What I Tell My Patients: Integrating New Research Information into Current Clinical Care

A Complimentary NCPD Hybrid Symposium Series Held During the 49th Annual ONS Congress

Ovarian Cancer

Friday, April 26, 2024
6:00 PM – 7:30 PM

Faculty

Courtney Arn, CNP
Floor J Backes, MD
Kathleen N Moore, MD, MS
Jaclyn Shaver, MS, APRN, CNP, WHNP

Moderator

Neil Love, MD

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Faculty

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and Solove Research Institute
The Ohio State University
Columbus, Ohio

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Moderator

Neil Love, MD
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Miami, Florida

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Ms Arn — Disclosures

Speakers Bureaus	AstraZeneca Pharmaceuticals LP, Eisai Inc, Genmab US Inc, ImmunoGen Inc, Merck, Seagen Inc

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Dr Backes — Disclosures

Advisory Committees and Consulting Agreements	AstraZeneca Pharmaceuticals LP, BioNTech SE, Clovis Oncology, Daiichi Sankyo Inc, Eisai Inc, EMD Serono Inc, GSK, ImmunoGen Inc, Merck

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Dr Moore — Disclosures

Advisory Committees	Aadi Bioscience, Aravive Inc, AstraZeneca Pharmaceuticals LP, Blueprint Medicines, Caris Life Sciences, Clovis Oncology, Duality Biologics, Eisai Inc, Genentech, a member of the Roche Group, GSK, ImmunoGen Inc, Janssen Biotech Inc, Lilly, Merck, Mersana Therapeutics Inc, Myriad Genetic Laboratories Inc, Panavance Therapeutics, Regeneron Pharmaceuticals Inc, VBL Therapeutics, Verastem Inc, Zentalis Pharmaceuticals
Consulting Agreements	Aadi Bioscience, Caris Life Sciences, Duality Biologics, Eisai Inc, Mersana Therapeutics Inc, Regeneron Pharmaceuticals Inc
Contracted Research	Genentech, a member of the Roche Group, GSK, Lilly, PTC Therapeutics

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Ms Shaver — Disclosures

No relevant conflicts of interest to disclose

Commercial Support

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

This educational activity contains discussion of non-FDA-approved uses of agents and regimens. Please refer to official prescribing information for each product for approved indications.

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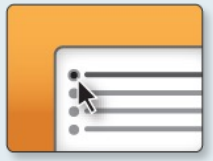
Clinicians in the Meeting Room

Networked iPads are available.

Review Program Slides: Tap the Program Slides button to review speaker presentations and other program content.



Answer Survey Questions: Complete the pre- and postmeeting surveys. Survey questions will be discussed throughout the meeting.

Ask a Question: Tap Ask a Question to submit a challenging case or question for discussion. We will aim to address as many questions as possible during the program.

For assistance, please raise your hand. Devices will be collected at the conclusion of the activity.

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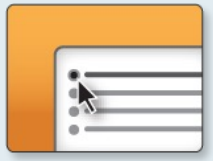
Clinicians Attending via Zoom

Review Program Slides: A link to the program slides will be posted in the chat room at the start of the program.



Answer Survey Questions: Complete the pre- and postmeeting surveys. Survey questions will be discussed throughout the meeting.

Ask a Question: Submit a challenging case or question for discussion using the Zoom chat room.

Get NCPD Credit: An NCPD credit link will be provided in the chat room at the conclusion of the program.

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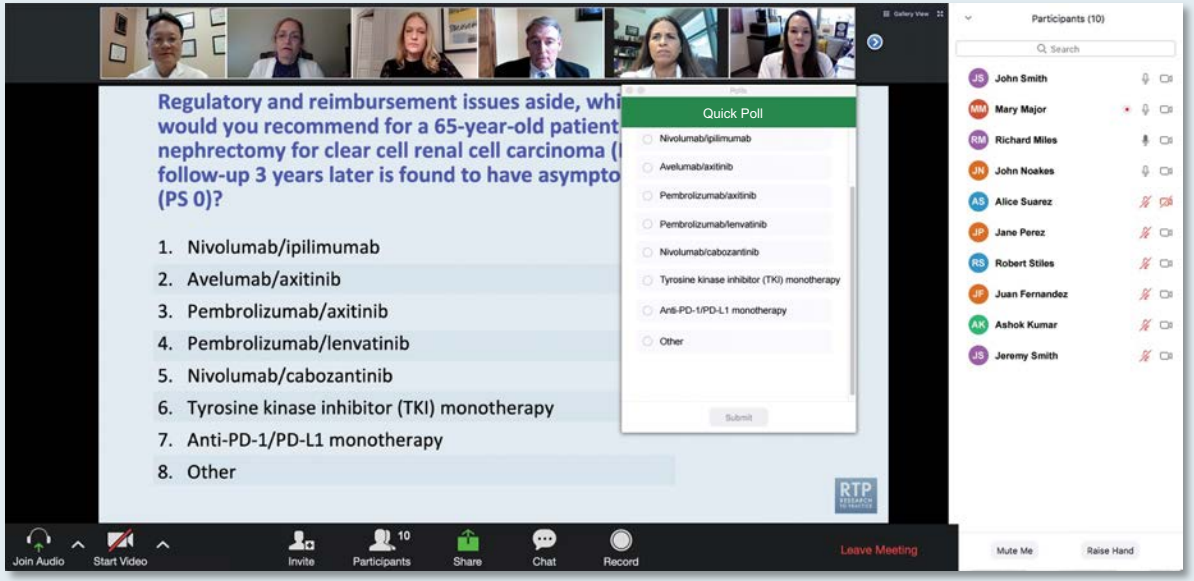
Clinicians, Please Complete the Pre- and Postmeeting Surveys



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About the Enduring Program

- The live meeting is being video and audio recorded.
- The proceedings from today will be edited and developed into an enduring web-based video/PowerPoint program.
  An email will be sent to all attendees when the activity is available.
- To learn more about our education programs, visit our website, **www.ResearchToPractice.com**

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“What I Tell My Patients”
Sixteenth Annual RTP-ONS NCPD Symposium Series

Wednesday April 24	**Hormone Receptor–Positive Breast Cancer** 6:00 PM – 8:00 PM ET
Thursday April 25	**Endometrial Cancer** 6:00 AM – 7:30 AM ET
	Antibody–Drug Conjugates 12:15 PM – 1:45 PM ET
	Chronic Lymphocytic Leukemia and Bispecific Antibodies in Lymphoma 6:00 PM – 8:00 PM ET
Friday April 26	**Head and Neck Cancer** 6:00 AM – 7:30 AM ET
	Non–Small Cell Lung Cancer with an EGFR Mutation 12:15 PM – 1:45 PM ET
	Ovarian Cancer 6:00 PM – 7:30 PM ET
Saturday April 27	**Hepatobiliary Cancers** 6:00 AM – 7:30 AM ET
	Myelofibrosis 12:15 PM – 1:45 PM ET
	Gastroesophageal and Colorectal Cancers 6:00 PM – 8:00 PM ET
Wednesday, May 1	**LIVE WEBINAR — Prostate Cancer** 7:00 PM – 8:00 PM ET

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Consulting Nurse Faculty

Jacqueline Broadway-Duren, PhD, DNP, APRN, FNP-BC
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Houston, Texas

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Duarte, California

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University of Arkansas for Medical Sciences
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Los Angeles, California

https://www.ResearchToPractice.com/ONS2024Clips

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What I Tell My Patients: Integrating New Research Information into Current Clinical Care

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Agenda

Module 1: Newly Diagnosed Advanced Ovarian Cancer

Module 2: Role of PARP Inhibitors in the Management of Relapsed/Refractory Ovarian Cancer

Module 3: Targeted Therapy for Patients with Advanced Ovarian Cancer

Agenda

Module 1: Newly Diagnosed Advanced Ovarian Cancer

Module 2: Role of PARP Inhibitors in the Management of Relapsed/Refractory Ovarian Cancer

Module 3: Targeted Therapy for Patients with Advanced Ovarian Cancer

The Incidence, Pathogenesis and Prognosis of Ovarian Cancer (OC); Genetic Testing in Newly Diagnosed Advanced OC

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Incidence of OC in the United States and the rest of the world**
- **Various histologic subtypes of OC and implications for prognosis and treatment**
- **Survival rates associated with various stages of OC**
- **Rationale for stable OC incidence yet rising number of patients with the disease; contribution of the availability of novel therapies to this phenomenon**
- **Similarities and differences between germline and somatic genetic mutations**

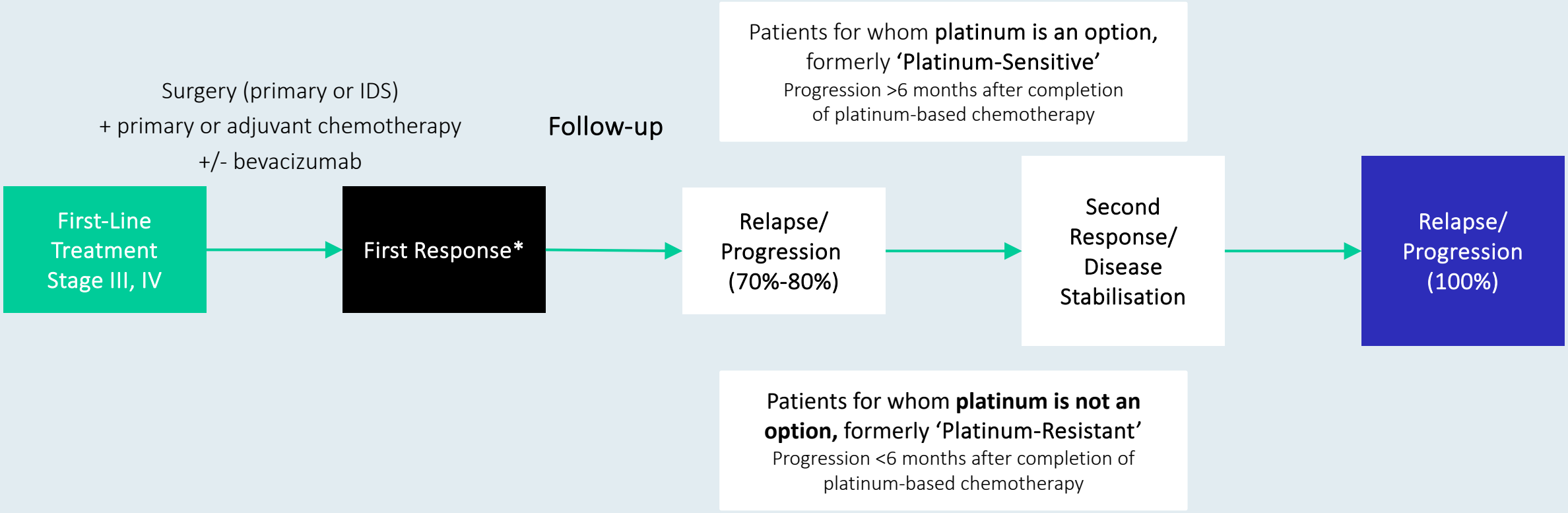
The Incidence, Pathogenesis and Prognosis of Ovarian Cancer (OC); Genetic Testing in Newly Diagnosed Advanced OC

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Incidence and clinical significance of BRCA mutations and other germline or somatic alterations in OC, such as PALB2, ATM and RAD51C/D**
- **Definition and frequency of homologous recombination deficiency (HRD) in OC; rationale for determining HRD status and available testing methodologies**
- **Current roles of next-generation sequencing and germline sequencing in advanced OC; similarities and differences among available genetic testing platforms**
- **Purpose and potential benefits of genetic counseling after a diagnosis of OC**

The Typical Course of Advanced Ovarian Cancer



*Around 5% of patients are primary treatment-refractory, meaning disease progressed during therapy or within 4 weeks after the last dose.
IDS=interval debulking surgery.

1. Ledermann JA et al. *Ann Oncol.* 2013;24(Suppl 6):vi24-vi32. 2. Giornelli GH. *Springerplus*. 2016;5(1):1197. 3. Pignata S et al. *Ann Oncol.* 2017;28(suppl_8):viii51-viii56. 4. du Bois A et al. *Cancer*. 2009;115(6):1234-1244. 5. Wilson MK et al. *Ann Oncol*. 2017;28(4):727-732.

Courtesy of Kathleen N Moore, MD, MS

Jaclyn Shaver, MS, APRN, CNP, WHNP

What I tell my patients with newly diagnosed advanced ovarian cancer about what to expect from initial treatment (surgery and/or chemotherapy) and the importance of genetic testing

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The Role of PARP Inhibitor Maintenance in Newly Diagnosed Advanced OC

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Mechanism of antitumor activity of PARP inhibitors and rationale for their use as maintenance therapy for patients with OC**
- **Similarities and differences between various PARP inhibitors approved in OC**
- **Long-term findings from Phase III studies, such as SOLO-1, PAOLA-1, PRIMA and PRIME, supporting the use of olaparib, niraparib and olaparib/bevacizumab maintenance for patients with newly diagnosed OC**
- **Clinical, biological and practical factors affecting the selection of up-front olaparib, niraparib or olaparib/bevacizumab maintenance**
- **Early findings with niraparib/bevacizumab maintenance after front-line platinum-based chemotherapy/bevacizumab; ongoing evaluation and potential clinical role**

Courtney Arn, CNP

What I tell my patients with advanced ovarian cancer who are about to begin maintenance treatment with a PARP inhibitor with or without bevacizumab

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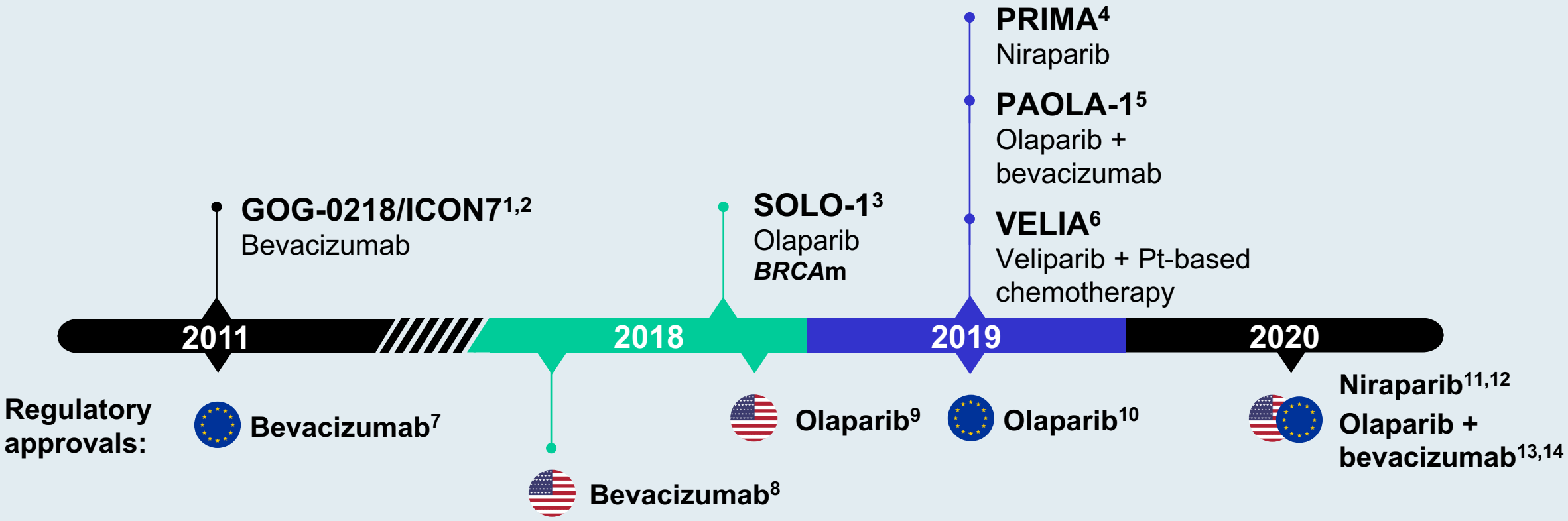
Pivotal Trials and Regulatory Milestones in First-Line Maintenance Therapy for Advanced Ovarian Cancer



Dates shown indicate the year of the publication of the pivotal studies and regulatory approvals for these compounds.

1. Burger RA et al. *N Engl J Med* 2011;365:2473. **2.** Perren TJ et al. *N Engl J Med* 2011;365:2484. **3.** Moore K et al. *N Engl J Med* 2018;379:2495. **4.** González-Martín A et al. *N Engl J Med*. 2019;381:239. **5.** Ray-Coquard I et al. *N Engl J Med* 2019;381:2416. **6.** Coleman RL et al. *N Engl J Med* 2019;381:2403. **7.** European Medicines Agency. Published September 22, 2011. Accessed June 7, 2021. **8.** F. Hoffmann-La Roche Ltd. Published June 13, 2018. Accessed June 7, 2021. **9.** FDA. Published December 26, 2018. Accessed June 7, 2021. **10.** EMA. Published April 26, 2019. Accessed June 7, 2021. **11.** GSK. Published April 29, 2020. Accessed June 7, 2021. **12.** GSK. Published October 29, 2020. Accessed June 7, 2021. **13.** FDA. Published May 11, 2020. Accessed June 7, 2021. **14.** EMA. Published September 17, 2020. Accessed June 7, 2021.

Content Courtesy of Kathleen N Moore, MD, MS

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].

The Potential Role of PARP Inhibitors in Combination with Anti-PD-1/PD-L1 Antibodies in Advanced OC Management

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Historical data with immune checkpoint inhibitors for OC**
- **Biological rationale for combining PARP inhibitors with anti-PD-1/PD-L1 antibodies for OC**
- **Available early-phase research results with PARP inhibitors with anti-PD-1/PD-L1 antibodies with or without bevacizumab for advanced OC**
- **Recent findings from the Phase III DUO-O trial evaluating up-front durvalumab with platinum-based chemotherapy/bevacizumab followed by durvalumab/bevacizumab/olaparib as maintenance therapy for advanced OC; clinical implications**
- **Other ongoing Phase III research evaluating PARP inhibitors in combination with anti-PD-1/PD-L1 antibodies for OC**

Jaclyn Shaver, MS, APRN, CNP, WHNP

What I tell my patients with advanced ovarian cancer who are being considered for or enrolling on a clinical trial with a PARP inhibitor in combination with an anti-PD-1/PD-L1 antibody with or without bevacizumab

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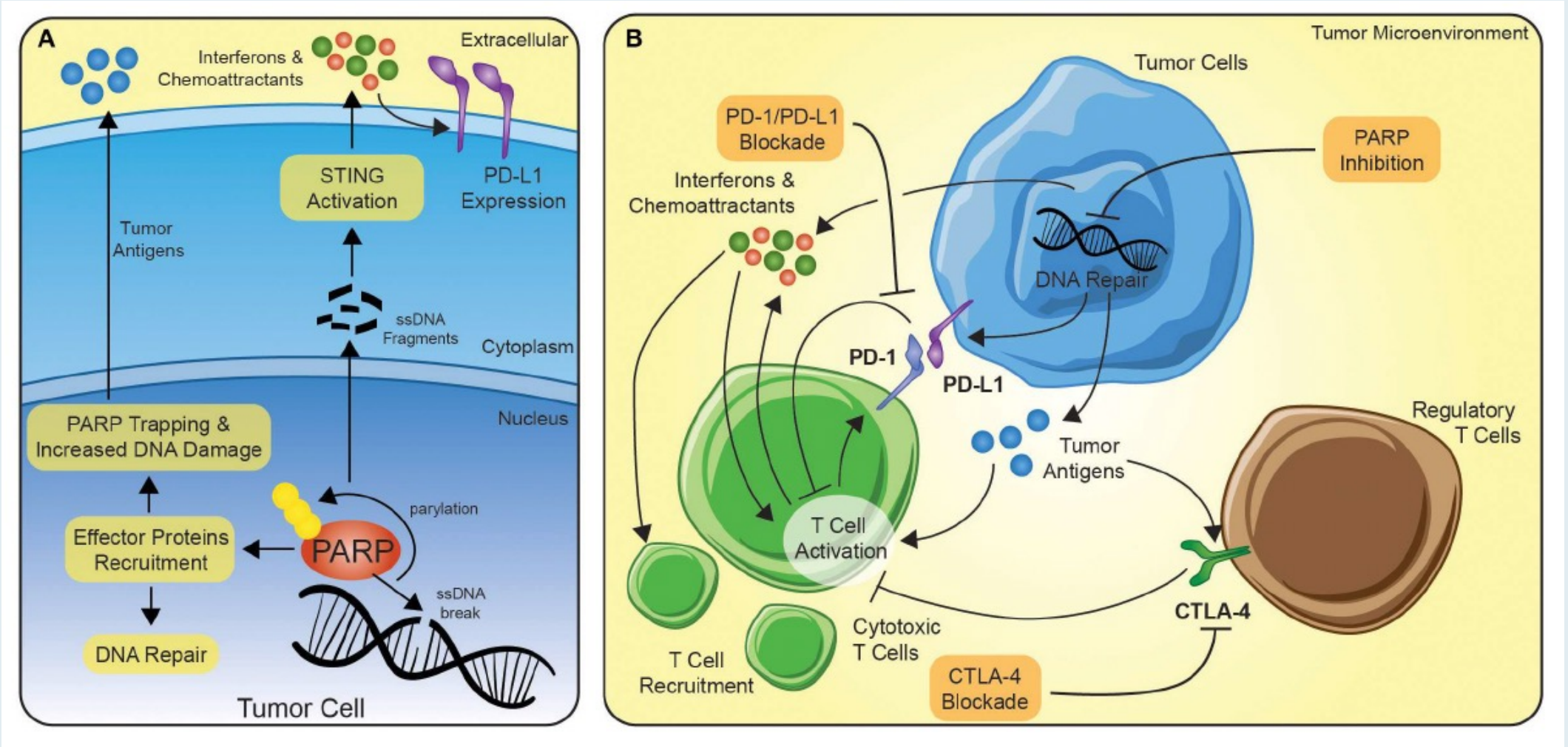
Potential Synergy Between PARP Inhibition and Immune Checkpoint Blockade



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

Side Effects Associated with PARP Inhibitors

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Spectrum, incidence and severity of common class- and agent-specific toxicities associated with PARP inhibitors in patients with OC**
- **Optimal monitoring and management paradigm for common PARP inhibitor-related toxicities**
- **Long-term risk of acute myeloid leukemia/myelodysplastic syndromes with PARP inhibitor therapy**
- **Role of switching to an alternative PARP inhibitor for patients who are experiencing unacceptable toxicity**

Dosing, Adherence and Other Issues with PARP Inhibitors for OC

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Initial dosing and appropriate dose-modification strategies for approved PARP inhibitors**
- **Optimal duration of PARP inhibitors in the maintenance setting**
- **Importance of adherence for patients receiving long-term oral medications, including PARP inhibitors; strategies to encourage and assess adherence**
- **Challenges of polypharmacy and the potential for drug-drug interactions between approved PARP inhibitors and other medications and supplements**

Consulting Nursing Faculty Comments

Patient adherence to therapy; dose modifications

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

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Agenda

Module 1: Newly Diagnosed Advanced Ovarian Cancer

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PARP Inhibitors for Relapsed/Refractory (R/R) OC

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Defining “platinum-sensitive” and “platinum-resistant” in relapsed OC**
- **Long-term follow-up from pivotal trials evaluating niraparib, olaparib and rucaparib for patients with platinum-sensitive and platinum-resistant recurrent OC**
- **Rationale for recent withdrawals of various indications for olaparib, niraparib and rucaparib, and implications for current management of R/R disease**
- **Key data documenting the clinical utility of rechallenge with a PARP inhibitor for patients who have experienced disease progression on or after prior PARP inhibitor therapy; current role in practice**

Courtney Arn, CNP

What I tell my patients with relapsed/refractory ovarian cancer about goals of treatment

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Voluntary Withdrawals of Late-Line Indications for 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://www.federalregister.gov/d/2024-06299; 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.hayesinc.com/news/market-withdrawal-rubraca-for-third-line-ovarian-cancer-indication/

cancers

MDPI

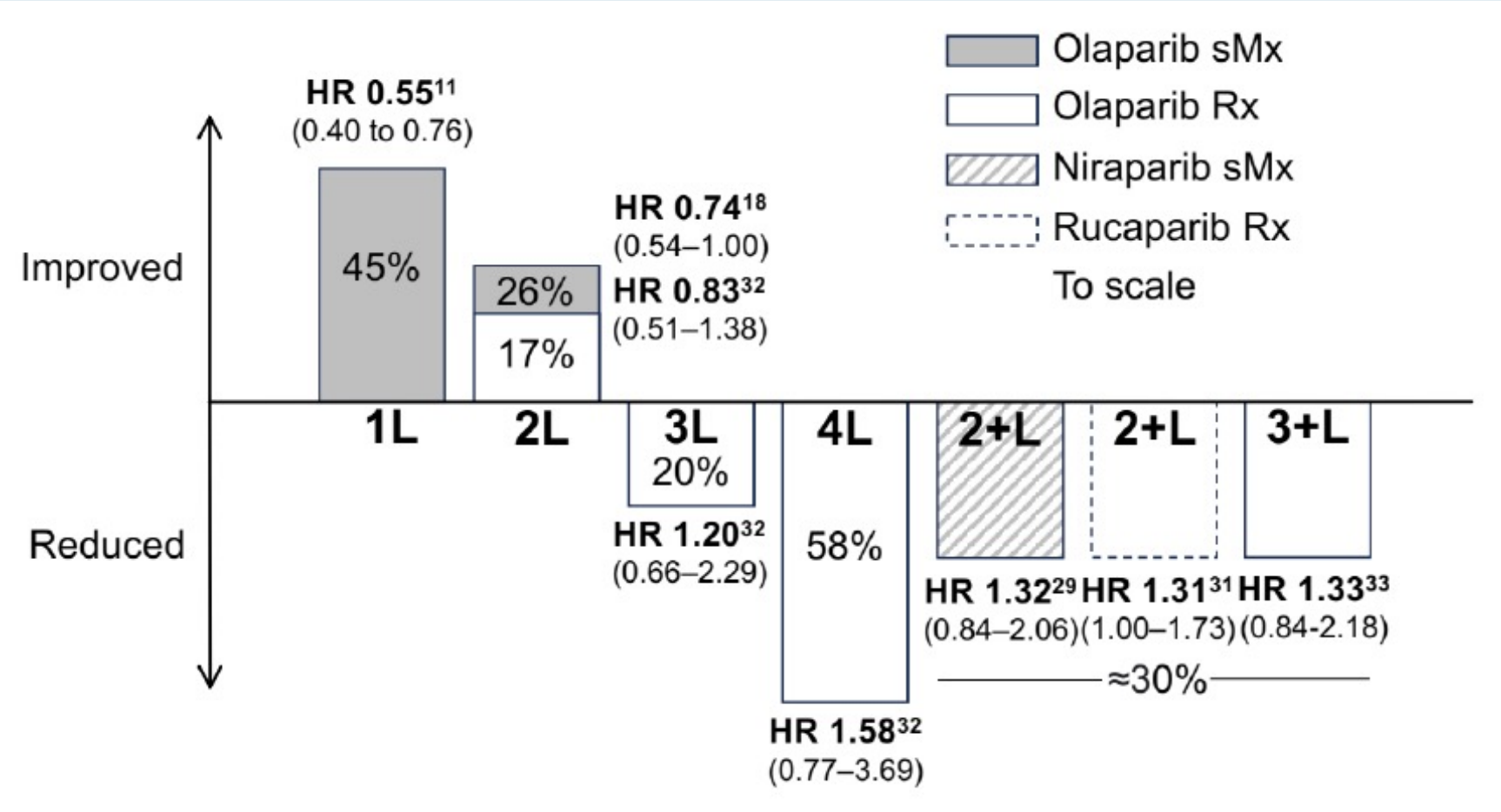
Review

PARP Inhibitors: Strategic Use and Optimal Management in Ovarian Cancer

Nicholas Hirschl, Wildnese Leveque, Julia Granitto, Valia Sammarco, Mervyns Fontillas and Richard T. Penson *

Cancers (Basel) 2024 February 25;16(5):932.

Overall Survival Impact of PARP Inhibition:
Hazard Ratios Translated into Percent Change in OS



HR = hazard ratio; sMx = switch maintenance; Rx = treatment; 1L = first line; 2L = second line; 3L = third line; 4L = fourth line; 2+L = two or more prior lines; 3+L = three or more prior lines

Hirschl N et al. *Cancers (Basel)* 2024 February 25;16(5):932.

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The Incidence and Management of HER2-Positive OC

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Frequency of HER2 expression and biological rationale for targeting HER2 in advanced OC**
- **Structural components and mechanism of antitumor activity of trastuzumab deruxtecan (T-DXd)**
- **Outcomes observed in the cohort of patients with OC in the Phase II DESTINY-PanTumor02 trial of T-DXd for pretreated HER2-expressing solid tumors**
- **Current nonresearch role, if any, of T-DXd in treatment for patients with HER2-positive advanced OC**
- **Recent tumor-agnostic approval of T-DXd for HER2-positive solid tumors**

Jaclyn Shaver, MS, APRN, CNP, WHNP

What I tell my patients about HER2 testing and potential therapy with trastuzumab deruxtecan

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FDA Grants Accelerated Approval to Trastuzumab Deruxtecan for Unresectable or Metastatic HER2-Positive Solid Tumors

Press Release: April 5, 2024

"On April 5, 2024, the Food and Drug Administration granted accelerated approval to fam-trastuzumab deruxtecan-nxki for adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options. Efficacy was evaluated in 192 adult patients with previously treated unresectable or metastatic HER2-positive (IHC 3+) solid tumors who were enrolled in one of three multicenter trials: DESTINY-PanTumor02 (NCT04482309), DESTINY-Lung01 (NCT03505710), and DESTINY-CRC02 (NCT04744831). All three trials excluded patients with a history of interstitial lung disease (ILD)/pneumonitis requiring treatment with steroids or ILD/pneumonitis at screening and clinically significant cardiac disease. Patients were also excluded for active brain metastases or ECOG performance status >1. Treatment was administered until disease progression, death, withdrawal of consent, or unacceptable toxicity.

The recommended fam-trastuzumab deruxtecan-nxki dosage for this indication is 5.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. This tumor agnostic indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-fam-trastuzumab-deruxtecan-nxki-unresectable-or-metastatic-her2

The Current Role of Mirvetuximab Soravtansine for OC Treatment

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Frequency of and scientific rationale for targeting folate receptor alpha (FRα) in OC**
- **Mechanism of action and structural components of mirvetuximab soravtansine**
- **Published research findings, such as SORAYA and MIRASOL, with mirvetuximab soravtansine for patients with FRα-high platinum-resistant OC**
- **Recent FDA approval of mirvetuximab soravtansine; implications for biomarker assessment and current OC management**
- **Ongoing studies of mirvetuximab soravtansine for platinum-sensitive advanced OC**

Toxicities with Mirvetuximab Soravtansine

Dr Backes
Columbus, Ohio

Dr Moore
Oklahoma City, Oklahoma

- **Pathophysiology and incidence of the ocular toxicities observed with mirvetuximab soravtansine**
- **Monitoring and management techniques for mirvetuximab soravtansine-related ocular events**
- **Importance of collaboration with eye care specialists for patients receiving mirvetuximab soravtansine**
- **Spectrum, frequency, severity and timing of other common toxicities reported with mirvetuximab soravtansine; optimal management approaches**

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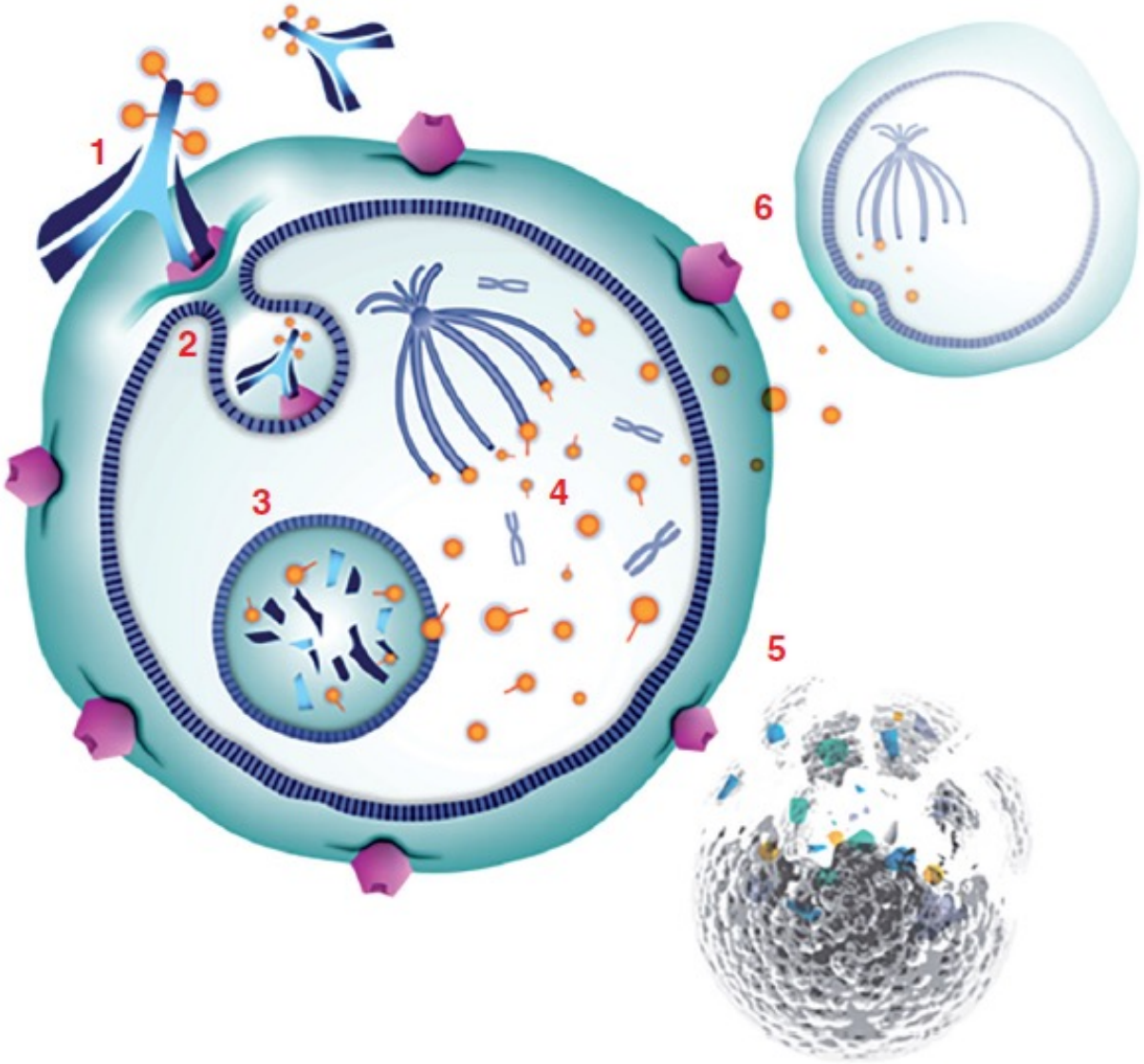
Courtney Arn, CNP

What I tell my patients about the mechanism of action and side effects of mirvetuximab soravtansine

Mirvetuximab Soravtansine: Mechanism of Action



(1) Mirvetuximab soravtansine binds with high affinity to FRα expressed on the tumor cell surface

(2) The antibody-drug conjugate (ADC)/receptor complex becomes internalized via antigen-mediated endocytosis

(3) Lysosomal processing releases active DM4 catabolites from the ADC molecule

(4) These maytansinoid derivatives inhibit tubulin polymerization and microtubule assembly

(5) The potent antimitotic effects result in cell-cycle arrest and apoptosis

(6) Active metabolites can also diffuse into neighboring cells and induce further cell death — in other words, bystander killing

Moore K et al. *Future Oncol* 2018:14(2);123-36.

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Mirvetuximab Soravtansine

Mechanism of action

- Antibody-drug conjugate directed against folate receptor alpha (FRα)

Indication

- For patients with FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received 1 to 3 prior systemic treatment regimens

Recommended dose

- 6 mg/kg adjusted ideal body weight administered as an IV infusion q3wk until disease progression or unacceptable toxicity

Key issues

- Boxed warning for severe ocular toxicity

Mirvetuximab soravtansine package insert, 3/2024.

FDA Approves Mirvetuximab Soravtansine-Gynx for FRα-Positive, Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Press Release: March 22, 2024

"On March 22, 2024, the Food and Drug Administration approved mirvetuximab soravtansine-gynx for adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.

Efficacy was evaluated in Study 0416 (MIRASOL, NCT04209855), a multicenter, open-label, active-controlled, randomized, two-arm trial in 453 patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. Patients were permitted to receive up to three prior lines of systemic therapy. The trial enrolled patients whose tumors were positive for FRα expression as determined by the FOLR1 (FOLR1-2.1) RxDx Assay.

The major efficacy outcome measures were overall survival (OS), investigator-assessed progression-free survival (PFS) and confirmed overall response rate (ORR) per investigator assessment. PFS and ORR were evaluated according to RECIST, version 1.1."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-mirvetuximab-soravtansine-gynx-fra-positive-platinum-resistant-epithelial-ovarian

Consulting Nursing Faculty Comments

Spirituality and religion

Jessica Mitchell, APRN, CNP, MPH

Consulting Nursing Faculty Comments

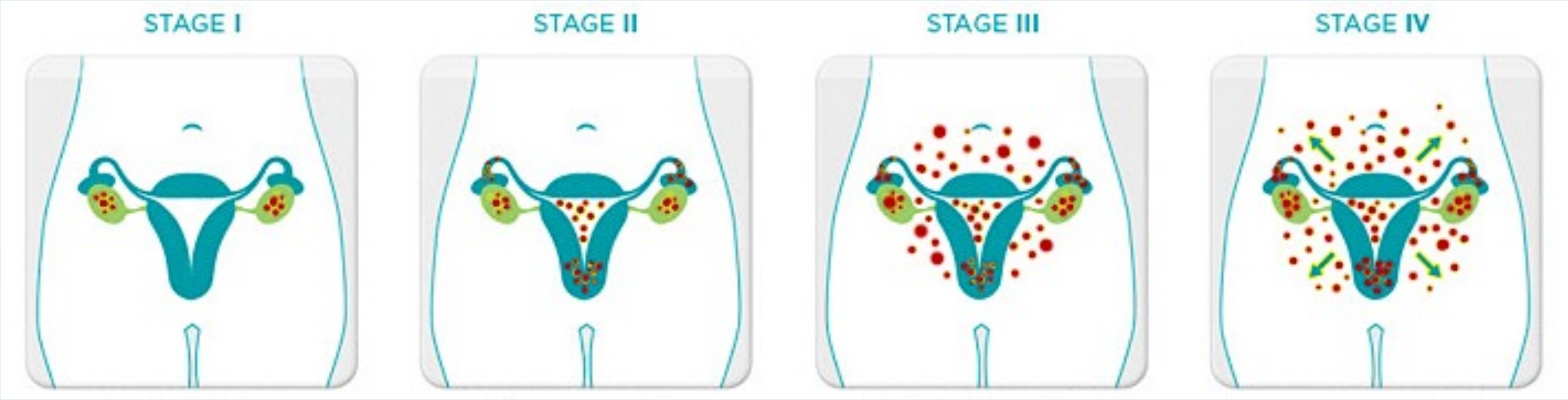
Self-care and avoiding professional burnout

Kathleen D Burns, RN, MSN, AGACNP-BC, OCN

RTP
RESEARCH
TO PRACTICE

APPENDIX

Stages of Epithelial OC



Confined to ovaries | Spread to pelvis | Spread to abdomen | Spread to distant sites

15% of patients present with Stage I

85% of patients present with Stage II-IV

5 y survival: 90% 70% 39% 17%

http://ovarian.org/about-ovarian-cancer/what-is-ovarian-cancer/types-a-stages; https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survival-rates.html;
Howlander N et al. SEER Cancer Statistics Review 1975-2014, http://seer.cancer.gov/csr/1975_2014/

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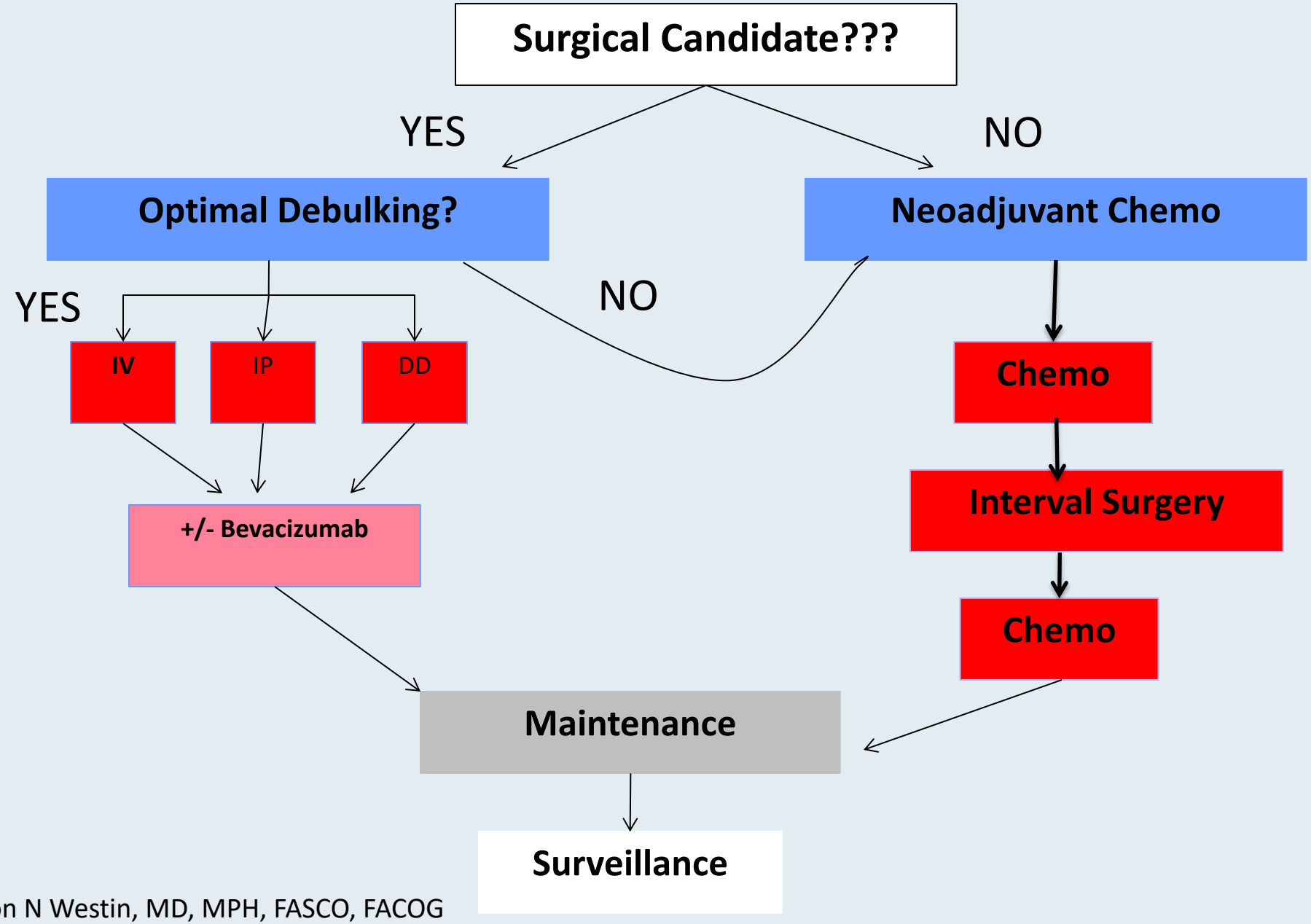
New Advanced Ovarian Cancer



Courtesy of Shannon N Westin, MD, MPH, FASCO, FACOG

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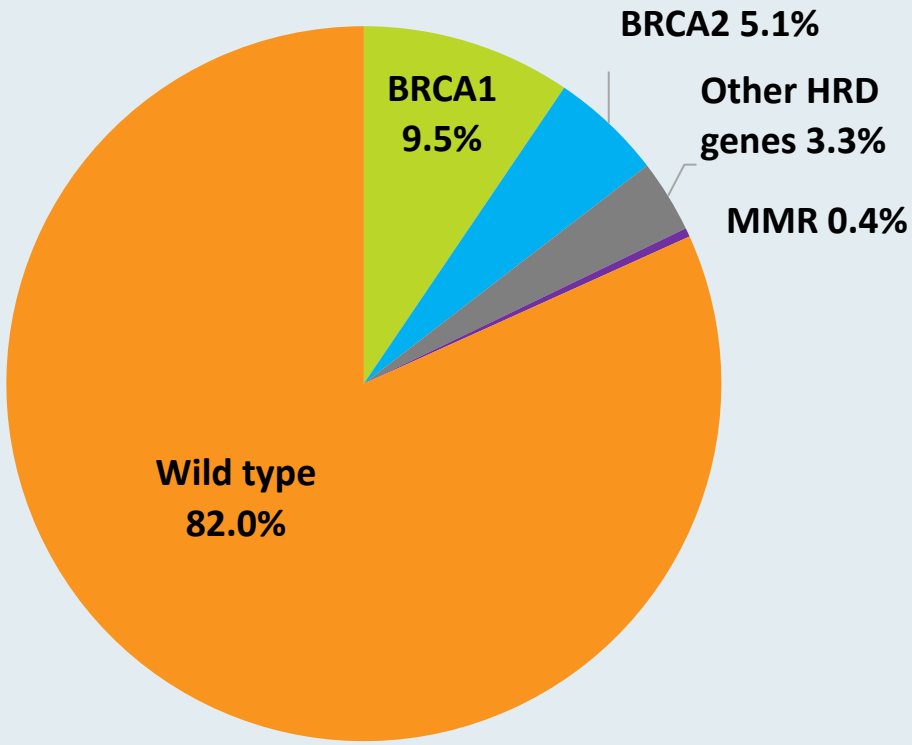
Genetic Mutations in Ovarian Cancer

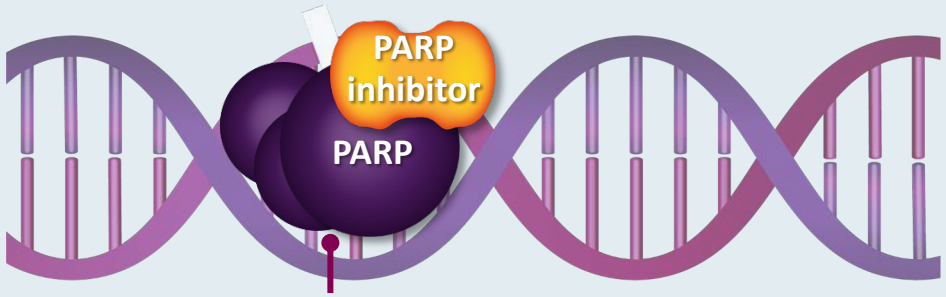
- **Germline mutations in women with OC**
  - **Germline DNA sequenced from women with OC (N = 1,915) using a targeted capture and multiplex sequencing assay**
- **Homologous recombination deficiency (HRD) gene mutations may be a risk for OC**
- **Somatic mutations: BRCA1/2: 6%, HRD genes: 17%**
- **Patients with mutations in HRD genes are more sensitive to platinum-based chemotherapy, PARP inhibitors**



MMR = mismatch repair

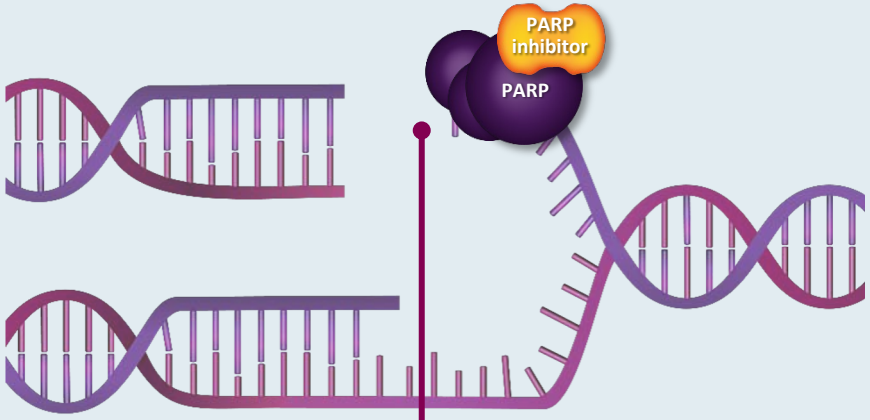
Norquist BM et al. *JAMA Oncol* 2016;2(4):482-90; Aghajanian C et al. ASCO 2017;Abstract 5545; Hennessy B et al. *J Clin Oncol* 2010;28(22):3570-6.

PARP Inhibition Exploits the Baseline Vulnerability of Cells with Inherent DNA Repair Deficiency



Trapped PARP on single-strand breaks

Increase in double-strand breaks in replicating cells



Double-strand breaks

HRR-deficient cancer cell

Reliance on error-prone pathways leads to DNA damage accumulation and cell death

Normal cell

Repair of double-strand breaks via the HRR pathway and cell survival

HRR = homologous recombination repair

O'Connor MJ. *Mol Cell* 2015.

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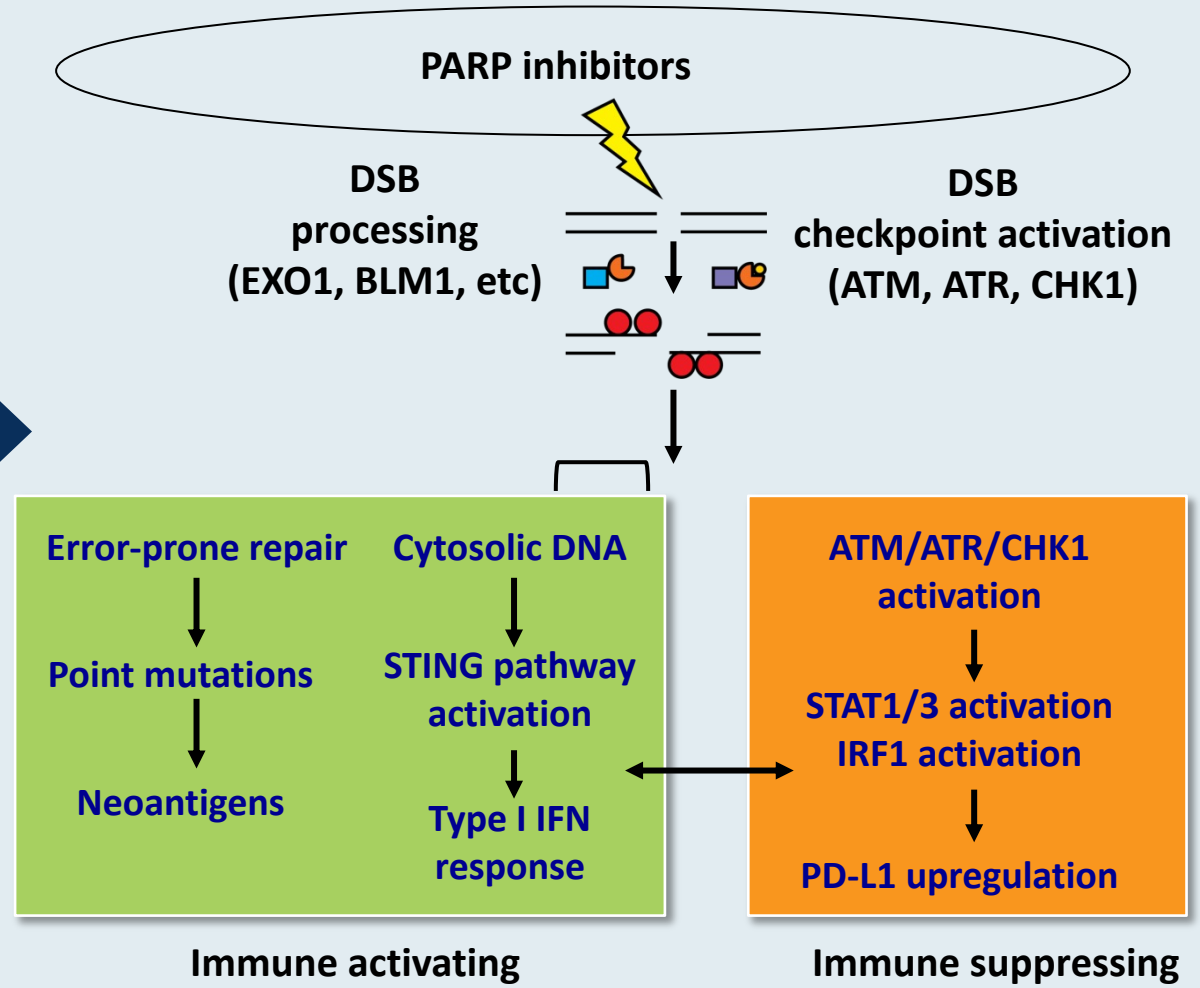
Biological Rationale for Combining a PARP Inhibitor with an Immune Checkpoint Inhibitor

Preclinical models indicate synergy between PARP inhibitors and anti-PD-1 agents regardless of BRCA mutation status or PD-L1 status



Preclinical data demonstrate synergy with PARP inhibitor and anti-PD-1 combinations.

DSB = double-strand break

Konstantinopoulos P et al. ASCO 2018;Abstract 106.

DUO-O Trial

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

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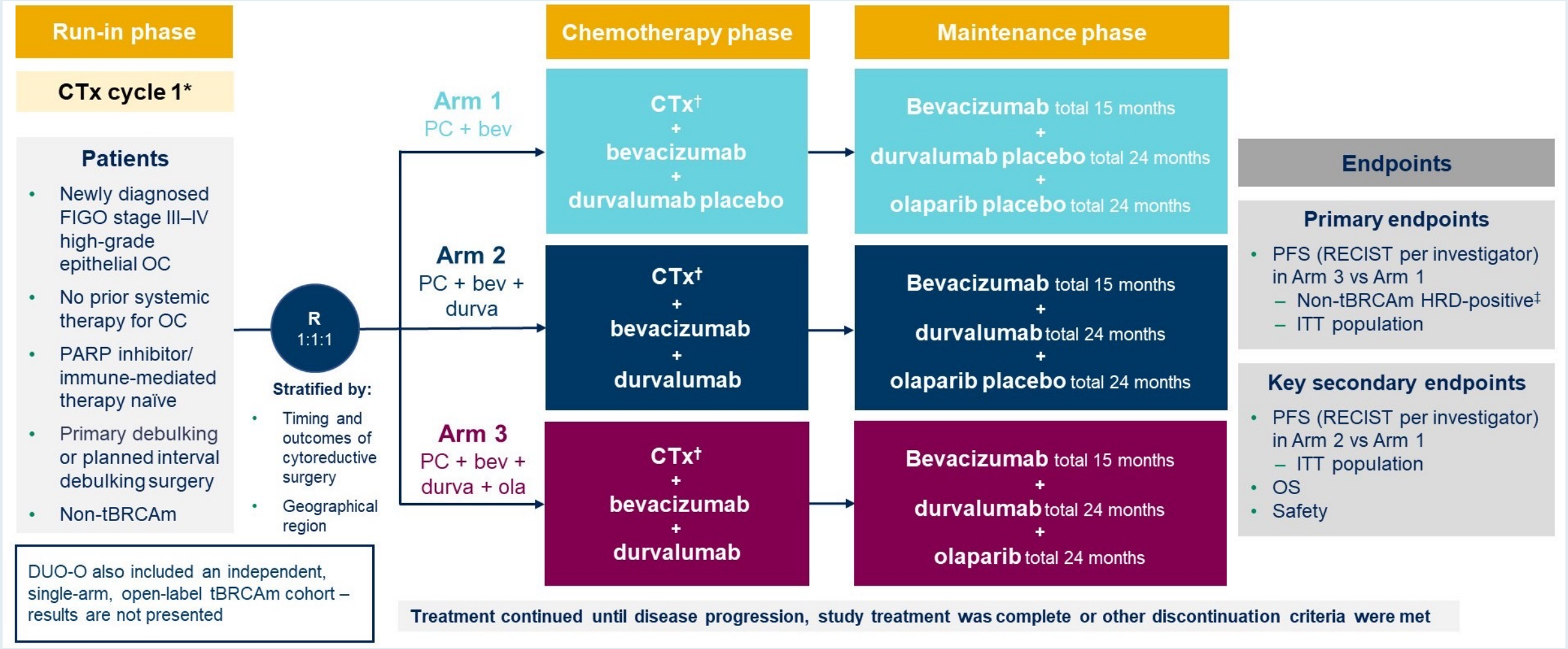
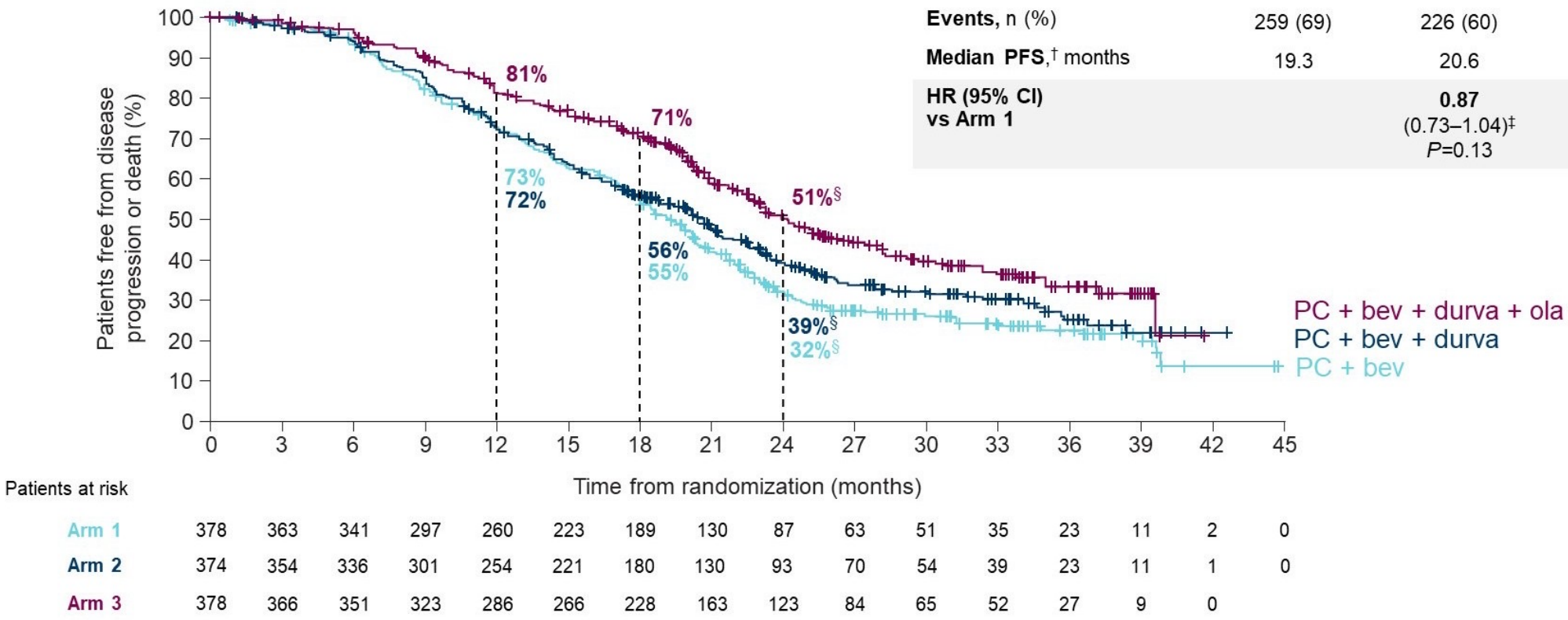
DUO-O: Study Design



Harter P et al. ASCO 2023;Abstract LBA5506.

DUO-O: Progression-Free Survival (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.

Harter P et al. ASCO 2023;Abstract LBA5506.

DUO-O: Safety Summary

AEs, n (%)	Overall (chemotherapy phase + maintenance phase)			Maintenance phase		
	Arm 1 PC + bev N=376	Arm 2 PC + bev + durva N=373	Arm 3 PC + bev + durva + ola N=378	Arm 1 PC + bev N=331	Arm 2 PC + bev + durva N=323	Arm 3 PC + bev + durva + ola N=336
Any-grade AE	373 (99)	371 (99)	375 (99)	308 (93)	303 (94)	328 (98)
Grade ≥3 AE	231 (61)	245 (66)	269 (71)	88 (27)	113 (35)	164 (49)
AE with outcome of death	4 (1)	9 (2)	6 (2)	2 (1)	3 (1)	4 (1)
Serious AE (including outcome of death)	128 (34)	161 (43)	148 (39)	50 (15)	91 (28)	83 (25)
AE of special interest to olaparib						
MDS/AML*	1 (<1)	0	2 (1)	1 (<1)	0	1 (<1)
New primary malignancies*	1 (<1)	1 (<1)	4 (1)	1 (<1)	1 (<1)	3 (1)
Pneumonitis	3 (1)	5 (1)	7 (2)	1 (<1)	3 (1)	6 (2)
Any immune-mediated AEs†	132 (35)	209 (56)	200 (53)	94 (28)	139 (43)	141 (42)
AEs leading to dose modification‡,§	272 (72)	299 (80)	323 (85)	163 (49)	182 (56)	254 (76)
AEs leading to discontinuation‡	77 (20)	98 (26)	131 (35)	44 (13)	54 (17)	88 (26)
AEs leading to discontinuation of PC/bevacizumab	57 (15)	59 (16)	70 (19)	27 (8)	24 (7)	35 (10)
AEs leading to discontinuation of durvalumab/placebo	24 (6)	62 (17)	65 (17)	14 (4)	39 (12)	40 (12)
AEs leading to discontinuation of olaparib/placebo	15 (4)	19 (5)	62 (16)	14 (4)	19 (6)	61 (18)

Includes AEs with onset or worsening on or after the date of first dose of durvalumab/placebo or olaparib/placebo (overall) or first dose of olaparib/placebo (maintenance phase) until initiation of the first subsequent anticancer therapy following last dose of study treatment or until the end of the safety follow-up period.
*Includes events from first dose of durvalumab/olaparib/placebo until end of study; †Investigator-assessed; ‡Based on action taken on AE CRF for at least one treatment. For durvalumab/placebo, dose modification includes skipped or delayed doses, or interruption of the infusion; §Either dose reduction or dose interruption. AE, adverse event; AML, acute myeloid leukemia; CRF, case report form; MDS, myelodysplastic syndrome.

Harter P et al. ASCO 2023;Abstract LBA5506.

PRIMA Trial

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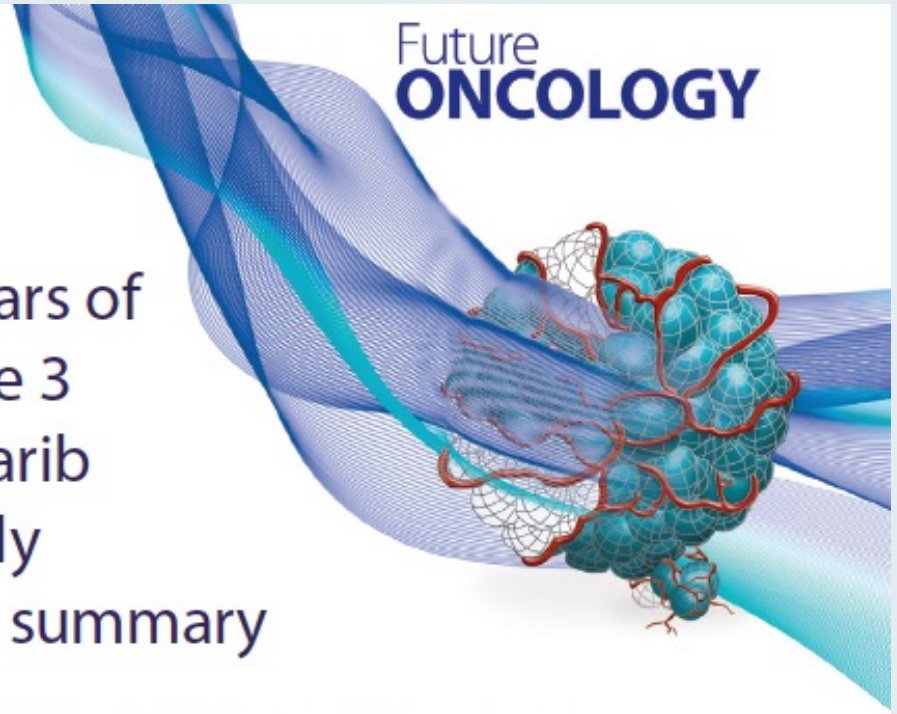
Future ONCOLOGY



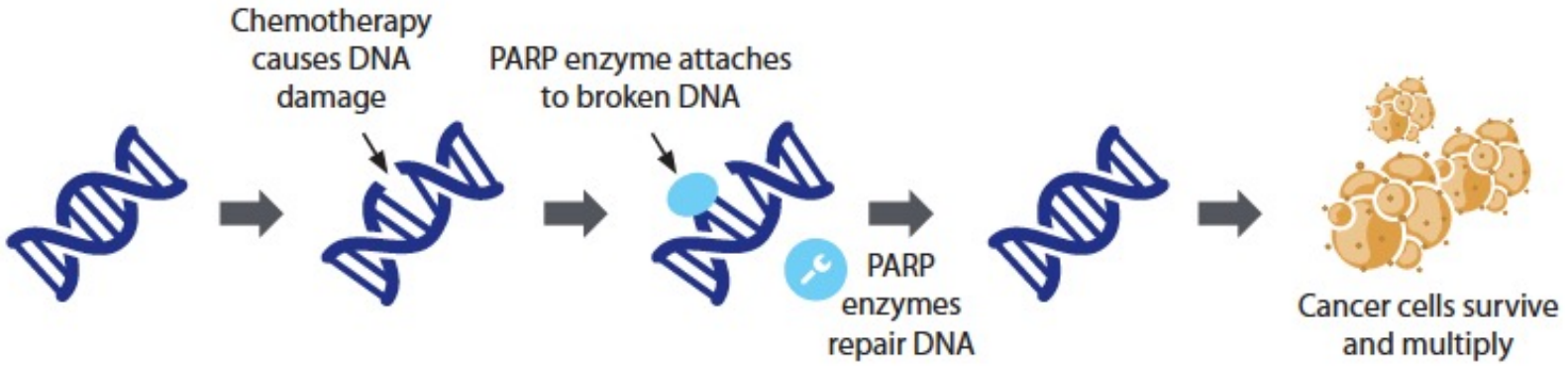
Progression-free survival and safety at 3.5 years of follow-up: results from the randomized phase 3 PRIMA/ENGOT-OV26/GOG-3012 trial of niraparib maintenance treatment in patients with newly diagnosed ovarian cancer – a plain language summary

Antonio González-Martín[1], Bhavana Pothuri[2], Ignace Vergote[3], Whitney Graybill[4], Domenica Lorusso[5], Colleen C McCormick[6], Gilles Freyer[7], Floor Backes[8], Florian Heitz[9], Andrés Redondo[10], Richard G Moore[11], Christof Vulsteke[12], Roisin E O'Cearbhaill[13], Izabela A Malinowska[14], Luda Shtessel[14], Natalie Compton[14], Mansoor R Mirza[15] and Bradley J Monk[16]

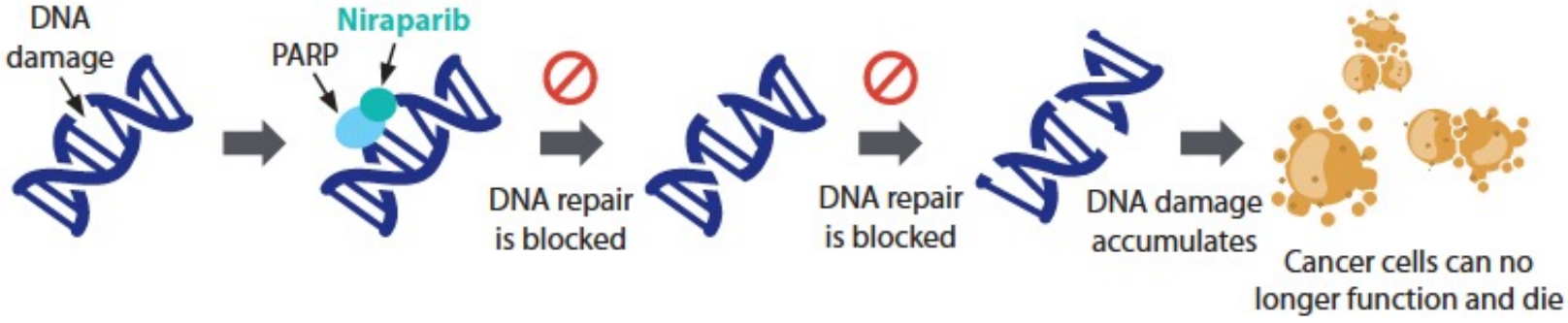
2024 March 19;[Online ahead of print].

Niraparib: Mechanism of Action

Chemotherapy kills cancer cells by damaging their DNA. Cancer cells can use **PARP** enzymes to fix the DNA damage, preventing chemotherapy from killing them.



Niraparib attaches (binds) to the PARP enzyme and stops it from fixing damaged DNA. With niraparib blocking DNA repair, the DNA damage gets worse over time. The DNA damage eventually gets so severe that the cancer cells can no longer function and they die.



González-Martín A et al. *Future Oncol* 2024 March 19;[Online ahead of print].

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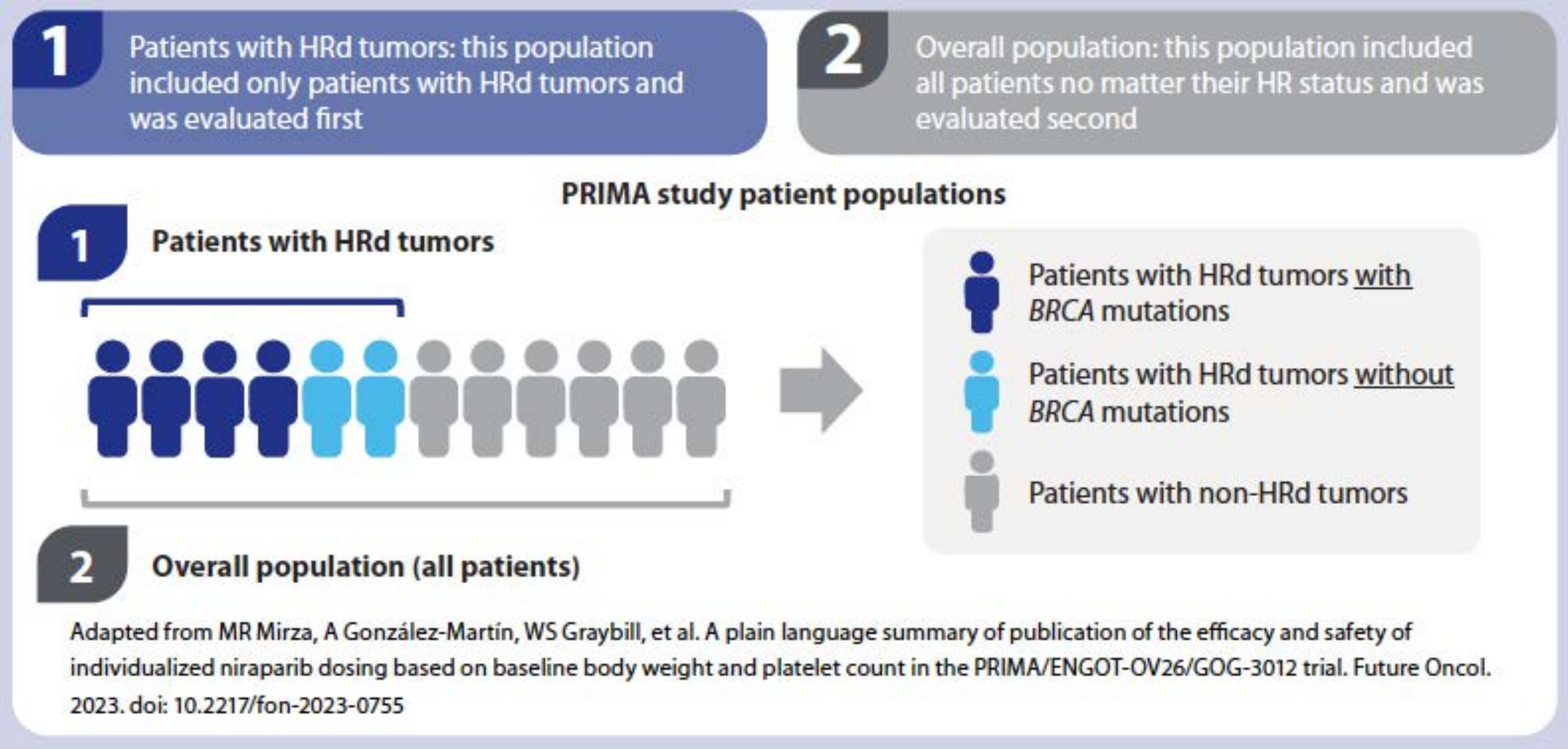
PRIMA: Patient Populations



Adapted from MR Mirza, A González-Martín, WS Graybill, et al. A plain language summary of publication of the efficacy and safety of individualized niraparib dosing based on baseline body weight and platelet count in the PRIMA/ENGOT-OV26/GOG-3012 trial. Future Oncol. 2023. doi: 10.2217/fon-2023-0755

HRd = homologous recombination deficient

González-Martín A et al. *Future Oncol* 2024 March 19;[Online ahead of print].

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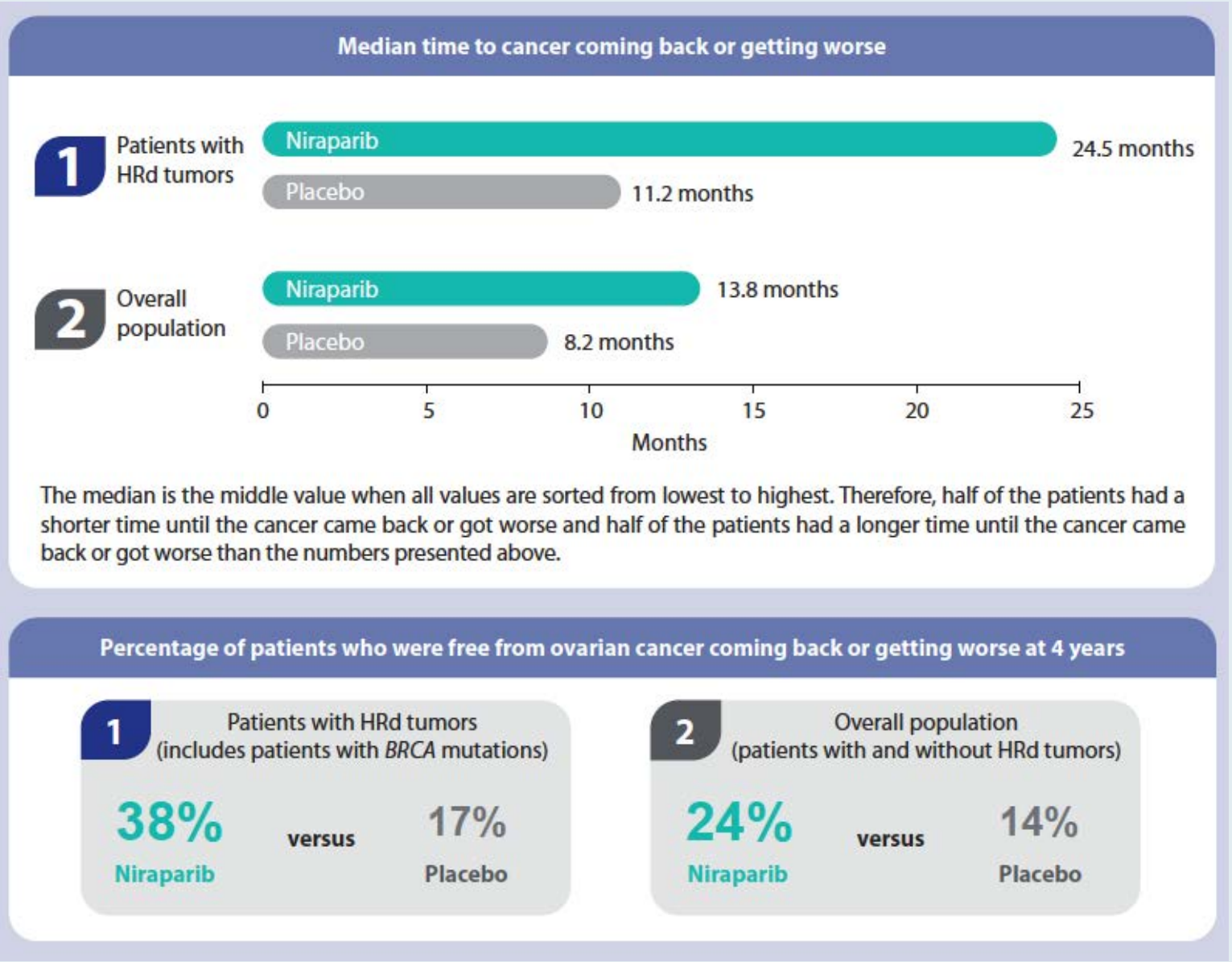
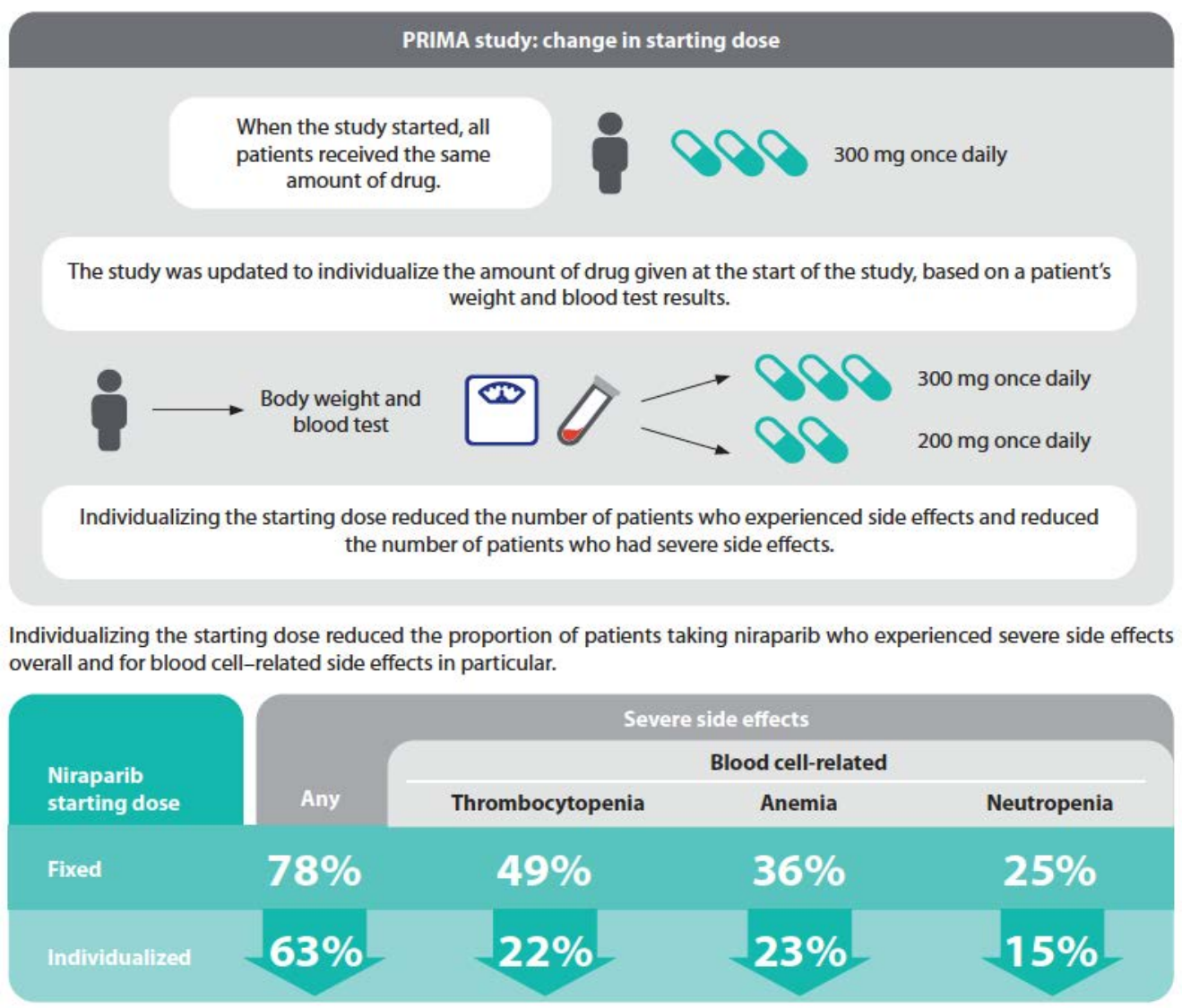
PRIMA: Survival Outcomes



González-Martín A et al. *Future Oncol* 2024 March 19;[Online ahead of print].

PRIMA: Change in Starting Dose Resulted in Reduced Incidence of Severe Side Effects



Individualizing the starting dose reduced the proportion of patients taking niraparib who experienced severe side effects overall and for blood cell–related side effects in particular.

Niraparib starting dose	Severe side effects: Any	Blood cell-related: Thrombocytopenia	Blood cell-related: Anemia	Blood cell-related: Neutropenia
Fixed	78%	49%	36%	25%
Individualized	63%	22%	23%	15%

González-Martín A et al. *Future Oncol* 2024 March 19;[Online ahead of print].

RTP RESEARCH TO PRACTICE

T-DXd

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RESEARCH
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2023 ASCO ANNUAL MEETING

Abstract LBA3000

DESTINY-PanTumor02

Efficacy and safety of trastuzumab deruxtecan in patients with HER2-expressing solid tumors: DESTINY-PanTumor02 interim results

Funda Meric-Bernstam

The University of Texas MD Anderson Cancer Center, Houston, TX, USA

June 5, 2023

Additional authors: Vicky Makker, Ana Oaknin, Do-Yo
Kyung Hae Jung, Iwona Ługowska, Luis Manso, Arán
Daniil Stroyakovskiy, Chiedozie Anoka, Yan Ma, Soha

On behalf of the DESTINY-PanTumor02

2023 ASCO ANNUAL MEETING #ASCO23 PRESENTED BY: Funda Meric-Bernstam, MD

J Clin Oncol 2024;42(1):47-58.

Original Reports | Gynecologic Cancer

Efficacy and Safety of Trastuzumab Deruxtecan in Patients With HER2-Expressing Solid Tumors: Primary Results From the DESTINY-PanTumor02 Phase II Trial

Funda Meric-Bernstam, MD[1]; Vicky Makker, MD[2,3]; Ana Oaknin, MD[4]; Do-Youn Oh, MD[5]; Susana Banerjee, PhD[6]; Antonio González-Martín, MD[7]; Kyung Hae Jung, MD[8]; Iwona Ługowska, MD[9]; Luis Manso, MD[10]; Aránzazu Manzano, MD[11]; Bohuslav Melichar, MD[12]; Salvatore Siena, MD[13]; Daniil Stroyakovskiy, MD[14]; Anitra Fielding, MBChB[15]; Yan Ma, MSc[16]; Soham Puvvada, MD[15]; Norah Shire, PhD[15]; and Jung-Yun Lee, MD[17]

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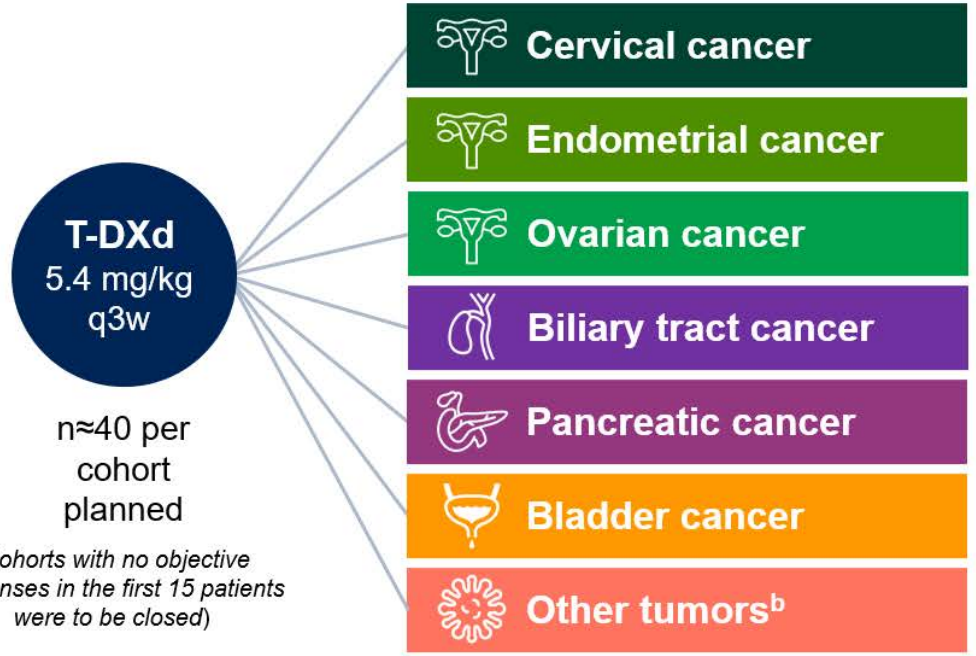
DESTINY-PanTumor02: Phase II Basket Trial Schema

An open-label, multicenter study (NCT04482309)

- Advanced solid tumors not eligible for curative therapy
- 2L+ patient population
- HER2 expression (IHC 3+ or 2+)
  - Local test or central test by HercepTest if local test not feasible (ASCO/CAP gastric cancer guidelines[1])[a]
- Prior HER2-targeting therapy allowed
- ECOG/WHO PS 0–1



Primary endpoint

- Confirmed ORR (investigator)[c]

Secondary endpoints

- DOR[c]
- DCR[c]
- PFS[c]
- OS
- Safety

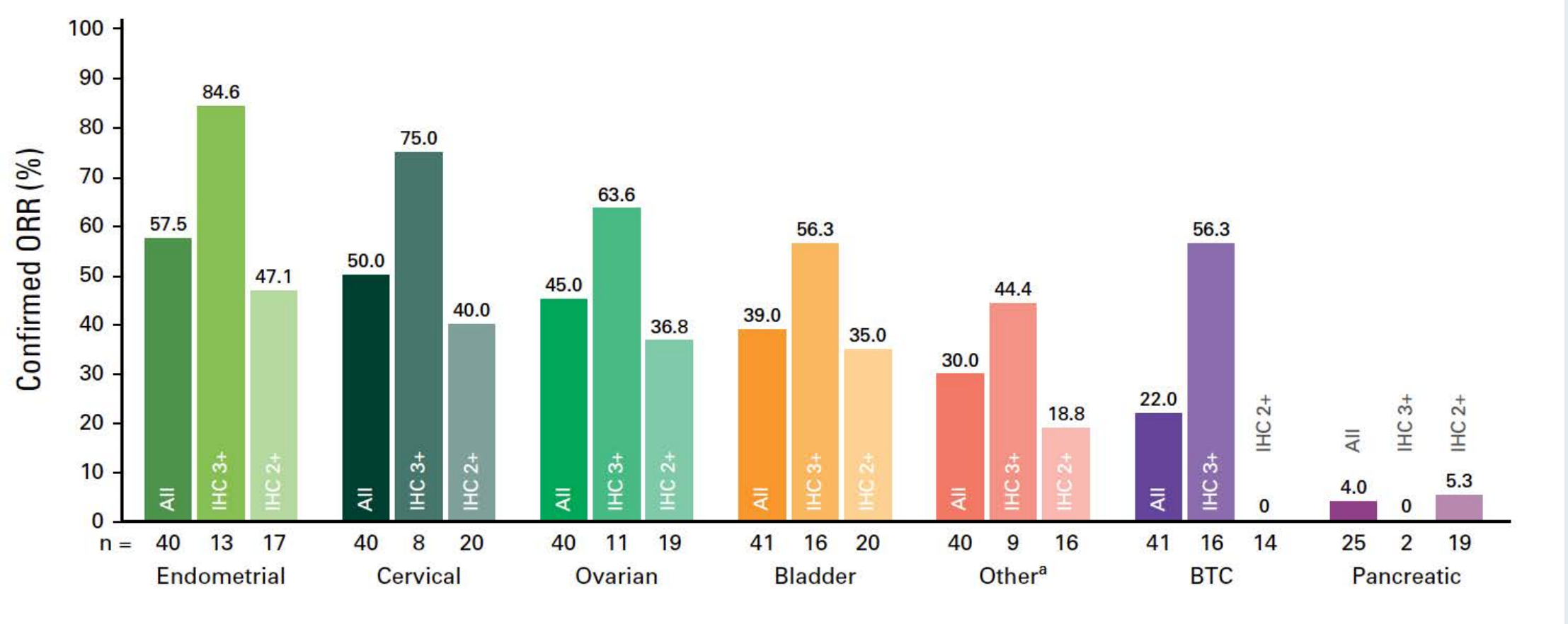
Data cut-off for analysis:

- Nov 16, 2022

2L+ = second or later line of treatment

Meric-Bernstam F et al. ASCO 2023;Abstract LBA3000; *J Clin Oncol* 2024;42(1):47-58.

DESTINY-PanTumor02: Objective Response Rate by HER2 Status



Meric-Bernstam F et al. ASCO 2023;Abstract LBA3000; *J Clin Oncol* 2024;42(1):47-58.

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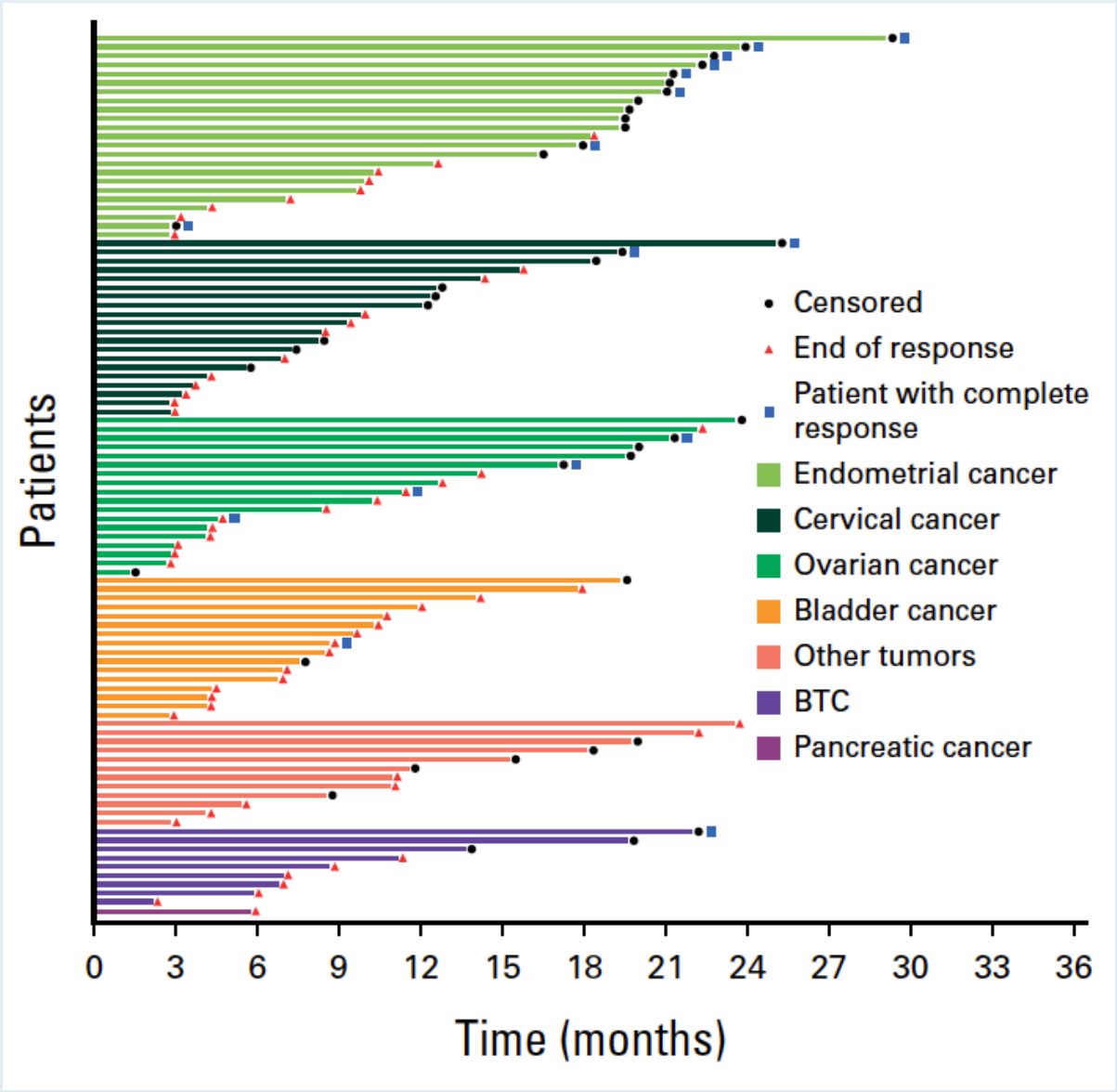
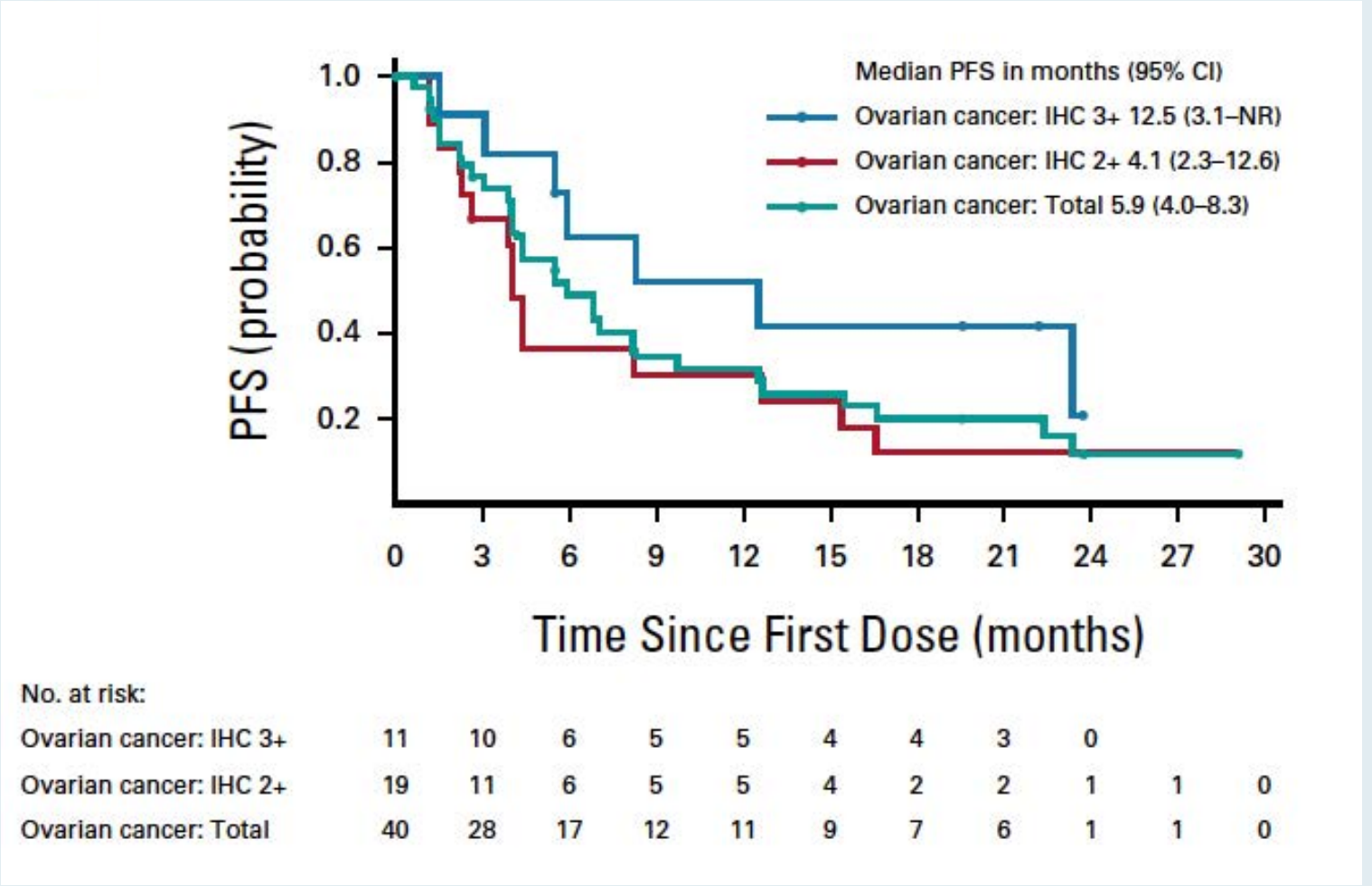
DESTINY-PanTumor02: Duration of Response



Meric-Bernstam F et al. *J Clin Oncol* 2024;42(1):47-58.

DESTINY-PanTumor02: PFS for Ovarian Cancer



Meric-Bernstam F et al. *J Clin Oncol* 2024;42(1):47-58.

RTP RESEARCH TO PRACTICE

Mirvetuximab Soravtansine

2023 ASCO ANNUAL MEETING

Abstract LBA5507

Phase III MIRASOL (GOG 3045/ENGOT-ov55) Study: Mirvetuximab Soravtansine vs. Investigator's Choice of Chemotherapy in Platinum-Resistant, Advanced High-Grade Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers with High Folate Receptor-Alpha (FRα) Expression

Kathleen N. Moore[1], Antoine Angelergues[2], Gottfried E. Konecny[3], Susana Banerjee[4], Sandro Pignata[5], Nicoletta Colombo[6], John Moroney[7], Casey Cosgrove[8], Jung-Yun Lee[9], Andrzej Roszak[10], Shani Breuer[11], Jacqueline Tromp[12], Diana Bello Roufai[13], Lucy Gilbert[14], Rowan Miller[15], Tashanna Myers[16], Lorusso[18], Toon Van Gorp[19]

[1]Stephenson Cancer Center University of Oklahoma College of Medicine, Oklahoma City, OK, USA; [2]Groupe Hospitalier
Comprehensive Cancer Center, Los Angeles, CA, USA; [4]The Royal Marsden NHS Foundation Trust - Royal Marsden Ho
[6]European Institute of Oncology IRCCS, Milan, Italy and University of Milan-Bicocca, Milan, Italy; [7]The University of Chica
[9]Severance Hospital, Seoul, South Korea; [10]Wielkopolskie Centrum Onkologii, Poznan, Poland; [11]Hadassah Ein Kerem –
Netherlands; [13]Hopital Rene Huguenin, Institut Curie, Saint-Cloud, France; [14]McGill University Health Centre, Montreal, C
Medical Center, Springfield, MA, USA; [17] ImmunoGen, Inc., Waltham, MA, USA; [18]Fondazione Policlinico Universitario A.
[19]University Hospital Leuven Leuven Cancer Institute, Leuven, Belgium

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

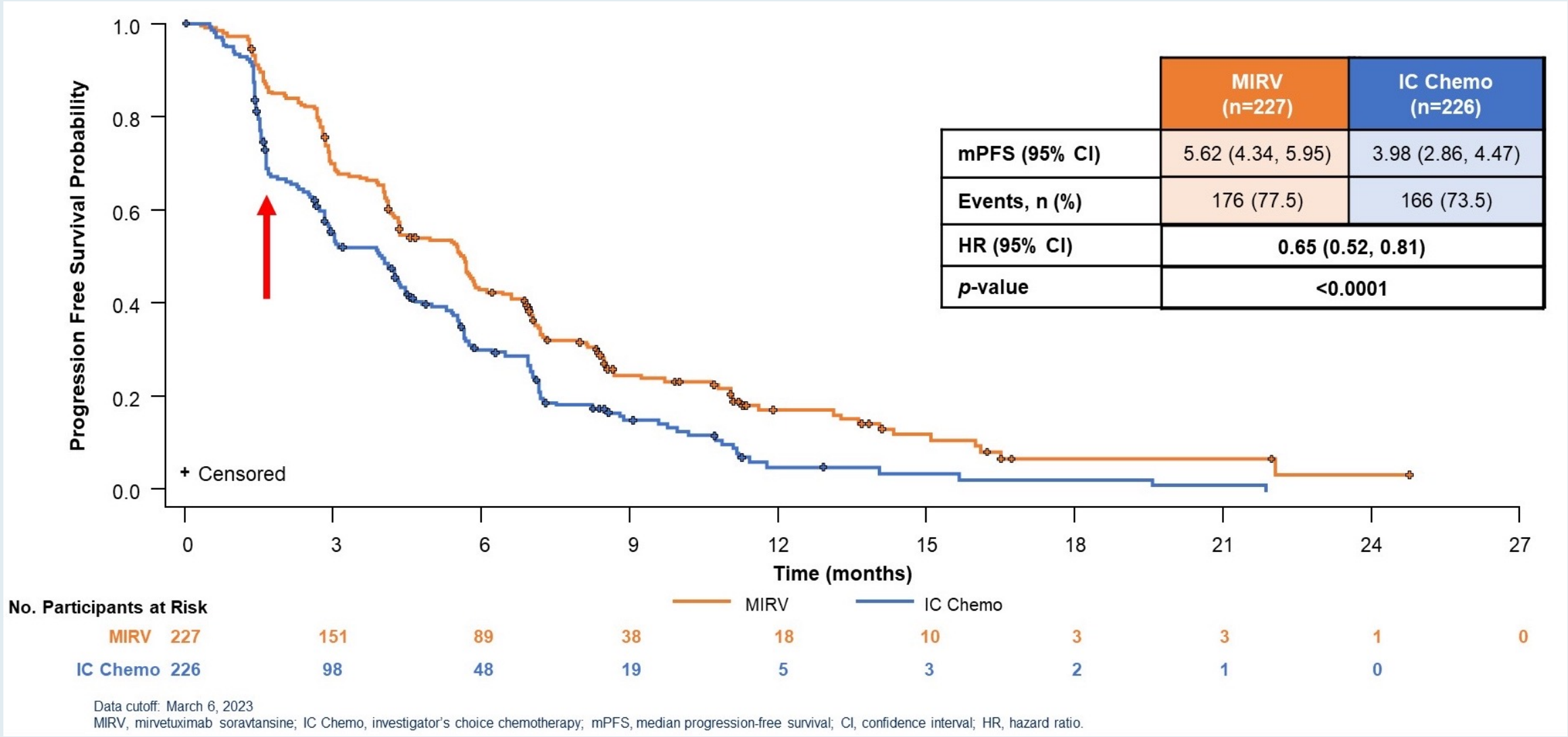
Mirvetuximab Soravtansine in FRα-Positive, Platinum-Resistant Ovarian Cancer

K.N. Moore, A. Angelergues, G.E. Konecny, Y. García, S. Banerjee, D. Lorusso, J.-Y. Lee, J.W. Moroney, N. Colombo, A. Roszak, J. Tromp, T. Myers, J.-W. Lee, M. Beiner, C.M. Cosgrove, D. Cibula, L.P. Martin, R. Sabatier, J. Buscema, P. Estévez-García, L. Coffman, S. Nicum, L.R. Duska, S. Pignata, F. Gálvez, Y. Wang, M. Method, A. Berkenblit, D. Bello Roufai, and T. Van Gorp, for Gynecologic Oncology Group Partners and the European Network of Gynaecological Oncological Trial Groups*

2023;389(23):2162-74.

RTP RESEARCH TO PRACTICE

MIRASOL: PFS by Investigator (Primary Endpoint)



	MIRV (n=227)	IC Chemo (n=226)
mPFS (95% CI)	5.62 (4.34, 5.95)	3.98 (2.86, 4.47)
Events, n (%)	176 (77.5)	166 (73.5)
HR (95% CI)	0.65 (0.52, 0.81)	
p-value	<0.0001	

No. Participants at Risk

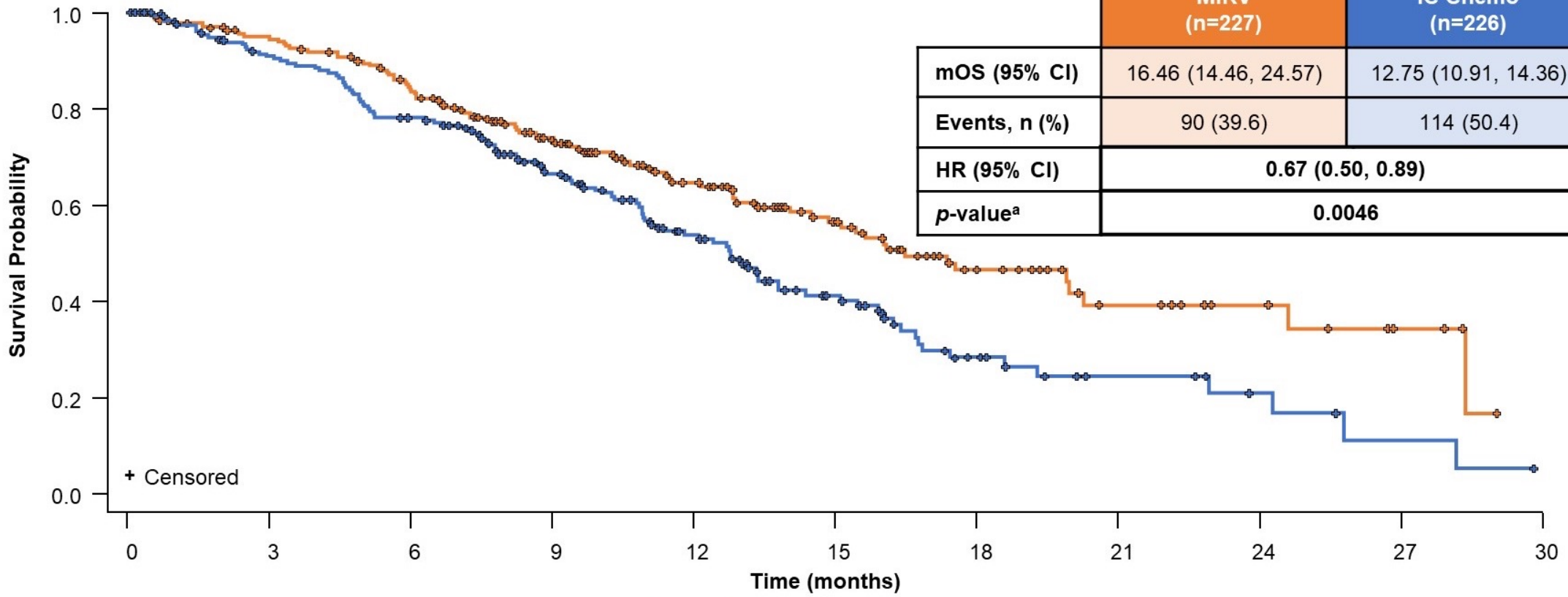
MIRV	227	151	89	38	18	10	3	3	1	0
IC Chemo	226	98	48	19	5	3	2	1	0	

Data cutoff: March 6, 2023

MIRV, mirvetuximab soravtansine; IC Chemo, investigator's choice chemotherapy; mPFS, median progression-free survival; CI, confidence interval; HR, hazard ratio.

Moore KN et al. ASCO 2023;Abstract LBA5507; *N Engl J Med* 2023;7(389):2162-74.

MIRASOL: Overall Survival



	MIRV (n=227)	IC Chemo (n=226)
mOS (95% CI)	16.46 (14.46, 24.57)	12.75 (10.91, 14.36)
Events, n (%)	90 (39.6)	114 (50.4)
HR (95% CI)	0.67 (0.50, 0.89)	
p-value[a]	0.0046	

No. Participants at Risk

MIRV	227	204	175	128	82	53	28	15	9	4	0
IC Chemo	226	185	157	107	68	39	18	9	5	2	0

Data cutoff: March 6, 2023; median follow-up time: 13.11 months
MIRV, mirvetuximab soravtansine; IC Chemo, investigator's choice chemotherapy; mOS, median overall survival; CI, confidence interval; HR, hazard ratio.
[a]Overall survival is statistically significant based on pre-specified boundary p-value at interim analysis = 0.01313

Moore KN et al. ASCO 2023;Abstract LBA5507; *N Engl J Med* 2023;7(389):2162-74.

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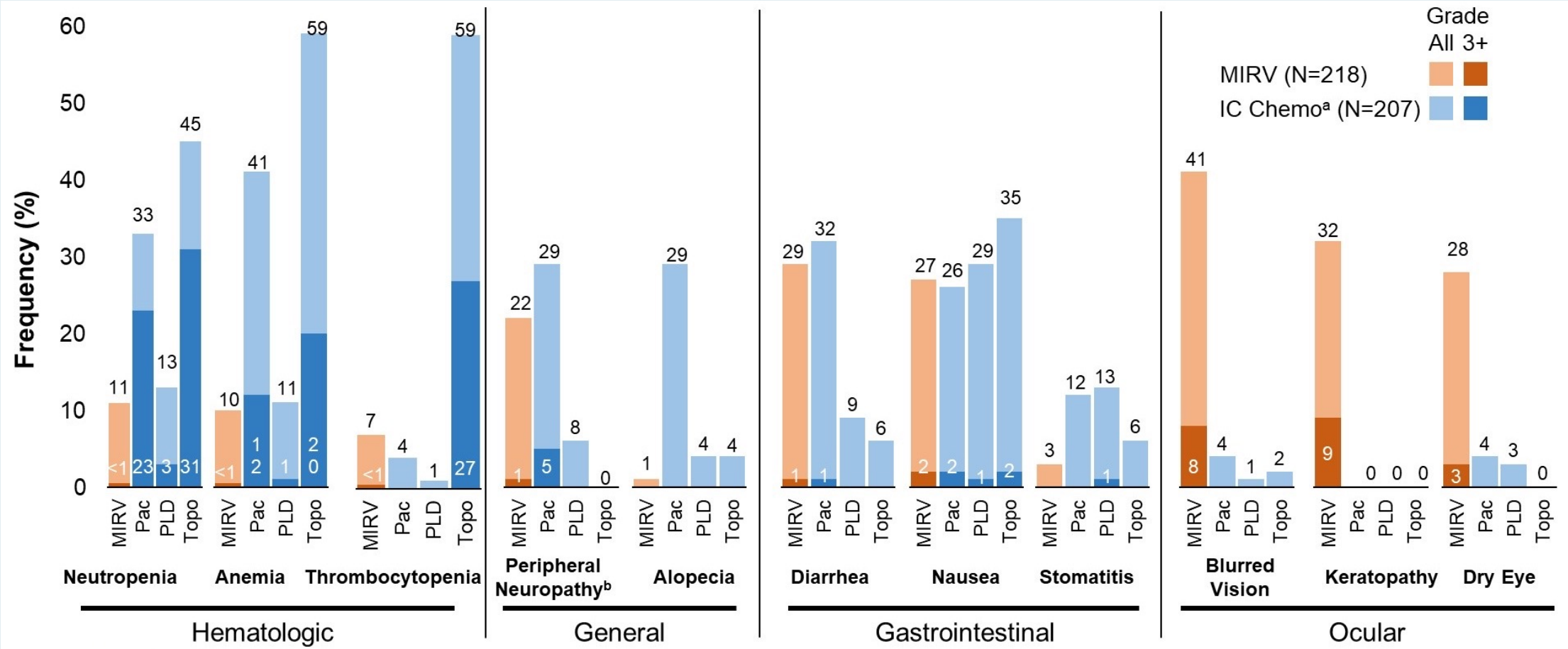
MIRASOL: Treatment-Emergent Adverse Events



Data cutoff: March 6, 2023
MIRV, mirvetuximab soravtansine; IC Chemo: investigator's choice chemotherapy; Pac, paclitaxel; PLD, pegylated liposomal doxorubicin; Topo, topotecan.
[a]Pac n=82 (39%), PLD n=76 (37%), Topo n=49 (24%). [b]Grade 2+ peripheral neuropathy events were observed in 12% and 16% of patients that received MIRV or paclitaxel, respectively.

Moore KN et al. ASCO 2023;Abstract LBA5507; *N Engl J Med* 2023;7(389):2162-74.

What I Tell My Patients: Integrating New Research Information into Current Clinical Care

A Complimentary NCPD Hybrid Symposium Series Held During the 49th Annual ONS Congress

Ovarian Cancer

Friday, April 26, 2024
6:00 PM – 7:30 PM

Faculty

Courtney Arn, CNP
Floor J Backes, MD
Kathleen N Moore, MD, MS
Jaclyn Shaver, MS, APRN, CNP, WHNP

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

What I Tell My Patients: Integrating New Research Information into Current Clinical Care

A Complimentary NCPD Hybrid Symposium Series Held During the 49th Annual ONS Congress

Hepatobiliary Cancers

Saturday, April 27, 2024
6:00 AM – 7:30 AM

Faculty

Blanca Ledezma, MSN, NP, AOCNP
Stacey Stein, MD
Amanda K Wagner, APRN-CNP, AOCNP
Mark Yarchoan, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

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 up to 5 minutes after the meeting ends.

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Virtual attendees: The NCPD credit link is posted in the chat room.

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