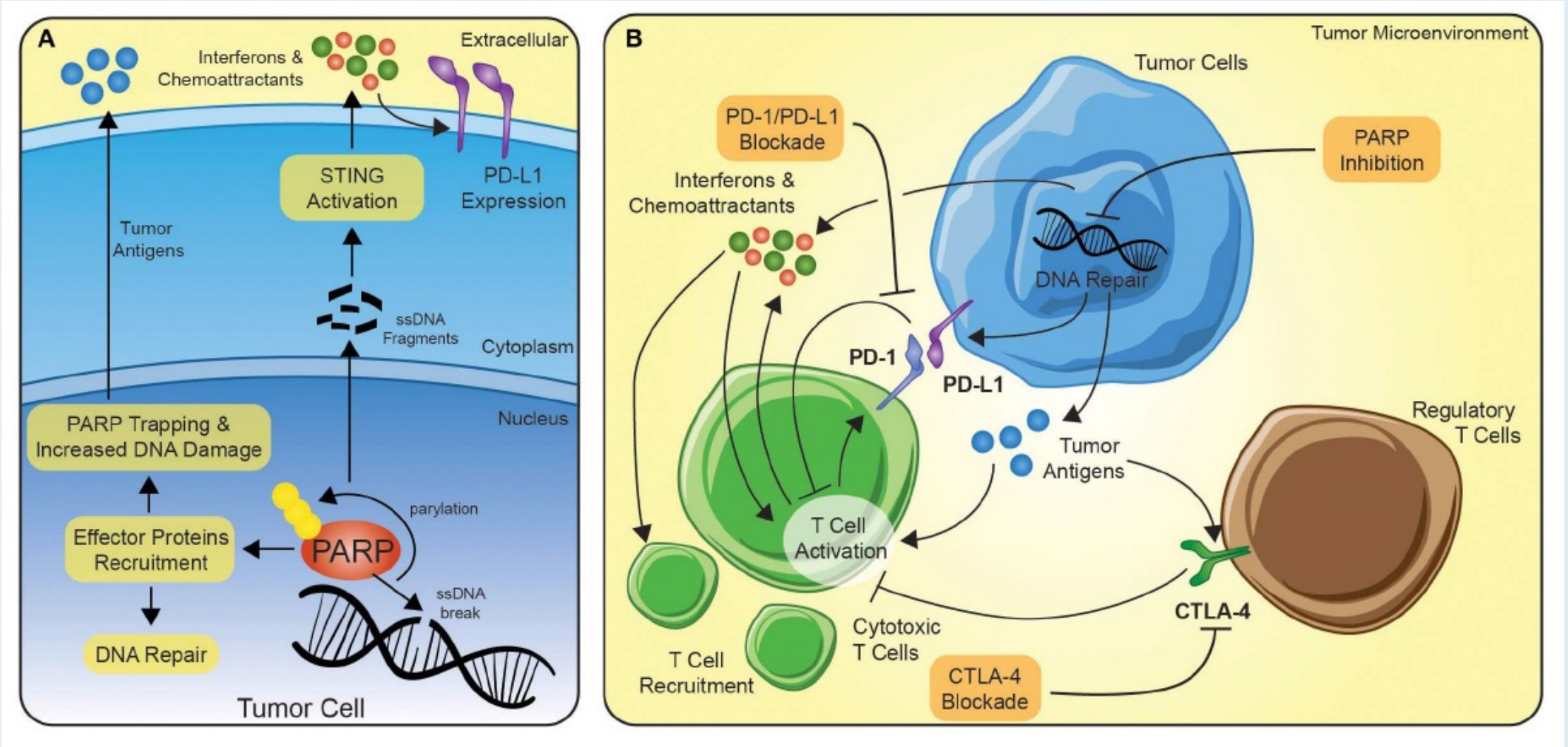
RESEARCH
TO PRACTICE

The Potential Synergy Between PARP Inhibition and Immune Checkpoint Blockade



Vikas P et al. *Front Oncol* 2020;10:570.

PARIS 2022 ESMO congress

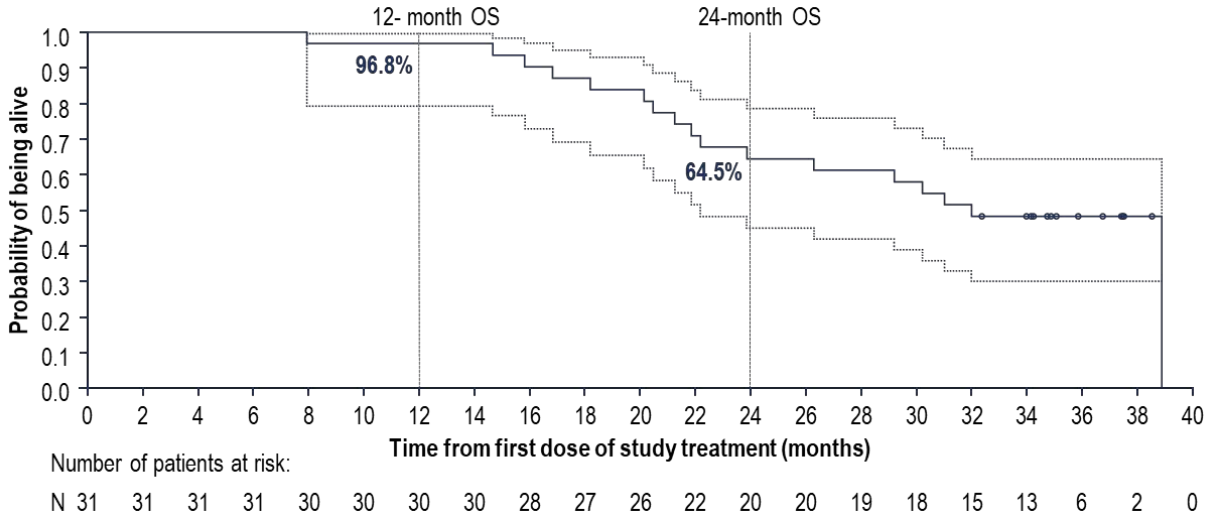
Abstract 529MO

Phase II study of olaparib plus durvalumab with or without bevacizumab (MEDIOLA): final analysis of overall survival in patients with non-germline BRCA-mutated platinum-sensitive relapsed ovarian cancer

Susana Banerjee,[1] Martina Imbimbo,[2] Patricia Roxburgh,[3] Jae-Weon Kim,[4] Min Hwan Kim,[5] Ruth Plummer,[6] Salomon M. Stemmer,[7] Benoit You,[8] Michelle Ferguson,[9] Richard T. Penson,[10] David M. O'Malley,[11] Kassondra Meyer,[12] Haiyan Gao,[13] Helen K. Angell,[14] Ana T. Nunes,[15] Susan Domchek,[16] Yvette Drew[6*]

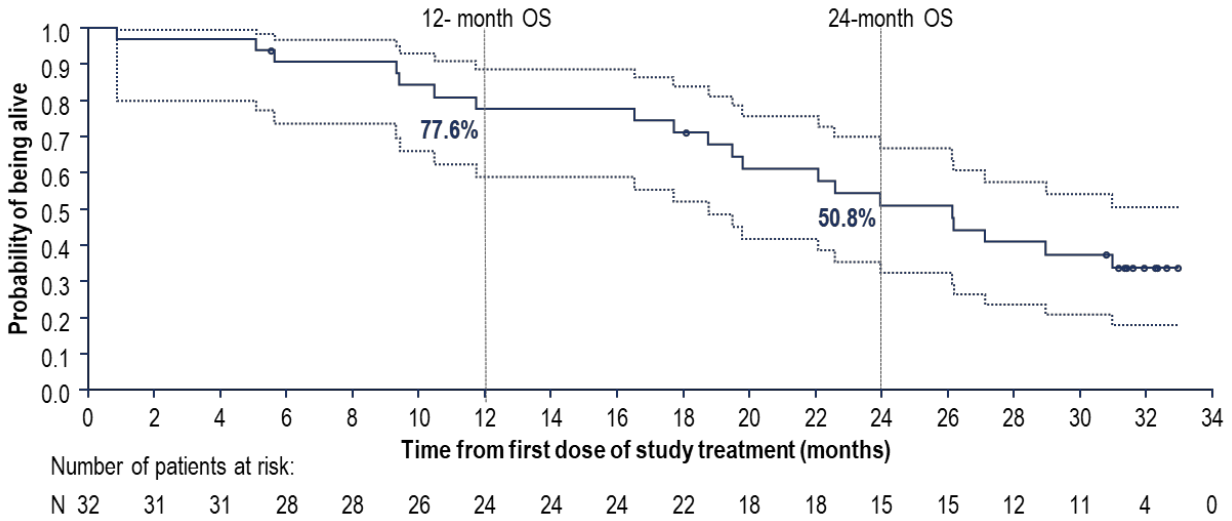
MEDIOLA Final Analysis: Median Overall Survival and 56-Week Disease Control Rate

Olaparib plus durvalumab and bevacizumab



	Olaparib plus durvalumab and bevacizumab
Median follow-up for OS, months	31.9
Events, n	17
Median OS (95% CI), months	**31.9 (22.1–NC)**
56-week DCR (90% CI), %	38.7 (24.1–55.0)

Olaparib plus durvalumab



	Olaparib plus durvalumab
Median follow-up for OS, months	23.2
Events, n	20
Median OS (95% CI), months	**26.1 (18.7–NC)**
56-week DCR (90% CI), %	9.4 (2.6–22.5)

Banerjee S et al. ESMO 2022;Abstract 529MO.

RTP RESEARCH TO PRACTICE

MEDIOLA: Adverse Events

	Olaparib plus durvalumab and bevacizumab N=31	Olaparib plus durvalumab N=32
Patients with any AE, n %	31 (100)	32 (100)
Patients with any Grade ≥3 AE, n (%)	19 (61.3)	21 (65.6)
Patients with any serious AE, n (%)	6 (19.4)	8 (25.0)
Patients with AEs leading to deaths,* n (%)	0	1 (3.1)
Patients with AEs leading to discontinuation of **any** study treatment,†,‡ n (%)	10 (32.3)	1 (3.1)
Olaparib‡	4 (12.9)	1 (3.1)
Durvalumab‡	5 (16.1)	1 (3.1)
Bevacizumab‡	9 (29.0)	–

	Olaparib plus durvalumab and bevacizumab N=31	Olaparib plus durvalumab N=32
Grade ≥3 AEs in ≥2 patients in any cohort, n (%)		
Anaemia	6 (19.4)	7 (21.9)
Hypertension	5 (16.1)	1 (3.1)
Fatigue	2 (6.5)	2 (6.3)
Lipase increased	2 (6.5)	2 (6.3)
Febrile neutropenia	2 (6.5)	1 (3.1)
Neutropenia	1 (3.2)	2 (6.3)
White blood cell count decreased	2 (6.5)	0

Banerjee S et al. ESMO 2022;Abstract 529MO.

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

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

Poster #23

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

SGO 2021 VIRTUAL ANNUAL MEETING ON WOMEN'S CANCER®

Abstract 10415

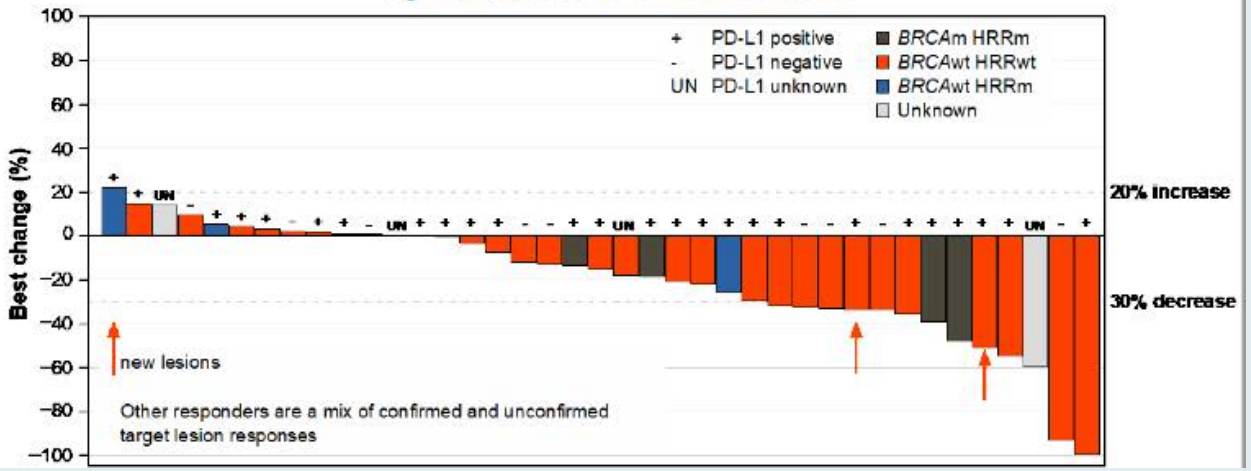
Society of Gynecologic Oncology

Antitumor Activity of Niraparib with Dostarlimab and Bevacizumab in Cohort A of the OPAL Trial

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

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

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



Liu JF et al. SGO 2021;Abstract 10415.

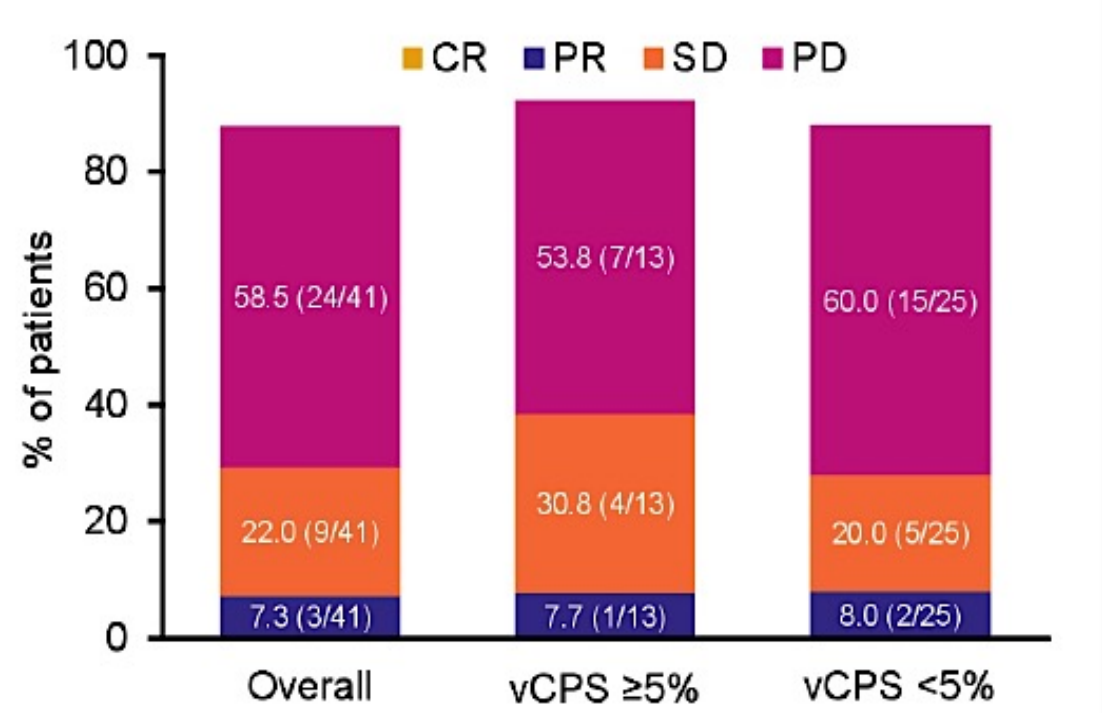
RTP RESEARCH TO PRACTICE

MOONSTONE/GOG-3032: Interim analysis of a phase 2 study of niraparib + dostarlimab in patients (pts) with platinum-resistant ovarian cancer (PROC).

ASCO 2022;Abstract 5573.

Leslie M. Randall, David M. O'Malley, Bradley J. Monk, Robert L. Coleman, Stephanie Gaillard, Sarah F. Adams, Linda R. Duska, Fabio Cappuccini, Heather Dalton, Robert W. Holloway, Marilyn Huang, Hye Sook Chon, Noelle Gillette Cloven, Adam ElNaggar, Roisin Eilish O'Cearbhaill, Steven E. Waggoner, Zebin Wang, Eric Zhi, Vivek Samnotra, Panagiotis A. Konstantinopoulos

MOONSTONE: Efficacy Summary of Niraparib with Dostarlimab for Platinum-Resistant Ovarian Cancer



Efficacy, n (%) [95% CI]*	Overall N=41	PD-L1 status	
		vCPS ≥5% n=13	vCPS <5% n=25
ORR (CR + PR)	3 (7.3) [1.5–19.9]	1 (7.7) [0.2–36.0]	2 (8.0) [1.0–26.0]
DCR (CR + PR + SD)	12 (29.3) [16.1–45.5]	5 (38.5) [13.9–68.4]	7 (28.0) [12.1–49.4]
Median PFS, months (95% CI)	2.1 (2.0–2.2)	2.2 (1.6–not evaluable)	2.1 (1.8–2.2)

"…the ORR observed with niraparib + dostarlimab did not reach the threshold for 2nd-stage accrual in this cohort of pts with PROC, no known *BRCA*m, and prior bevacizumab treatment. PD-L1 status did not predict response; HRD testing is in process. Although DCR was 29%, futility was declared based on low ORR. The safety of the combination was similar to the safety profile of each monotherapy."

Randall LM et al. ASCO 2022;Abstract 5573.

MOONSTONE: Select Treatment-Related Adverse Events in >10% of Patients

Adverse event n (%)	Related to either niraparib or dostarlimab	Related to niraparib	Related to dostarlimab
Nausea	23 (56.1)	21 (51.2)	11 (26.8)
Fatigue	14 (34.1)	13 (31.7)	13 (31.7)
Vomiting	13 (31.7)	13 (31.7)	7 (17.1)
Anemia	13 (31.7)	13 (31.7)	7 (17.1)
Platelet count decreased	11 (26.8)	11 (26.8)	0 (0)
Thrombocytopenia	8 (19.5)	8 (19.5)	0 (0)

Randall LM et al. ASCO 2022;Abstract 5573.

Selection and Sequencing of Therapy for Patients with Relapsed/Refractory Ovarian Cancer

RTP
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Voluntary Withdrawals of Late-Line Indications of PARP Inhibitors

Niraparib – September 14, 2022

The indication for niraparib has been voluntarily withdrawn for the treatment of advanced ovarian, fallopian tube or primary peritoneal cancer in adult patients who have received 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency status. The decision was made in consultation with the US FDA and based on a totality of information from PARP inhibitors for ovarian cancer in the late line treatment setting.

Olaparib – August 26, 2022

The indication for olaparib has been voluntarily withdrawn for the treatment of deleterious or suspected deleterious gBRCAm advanced ovarian cancer in adult patients who have received 3 or more prior lines of chemotherapy. The decision was made in consultation with the US FDA after a recent subgroup analysis indicated a potential detrimental effect on overall survival for olaparib compared to the chemotherapy control arm in the subgroup of patients who had received 3 or more prior lines of chemotherapy in the randomized Phase III study SOLO-3.

Rucaparib – June 10, 2022

The indication for rucaparib has been voluntarily withdrawn for the treatment of BRCA-mutated ovarian cancer after 2 or more chemotherapies. The withdrawal is based on discussions with the US FDA following submission of overall survival data from the ARIEL4 trial, which demonstrated an increased risk of death in participants with BRCA-mutated ovarian cancer treated with rucaparib after 2 or more therapies.

https://medinfo.gsk.com/5f95dbd7-245e-4e65-9f36-1a99e28e5bba/57e2a3fa-7b9b-432f-a220-5976a509b534/57e2a3fa-7b9b-432f-a220-5976a509b534_viewable_rendition__v.pdf?medcommid=REF--ALL-004447; https://www.lynparzahcp.com/content/dam/physician-services/us/590-lynparza-hcp-branded/hcp-global/pdf/solo3-dhcp-final-signed.pdf; https://www.hayesinc.com/news/market-withdrawal-rubraca-for-third-line-ovarian-cancer-indication/

RTP RESEARCH TO PRACTICE

Pivotal Studies of PARP Inhibitors for Recurrent, Platinum-Sensitive or Platinum-Resistant Ovarian Cancer

	NOVA[1,2] (niraparib)	SOLO-3[3] (olaparib)	ARIEL4[4] (rucaparib)
BRCA status	With or without gBRCA mutation	gBRCA mutation	Germline or somatic BRCA mutation
HRD testing	Yes	No	No
Tumor assessment schedule	Every 8 wk to C14 → every 12 wk	Every 8 wk x 48 wk→ every 12 wk	Every 8 wk x 10 mo → every 16 wk
Dosing/formulation	300 mg qd	300 mg BID	600 mg BID
No. of prior lines of chemo	2 or more	2 or more	2 or more
Median OS	gBRCAm: 40.9 vs 38.1 mo HR 0.85 Non-gBRCAm: 31.0 vs 34.8 mo HR 1.06	34.9 vs 32.9 mo HR 1.07	19.4 vs 25.4 mo HR 1.313

[1] Mirza MR et al. *N Engl J Med* 2016;375:2154-64; [2]https://www.zejulahcp.com/content/dam/cf-pharma/hcp-zejulahcp-v2/en_US/pdf/ZEJULA%20(niraparib)%20Dear%20HCP%20Letter%20November%202022.pdf [3] Leath C et al. IGCS 2022;Abstract LB001/1731; [4] Oza AM et al. ESMO 2022;Abstract 518O.

RTP RESEARCH TO PRACTICE

2021 ESMO congress

Abstract LBA33

ENGOT European Network of Gynaecological Oncological Trial groups

GINECO

Maintenance olaparib rechallenge in patients with ovarian carcinoma previously treated with a PARP inhibitor: Phase IIIb OReO/ENGOT Ov-38 trial

Eric Pujade-Lauraine,[1] Frédéric Selle,[2] Giovanni Scambia,[3] Bernard Asselain,[4] Frederik Marmé,[5] Kristina Lindemann,[6] Nicoletta Colombo,[7] Radoslaw Madry,[8] Rosalind Glasspool,[9] Coraline Dubot,[10] Ana Oaknin,[11] Claudio Zamagni,[12] Florian Heitz,[13] Laurence Gladieff,[14] Maria Jesús Rubio-Pérez,[15] Paolo Scollo,[16] Christopher Blakeley,[17] Bob Shaw,[17] Isabelle Ray-Coquard,[18] Andrés Redondo[19]

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Meet The Professor

Optimizing the Management of Acute Myeloid Leukemia and Myelodysplastic Syndromes

Tuesday, September 19, 2023
5:00 PM – 6:00 PM ET

Faculty

Naval Daver, MD

Moderator

Neil Love, MD

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Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.

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

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