

Consensus or Controversy? Documenting and Discussing Investigators' Approaches to the Management of Ovarian Cancer

Saturday, May 30, 2026

7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)

Faculty

Ramez N Eskander, MD

Ursula Matulonis, MD

Alexander B Olawaiye, MD

David M O'Malley, MD

Moderator

Kathleen N Moore, MD, MS

Faculty



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Dr Matulonis — Disclosures Faculty

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Dr Moore — Disclosures

Moderator

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Prof Colombo — Disclosures

Contributing Clinical Investigators

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Research To Practice President Neil Love, MD — 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: Aadi Bioscience, AbbVie Inc, ADC Therapeutics, Agendia Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Arvinas, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeOne, Biotheranostics Inc, A Hologic Company, Black Diamond Therapeutics Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol Myers Squibb, Celcuity, Clovis Oncology, Coherus BioSciences, Corcept Therapeutics Inc, CTI BioPharma, a Sobi Company, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, Exact Sciences Corporation, Exelixis Inc, Genentech, a member of the Roche Group, Genmab US Inc, Geron Corporation, Gilead Sciences Inc, GSK, Helsinn Therapeutics (US) Inc, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Jazz Pharmaceuticals Inc, Johnson & Johnson, Karyopharm Therapeutics, Kite, A Gilead Company, Kura Oncology, Legend Biotech, Lilly, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Mural Oncology Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Nuvalent, Nuvation Bio Inc, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Revolution Medicines Inc, Rigel Pharmaceuticals Inc, R-Pharm US, Sanofi, Seagen Inc, Servier Pharmaceuticals LLC, SpringWorks Therapeutics Inc, Stemline Therapeutics Inc, Sumitomo Pharma America, Summit Therapeutics, Syndax Pharmaceuticals, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, and Tesaro, A GSK Company.

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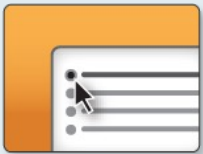
This educational activity contains discussion of non-FDA-approved uses of agents and regimens. Please refer to official prescribing information for each product for approved indications.

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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.



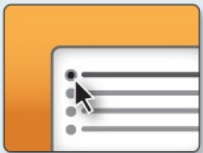
Ask a Question: Tap Ask a Question to submit a challenging case or question for discussion. We will aim to address as many questions as possible during the program.

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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 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



Friday May 29	Gastroesophageal Cancers 11:30 AM – 1:00 PM CT (12:30 PM – 2:00 PM ET)
	Non-Small Cell Lung Cancer 6:30 PM – 8:30 PM CT (7:30 PM – 9:30 PM ET)
	Chronic Lymphocytic Leukemia 6:30 PM – 8:30 PM CT (7:30 PM – 9:30 PM ET)
	Colorectal Cancer 6:30 PM – 8:00 PM CT (7:30 PM – 9:00 PM ET)
Saturday May 30	Ovarian Cancer 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Prostate Cancer 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Small Cell Lung Cancer 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
Sunday May 31	Oral SERDs and Agents Targeting the PI3K/AKT/mTOR Pathway for Breast Cancer 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Endometrial Cancer 7:00 PM – 8:30 PM CT (8:00 PM – 9:30 PM ET)
	CAR T-Cell Therapy and Bispecific Antibodies for Non-Hodgkin Lymphoma 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
Monday June 1	ADCs for Breast Cancer 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Novel Therapies for Non-Hodgkin Lymphoma 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Relapsed/Refractory Multiple Myeloma 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
Tuesday June 2	Myelofibrosis (Webinar)

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Agenda

Module 1: Current Role of PARP Inhibitors in the Management of Advanced Ovarian Cancer (OC) — Prof Eskander

Module 2: Strategies Targeting Folate Receptor Alpha in Advanced OC — Dr Matulonis

Module 3: Other Approved and Promising Investigational Antibody-Drug Conjugates for Advanced OC — Dr Moore

Module 4: Other Novel Agents and Strategies for Advanced OC — Dr O'Malley

Module 5: Diagnosis and Management of Adverse Events Associated with Common Therapies for Advanced OC — Dr Olawaiye

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Current Role of PARP Inhibitors in Advanced Ovarian Cancer

Biomarkers · long-term survival · regimen selection · ongoing trials · the relapsed setting

Ramez N. Eskander, MD

Julie St. John Endowed Chair in Gynecologic Oncology
Professor of Obstetrics, Gynecology and Reproductive Sciences
Medical Director, Clinical Trials Office
Fellowship Program Director, Gynecologic Oncology
UC San Diego Health | Moores Cancer Center | La Jolla, CA

01

Biomarker testing

Germline & somatic BRCA, HRD/genomic instability — and why they drive decisions

02

Long-term & OS data

SOLO-1, PAOLA-1, PRIMA, ATHENA-MONO maintenance outcomes

03

Choosing therapy

Clinical, biologic & practical factors for olaparib, olaparib/bev, niraparib

04

Ongoing phase III

MONO-OLA1 and NRG-GY036 — refining who and how long

05

Relapsed / post-PARP

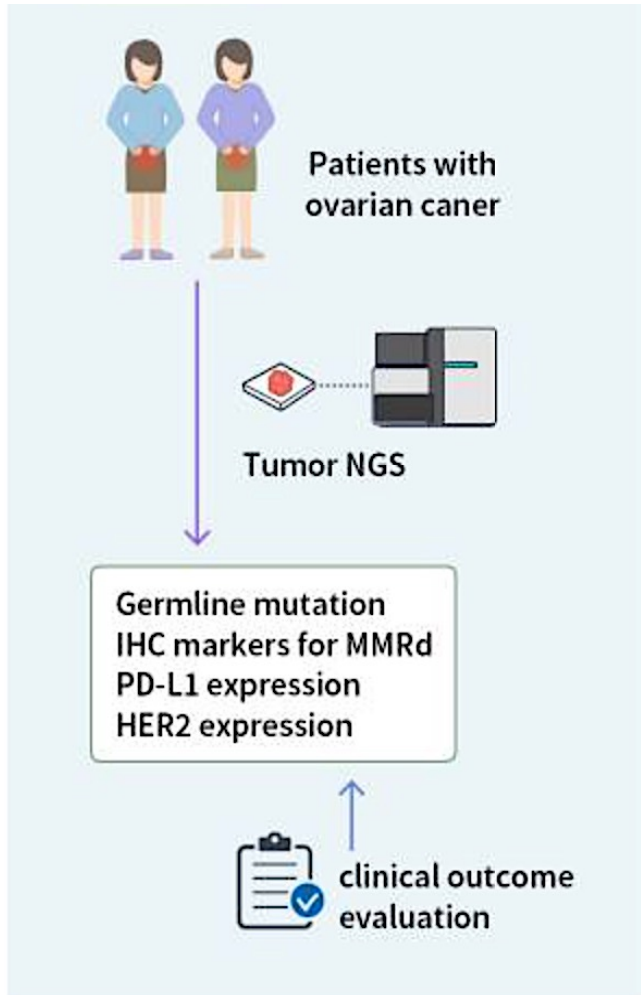
Utility after progression, including prior PARP exposure

SECTION 01

Biomarker testing in newly diagnosed advanced ovarian cancer

Germline & somatic BRCA and HRD status are prerequisites — not afterthoughts — for first-line decisions.

Biomarker Testing: When, What and Where?



1. Ascites Fluid
2. CT guided biopsy
3. Surgical Procedure
4. ctDNA
5. At time of recurrence?



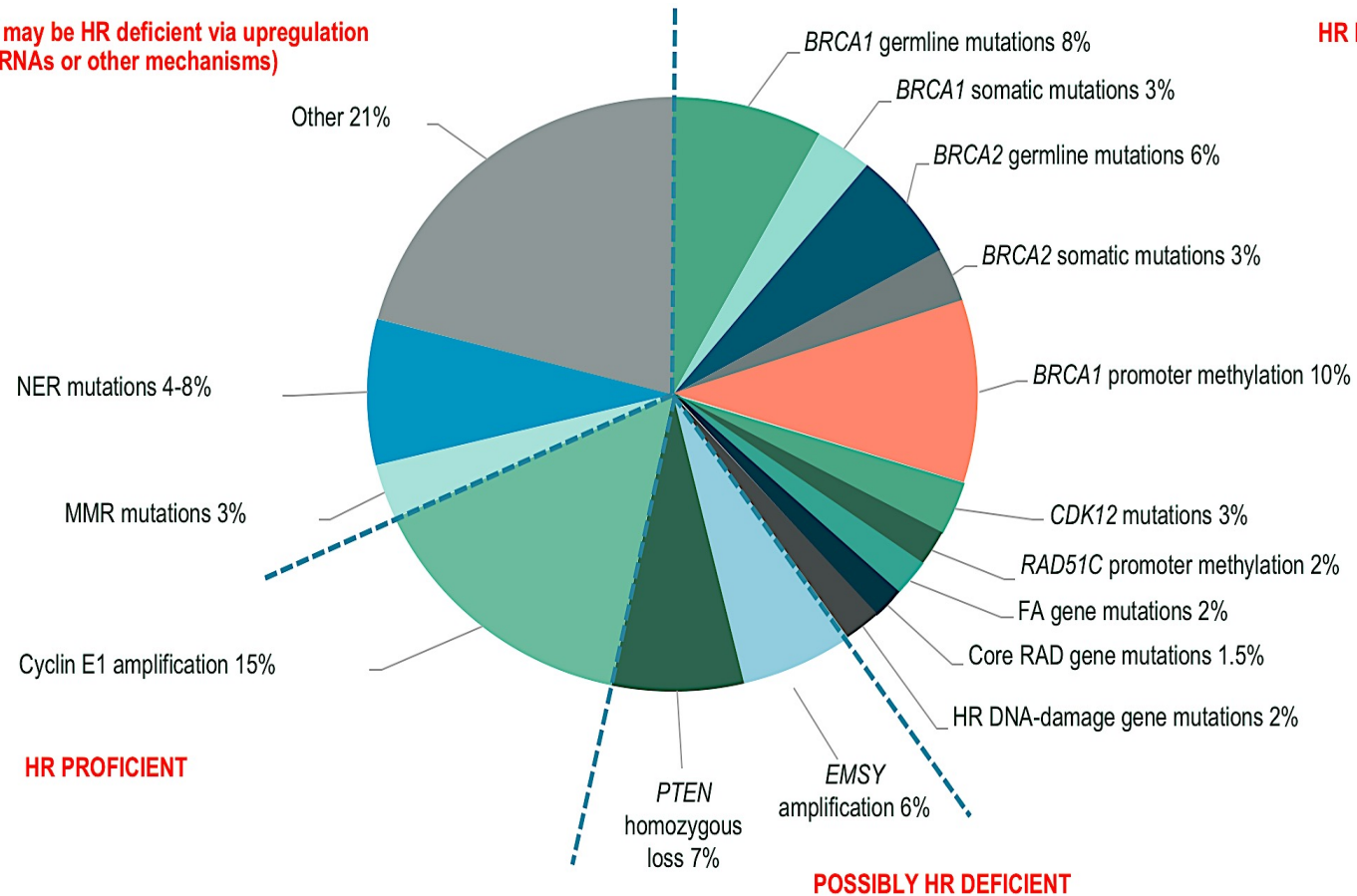
1. Commercial Assay
e.g. Foundation Medicine, CARIS, Tempus
2. In house Assay



- ACTIONABLE BIOMARKERS (?)**
1. HRD (GIS, LOH, etc.)
 2. Germline/Somatic BRCA
 3. FOLR alpha
 4. HER2 IHC
 5. MMR/TMB/MSI
 6. KRAS (LGSOC)
- Others...

Homologous Recombination Deficiency

OTHER (some may be HR deficient via upregulation of miRNAs or other mechanisms)



HR DEFICIENT

~50% of high-grade serous OC is HRD

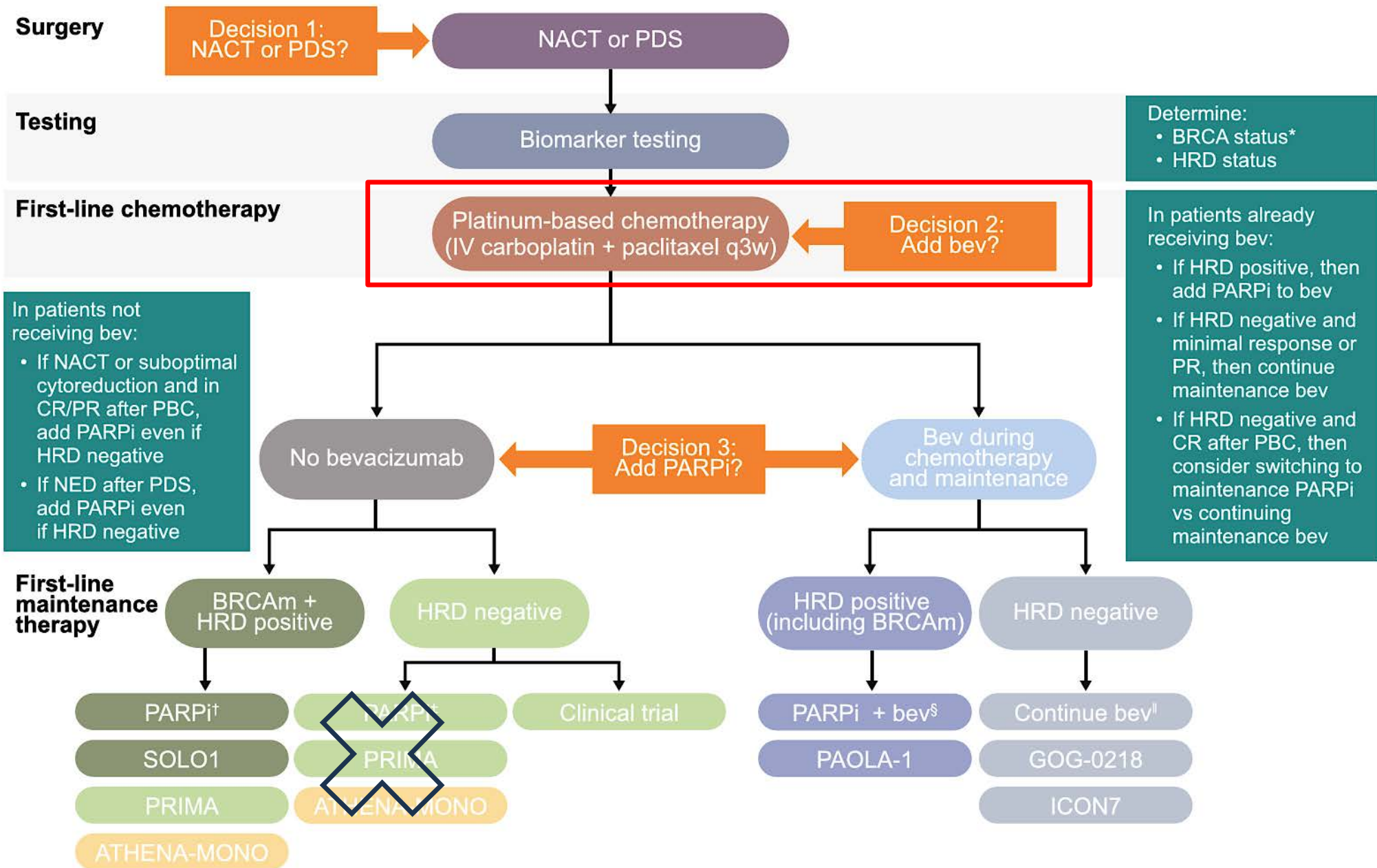
- **BRCA1/2 mutation** — ~22% (~15% germline, ~7% somatic);
- **BRCA-wildtype / HRD-positive** — ~28%; genomic instability without a BRCA mutation
- **HR-proficient** — ~50%

Somatic and germline BRCA mutations confer similar PARP sensitivity — but germline status additionally drives cascade testing and risk-reduction.

SECTION 02

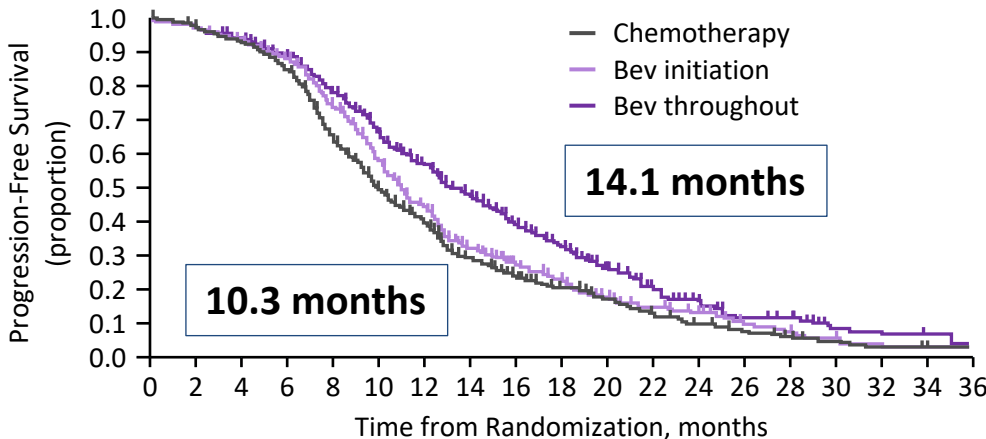
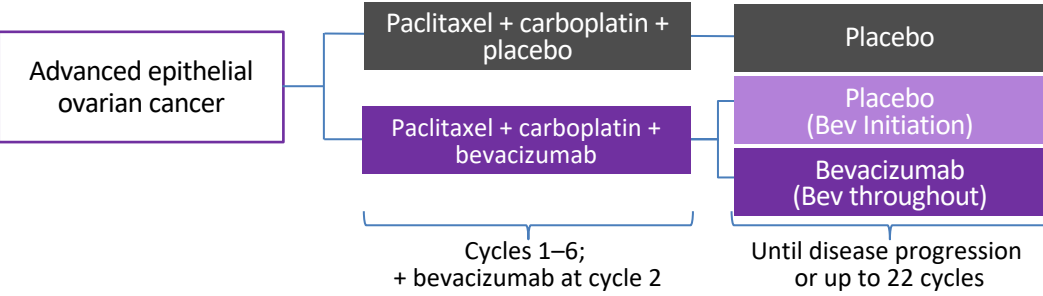
Front-line maintenance: long-term and overall-survival outcomes

What the mature data — including OS — now show for each regimen.



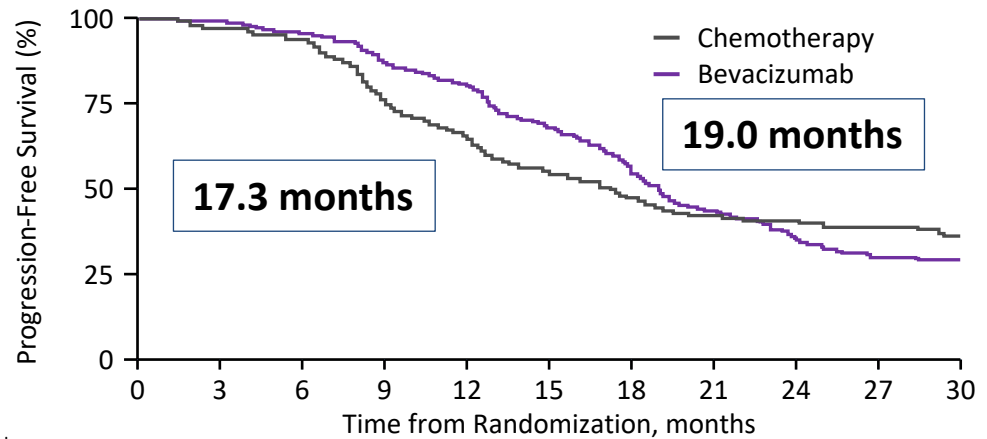
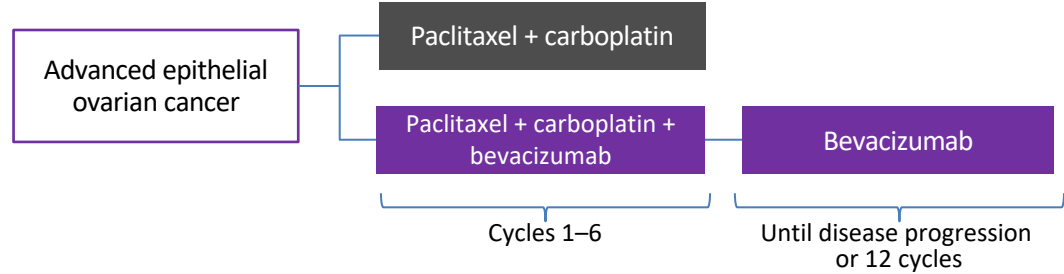
First-Line Chemotherapy: Carboplatin, Paclitaxel & Bevacizumab + Maintenance

GOG 218¹



No. at risk				
Chemotherapy	625	199	33	8
Bev initiation	625	219	29	6
Bev throughout	623	254	38	8

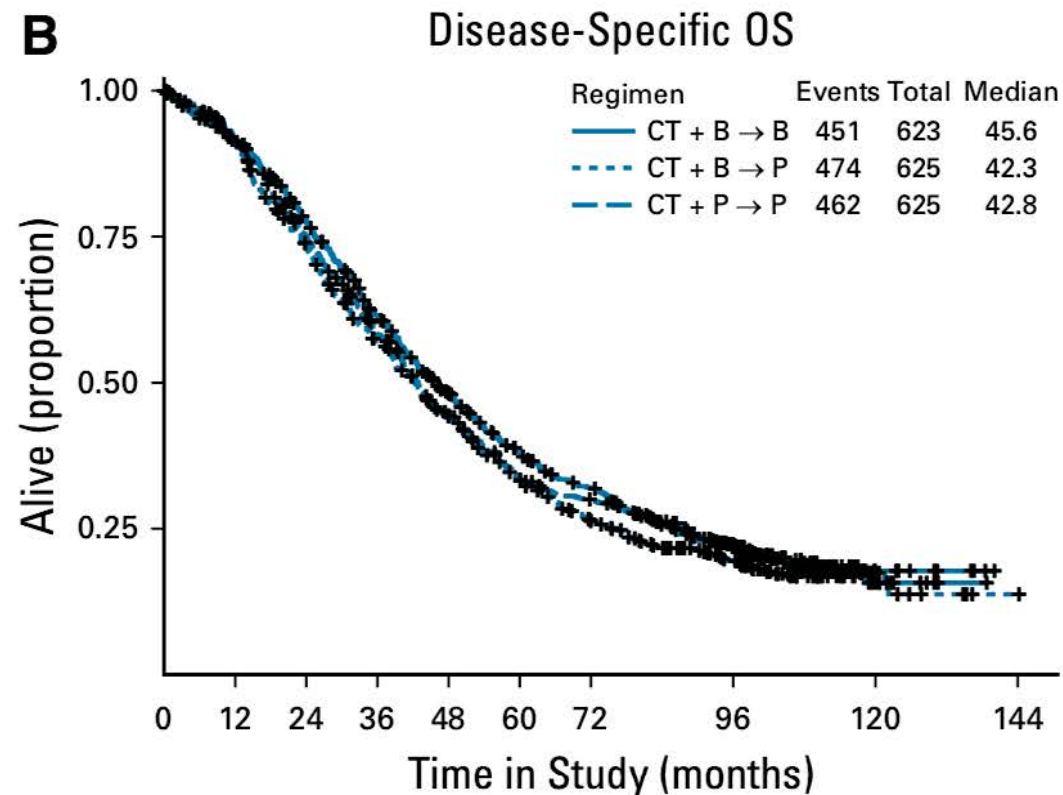
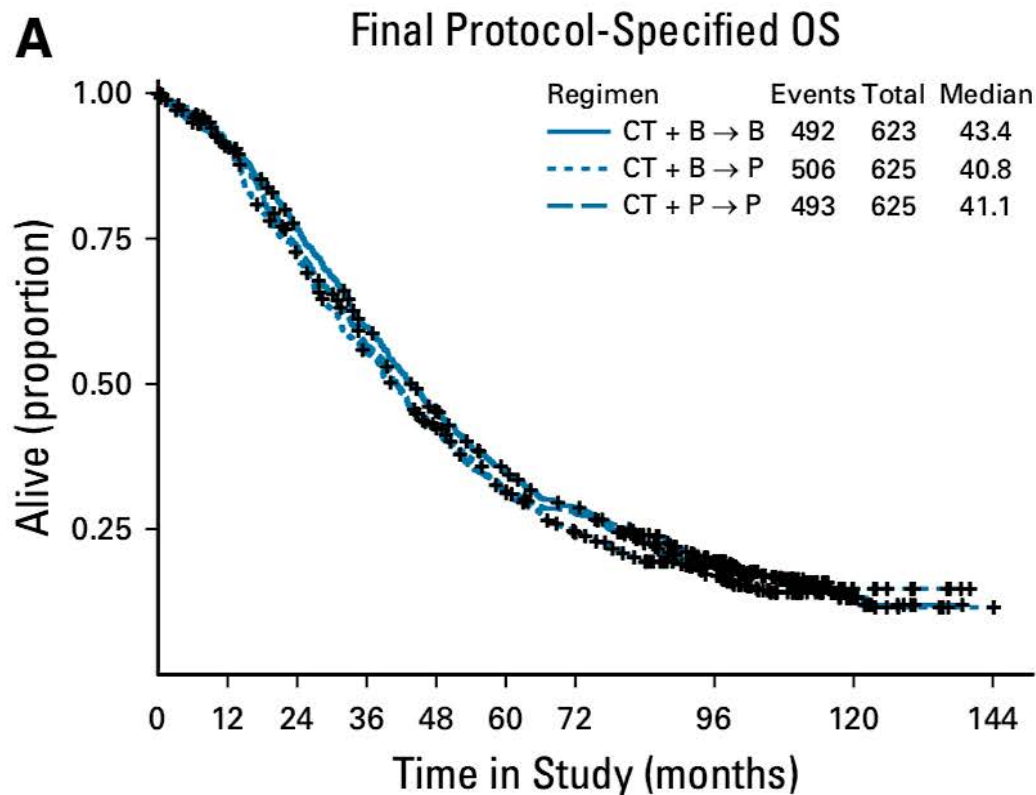
ICON7²



No. at risk						
Chemotherapy	764	693	464	216	91	25
Bevacizumab	764	715	585	263	73	19

1. Burger RA et al. *N Engl J Med.* 2011;365(26):2473-2483. 2. Perren TJ et al. *N Engl J Med.* 2011;365(26):2484-2496

GOG 218: Final OS



No. at risk

	0	12	24	36	48	60	72	96	120	144
CT + B → B	623	561	464	358	267	201	161	85	11	0
CT + B → P	625	558	443	334	252	185	136	74	11	1
CT + P → P	625	558	448	340	252	183	158	90	9	0

No. at risk

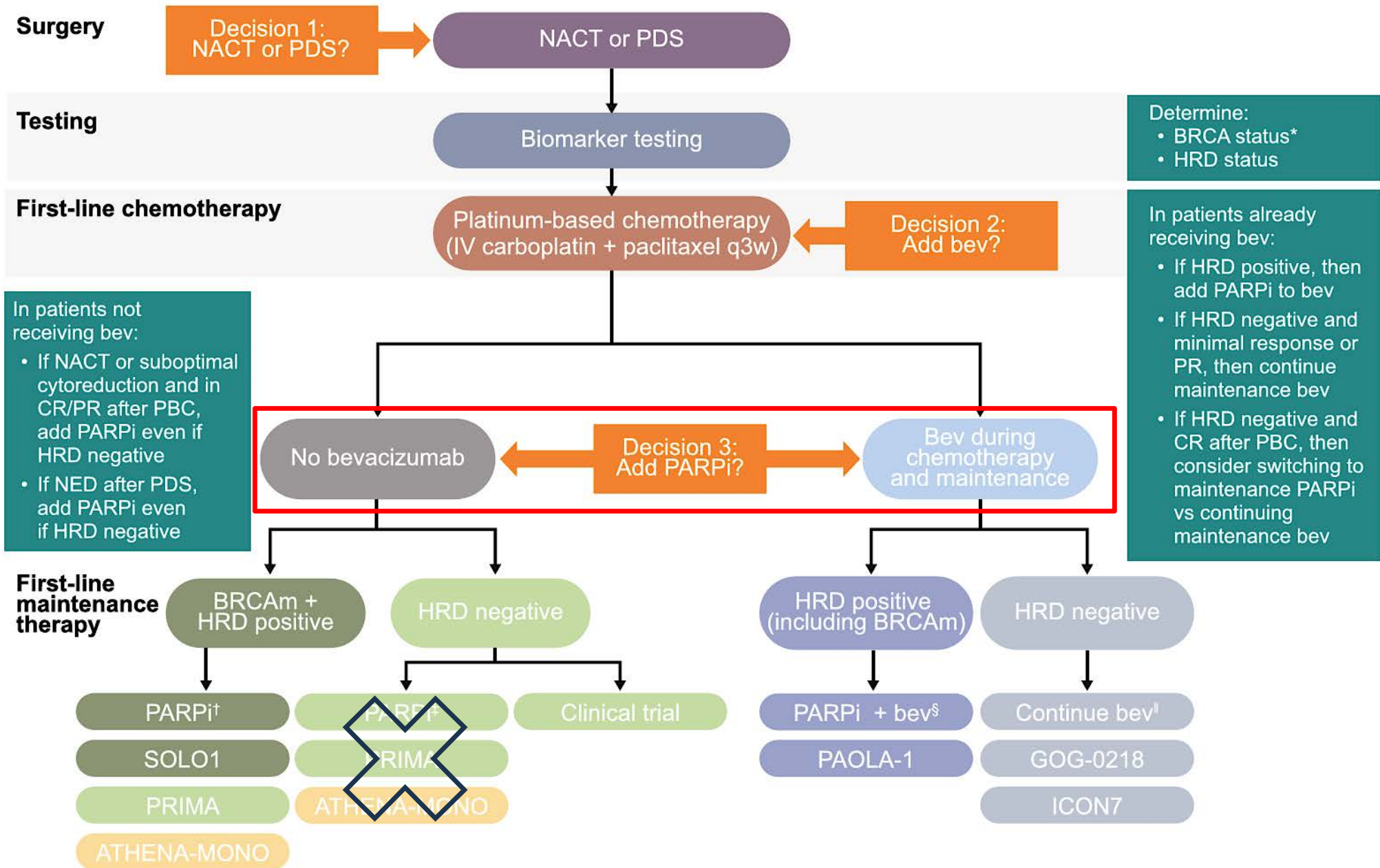
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CT + P → P	625	558	448	340	252	183	158	90	9	0

To Bev or Not to Bev...That is the Question?

Study	Arms	Sample size	Median PFS (months)	Hazard ratio	P-value	Survival advantage
GOG 218 [7]	Arm 1: carboplatin + paclitaxel + placebo	625	10.3 (12.0 π)			
	Arm 2: carboplatin + paclitaxel + bevacizumab + placebo	623	11.2	0.91	0.16	No
	Arm 3: carboplatin + paclitaxel + bevacizumab with maintenance (total 15 months)	625	14.1 (18.0 π)	0.72 0.65 π	<0.0001 <0.0001 π	Stage IV
ICON7 [8]	Arm 1: carboplatin + paclitaxel	764	17.3 α			
	Arm 2: carboplatin + paclitaxel + bevacizumab with maintenance (total 12 months)	764	19.0 α	0.81	0.004	'Patients at high risk for progression'
AURELIA [9]	Arm 1: chemotherapy*	182	3.4 α			
	Arm 2: chemotherapy* + bevacizumab	179	6.7 α	0.48	0.001	No
OCEANS [10]	Arm 1: carboplatin + gemcitabine + placebo	242	8.4 α			
	Arm 2: carboplatin + gemcitabine + bevacizumab until progression	242	12.4 α	0.48	<0.0001	No

? Standard of Care

? For “high-risk” patients only



Frontline Maintenance – The PARPi story

PAOLA-1

ORIGINAL ARTICLE

Olaparib plus Bevacizumab as First-Line Maintenance in Ovarian Cancer

I. Ray-Coquard, P. Pautier, S. Pignata, D. Pérol, A. González-Martín, R. Berger, K. Fujiwara, I. Vergote, N. Colombo, J. Mäenpää, F. Selle, J. Sehouli, D. Lorusso, E.M. Guerra Alía, A. Reinthaller, S. Nagao, C. Lefeuve-Plesse, U. Canzler, G. Scambia, A. Lortholary, F. Marmé, P. Combe, N. de Gregorio, M. Rodrigues, P. Buderath, C. Dubot, A. Burges, B. You, E. Pujade-Lauraine, and P. Harter, for the PAOLA-1 Investigators*

SOLO-1

ORIGINAL ARTICLE

Maintenance Olaparib in Patients with Newly Diagnosed Advanced Ovarian Cancer

K. Moore, N. Colombo, G. Scambia, B.-G. Kim, A. Oaknin, M. Friedlander, A. Lisyanskaya, A. Floquet, A. Leary, G.S. Sonke, C. Gourley, S. Banerjee, A. Oza, A. González-Martín, C. Aghajanian, W. Bradley, C. Mathews, J. Liu, E.S. Lowe, R. Bloomfield, and P. DiSilvestro

N Engl J Med. 2018;379(26):2495-2505.

PRIMA

ORIGINAL ARTICLE

Niraparib in Patients with Newly Diagnosed Advanced Ovarian Cancer

A. González-Martín, B. Pothuri, I. Vergote, R. DePont Christensen, W. Graybill, M.R. Mirza, C. McCormick, D. Lorusso, P. Hoskins, G. Freyer, K. Baumann, K. Jardon, A. Redondo, R.G. Moore, C. Vulsteke, R.E. O’Cearbhaill, B. Lund, F. Backes, P. Barretina-Ginesta, A.F. Haggerty, M.J. Rubio-Pérez, M.S. Shahin, G. Mangili, W.H. Bradley, I. Bruchim, K. Sun, I.A. Malinowska, Y. Li, D. Gupta, and B.J. Monk, for the PRIMA/ENGOT-OV26/GOG-3012 Investigators*

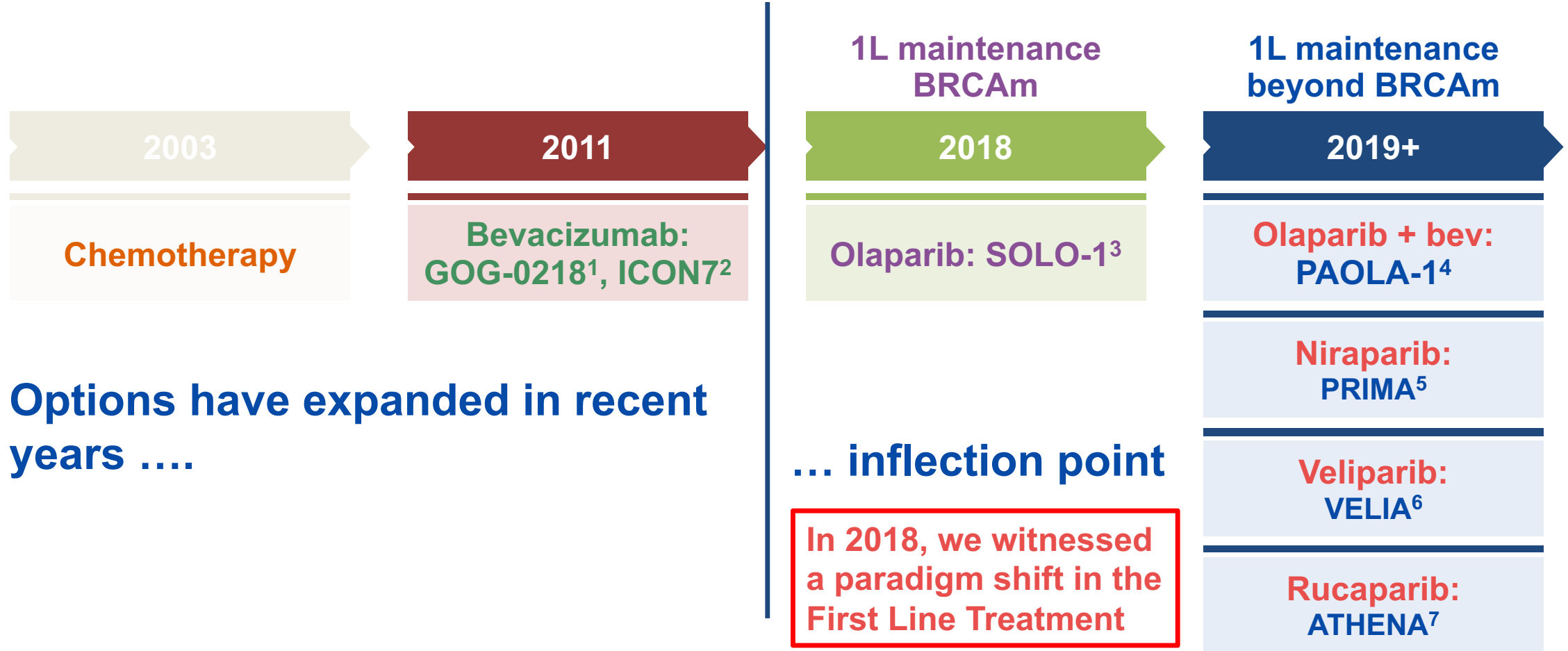
VELIA

ORIGINAL ARTICLE

Veliparib with First-Line Chemotherapy and as Maintenance Therapy in Ovarian Cancer

R.L. Coleman, G.F. Fleming, M.F. Brady, E.M. Swisher, K.D. Steffensen, M. Friedlander, A. Okamoto, K.N. Moore, N. Efrat Ben-Baruch, T.L. Werner, N.G. Cloven, A. Oaknin, P.A. DiSilvestro, M.A. Morgan, J.-H. Nam, C.A. Leath III, S. Nicum, A.R. Hagemann, R.D. Littell, D. Cella, S. Baron-Hay, J. Garcia-Donas, M. Mizuno, K. Bell-McGuinn, D.M. Sullivan, B.A. Bach, S. Bhattacharya, C.K. Rataiczak, P.I. Ansell, M.H. Dinh, C. Aghajanian, and M.A. Bookman

First Line Treatment Options in Newly Diagnosed Advanced Ovarian Cancer

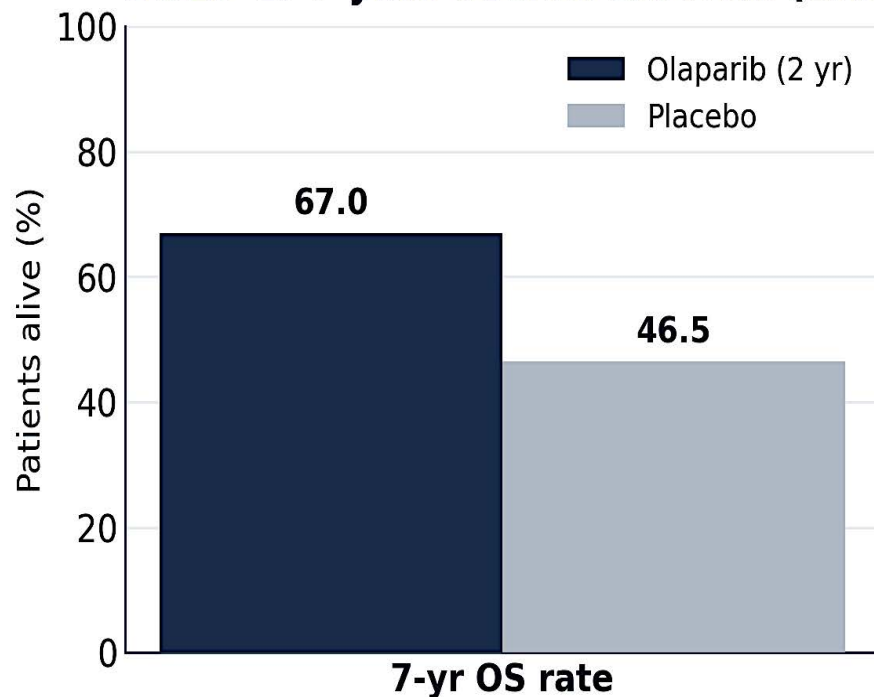


1. Burger R, et al. N Engl J Med. 2011;365:2473-2483; 2. Perren TJ, et al. N Engl J Med. 2011;365:2484-2496; 3. Moore K, et al. N Engl J Med. 2018;379:2495-2505; 4. Ray-Coquard I, et al. N Engl J Med. 2019;381:2416-2428; 5. Gonzalez-Martin A, et al. N Engl J Med. 2019;381:2391-2402; 6. Coleman RL, et al. N Engl J Med. 2019;381:2403-2415; 7. Monk BJ, et al. J Clin Oncol. 2022;40:3952-3964.

SOLO-1: Olaparib in BRCA-mutated disease

SECTION 02 · LONG-TERM OUTCOMES

SOLO-1: 7-year overall survival (BRCAm)



Median OS: not reached vs 75.2 mo · HR 0.55 (95% CI 0.40–0.76), 38% maturity

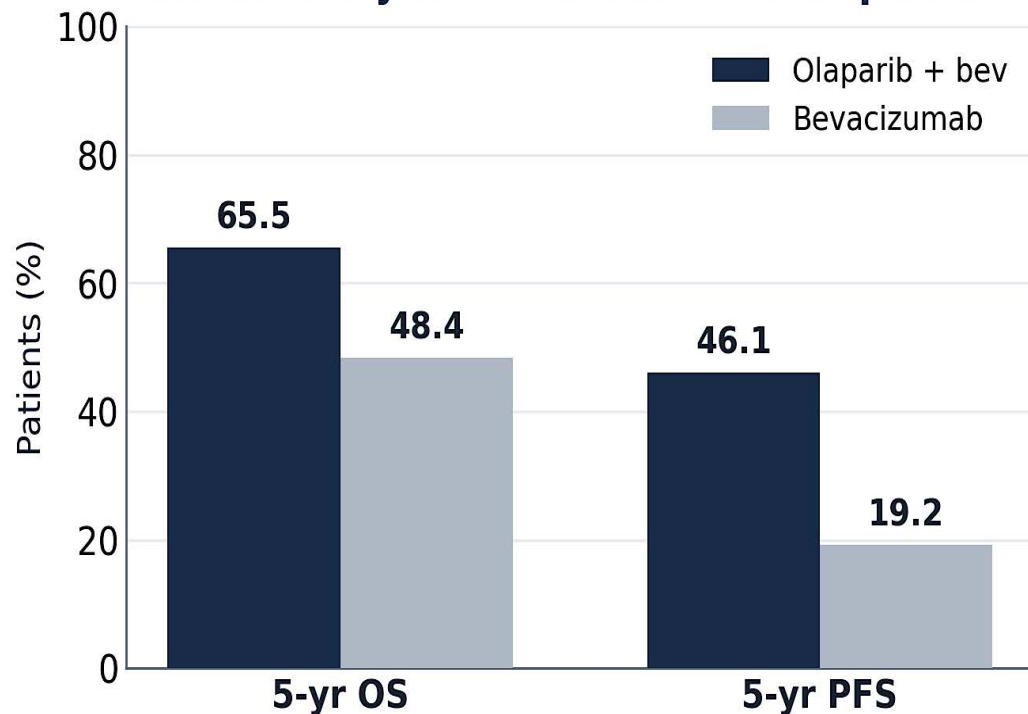
Banerjee et al. Lancet Oncol 2021 (5-yr PFS); DiSilvestro et al. J Clin Oncol 2023 (7-yr OS). SOLO-1/GOG-3004.

- **Population:** BRCA1/2-mutated newly diagnosed; olaparib × 2 years (n=260) vs placebo (n=131)
 - **Practice-defining PFS:** median 56.0 vs 13.8 months (HR 0.33) at 5 years
 - **Longest PARP follow-up:** 7-yr OS 67.0% vs 46.5%; median OS not reached vs 75.2 mo
 - **OS HR 0.55** (95% CI 0.40–0.76) — clinically meaningful; not formally significant (38% maturity)
- 44.3% of patients in the placebo arm receiving subsequent PARPi therapy compared with 14.6% in the Olaparib arm**
- **Takeaway:** a finite 2-year course yields durable, plateau-like benefit in BRCAm disease

PAOLA-1: olaparib + bevacizumab (HRD-positive)

SECTION 02 · LONG-TERM OUTCOMES

PAOLA-1: 5-year outcomes in HRD-positive disease



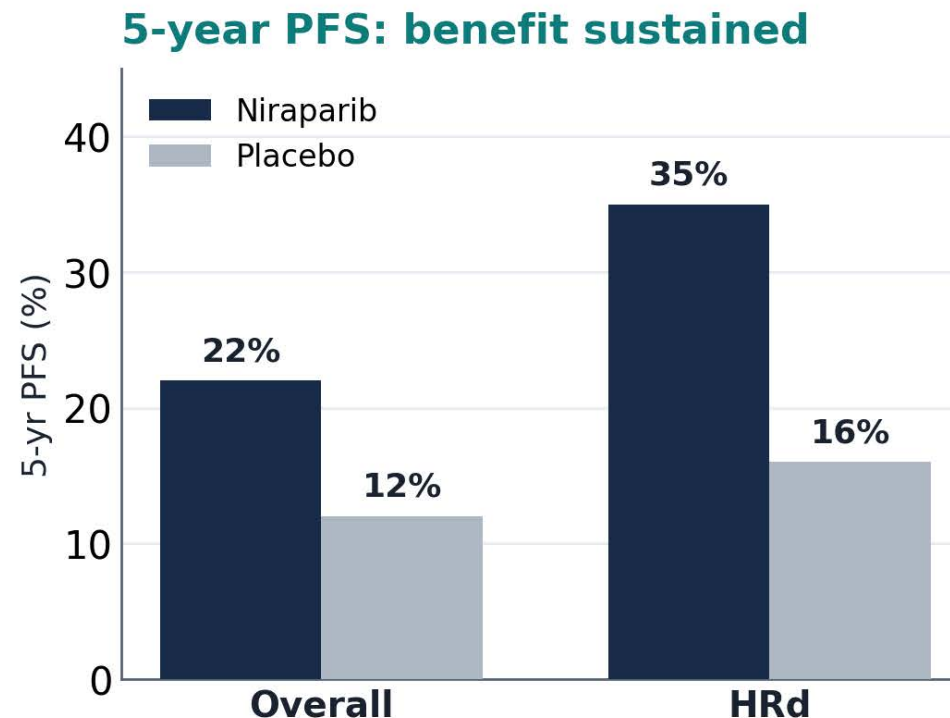
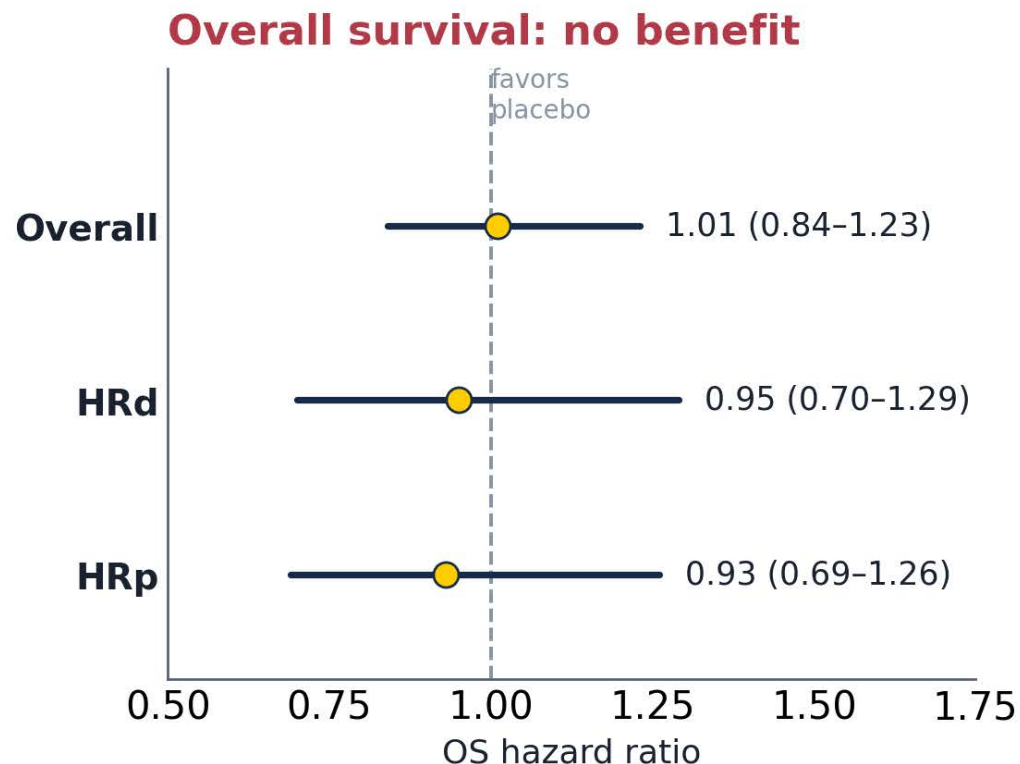
OS HR 0.62 (0.45–0.85) · PFS HR 0.41 (0.32–0.54) · no OS benefit in HRD-negative

Ray-Coquard et al. NEJM 2019; final OS Ann Oncol 2023; risk-stratified IJGC 2024. PAOLA-1/ENGOT-ov25.

- **Design:** olaparib + bev vs bev alone, on a bevacizumab backbone; benefit confined to HRD-positive
- **5-yr PFS:** 46.1% vs 19.2% (HR 0.41, 95% CI 0.32–0.54)
- **5-yr OS:** 65.5% vs 48.4% (HR 0.62, 95% CI 0.45–0.85) in HRD-positive
- **By clinical risk group (5-yr OS):**
 - Higher-risk HRD+ 55% vs 42%
 - Lower-risk HRD+ 88% vs 61%

PRIMA: niraparib — the PFS / OS disconnect

SECTION 02 · LONG-TERM OUTCOMES



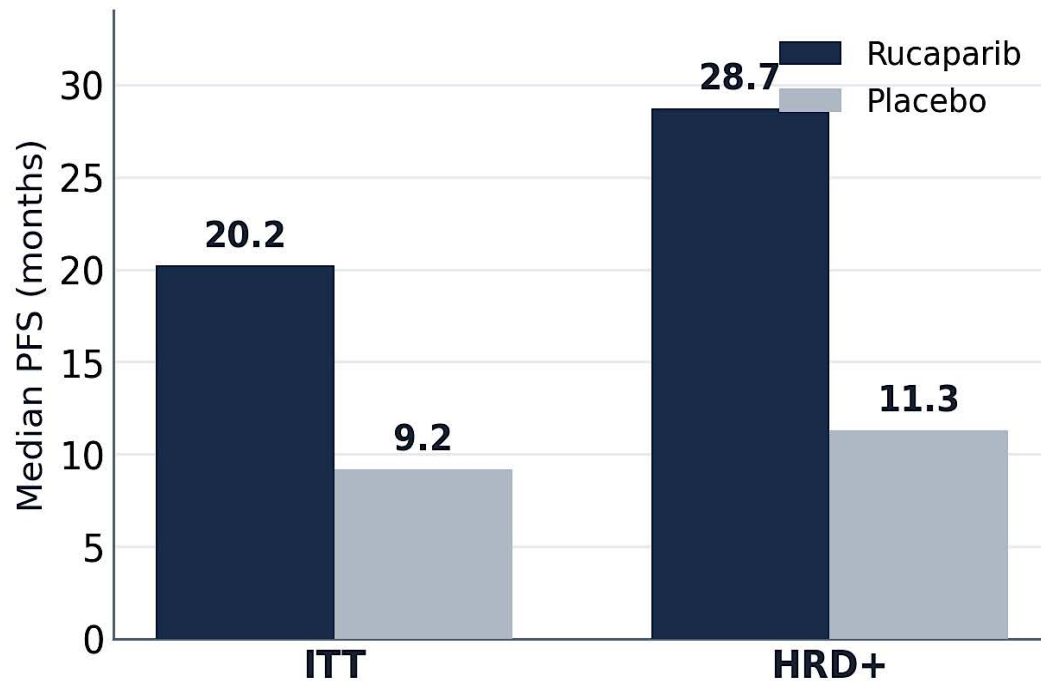
Summary: Durable PFS benefit (sustained at 5 years) that did not translate into a significant OS benefit in any subgroup — tension behind biomarker-unselected use

González-Martín et al. *NEJM* 2019; final OS *Ann Oncol* 2024. PRIMA/ENGOT-OV26/GOG-3012.

ATHENA-MONO: rucaparib first-line maintenance

SECTION 02 · LONG-TERM OUTCOMES

ATHENA-MONO: rucaparib first-line maintenance



ITT HR 0.52 · HRD+ HR 0.47 (0.31-0.72)

- **All-comers:** rucaparib × 2 years vs placebo after response to platinum
- **ITT PFS:** 20.2 vs 9.2 months (HR 0.52)
- **HRD-positive PFS:** 28.7 vs 11.3 months (HR 0.47, 95% CI 0.31–0.72)
- **HRD-negative:** more modest benefit, consistent with the HR gradient
- **Regulatory note:** Not FDA-approved for 1L maintenance in the US

Monk et al. J Clin Oncol 2022; 5-yr interim update Ann Oncol 2025. ATHENA-MONO/GOG-3020/ENGOT-ov45.

No randomized clinical trial data available to directly demonstrate efficacy contribution of bevacizumab to 1L PARPi maintenance

No olaparib monotherapy arm in

PAOLA-1¹

No bevacizumab combination arm in

SOLO1²

PRIMA³

ATHENA-MONO⁴

Ongoing trials will allow a direct comparison of 1L PARPi with and without bevacizumab

NIRVANA-1⁵

Niraparib ± bevacizumab as maintenance after complete cytoreduction

AGO-OVAR 28⁶

Niraparib vs niraparib + bevacizumab as maintenance after platinum + bevacizumab

MITO25⁷

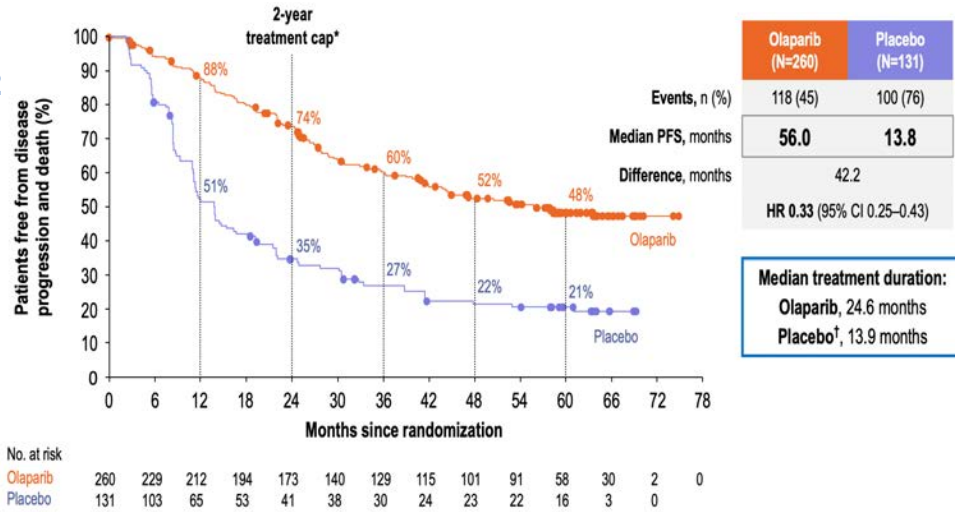
Chemotherapy ± bevacizumab followed by rucaparib maintenance ± bevacizumab or bevacizumab alone

But what evidence is available to guide clinical practice for today?

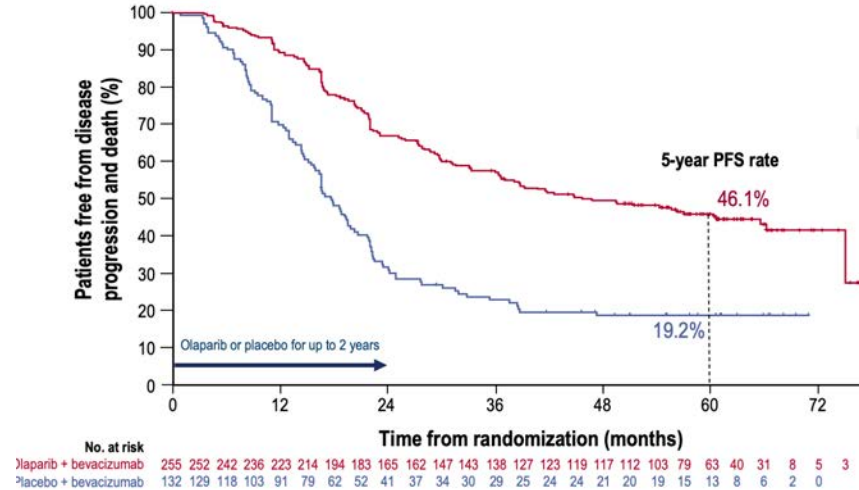
1. Ray-Coquard I, et al. *N Engl J Med* 2019;381:2416–242; 2. Moore K, et al. *N Engl J Med* 2018;379:2495–2505. 3. Gonzalez-Martin A, et al. *N Engl J Med* 2019;381:2391–2402; 4. Monk BJ, et al. *Int J Gynecol Cancer* 2021;31:1589–1594; 5. ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/ct2/show/NCT05183984> (Accessed November 2022); 6. ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/ct2/show/NCT05009082> (Accessed November 2022); 7. ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/ct2/show/NCT03462212> (Accessed November 2022)

The Improvement of PFS By PARP Inhibitors in HRD Population Is Clinically Meaningful.

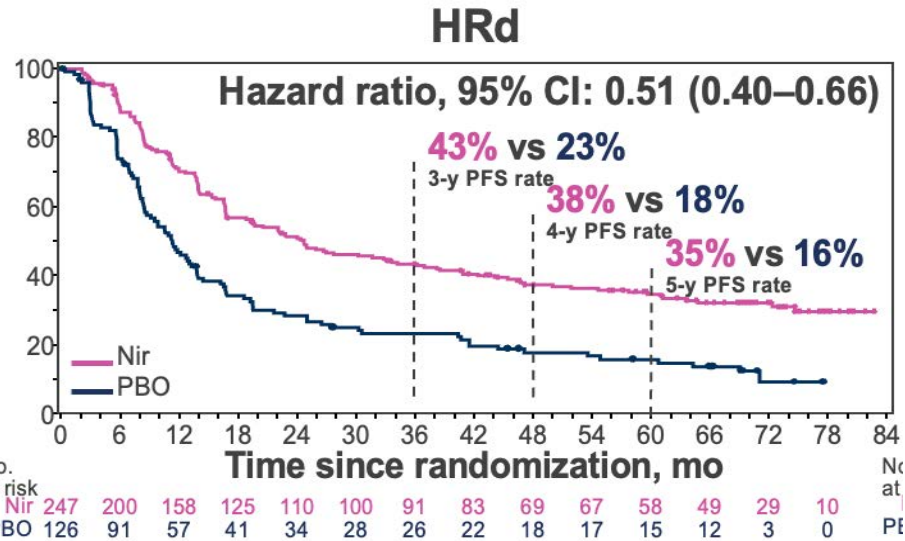
SOLO-1^{1,2}



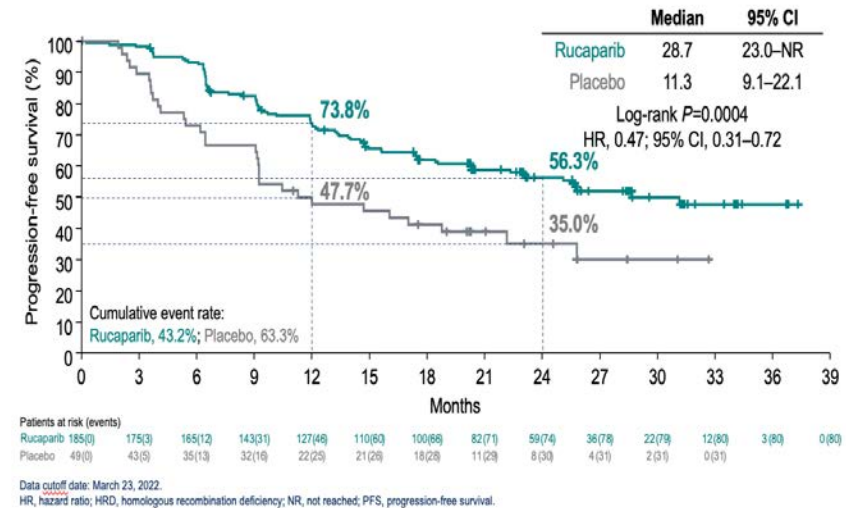
PAOLA-1³



PRIMA⁴



ATHENA⁵



1. Banerjee S, et al. Lancet Oncol. 2021;12:1721-1731; 2. Moore K, et al. N Engl J Med. 2018;379:2495-2505; 3. Ray-Coquard I, et al. Ann Oncol. 2023;34:681-692; 4. Monk B, et al. Ann Oncol. 2024;35:981-992; 5. Monk BJ, et al. J Clin Oncol. 2022;40:3952-3964.

SECTION 03

Selecting up-front maintenance therapy

Matching regimen to biology, the chemotherapy backbone, and the patient.

Biomarker-directed regimen selection

SECTION 03 · CHOOSING THERAPY

BRCA-mutated

- Olaparib × 2 y (SOLO-1)
- Olaparib + bev if bev used (PAOLA-1)
- Niraparib is an option

- **Largest, most durable benefit** — including provocative directional OS benefit

BRCAwt / HRD+

- Olaparib + bev (PAOLA-1) — Suggested OS benefit
- Niraparib (PRIMA) — PFS benefit
- Clear PFS gain

- **Contribution of Bevacizumab use at the start of treatment?**

HR-proficient

- **NO current US FDA approved indication for maintenance PARPi** (prior niraparib indication retracted)
- Bevacizumab alone is reasonable

- **Is observation an option for some?**

SECTION 04



Ongoing phase III trials

Refining the unanswered questions: who benefits, and for how long.

Is there an opportunity to de-escalate therapy in the HRD+ population? NRG GY036



*Ovarian cancer = fallopian tube cancer, ovarian cancer, or primary peritoneal cancer. **Using any commercially available test for *BRCA1/2* and HRD (ex. Myriad MyChoice).

†Patients must have received ≥3 and ≤9 cycles of platinum-based chemotherapy

§Bevacizumab 15 mg/kg every 3 weeks for a total of 15 months, including when administered with chemotherapy. Patients must have received ≥3 cycles of bevacizumab with the last 3 cycles of chemotherapy, apart from patients undergoing interval surgery who were permitted to receive only 2 cycles of bevacizumab with the last 3 cycles of chemotherapy;

PFS, times from randomization to first progression or death; PFS2, time from randomization to second progression or death;

Abbreviations: bid, twice daily; FIGO, International Federation of Gynecology and Obstetrics; RECIST, Response Evaluation Criteria in Solid Tumours.

Do we need two years of PARPi in HRD tumors? Opportunity to de-escalate?

MONO-OLA1 and NRG-GY036

SECTION 04 · ONGOING TRIALS

MONO-OLA1

NCT04884360

Question: Does olaparib monotherapy help BRCA-wildtype patients (without bevacizumab)?

Design: Phase III, olaparib vs placebo maintenance after 1L platinum response

Population: BRCA-wildtype stage III–IV high-grade serous/endometrioid OC

Primary: PFS in BRCAwt/HRD+ and in the overall BRCAwt population

NRG-GY036

NCT06580314

Question: Is 1 year of maintenance olaparib as good as 2 years?

Design: Phase III, 1 vs 2 y olaparib ± bev; NRG's first pragmatic/streamlined trial

Population: BRCA-mutated or HRD-positive OC after 1L platinum response

Primary: Non-inferiority of shorter duration (de-escalation)

SECTION 05

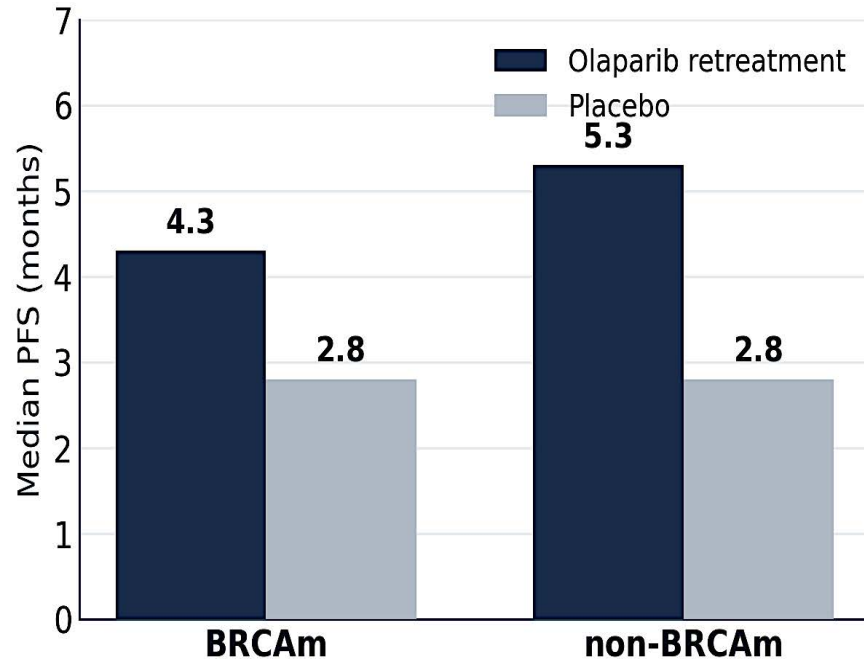
PARP inhibitors in the relapsed / refractory setting

Including patients who progress after prior PARP-inhibitor therapy.

Relapsed disease and PARP rechallenge

SECTION 05 · RELAPSED / POST-PARP

OReO/ENGOT-ov38: PARP-inhibitor rechallenge



BRCAm HR 0.57 ($p=0.022$) · non-BRCAm HR 0.43 ($p=0.0023$) · 1-yr PFS 14–19% vs 0%

Pujade-Lauraine et al. (OReO/ENGOT-ov38) *Ann Oncol* 2023. ARIEL4; FDA label revisions 2022.

- **2L+ maintenance has narrowed**

Most patients now receive PARP in 1L; later-line treatment indications were withdrawn in the US

- **OReO: rechallenge is feasible**

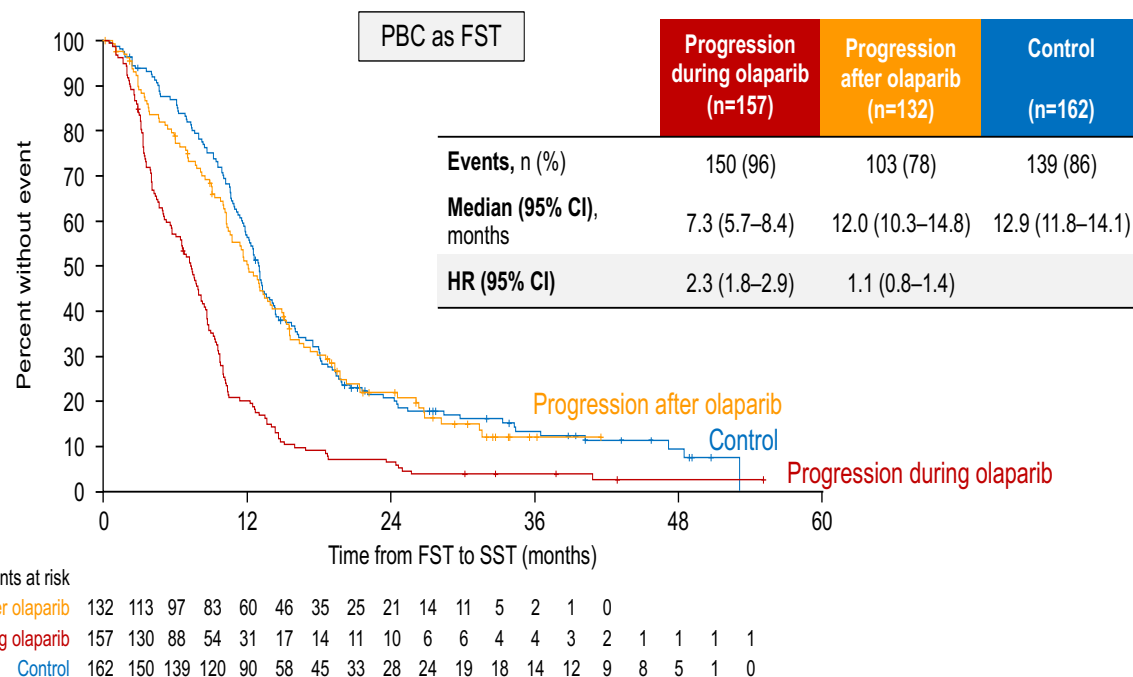
Modest PFS gain after prior PARP — BRCAm HR 0.57, non-BRCAm HR 0.43; 1-yr PFS 14–19% vs 0%

- **Post-PARP progression = ? cross-resistance**

Reversion mutations / restored HR

Response to subsequent platinum rechallenge may be compromised

Efficacy of Platinum-based Chemotherapy Appears To Be Reduced After Progression On PARPi In The Retrospective Post Hoc Exploratory Analysis Of PAOLA-1









One patient in the olaparib arm did not receive study treatment and is not included in this analysis.

Best response to combination therapy with PBC as FST¹







Best overall response, n (%)	Progression during first-line olaparib maintenance therapy	Progression after first-line olaparib maintenance therapy	Placebo plus bevacizumab arm
Any chemotherapy as FST	n = 192	n = 145	n = 206
Complete response	11 (5.7)	33 (22.8)	38 (18.4)
Partial response	37 (19.3)	39 (26.9)	75 (36.4)
Progressive disease	88 (45.8)	26 (17.9)	38 (18.4)
Stable disease	43 (22.4)	30 (20.7)	43 (20.9)
Not evaluable	13 (6.8)	17 (11.7)	12 (5.8)
Combination PBC as FST	n = 157	n = 132	n = 162
Complete response	11 (7.0)	32 (24.4)	35 (21.6)
Partial response	36 (22.9)	37 (28.0)	68 (42.0)
Progressive disease	64 (40.8)	22 (16.7)	18 (11.1)
Stable disease	39 (24.8)	29 (22.0)	32 (19.8)
Not evaluable	7 (4.5)	12 (9.1)	9 (5.6)

Regulatory and reimbursement issues aside, what would you most likely recommend as maintenance therapy for a woman with Stage IIIC ovarian cancer (OC) after optimal debulking surgery and chemotherapy with the following biomarker status?







	Germline BRCA	BRCA-negative, HRD-positive	BRCA-negative, HRD-negative
 Prof Eskander	Olaparib	Olaparib/bevacizumab	Bevacizumab
 Dr Matulonis	Olaparib	Niraparib	Bevacizumab
 Dr Moore	Olaparib	Olaparib/bevacizumab	Bevacizumab
 Dr Olawaiye	Olaparib	Olaparib/bevacizumab	Observation
 Dr O'Malley	Olaparib/bevacizumab	Olaparib/bevacizumab	Bevacizumab
 Prof Colombo	Olaparib	Olaparib/bevacizumab	Bevacizumab

HRD = homologous recombination deficiency







Regulatory and reimbursement issues aside, what would you most likely recommend as maintenance therapy for a woman with BRCA-negative Stage IIIC ovarian cancer (OC) after optimal debulking surgery and chemotherapy with the following biomarker status?

	HRD-indeterminate on 3 attempts	HRD-indeterminate on 3 attempts, rapid response to neoadjuvant chemo
 Prof Eskander	Depends on reason for HRD-indeterminant results	Olaparib/bevacizumab
 Dr Matulonis	Bevacizumab	Bevacizumab
 Dr Moore	Bevacizumab	Niraparib
 Dr Olawaiye	Observation	Olaparib/bevacizumab
 Dr O'Malley	Olaparib/bevacizumab	Olaparib/bevacizumab
 Prof Colombo	Bevacizumab	Niraparib or rucaparib

Regulatory and reimbursement issues aside, what would you most likely recommend as maintenance therapy for a woman with Stage IIIC OC after optimal debulking surgery and chemotherapy/bevacizumab with the following biomarker status?

	Germline BRCA	BRCA-negative, HRD-positive	BRCA-negative, HRD-negative
 Prof Eskander	Olaparib/bevacizumab	Olaparib/bevacizumab	Bevacizumab
 Dr Matulonis	Olaparib/bevacizumab	Olaparib/bevacizumab	Bevacizumab
 Dr Moore	Olaparib/bevacizumab	Olaparib/bevacizumab	Bevacizumab
 Dr Olawaiye	Olaparib/bevacizumab	Olaparib/bevacizumab	Observation
 Dr O'Malley	Olaparib/bevacizumab	Olaparib/bevacizumab	Bevacizumab
 Prof Colombo	Olaparib/bevacizumab	Olaparib/bevacizumab	Bevacizumab

How would you indirectly compare the global efficacy of olaparib, olaparib/bevacizumab and niraparib when administered as up-front maintenance therapy for patients with advanced OC and the following biomarker status?

	BRCA mutation	BRCA wild type, HRD-positive
 Prof Eskander	Efficacy is about the same	Olaparib/bevacizumab is the most efficacious
 Dr Matulonis	Either olaparib alone or olaparib/bevacizumab in this setting	Efficacy is about the same
 Dr Moore	Olaparib/bevacizumab is the most efficacious	Olaparib/bevacizumab is the most efficacious
 Dr Olawaiye	Olaparib is most efficacious	Olaparib/bevacizumab is the most efficacious
 Dr O'Malley	Efficacy is about the same	Olaparib/bevacizumab is the most efficacious
 Prof Colombo	Olaparib/bevacizumab is the most efficacious	Olaparib/bevacizumab is the most efficacious

In which situations, if any, are you currently offering up-front PARP inhibitor maintenance to patients with BRCA wild-type, HRD-negative disease?



Prof Eskander

None



Dr Matulonis

None



Dr Moore

None



Dr Olawaiye

None



Dr O'Malley

None



Prof Colombo

**Only in case of an optimal response to chemotherapy,
with favorable KELIM score and CRS3**

In which situations, if any, will you rechallenge with a PARP inhibitor for a patient who has received one in the up-front maintenance setting and subsequently experienced disease progression?



Prof Eskander

Patients with a BRCA mutation who completed their PARPi maintenance therapy and then developed a recurrence



Dr Matulonis

After at least 3-5 years since completion of upfront PARPi and recurrence



Dr Moore

Would consider if no reversion mutation in a patient with a BRCA mutation who experiences good response to 2L platinum



Dr Olawaiye

Still platinum sensitive with >12 months platinum-free/PARP inhibitor-free/progression-free interval/survival



Dr O'Malley

If they did not experience progression on PARPi and had a long (2+ years) disease-free interval



Prof Colombo

None, no data to support this option

Agenda

Module 1: Current Role of PARP Inhibitors in the Management of Advanced Ovarian Cancer (OC) — Prof Eskander

Module 2: Strategies Targeting Folate Receptor Alpha in Advanced OC — Dr Matulonis

Module 3: Other Approved and Promising Investigational Antibody-Drug Conjugates for Advanced OC — Dr Moore

Module 4: Other Novel Agents and Strategies for Advanced OC — Dr O'Malley

Module 5: Diagnosis and Management of Adverse Events Associated with Common Therapies for Advanced OC — Dr Olawaiye



Dana-Farber
Cancer Institute

Strategies Targeting Folate Receptor Alpha (FR α) in Advanced Ovarian Cancer

Ursula Matulonis, MD
Chief, Division of Gynecologic Oncology
Dana-Farber Cancer Institute
Professor of Medicine
Harvard Medical School
Boston MA

Folate receptor alpha expression in ovarian cancer histologies and testing

Ventana assay for FOLR1 expression: FDA approved to select patients who are eligible to receive mirvetuximab soravtansine

Positive test: $\geq 75\%$ of viable tumor cells exhibiting at least 2+ level (moderate and/or strong intensity levels) of membrane staining by IHC

Ovarian cancer histology	Level of high FOLR1 expression:
High Grade Serous	~35%
Low Grade Serous	30-40%
Clear Cell	8%
Endometrioid	6%
Mucinous	0%

Matulonis et al, JCO 2023
Manning Geist, Gyn Onc 2024
Leung et al, J Gyn Oncology 2025

Early clinical trial testing of Mirvetuximab soravtansine

Phase 1: 44 patients enrolled

Doses started at 0.15 up through 7.0 mg/kg

Ocular toxicities found to correlate with dose and exposure, so Adjusted Ideal Body weight was used

Dose escalation went to 7 mg/kg (low phos and eye tox)

Both 5 and 6 mg/kg were then tested (n=7 per group) and no DLTs were observed

6 mg/kg via AIBW was selected as the RP2D

Phase I expansion cohort (46 pts):

ORR for pts who received 1 to 3 prior lines: 39%

ORR for pts who had received ≥ 4 lines was 13%

Good concordance of FR α expression in archival and pre-treatment biopsy tissues, ranging from 71%-86%

65 yo F

Diagnosed with advanced high grade serous ovarian cancer via an omental biopsy that showed HGSC



Received 3 cycles of neoadjuvant carbo/paclitaxel and underwent cytoreductive surgery

Completed 3 additional cycles of carboplatin, paclitaxel, bevacizumab

Continued bevacizumab maintenance

3 month CT following completion of platinum showed PD

initial scan



Went on to receive mirvetuximab:
After 2 cycles, CA125 went down transiently but just after cycle #2, started to rise

CT scan showed PD

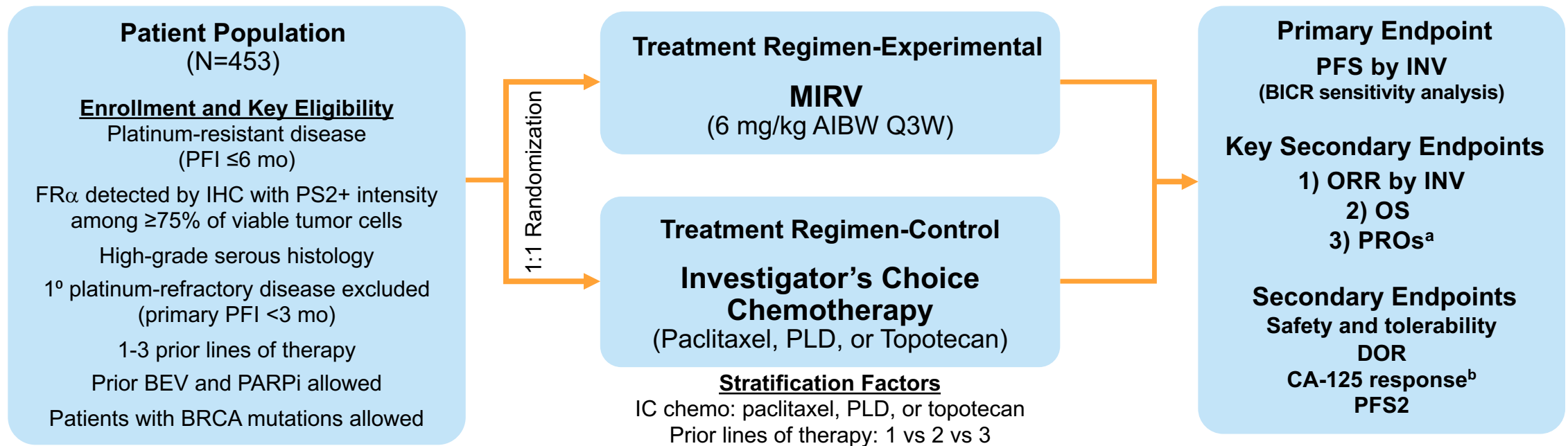
Date of specimen	Location	Result of FOLR1	HER2 IHC
Initial Biopsy	Omentum	85%	1+
Interval surgery	Omentum	15%	1+

Mirvetuximab and SORAYA

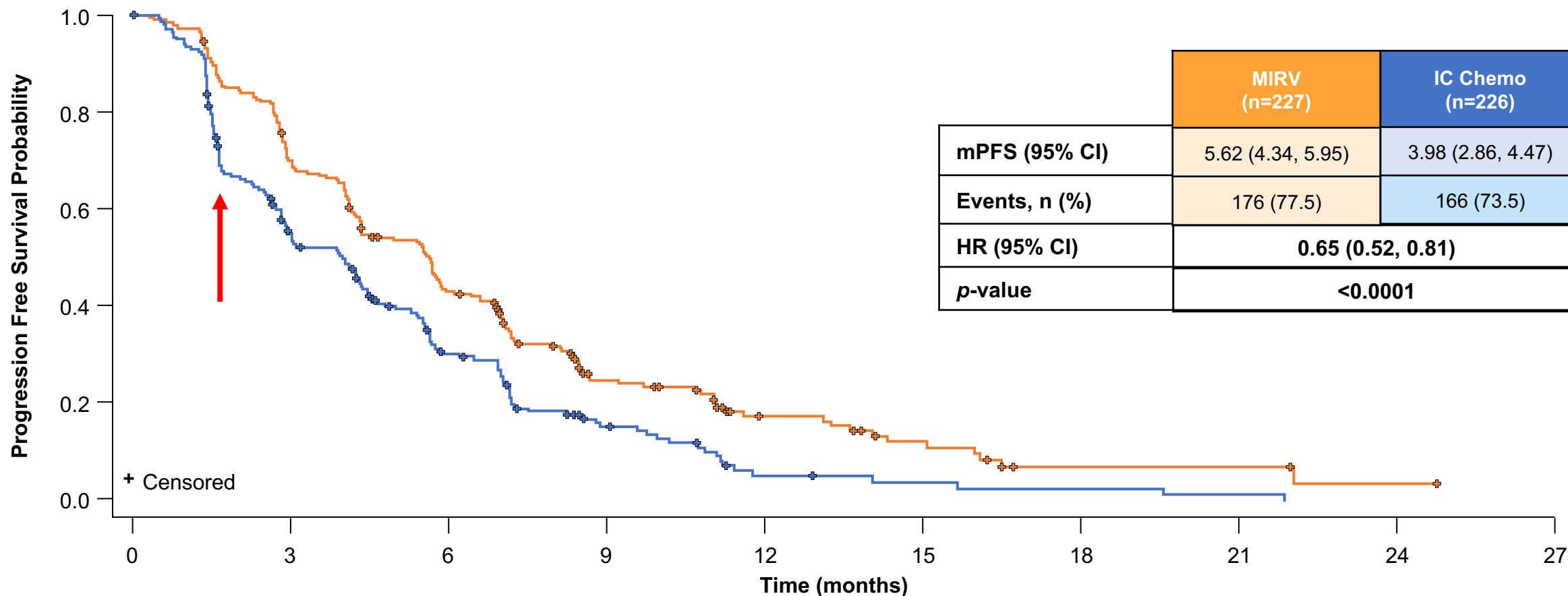
- **SORAYA:** evaluated Mirvetuximab soravtansine for PROC, HGSC with high FR α expression
 - 106 pts enrolled
 - Primary endpoint: Investigator assessed cORR; Key secondary endpoint: DOR
 - Additional eligibility:
up to 3 prior therapies, including requirement of prior bevacizumab
Tumor demonstrated FR α -high membrane staining with IHC PS (Proportion Score) 2+ scoring:
 $\geq 75\%$ of cells staining positive with **$\geq 2+$** staining intensity
 - Results:
ORR 32.4%
mDOR 6.9 m
- N.B.: ORR of 34.8% for pts whose 1st treatment was mirve versus 28.2% for pts receiving mirve as 2nd line + for PROC
- November 2022: accelerated FDA approval

MIRASOL – Study Design^{1,2}

An open-label, phase 3 randomized trial of MIRV vs investigator's choice chemotherapy in patients with FR α -high platinum-resistant ovarian cancer



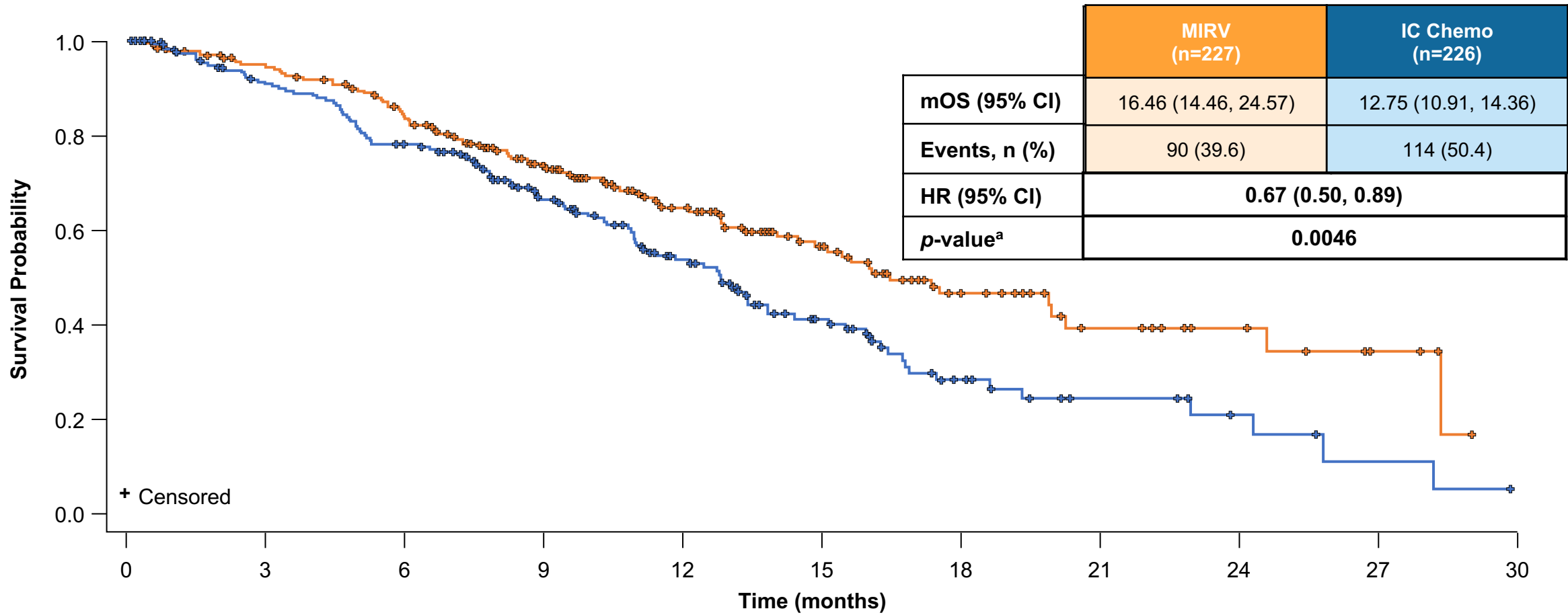
Primary Endpoint: Progression-Free Survival by Investigator



No. Participants at Risk

	0	3	6	9	12	15	18	21	24	27
MIRV 227	227	151	89	38	18	10	3	3	1	0
IC Chemo 226	226	98	48	19	5	3	2	1	0	0

Overall Survival



No. Participants at Risk

	0	3	6	9	12	15	18	21	24	27	30
MIRV 227	227	204	175	128	82	53	28	15	9	4	0
IC Chemo 226	226	185	157	107	68	39	18	9	5	2	0

Overall Response Rate by Investigator (N=453)

	MIRV (n=227)	IC Chemo (n=226)
ORR n, 95% CI	42% 96, (35.8, 49.0)	16% 36, (11.4, 21.4)
Best overall response, n (%)		
CR	12 (5%)	0
PR	84 (37%)	36 (16%)
SD	86 (38%)	91 (40%)
PD	31 (14%)	62 (27%)
Not evaluable	14 (6%)	37 (16%)
ORR Difference 26.4% (18.4, 34.4) OR 3.81 (2.44, 5.94) p<0.0001		

Received full FDA approval on March 22, 2024 for patients with FR α positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received up to 3 prior systemic treatment regimens.

PICCOLO study: Phase 2 of MIRV as $\geq 3L$ treatment in patients with recurrent platinum sensitive ovarian cancer

Other eligibility: FRa-positive ($\geq 75\%$ of cells with 2+ staining intensity)

Primary endpoint: ORR

Treatment: MIRV 6 mg/kg via AIBW q3 wks IV until PD, tox, withdrawal of consent

79 pts enrolled

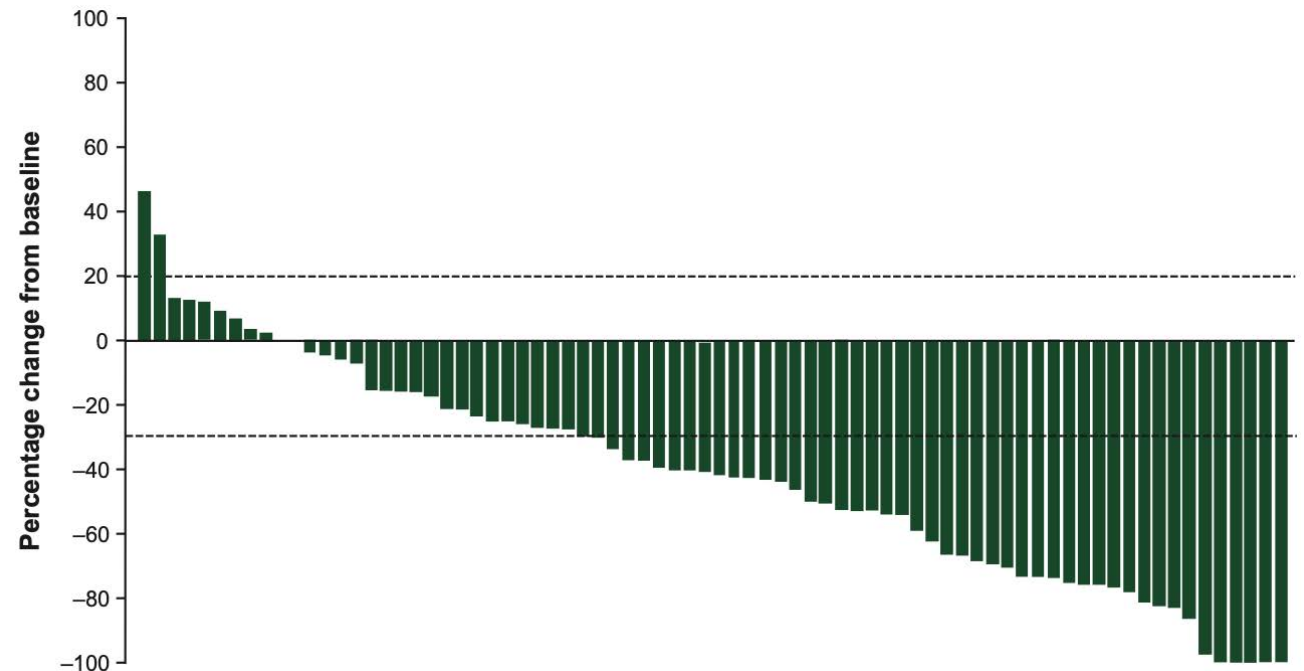
Results:

ORR: 51.9% (95% CI 40.4% to 63.3%)

mDOR: 8.25 months

mPFS 6.93 months

OS was not mature



PICCOLO study: Phase 2 of MIRV as $\geq 3L$ treatment in patients with recurrent platinum sensitive ovarian cancer

Subgroup	ORR subgroup, <i>n</i>	ORR, <i>n</i> (%) [95% CI]	DOR subgroup, <i>n</i>	Median DOR, months [95% CI]
Prior lines of therapy				
1 or 2	49	27 (55.1) [40.2-69.3]	27	7.44 [4.63-9.66]
3	24	12 (50.0) [29.1-70.9]	12	8.41 [4.63-NR]
≥ 4	6	2 (33.3) [4.3-77.7]	2	NR [2.69-NR]

4.2026 For plat
NCCN: sensitive

- Mirvetuximab soravtansine-gynx^w (for FR α -expressing tumors [$\geq 75\%$ positive tumor cells])³⁵
- Mirvetuximab soravtansine-gynx + Bevacizumab^r (for FR α -expressing tumors [$\geq 50\%$ positive tumor cells]) (category 2B)³⁶

Ph 2 of Mirvetuximab/Bevacizumab for recurrent platinum resistant ovarian cancer

Eligibility:

Recurrent platinum resistant high grade serous ovarian cancer

No more than 3 prior lines of treatment

FOLR1 requirements: FOLR1 $\geq 25\%$ of tumor staining at $\geq 2+$ intensity

Prior Bev and/or PARPi allowed

Primary endpoint: confirmed ORR

Secondary endpoints: DOR, PFS and safety

Treatment:

mirvetuximab soravtansine 6 mg/kg AIBW q3 wks

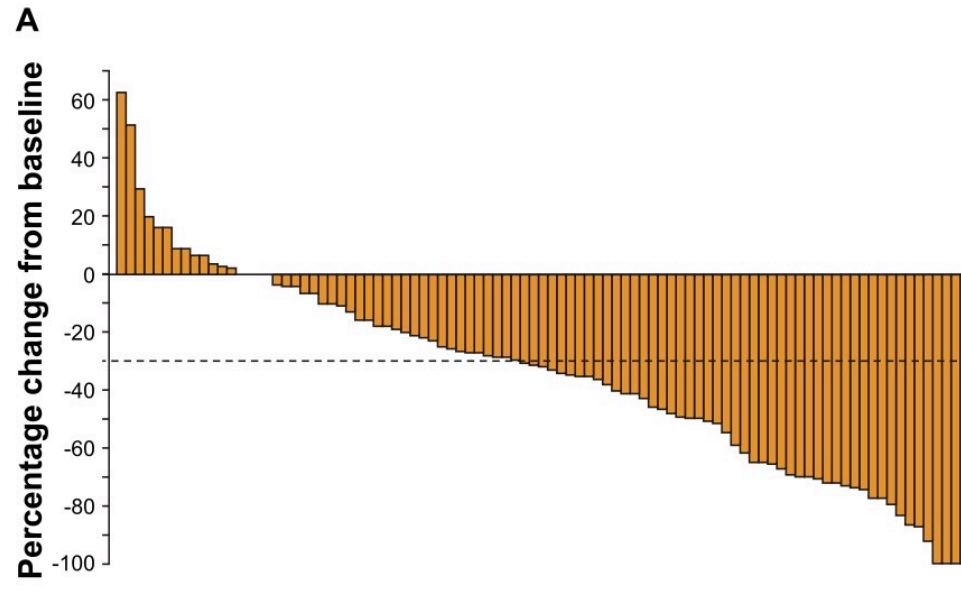
Bevacizumab 15 mg/kg q3 wks

Phase 2 of Mirve/Bev in platinum resistant ovarian cancer

44% confirmed ORR
Median DOR 9.7 months

Median PFS 8.2 months

Efficacy was demonstrated
at all levels FR alpha
expression
(25% and higher)



These results led to inclusion of this regimen for PROC in Ovarian cancer NCCN guidelines:

2A recommendation for $\geq 25\%$ FOLR1

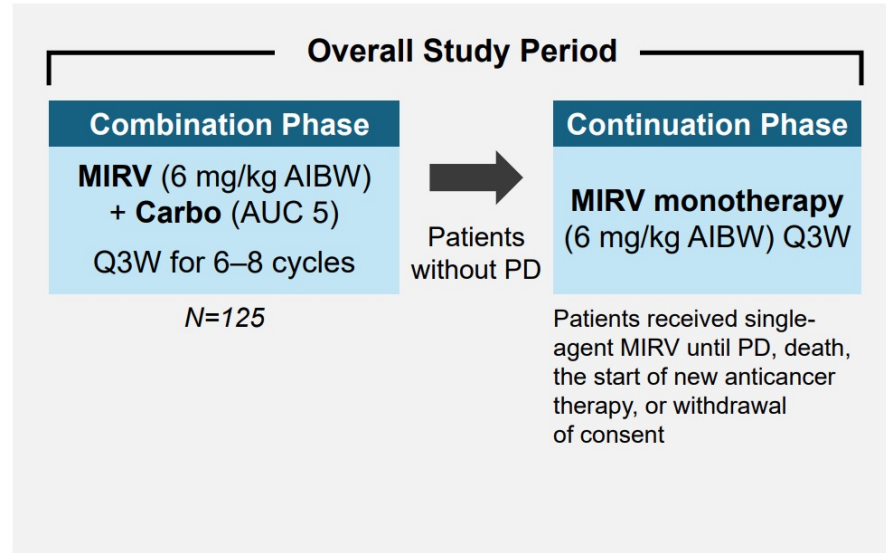
Table 3
Summary of efficacy in patients by subgroups.

Endpoint	FR α $\geq 75\%$ (n = 44)	FR α 50–74% (n = 39)	FR α 25–49% (n = 11)	BEV-naïve (n = 39)	BEV-pretreated (n = 55)
Confirmed objective response rate, n (%)	21 (48)	16 (41)	4 (36)	22 (56)	19 (35)
95% CI	(33, 63)	(26, 58)	(11, 69)	(40, 72)	(22, 49)
Median duration of response, (months)	9.7	9.7	18.5	10.4	9.7
95% CI	(6.0, 12.0)	(3.0, NR)	(NE)	(6.9, 14.5)	(4.2, NR)
Median progression-free survival, (months)	9.7	6.9	8.6	10.6	6.8
95% CI	(6.8, 11.0)	(5.1, 9.9)	(1.3, NR)	(8.2, 14.5)	(5.3, 8.2)

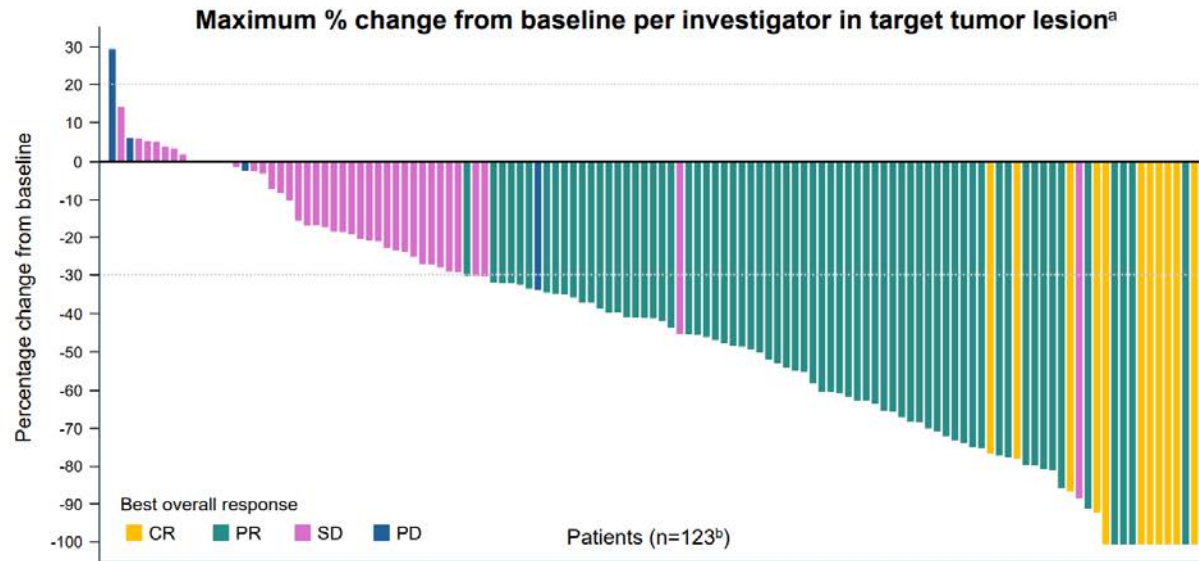
BEV, bevacizumab; FR α , folate receptor alpha; NE, not evaluable; NR, not reached.

IMGN853-0420 Mirvetuximab Soravtansine Plus Carboplatin in Folate Receptor Alpha-Expressing Recurrent Platinum-Sensitive Ovarian Cancer

- ### Eligibility
- Platinum-sensitive, high-grade serous EOC^a
 - 1 prior line of platinum-based chemotherapy
 - FR α positivity detected by IHC ($\geq 25\%$ tumor cells with $\geq 2+$ membrane intensity)^b
 - Prior PARPi required for patients with somatic and/or germline *BRCA* mutations
 - Measurable disease by RECIST v1.1



- ### Primary Endpoint
- ORR by INV^c by the end of 6 combination cycles in a subset of patients from the overall population (ie, patients with $\geq 25\%$ FR α expression) who had $\geq 50\%$ FR α expression
- ### Key Secondary Endpoint
- ORR by INV^c by the end of 6 combination cycles in the overall population (ie, patients with $\geq 25\%$ FR α expression)
- ### Additional Secondary Endpoints
- In the overall study period:
- DOR^c
 - PFS^c
 - CA-125 response
 - OS
 - TEAEs



Overall population ($\geq 25\%$ FR α expression)	
Total (N=125)	$\geq 50\%$ FR α subset (n=102)

By the end of 6 combination cycles		
ORR, % (95% CI)	62.4 (53.3–70.9)	62.7 (52.6–72.1)

- Adjudicated treatment-related pneumonitis occurred in 19 patients (15.2%)**
- 14 (11.2%) had grade 1-2 events
 - 3 (2.4%) had grade 3–4 events
 - 2 (1.6%) deaths occurred (grade 5); both with underlying cardiopulmonary disorders
 - 16/19 patients had a final grade of 1 or better**, including 10 with complete resolution
 - 11/19 patients were **retreated with MIRV**
 - Median (range) time to onset was 32.1 (8.6–72.0) weeks**

MIROVA/AGO-OVAR 2.34: RP2 of mirvetuximab soravtansine/carboplatin vs SOC plat doublet

- Recurrent epithelial cancer of the ovary, fallopian tube or peritoneum
- TFIp > 3 months
- All histologic subtypes
- FR α high status by PS2+ scoring ($\geq 75\%$ of tumor cells with FR α membrane staining and $\geq 2+$ intensity*)
- ≥ 1 prior lines of chemotherapy
- Measurable disease or evaluable disease in combination with GCIG CA-125 criteria
- Not a candidate for bevacizumab
- Prior PARPi mandatory for BRCAmut tumors

* using Ventana FOLR1 (FOLR1 2.1) CDx assay

N=145



Carboplatin
AUC 5 and
Mirvetuximab
6 mg/kg x 6
cycles



Mirvetuximab

Carboplatin
Doublet
(paclitaxel, PLD
or gemcitabine)
x 6 cycles



PARPi
maintenance if
applicable

Primary endpoint
PFS

Stratification factors:
BRCA-status
Platinum-free interval
Number of prior lines of chemotherapy

Patient characteristics II

	Standard (N=70)	Carbo+Mirv (N=75)
Initial FIGO stage		
I	1 (1.4%)	3 (4%)
II	5 (7.1%)	4 (5.3%)
III	48 (68.6%)	45 (60%)
IV	15 (21.4%)	22 (29.3%)
Not available/unknown	1 (1.4%)	1 (1.3%)
BRCA-Status		
<i>BRC</i> Awt	61 (87.1%)	63 (84%)
<i>gBRC</i> Amut	5 (7.1%)	9 (12%)
<i>sBRC</i> Amut	4 (5.7%)	3 (4%)
No. of prior treatment lines		
1	38 (54.3%)	36 (48%)
2	22 (31.4%)	26 (34.7%)
3	9 (12.9%)	8 (10.7%)
4	1 (1.4%)	3 (4%)
5	0	2 (2.7%)

Patient characteristics III

	Standard (N=70)	Carbo+Mirv (N=75)
Prior treatments (at any line)		
Carboplatin	70 (100%)	75 (100%)
Taxane	70 (100%)	75 (100%)
Bevacizumab	53 (75.7%)	59 (78.7%)
PARPi	49 (70%)	48 (64%)
Platinum free interval [months]		
3-6	5 (7.1%)	6 (8%)
6-12	18 (25.7%)	19 (25.3%)
> 12	47 (67.1%)	50 (66.7%)

Reasons for discontinuation (ITT population)



	Standard (N=70)	Carbo+Mirv (N=75)
Did not receive any study therapy	7 ¹ (10%)	1 ² (1.3%)
Tumor related	41 (58.6%)	52 (69.3%)
Progressive disease by RECIST v1.1	34 (48.6%)	46 (61.3%)
CA-125 progression	1 (1.4%)	2 (2.7%)
Symptomatic deterioration	4 (5.7%)	3 (4.0%)
Death - cancer related without RECIST assessment	2 (2.9%)	1 (1.3%)
Potentially toxicity related	13 (18.6%)	17 (22.7%)
Termination by investigator	8 (11.4%)	13 (17.3%)
Patient wishes to stop treatment	5 (7.1%)	2 (2.7%)
Withdrawal of patients consent	0	2 (2.7%)
Death	1 ³ (1.4%)	1 ⁴ (1.3%)
Other	7 ⁵ (10%)	1 ⁶ (1.3%)

¹withdrawal of consent (n=6), other/patient wish (n=1); ²withdrawal of consent (n=1); ³Brain hemorrhage; ⁴unknown; ⁵maintenance not indicated (n=6), patient wish (n=1); ⁶secondary malignancy.

Patient disposition (safety population = at least one dose of study treatment)

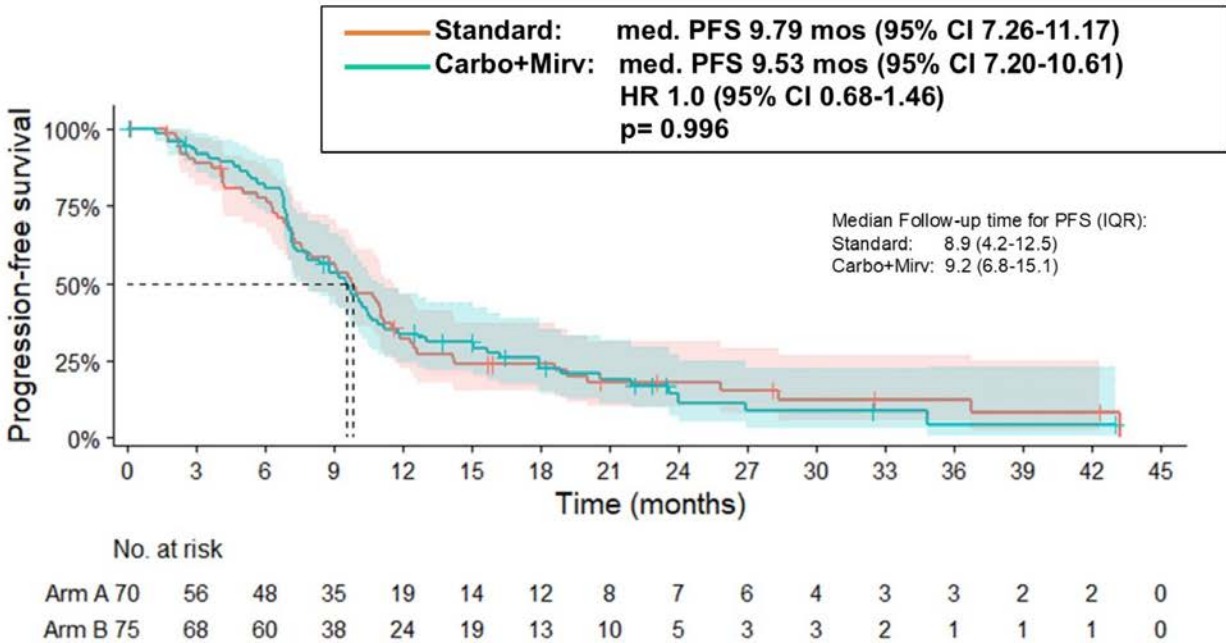


	Standard (N=63)	Carbo+Mirv (N=74)
CHEMOTHERAPY PHASE (Cycle 1-6)		
Carboplatin	63 (100%)	74 (100%)
PLD	40 (63.5%)	0
Gemcitabine	18 (28.6%)	0
Paclitaxel	5 (7.9%)	0
Mirvetuximab soravtansine	0	74 (100%)
At least 6 cycles platinum-based therapy	45 (71.4%)	64 (86.5%)
Median no. of cycles	6	6
Discontinuations for other reasons than PD ¹	19 (30.2%)	8 (10.8%)
„MAINTENANCE PHASE“ (Cycle 7+)		
Active therapy after cycle 6 („maintenance-phase“)	29 (46%) ²	59 (79.7%)
Mirvetuximab soravtansine	0 (0)	59 (79.7%)
PARPi	27 (42.9%)	0 (0)
Discontinuations for other reasons than PD ¹	2 (3.2%)	11 (14.9%)
Still on study treatment	1 (1.6%)	3 (4.1%)
TOTAL STUDY DURATION		
Patients with at least one dose reduction	27 (42.9%)	43 (58.1%)
	Carboplatin	Carboplatin
	16 (25.4%)	26 (35.1%)
	Chemo/PARPi	Mirvetuximab
	20 (31.7%)	27 (36.5%)
Median duration of treatment [months] ³	11.1	7.82
No. of SAEs	42	78

¹ includes also cancer-related death for patients starting a maintenance therapy, ² 2 patients with 7 respectively 12 cycles of chemotherapy, ³ calculated from randomization. Only patients with active therapy after cycle 6 in standard arm

Results

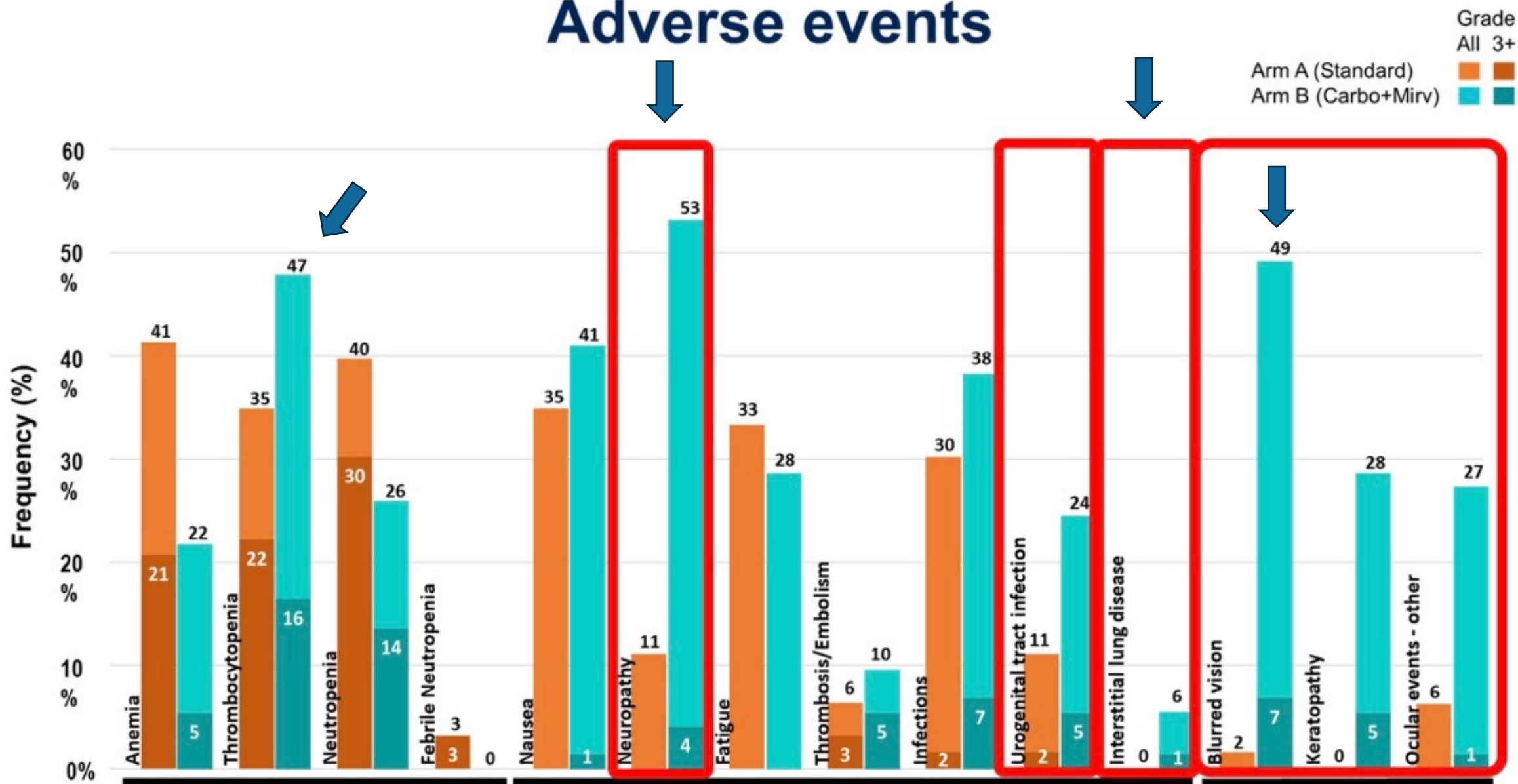
PFS Primary analysis (ITT)



Response rates

ITT population	Standard (n=70)	Carbo+Mirv (n=75)
Response rate		
CR	3 (4.3%)	3 (4%)
PR	17 (24.3%)	44 (58.7%)
SD	38 (54.3%)	20 (26.7%)
PD	3 (4.3%)	4 (5.3%)
not evaluable	9 (12.9%)	4 (5.3%)
Overall response rate (CR/PR)*	32.8%	66.2%
Clinical benefit rate (CR/PR/SD)*	95.1%	94.4%
First timepoint of response	n=20	n=47
Cycle 1-6	18 (90.0%)	40 (85.1%)
During maintenance-phase	2 (10.0%)	7 (14.9%)

Adverse events



*Any ocular toxicity in Arm B was observed in 60 pts (81.1%)

Other anti-FOLR1 ADCs: Ovarian cancer results

Drug	Payload	ORR (Ph2)	Phase 3 trial
Rinatabart Sesutecan (NCT05579366)	topo 1 exatecan DAR 8	55.6% Responses occurred regardless of FOLR1 levels	Platinum resistant RAINFOL-02: NCT06619236 Platinum sensitive maintenance: RAINFOL-04: NCT07225270
Torvutatug samrotecan (AZD5335) (NCT05797168)	topo 1 exatecan DAR 8	60.7% high FR α ($\geq 75\%$) 47.5% low FR α ($\geq 25\%$)	Platinum resistant TREVI-OC-01: NCT07218809
sofetabart mipitecan (NCT06400472)	topo 1 exatecan DAR 8	40% FR α 0-24% 50% FR α 25-49% and 50-74% 54% FR α $\geq 75\%$	Platinum resistant and Platinum sensitive: (PD on PARPi <6 months and PARP naive) FRAmework-01: NCT07213804

Comparison amongst the Topo1 payload FOLR1 ADCs

	Rinatabart sesutecan	Torvutatug samrotecan	Sofetabart mipitecan
Antibody	Human monoclonal antibody targeting FR α	Human monoclonal antibody targeting FR α	Fc-silent humanized monoclonal antibody targeting FR α
Linker Type	Hydrophilic, protease-cleavable	Cleavable linker system	Proprietary cleavable polysarcosine (PSARlink™)
Payload (all exatecans)	Sesutecan	samrotecan	Mipitecan

GLORIOSA Study: Mirve Maintenance

Eligibility:
Platinum sensitive
recurrence after 1st line
therapy

FOLR1 \geq 75%

Must be appropriate for,
currently on, or have
completed 2L platinum-
based chemotherapy
doublet plus
bevacizumab

O'Malley et al,
Future Oncology
2024

NCT05445778

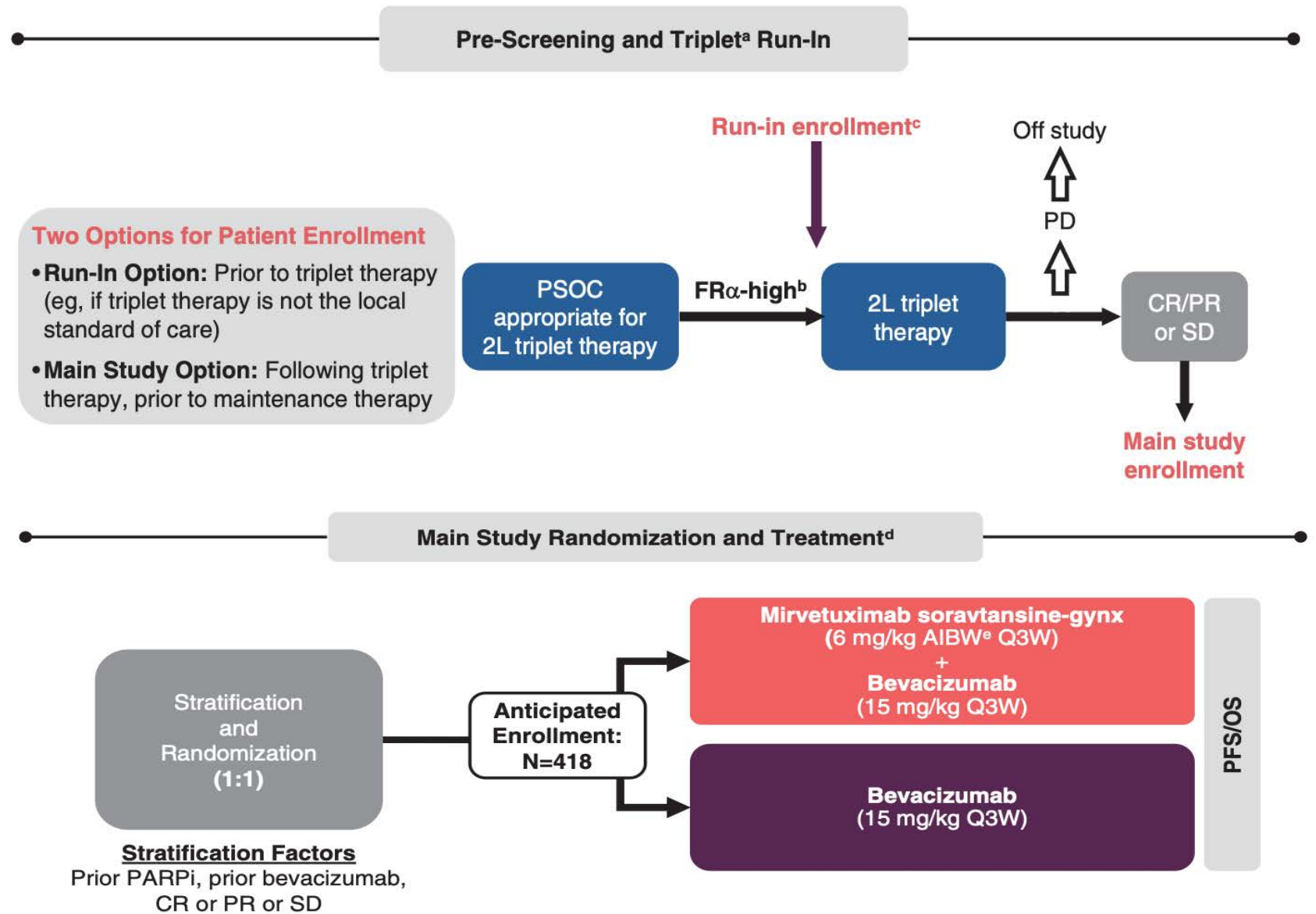


Figure 2. GLORIOSA enrollment and trial design.

When in the treatment course do you test for folate receptor alpha (FR α) expression in your patients with advanced OC?



Prof Eskander

At initial diagnosis



Dr Matulonis

At initial diagnosis



Dr Moore

At initial diagnosis



Dr Olawaiye

At the time of first platinum-resistant relapse



Dr O'Malley







At initial diagnosis



Prof Colombo

At the time of first platinum-resistant relapse

What testing methodology do you generally use to test for FR α expression in your patients with advanced OC? What threshold for FR α expression do you require to employ mirvetuximab soravtansine for your patients with platinum-resistant advanced OC?

	Testing methodology	FR α expression threshold
 Prof Eskander	In-house testing and outside NGS	75% or greater
 Dr Matulonis	VENTANA FOLR1-2.1 RxDx assay	75% or greater
 Dr Moore	IHC	Will consider for anyone >25% but really look at >50% with bev
 Dr Olawaiye	IHC	75%
 Dr O'Malley	IHC	Greater than 25% for mirv/bev; 75% mirv alone
 Prof Colombo	IHC	75% or greater

NGS = next-generation sequencing; IHC = immunohistochemistry; bev = bevacizumab; mirv = mirvetuximab soravtansine

In the absence of other actionable biomarkers, in which line of therapy are you typically employing mirvetuximab soravtansine for your patients with FR α -positive, platinum-resistant OC?



Prof Eskander

First line after platinum resistance



Dr Matulonis

First line after platinum resistance



Dr Moore

First line after platinum resistance



Dr Olawaiye

Second line after platinum resistance



Dr O'Malley

First line after platinum resistance



Prof Colombo

First line after platinum resistance

Would you employ mirvetuximab soravtansine in combination with another systemic therapy under any circumstances?



Prof Eskander

Yes, with carboplatin on clinical trial



Dr Matulonis

Yes, with bevacizumab if FR α expression is 25% or greater



Dr Moore

Yes, with bevacizumab



Dr Olawaiye

Yes, if less than 75% FR α expression and no other good therapy options



Dr O'Malley

Yes, with bevacizumab



Prof Colombo

No

In your opinion, do the mechanistic differences between the FR α -targeted antibody-drug conjugates (ADCs) in development (eg, rinatabart sesutecan, torvutatug samrotecan, sofetabart mipitecan) and mirvetuximab soravtansine offer any potential advantages for the former from either an efficacy or a tolerability perspective?



Prof Eskander

Yes, there is potential for greater use as it is not biomarker restricted; there is also no need for ocular assessments



Dr Matulonis

I'm not sure



Dr Moore

Yes, I think some will have less hematologic toxicity than others and that may be important



Dr Olawaiye

Yes, these agents are initially showing good efficacy signals in tumors with low FR α expression



Dr O'Malley

Yes, likely improved efficacy and less eye toxicity than mirvetuximab soravtansine



Prof Colombo

Yes, different payload, potentially more effective with a different spectrum of toxicity

Agenda

Module 1: Current Role of PARP Inhibitors in the Management of Advanced Ovarian Cancer (OC) — Prof Eskander

Module 2: Strategies Targeting Folate Receptor Alpha in Advanced OC — Dr Matulonis

Module 3: Other Approved and Promising Investigational Antibody-Drug Conjugates for Advanced OC — Dr Moore

Module 4: Other Novel Agents and Strategies for Advanced OC — Dr O'Malley

Module 5: Diagnosis and Management of Adverse Events Associated with Common Therapies for Advanced OC — Dr Olawaiye

Other Approved and Promising Investigational Antibody-Drug Conjugates for Advanced OC

Kathleen N. Moore, MD, MS, FASCO

Deputy Director & Director of Phase 1

Fred & Pamela Buffett Cancer Center

Omaha, NE

GOG F BOD

ASCO BOD



FRED & PAMELA BUFFETT
CANCER CENTER



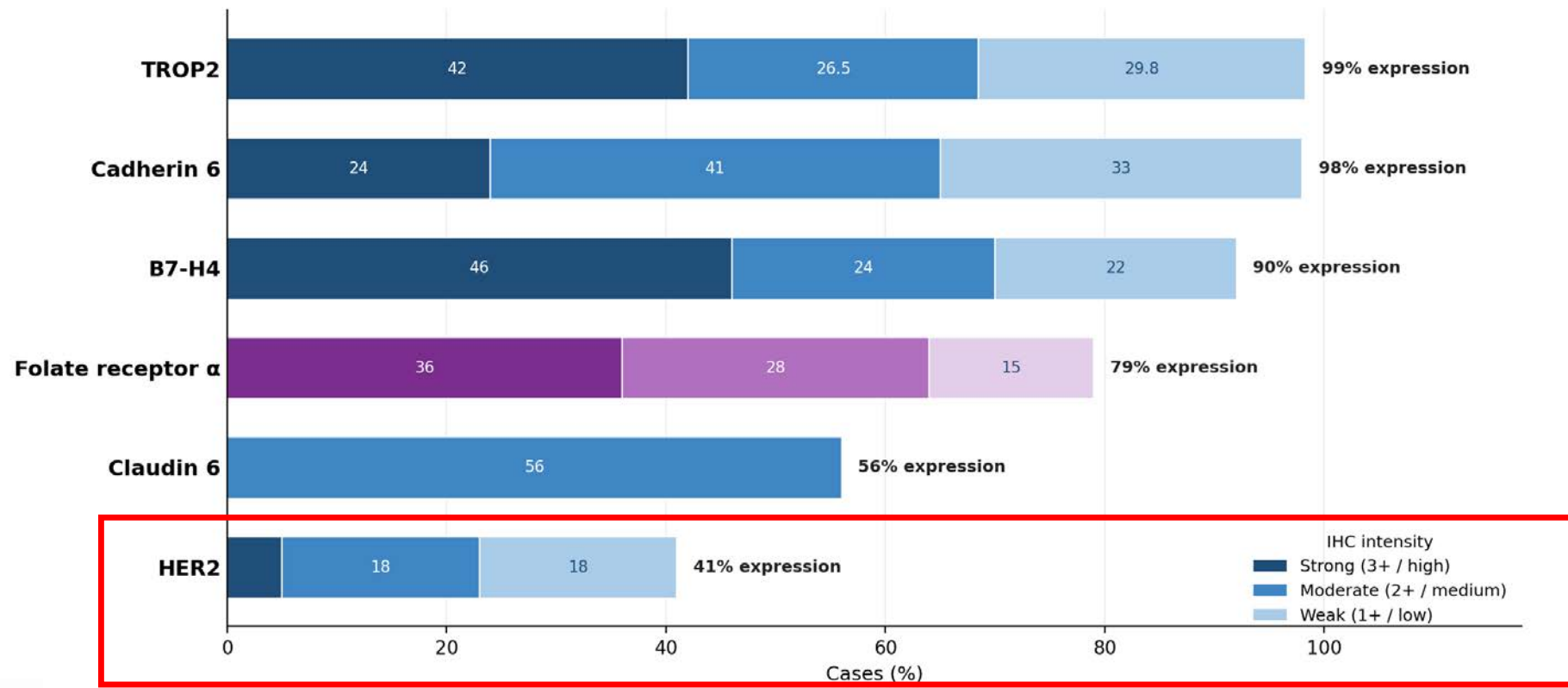
@DrKatyMoore

The Growing Complexity of Biomarkers in Ovarian Cancer

Overlapping targets by any expression and by levels of expression (many not yet validated), with prevalence differing across histotypes

Antibody-Drug Conjugate Target Landscape in HGSOC

Overall positivity and level of expression across candidate IHC targets — high-grade serous ovarian cancer

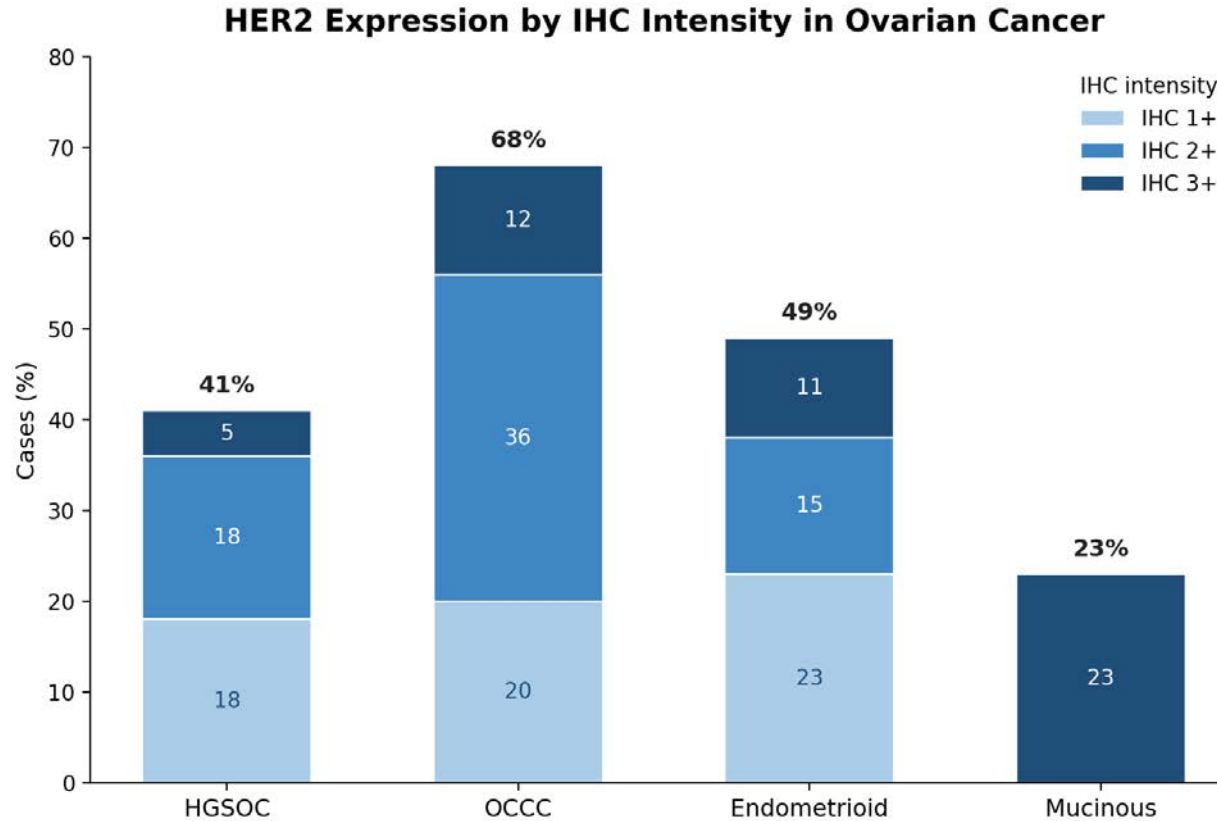


Bars stacked by IHC intensity; total expression labeled at right. FR α four-tier intensity (high 36% / medium 28% / low 15% / negative 21%) — 21% negative, so 79% express. Claudin 6 reported as total expression without a full intensity split.



The Growing Complexity of Biomarkers in Ovarian Cancer

HER2: Estimates vary widely based on sample size



Stacked bars show IHC intensity tiers (1+/2+/3+); total expression labeled above each bar. Mucinous: 3+ only reported. OCCC 3+ reported as 9-15%; midpoint (12%) shown.



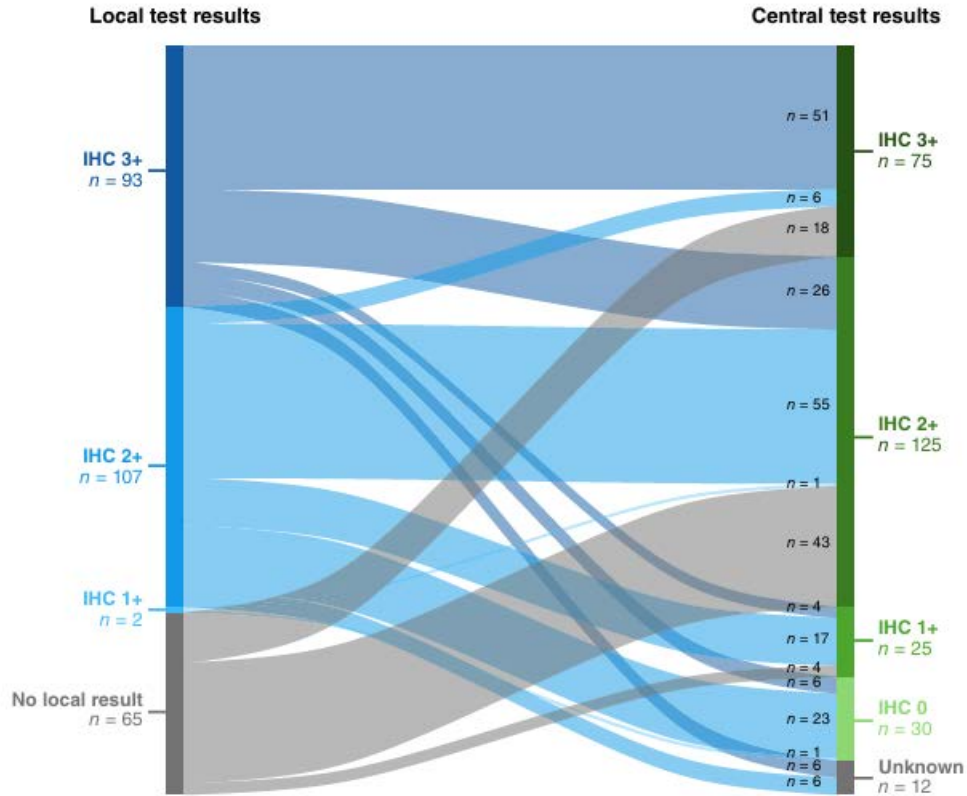
FRED & PAMELA BUFFETT
CANCER CENTER

Leung et al. *J Gynecol Oncol* 2025; Deutschman E, et al. *Arch Pathol Lab Med.* 2025;149:930-937; Hamagawa K et al. *ESMO Gyne* 2025; Ettore VM et al. *Int J Gynecol Cancer* 2025; Dum D et al. *Pathobiology* 2022; Liang L et al. *Hum Pathol.* 2017



@DrKatyMoore

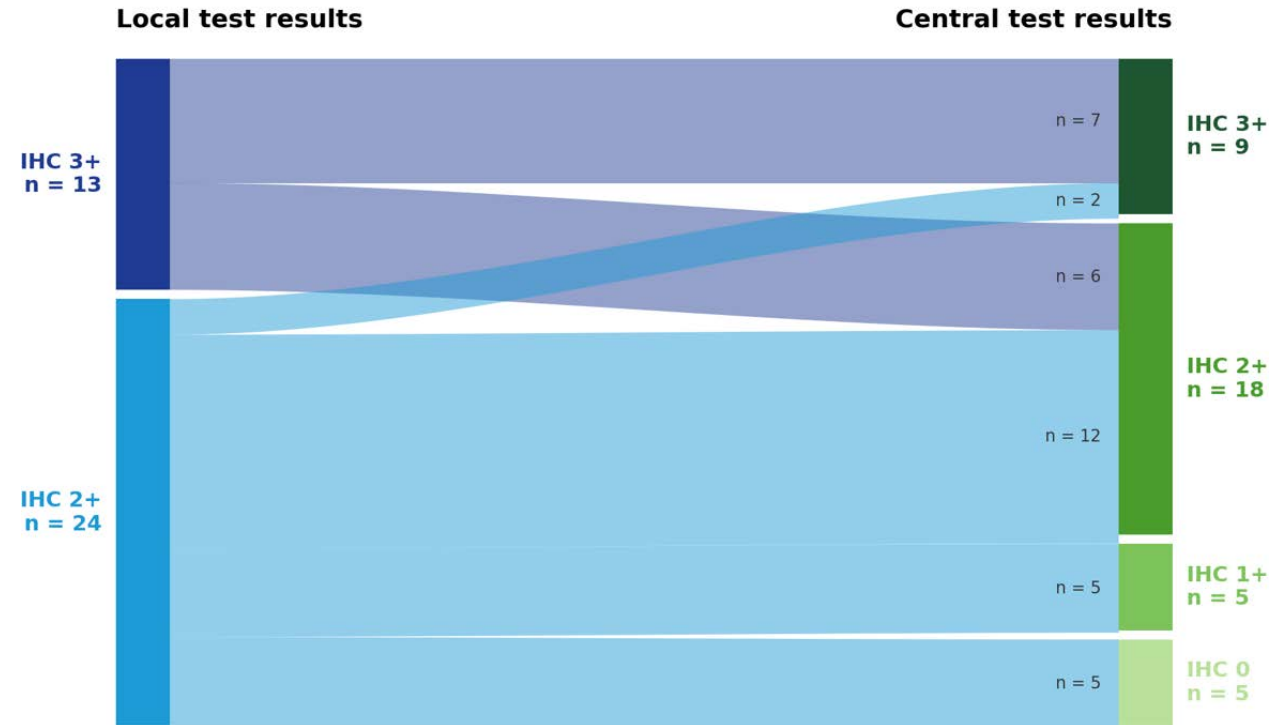
HER2 IHC expression by local vs central review: Ovarian Highlight - DESTINY-PanTumor02



Overall concordance of local and central testing
(Makker et al. Clin Cancer Research 2026)

Ovarian Cancer — HER2 Test Concordance

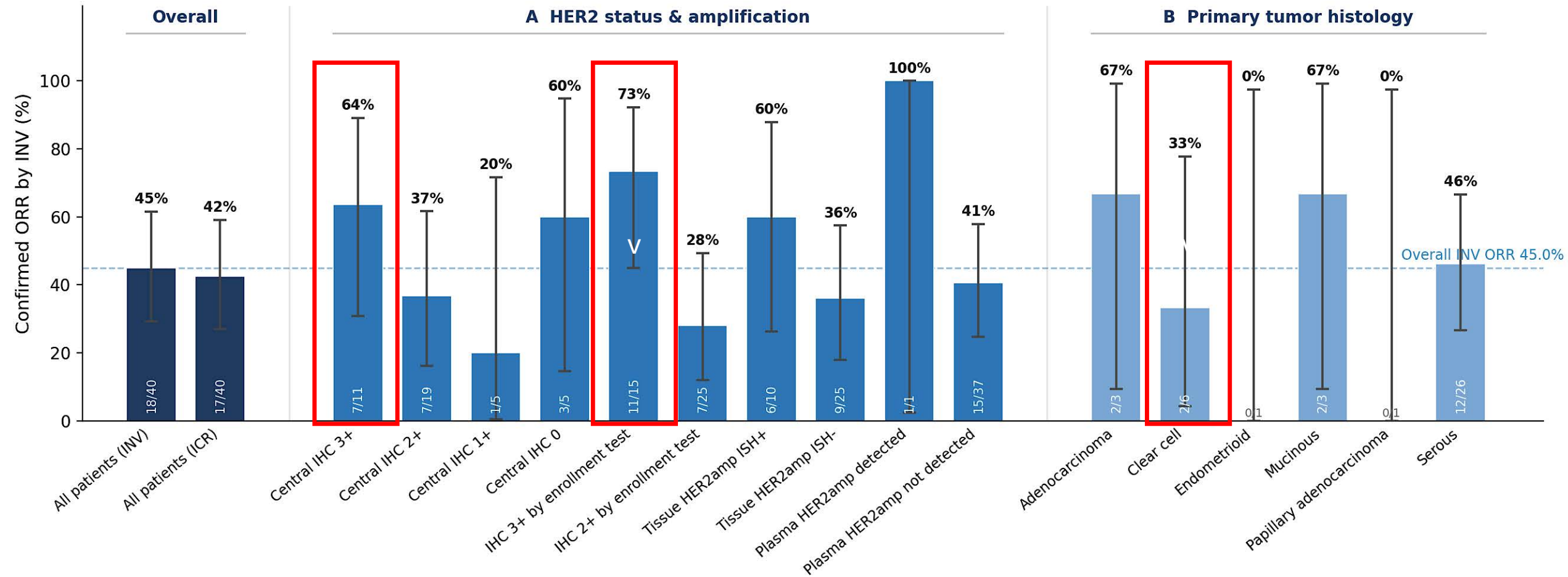
DESTINY-PanTumor02 · local vs central HER2 IHC · n = 37 (19/37 concordant, 51%)



Concordance of local and central testing for ovarian cancer
(Figure derived from Makker et al. Clin Cancer Research 2026)

DESTINY-PanTumor02: Efficacy of T-DXd by local vs central IHC & Histology

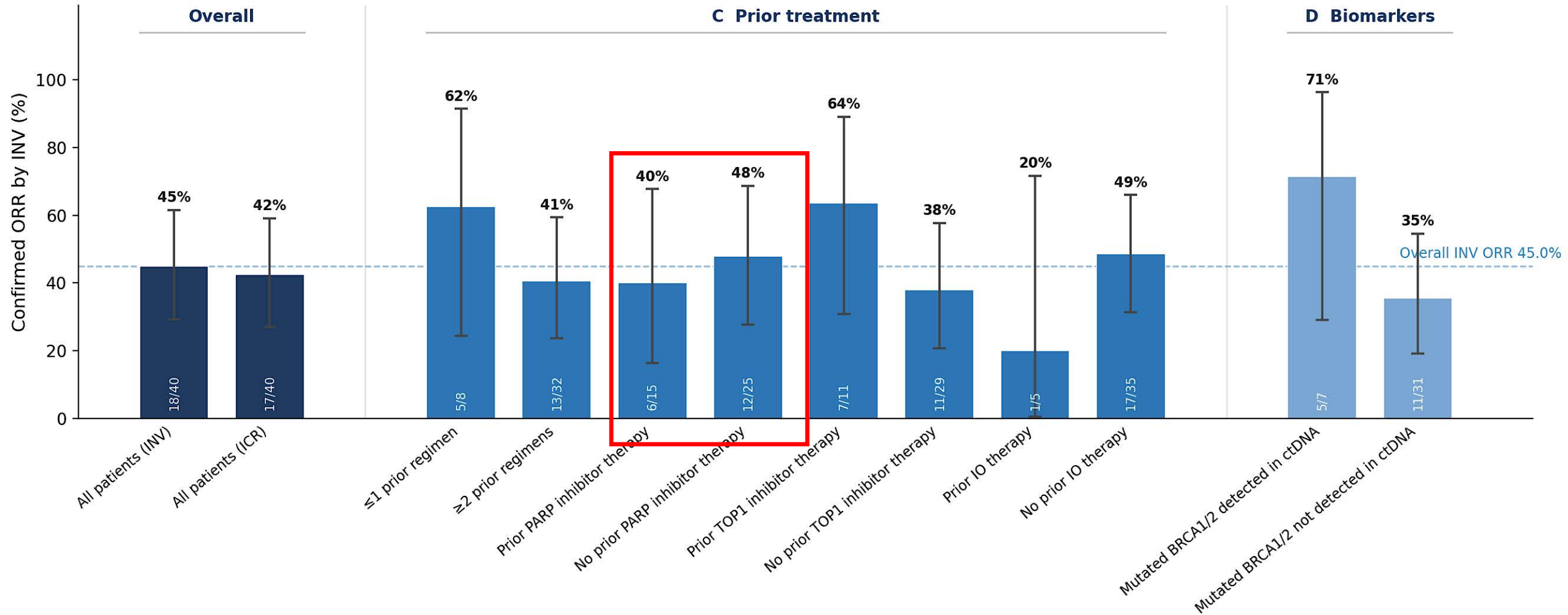
Ovarian cancer (n=40) — HER2 status & histology



Confirmed ORR by INV; error bars are 95% Clopper-Pearson exact CIs; n/N shown below each bar. Dashed line = overall INV ORR (45.0%). HER2amp evaluated centrally (tissue dual ISH; plasma ctDNA GuardantOMNI).

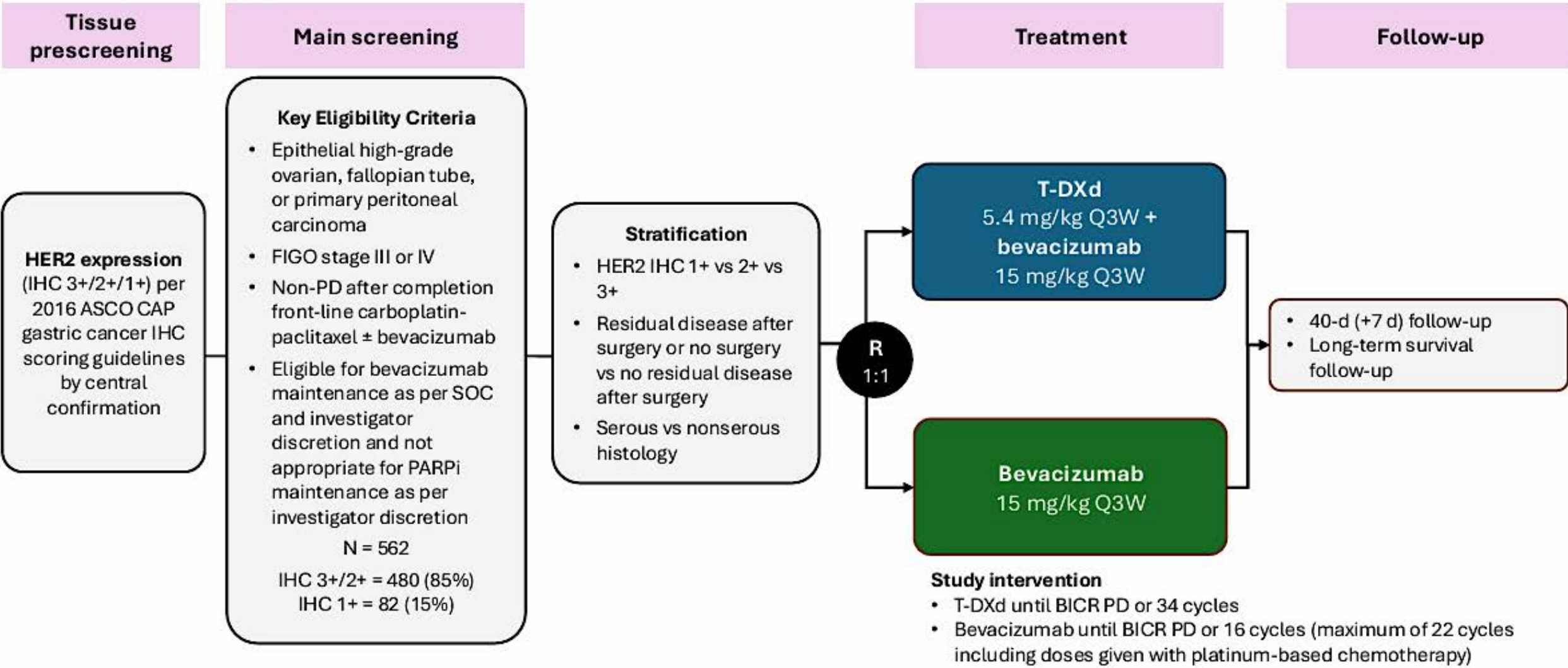
Efficacy by Number of LOT and Prior Lines: What Drives Benefit?

Ovarian cancer (n=40) — Prior treatment & biomarkers



Confirmed ORR by INV; error bars are 95% Clopper-Pearson exact CIs; n/N shown below each bar. Dashed line = overall INV ORR (45.0%). ctDNA BRCA1/2 status measured via GuardantOMNI as a proxy measure.

Phase 3 DESTINY-Ovarian01: T-DXd + Bevacizumab as 1L maintenance therapy in HER2-Expressing Ovarian Cancer¹



DESTINY-Ovarian01 Safety Run-in (SRI)

- 21 pts received a median of 4 cycles (range, 2-8) of T-DXd + BEV; no pt withdrew before cycle 2.
- At data cut-off, 20 pts (95.2%) completed DLT evaluation and remained on treatment; DLTs occurred in 2 pts (10.0%)
- Most common drug-related TEAEs (>50%) were nausea (76.2%), leukopenia (52.4%), and neutropenia (52.4%). No cases of adjudicated drug-related interstitial lung disease or left ventricular dysfunction were reported.

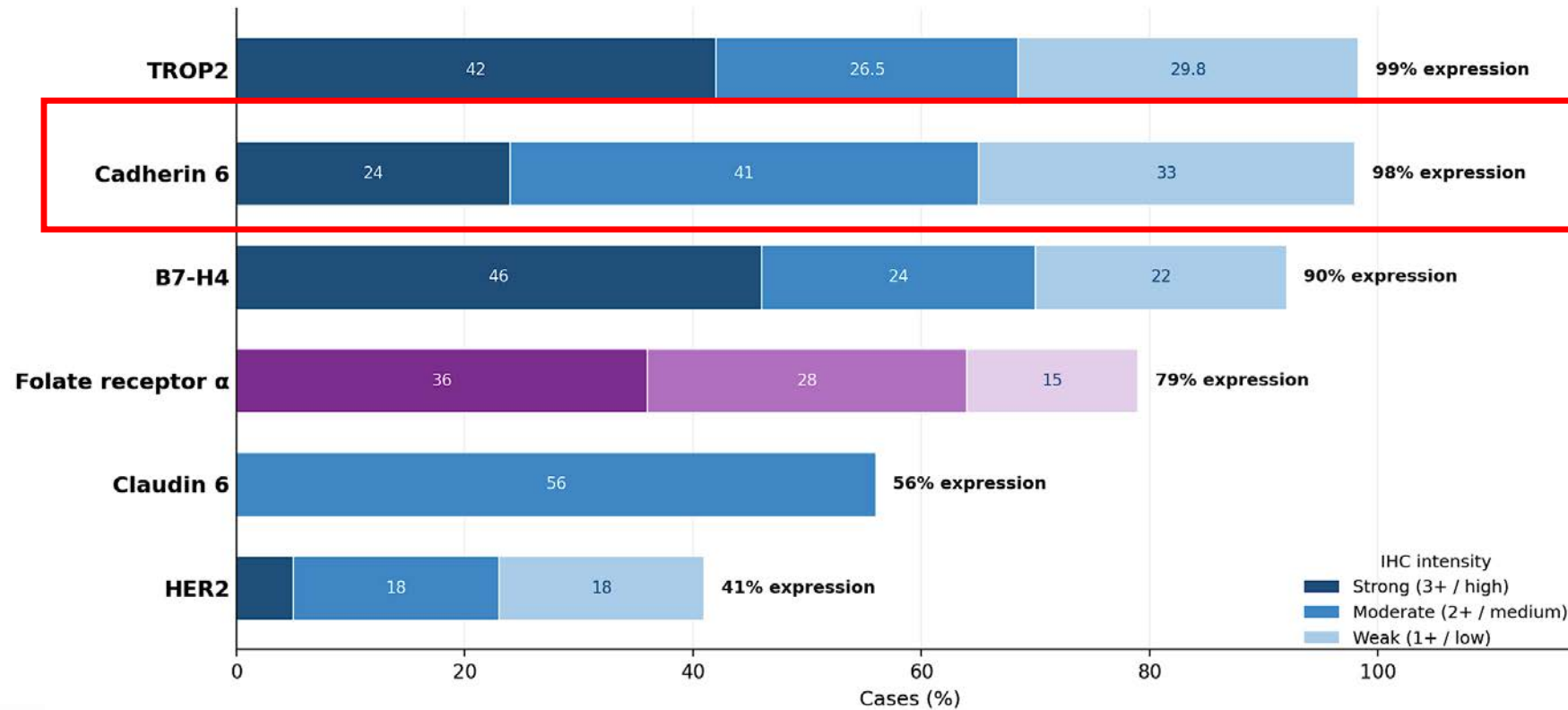
Pts with events, n (%)	T-DXd + BEV N = 21
Drug-related TEAEs	21 (100)
Drug-related grade \geq 3 TEAEs	9 (42.9)
Drug-related TEAEs leading to discontinuation	0
Drug-related TEAEs leading to dose reduction	5 (23.8)
Drug-related TEAEs leading to dose delay	6 (28.6)
TEAEs with outcome of death	0

The Growing Complexity of Biomarkers in Ovarian Cancer

Overlapping targets by any expression and by levels of expression (many not yet validated), with prevalence differing across histotypes

Antibody-Drug Conjugate Target Landscape in HGSOc

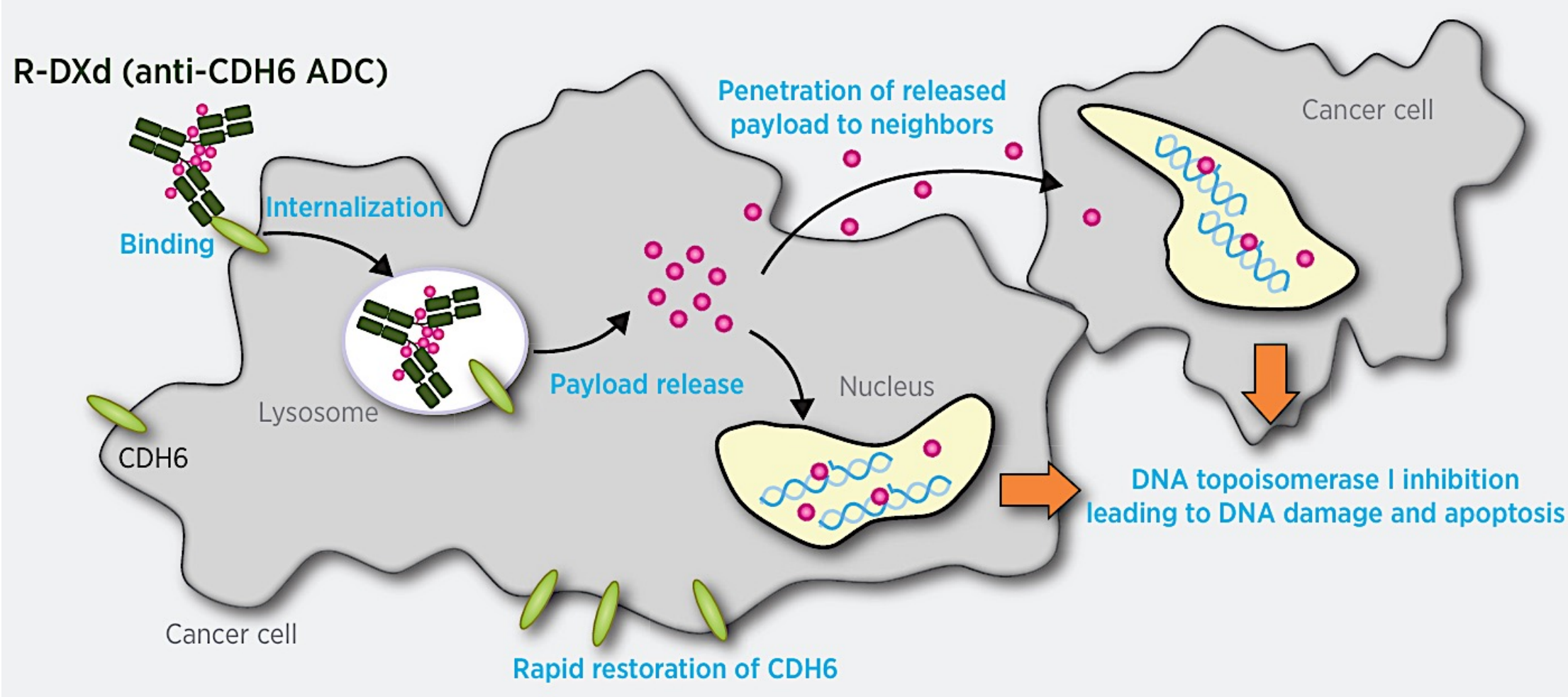
Overall positivity and level of expression across candidate IHC targets — high-grade serous ovarian cancer



Bars stacked by IHC intensity; total expression labeled at right. FR α four-tier intensity (high 36% / medium 28% / low 15% / negative 21%) — 21% negative, so 79% express. Claudin 6 reported as total expression without a full intensity split.

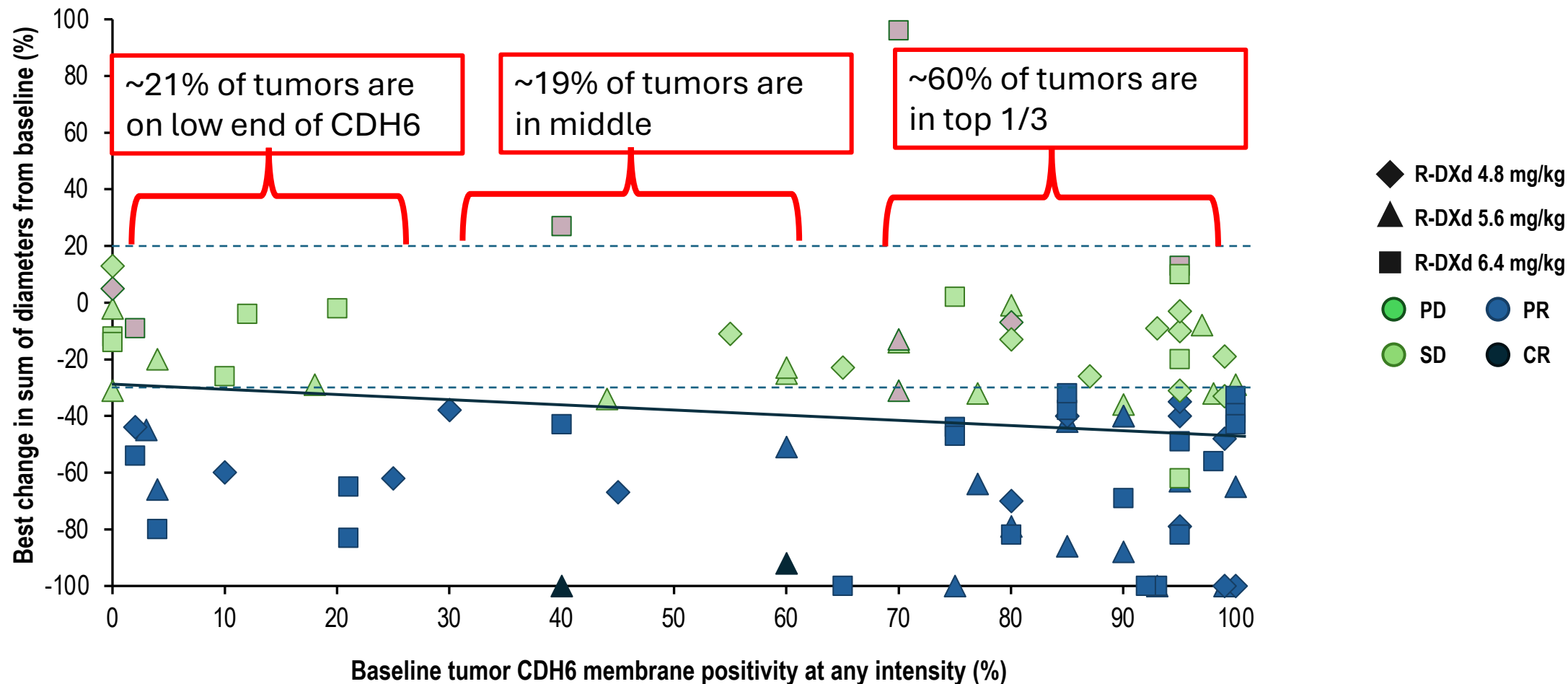


Raludotatug Deruxtecan (R-DXd) Mechanism of Action



ADC = antibody-drug conjugate

Clinically meaningful tumor responses were observed across a range of CDH6 expression levels with raludotatug-deruxtecan (R-DXd)

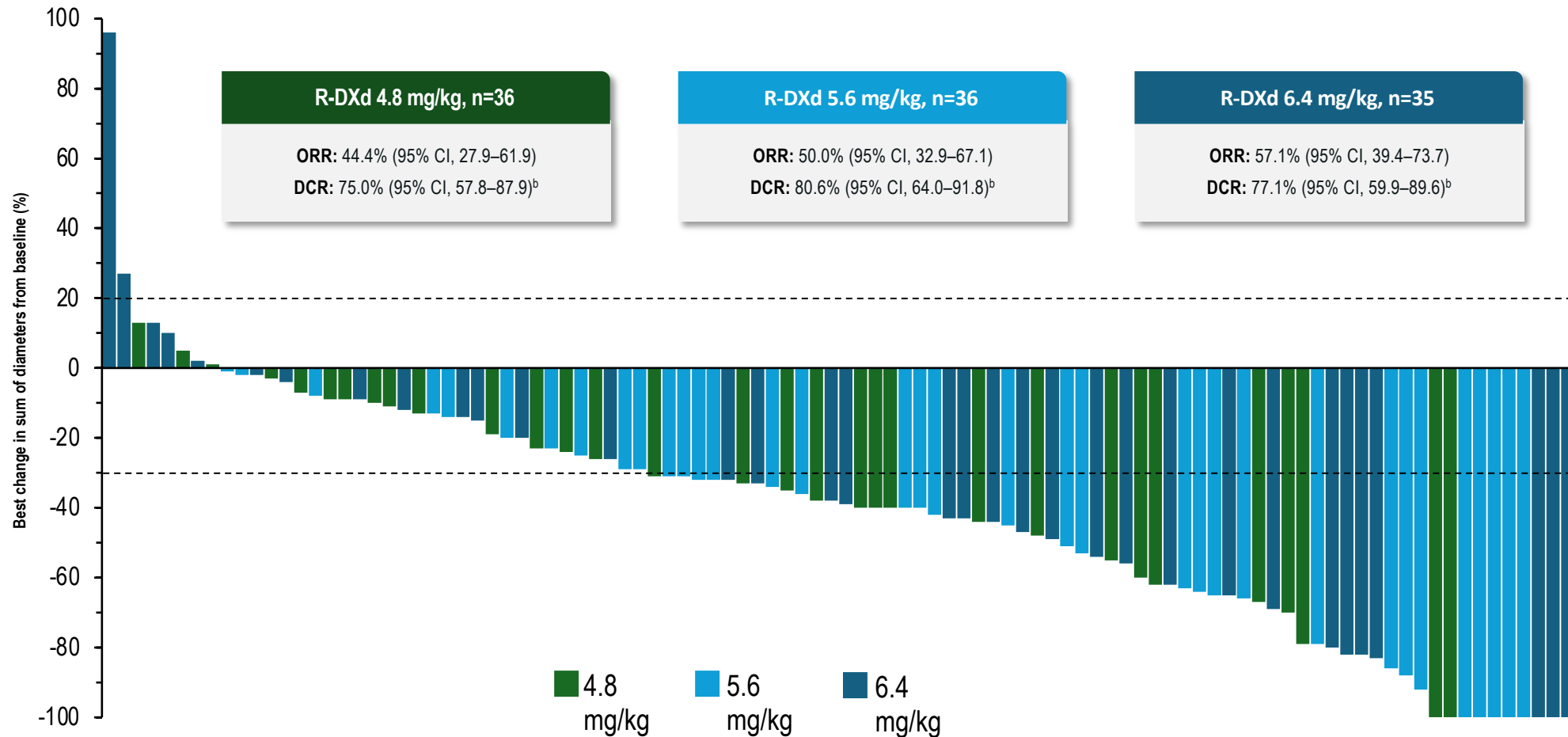


Data cutoff: February 26, 2025. The median follow-up for 4.8-mg/kg, 5.6-mg/kg, and 6.4-mg/kg cohorts was 5.6 months (95% CI, 4.7–6.3), 5.6 months (95% CI, 4.6–5.8), and 5.2 months (95% CI, 4.9–5.8), respectively.

Patients with available baseline tumor CDH6 expression data, who had measurable disease at baseline and ≥ 1 post-baseline tumor scan (assessed by BICR), were included in the scatter plot (n=94).

REJOICE 01: Phase 2

Raludotatug deruxtecan



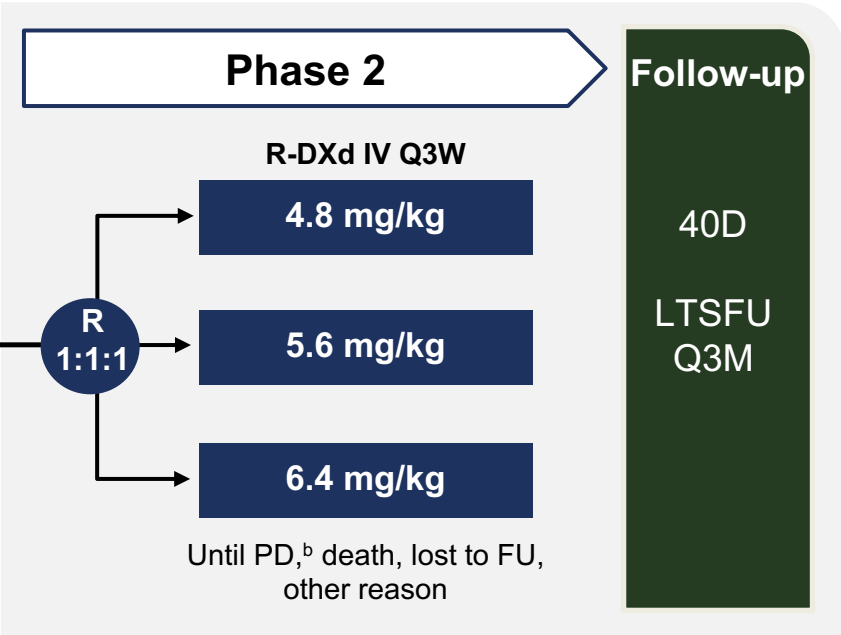
REJOICE-Ovarian01/GOG-3096: Phase 2/3 Randomized Study of R-DXd in Platinum-Resistant EOC

Key eligibility criteria:

- High-grade serous or endometrioid ovarian, primary peritoneal, or fallopian tube cancer
- 1–3 prior LOT (inc. bevacizumab)
- Platinum-resistant disease
- Prior MIRV if high FR α^a
- ECOG PS 0–1
- No prior CDH6-targeting agents or ADCs with linked TOPO I inhibitor
- Patients with primary platinum-refractory disease are not eligible

Stratification:

- Number of prior LOT (1 vs 2/3)
- CDH6 expression (high vs low)
- TPC (paclitaxel vs others; *Ph 3 only*)

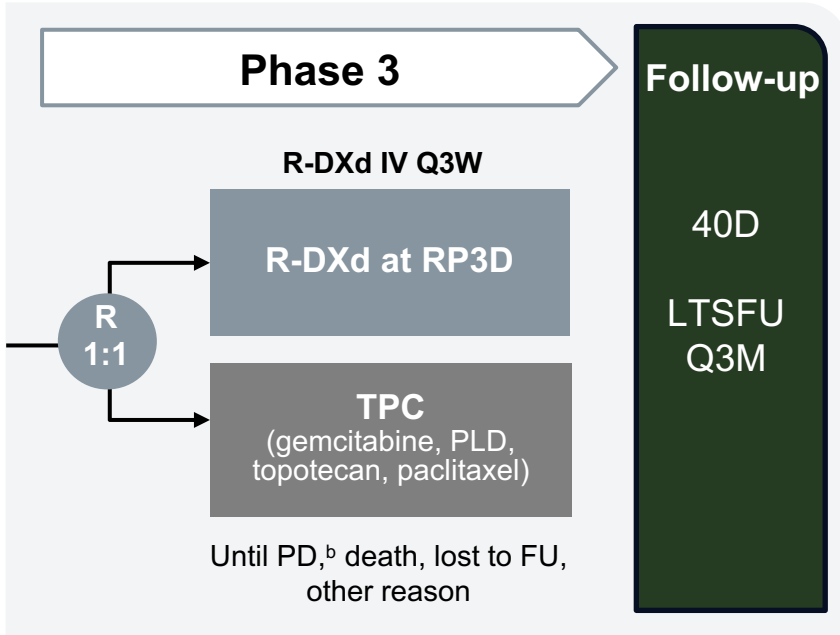


Primary endpoints:

- ORR per BICR^b

Key secondary endpoints:

- ORR per inv^b
- DOR



Primary endpoints:

- ORR per BICR^b
- PFS per BICR^b

Key secondary endpoints:

- OS
- QOL

NCT06161025

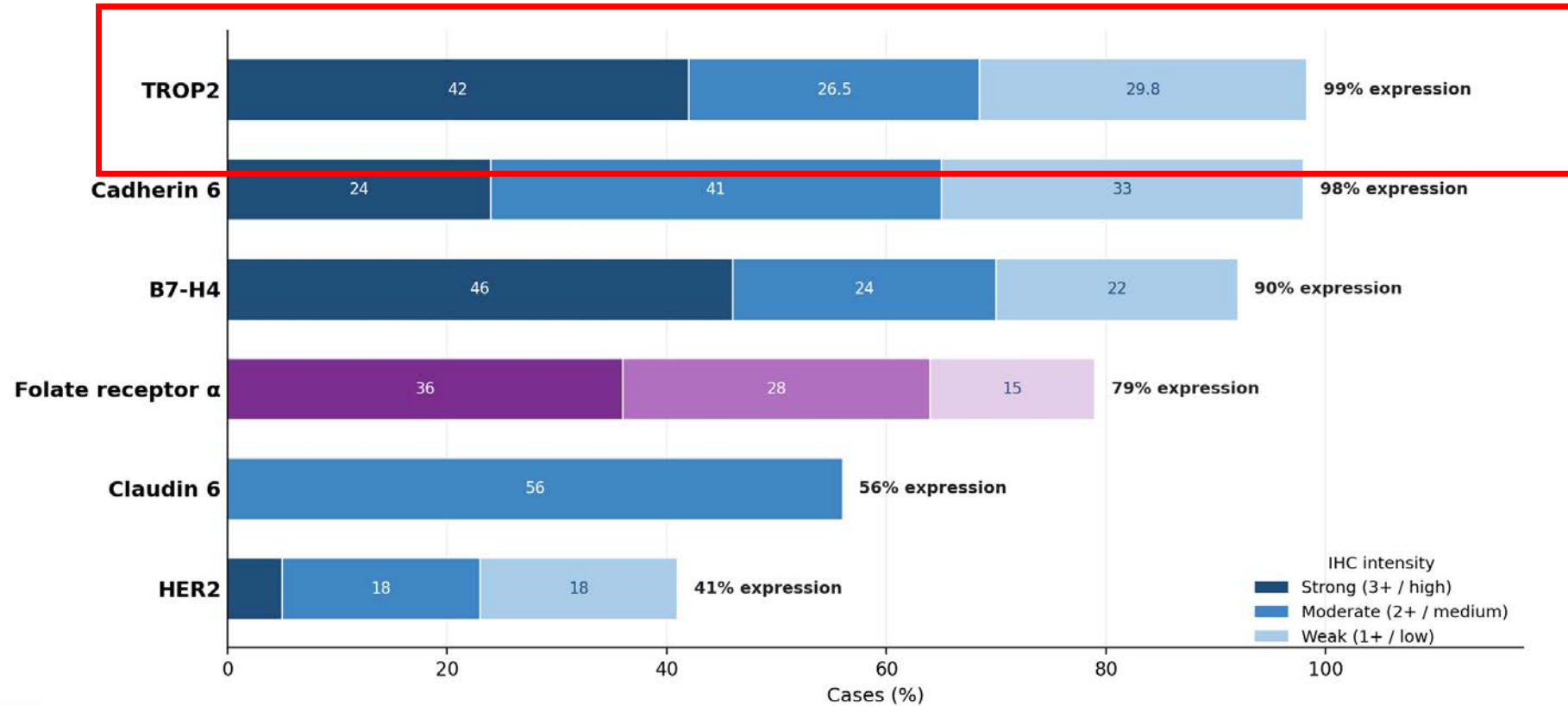


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Overall positivity and level of expression across candidate IHC targets — high-grade serous ovarian cancer



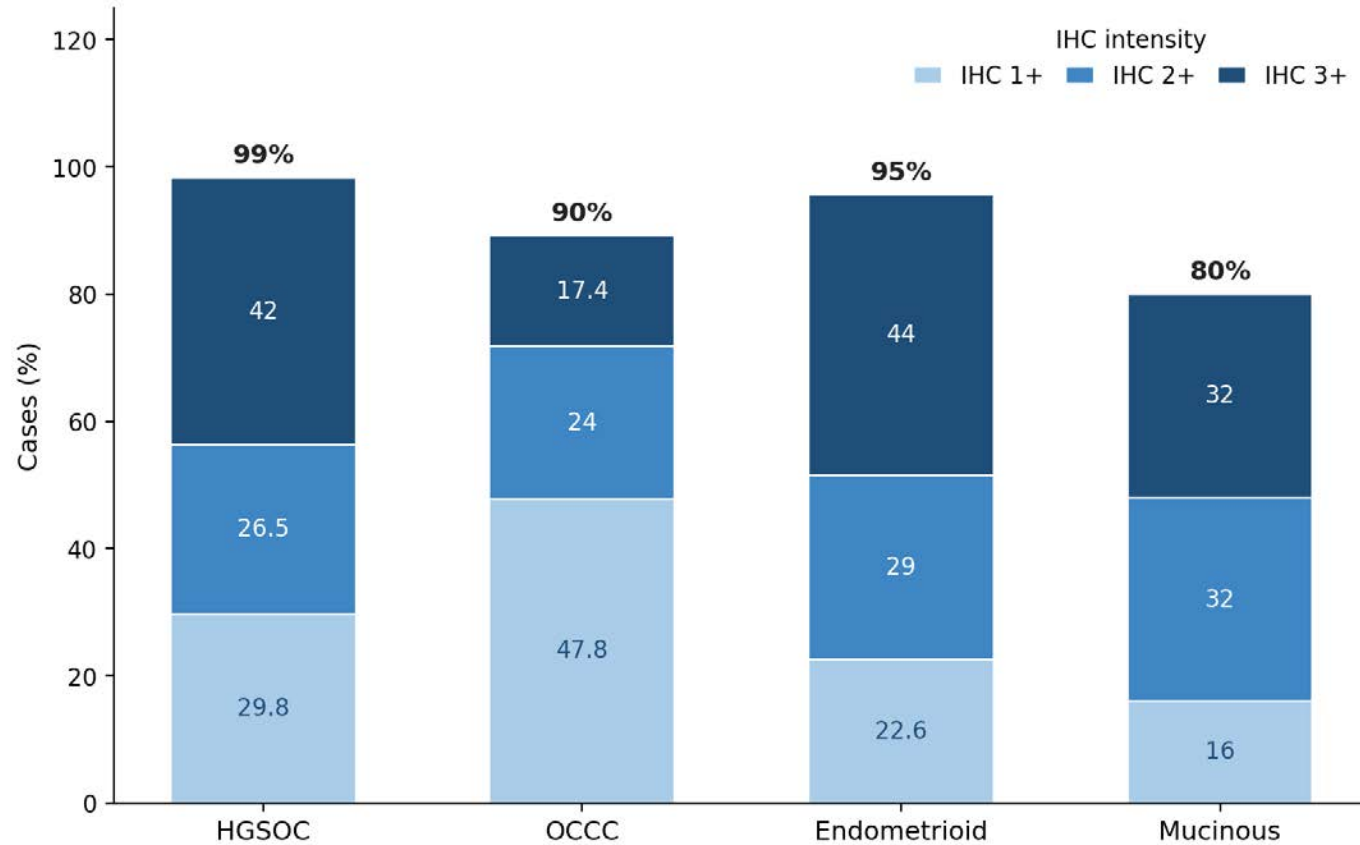
Bars stacked by IHC intensity; total expression labeled at right. FR α four-tier intensity (high 36% / medium 28% / low 15% / negative 21%) — 21% negative, so 79% express. Claudin 6 reported as total expression without a full intensity split.



The Growing Complexity of Biomarkers in Ovarian Cancer

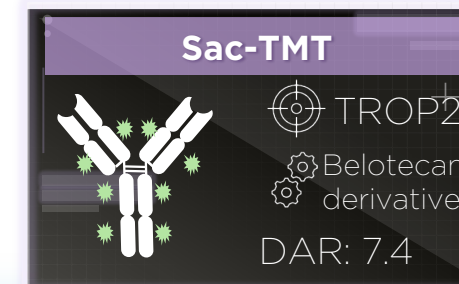
TROP2: Levels of positivity not yet validated/public

TROP2 Expression by IHC Intensity in Ovarian Cancer



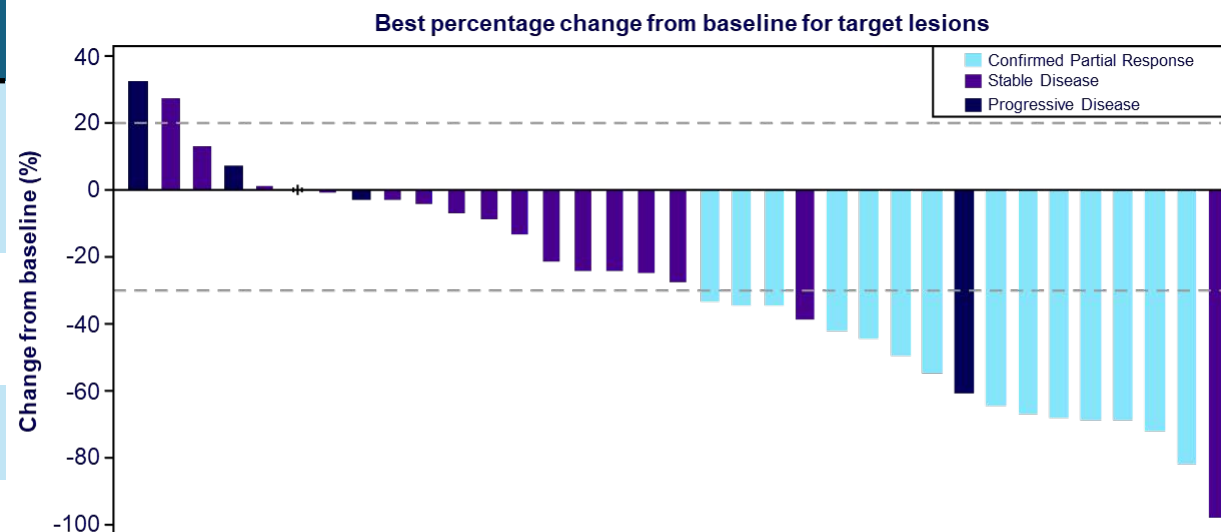
Stacked bars show IHC intensity tiers (1+/2+/3+); total expression labeled above each bar.
LGSOC (n=26): 100% expression, 81% 2+/3+ (full intensity split not reported).

Sacituzumab tirumotecan (Sac-TMT): Antitumour activity and safety profile in OC



	OC (N=40)*
ORR, % (n/N)	40.0 (16/40)
Confirmed ORR	35.0 (14/40)
TROP2 H-score >200	61.5 (8/13)
Platinum-resistant	37.1 (13/35)
DCR, % (n/N)	75.0 (30/40)
PR	40.0 (16/40)
SD	35.0 (14/40)
DOR, % (n/N)	
Median (range), months	5.3 (2.1, 24.4+)
PFS	
Median (95% CI), months	6.0 (3.9, 7.3)

*Responses assessed per RECIST v1.1 by investigator



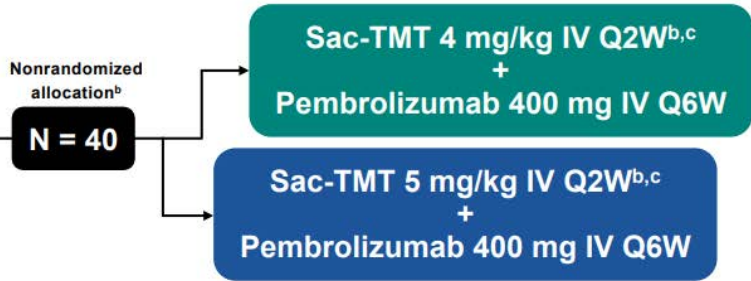
The most common TRAEs were anaemia (**85.0%**), WBC decreased (**60.0%**), and neutrophil count decrease (**57.5%**)

Grade ≥ 3 TEAEs were reported by **67.5%** of participants and led to discontinuation in **12.5%** of participants

Sac-TMT plus Pembrolizumab 4mg/kg q 2W vs 5 mg/kg q 2 w in PSOC

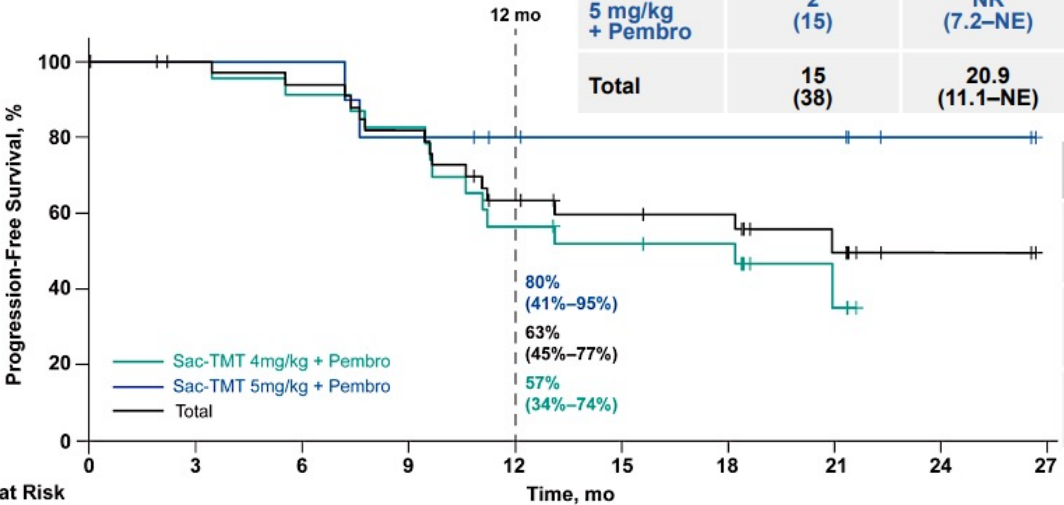
Key Eligibility Criteria for Ovarian Cohort (Cohort C)

- Aged ≥18 y
- Histologically or cytologically confirmed platinum-sensitive, *BRCA* wild-type ovarian cancer, primary peritoneal cancer, or fallopian tube cancer
- 2 prior courses of platinum-containing therapy
- Objective response of CR or PR to the last platinum-based regimen^a; response must be ongoing at time of enrollment
- ECOG PS 0 or 1



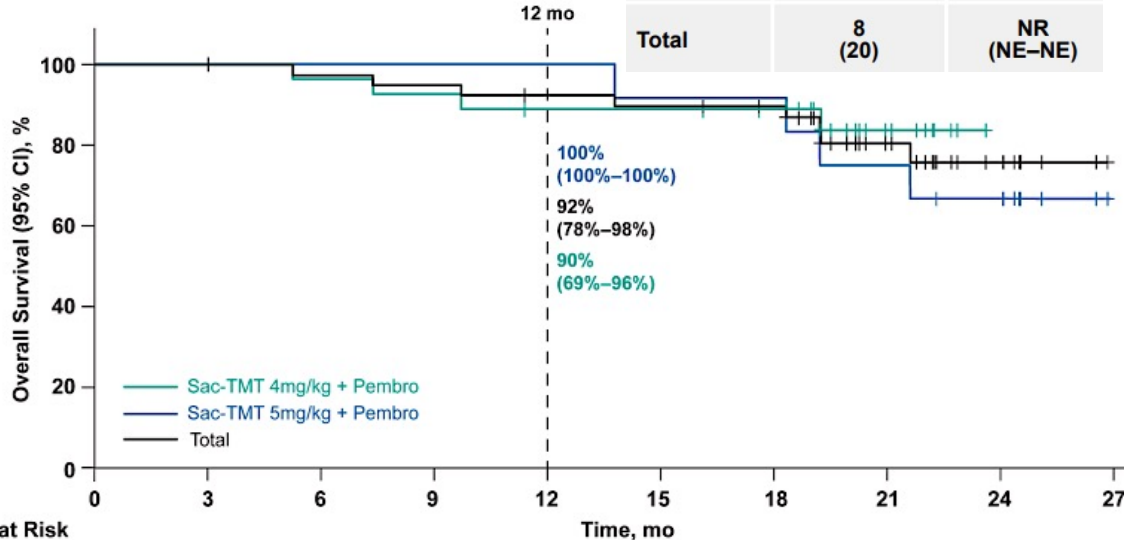
- **Primary endpoints:** include safety (incidence of AEs and AEs that led to discontinuation)
- **Secondary endpoints:** include DCR, DOR, and PFS per RECIST v1.1 and OS

	Events, n (%)	Median (95% CI), mo
Sac-TMT 4 mg/kg + Pembro	13 (48)	18.2 (9.7–NE)
Sac-TMT 5 mg/kg + Pembro	2 (15)	NR (7.2–NE)
Total	15 (38)	20.9 (11.1–NE)



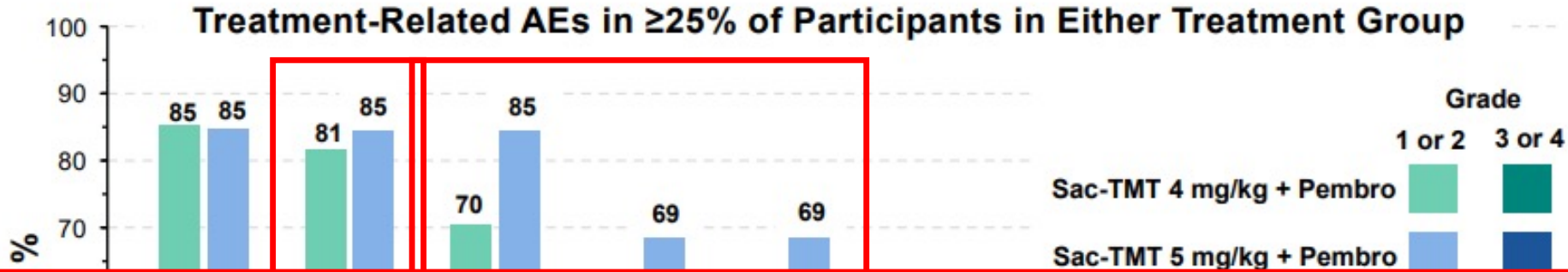
No. at Risk	0	3	6	9	12	15	18	21	24	27
Sac-TMT 4 mg/kg + Pembro	27	23	21	19	13	11	10	3	0	0
Sac-TMT 5 mg/kg + Pembro	13	10	10	8	6	5	5	5	2	0
Total	40	33	31	27	19	16	15	8	2	0

	Events, n (%)	Median (95% CI), mo
Sac-TMT 4 mg/kg + Pembro	4 (15)	NR (NE–NE)
Sac-TMT 5 mg/kg + Pembro	4 (31)	NR (18.3–NE)
Total	8 (20)	NR (NE–NE)

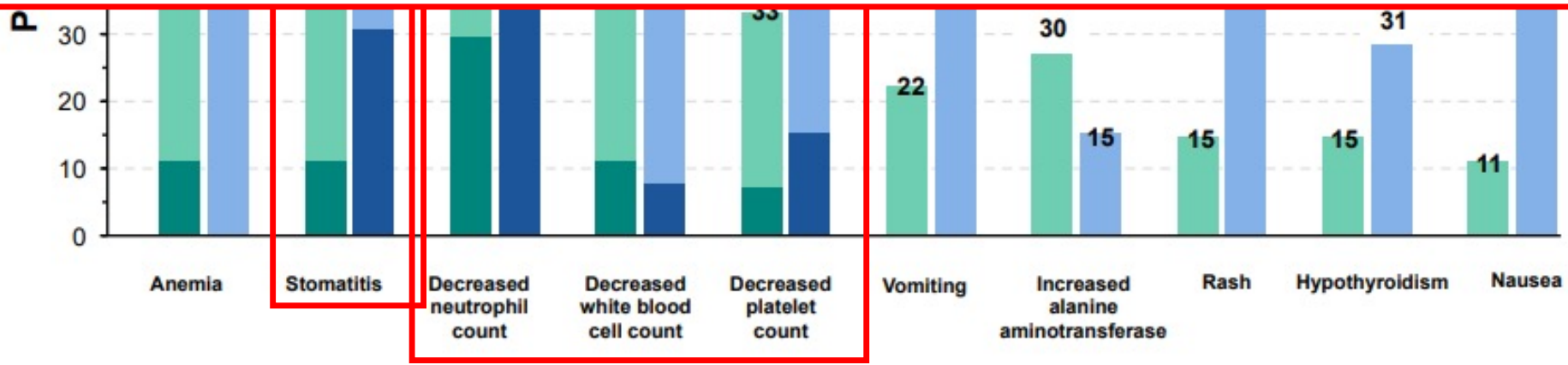


No. at Risk	0	3	6	9	12	15	18	21	24	27
Sac-TMT 4 mg/kg + Pembro	27	27	26	25	23	23	21	9	0	0
Sac-TMT 5 mg/kg + Pembro	13	13	12	12	12	11	11	9	7	0
Total	40	40	38	37	35	34	32	18	7	0

Sac-TMT plus Pembrolizumab 4mg/kg q 2W vs 5 mg/kg q 2 w in PSOC



The global phase 3 studies, TroFuse-021/ENGOTov85/GOG-3102 (NCT07318558) and TroFuse-022/ENGOT-0184/GOG-3103 (NCT06824467) are investigating sac-TMT with or without bevacizumab as maintenance in participants with ovarian cancer

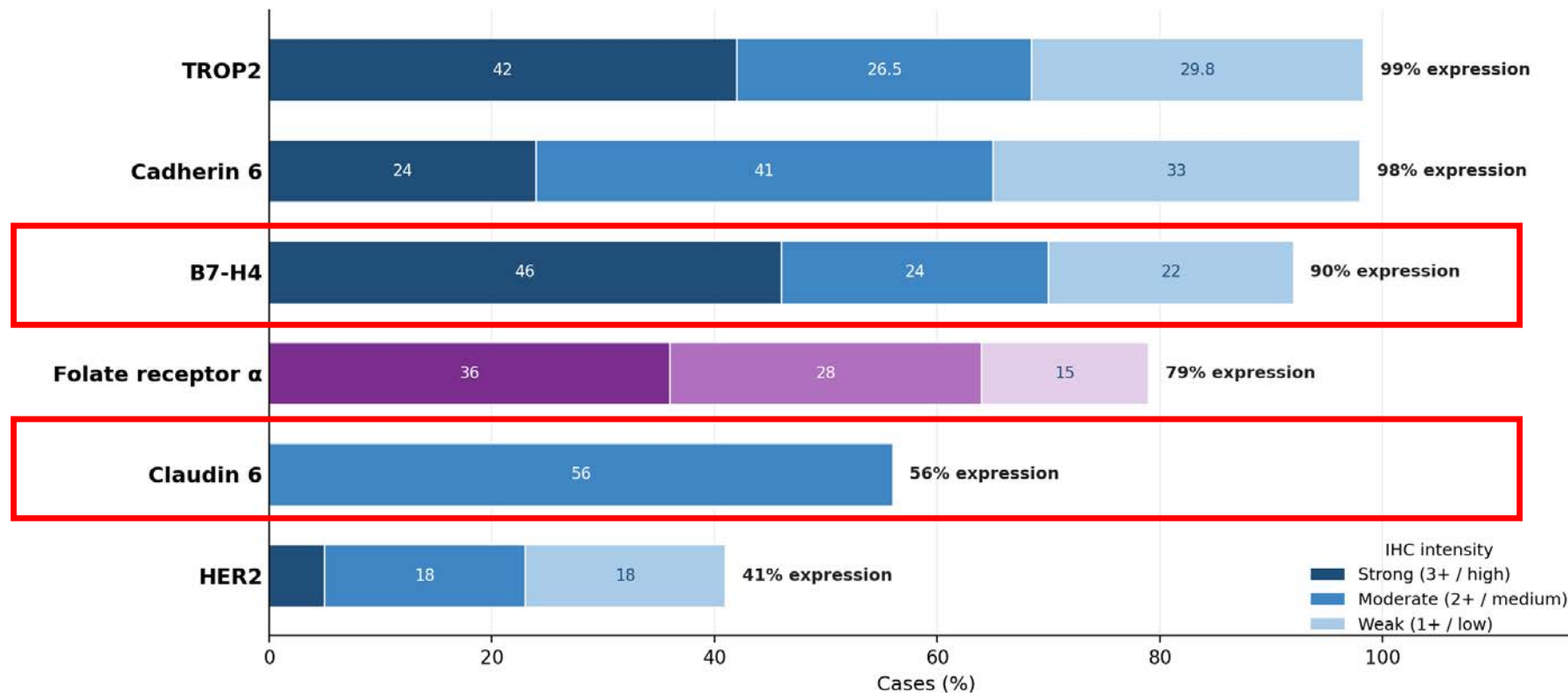


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Overlapping targets by any expression and by levels of expression (many not yet validated), with prevalence differing across histotypes

Antibody-Drug Conjugate Target Landscape in HGSOc

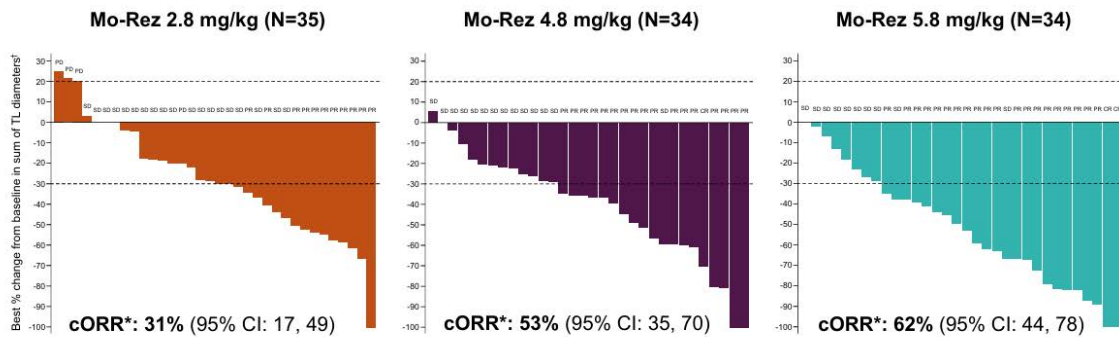
Overall positivity and level of expression across candidate IHC targets — high-grade serous ovarian cancer



Bars stacked by IHC intensity; total expression labeled at right. FR α four-tier intensity (high 36% / medium 28% / low 15% / negative 21%) — 21% negative, so 79% express. Claudin 6 reported as total expression without a full intensity split.

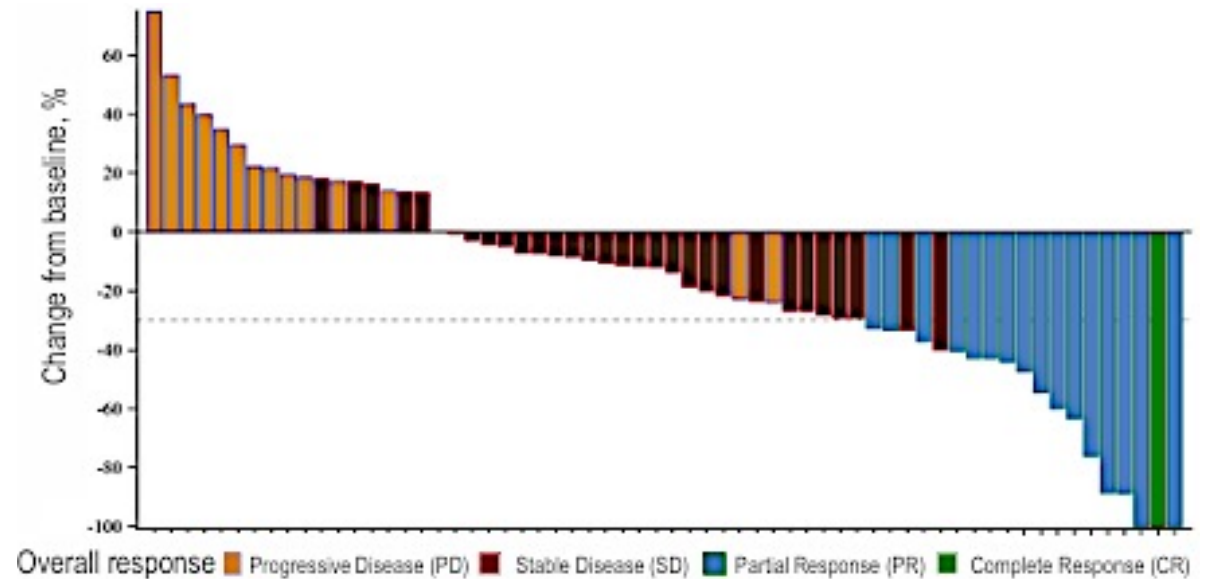
New Agents targeting B7H4 and CLDN6 entering late phase trials

Mocertatug Rezetecan (GSK5733584) in PROC

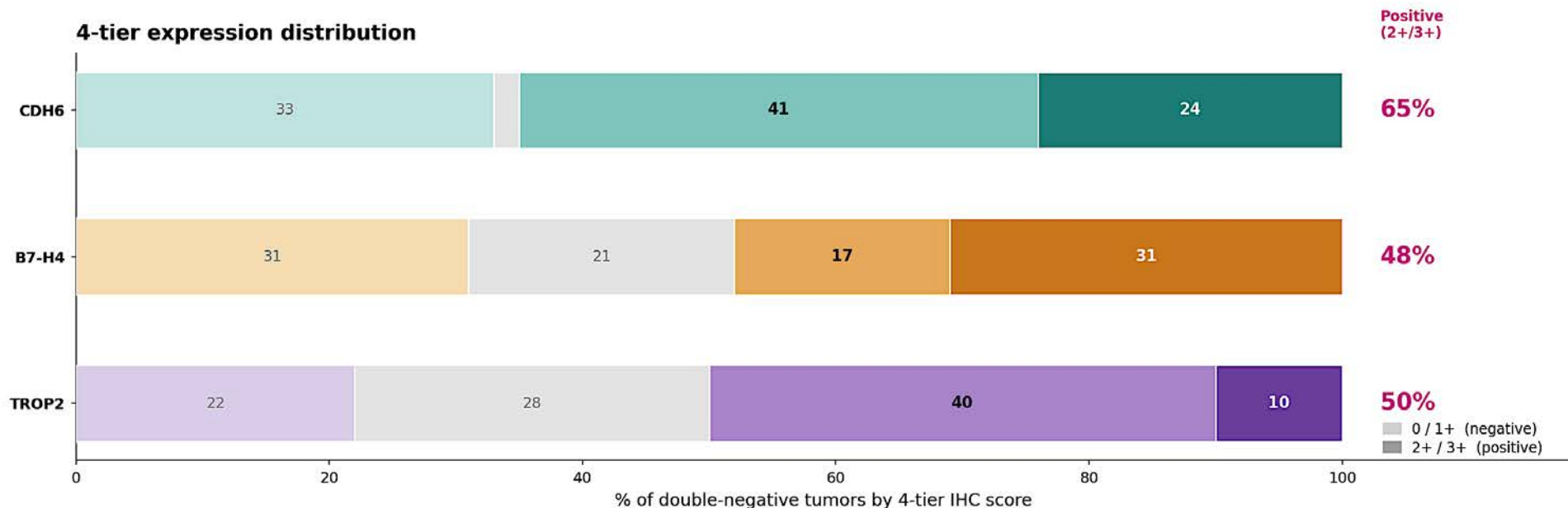


☺ Responses were observed across a range of B7-H4 expression levels

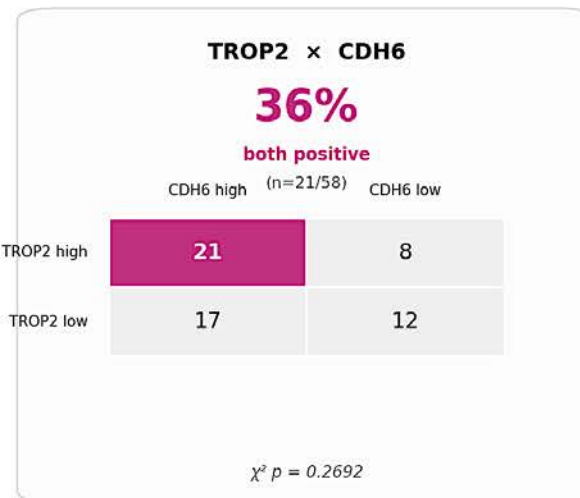
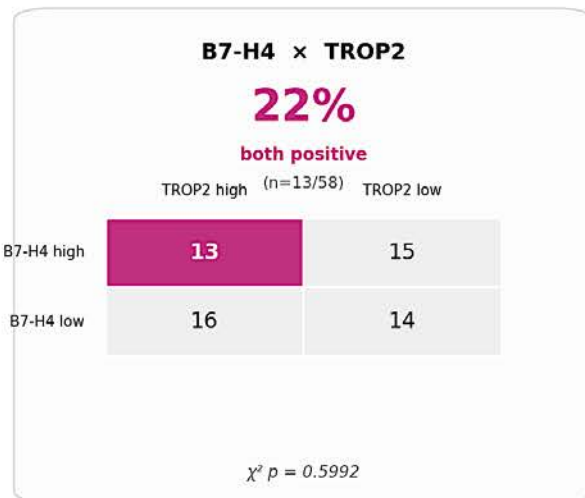
Ixotatug vedotin (TORL-1-23)



CDH6, B7-H4 and TROP2 are frequently expressed — and co-expressed — in FRα-negative / HER2 non-3+ (“double-negative”) ovarian tumors



Pairwise co-expression (high = 2+/3+)



Why it matters

Most double-negative tumors express at least one of these targets, and pairwise co-expression is common.

No pair was mutually exclusive (all p = NS): a tumor positive for one marker is not less likely to express the others — supporting a multi-target strategy.

Conclusions

The efficacy data for ADCs in EOC are compelling.

Mirvetuximab soravtansine has already established FR α -targeted ADCs as standard of care in FR α -positive PROC, and a new wave of Phase 3 trials is poised to extend ADC benefit further in PROC

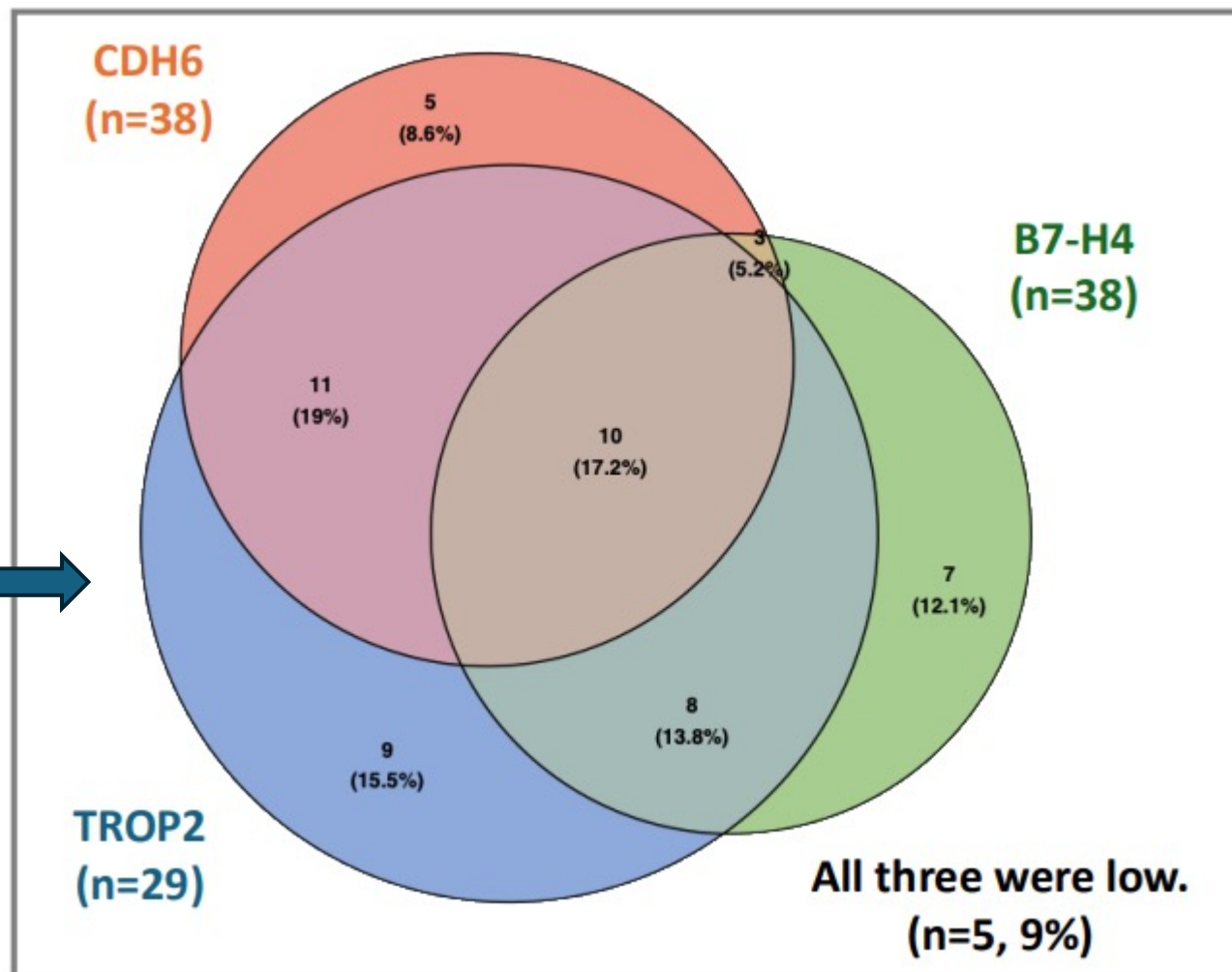
RAINFOL-02: rinatubart sesutecan FR α /topo-1 A

REJOICE-Ovarian01: raludotatug deruxtecan, CDH6/topo-1

Choosing among the topo-1 ADCs will ultimately come down to efficacy, safety, schedule, and tolerability; not target alone.







And because these tumors frequently co-express multiple targets, understanding the *predictive* value of each biomarker becomes critical,

especially if topo-1 ADCs prove to be "one and done," where sequencing one after another offers diminishing returns.



Hamagawa et al. ESMO Gynaecological Cancers 2025

When in the treatment course do you test for HER2 expression in your patients with advanced OC? What testing methodology do you generally use to test for HER2 expression in your patients with advanced OC?

	When do you test?	Testing methodology?
 Prof Eskander	At initial diagnosis	IHC
 Dr Matulonis	At initial diagnosis	IHC
 Dr Moore	At initial diagnosis	IHC
 Dr Olawaiye	At the time of first platinum-resistant relapse	IHC
 Dr O'Malley	At initial diagnosis	IHC
 Prof Colombo	At initial diagnosis	IHC

What threshold for HER2 expression (eg, IHC 3+, IHC 2+, IHC 1+, ISH-amplified) do you require to employ T-DXd for your patients with platinum-resistant advanced OC?



Prof Eskander

IHC 2+ or 3+



Dr Matulonis

IHC 2+ or 3+



Dr Moore

IHC 1+ and higher



Dr Olawaiye

IHC 2+ or 3+



Dr O'Malley

IHC 3+



Prof Colombo

IHC 2+ or 3+

For a patient with advanced OC who is eligible to receive both strategies, how would you generally sequence T-DXd and mirvetuximab soravtansine?



Prof Eskander

Mirvetuximab soravtansine → T-DXd



Dr Matulonis

Mirvetuximab soravtansine → T-DXd



Dr Moore

Mirvetuximab soravtansine → T-DXd



Dr Olawaiye

Mirvetuximab soravtansine → T-DXd



Dr O'Malley

Mirvetuximab soravtansine → T-DXd



Prof Colombo

T-DXd → mirvetuximab soravtansine

If R-DXd were available today, would you be comfortable using it in sequence with other antibody-drug conjugates currently employed in advanced OC?



Prof Eskander

Yes, both mirvetuximab soravtansine and T-DXd



Dr Matulonis

Yes, only mirvetuximab soravtansine



Dr Moore

Yes, only mirvetuximab soravtansine



Dr Olawaiye

Yes, only mirvetuximab soravtansine



Dr O'Malley

Yes, only mirvetuximab soravtansine



Prof Colombo

Yes, only mirvetuximab soravtansine

How would you indirectly compare the rates and severity of interstitial lung disease (ILD) with R-DXd to those with T-DXd for patients with advanced OC?



Prof Eskander

ILD is about the same



Dr Matulonis

ILD is worse with T-DXd



Dr Moore

ILD is worse with T-DXd



Dr Olawaiye

ILD is worse with T-DXd



Dr O'Malley

ILD is about the same



Prof Colombo

ILD is worse with T-DXd

Agenda

Module 1: Current Role of PARP Inhibitors in the Management of Advanced Ovarian Cancer (OC) — Prof Eskander

Module 2: Strategies Targeting Folate Receptor Alpha in Advanced OC — Dr Matulonis

Module 3: Other Approved and Promising Investigational Antibody-Drug Conjugates for Advanced OC — Dr Moore

Module 4: Other Novel Agents and Strategies for Advanced OC — Dr O'Malley

Module 5: Diagnosis and Management of Adverse Events Associated with Common Therapies for Advanced OC — Dr Olawaiye

Other Novel Agents and Strategies for Advanced Ovarian Cancer

David O'Malley, MD

Director for Translational and Clinical Research Partnerships at OSUCCC

Leader of Clinical Trial Innovation in the Center for Cancer Innovation

Professor, Division of Gyn Oncology in OB/Gyn

John G. Boutselis Chair in Gynecologic Oncology

Co-Director, Gyn Oncology Phase I Program

Ovarian Cancer Portfolio Lead, GOG-P

BOD, GOG Foundation

The James



THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER



Creating a cancer-free world. One person, one discovery at a time.



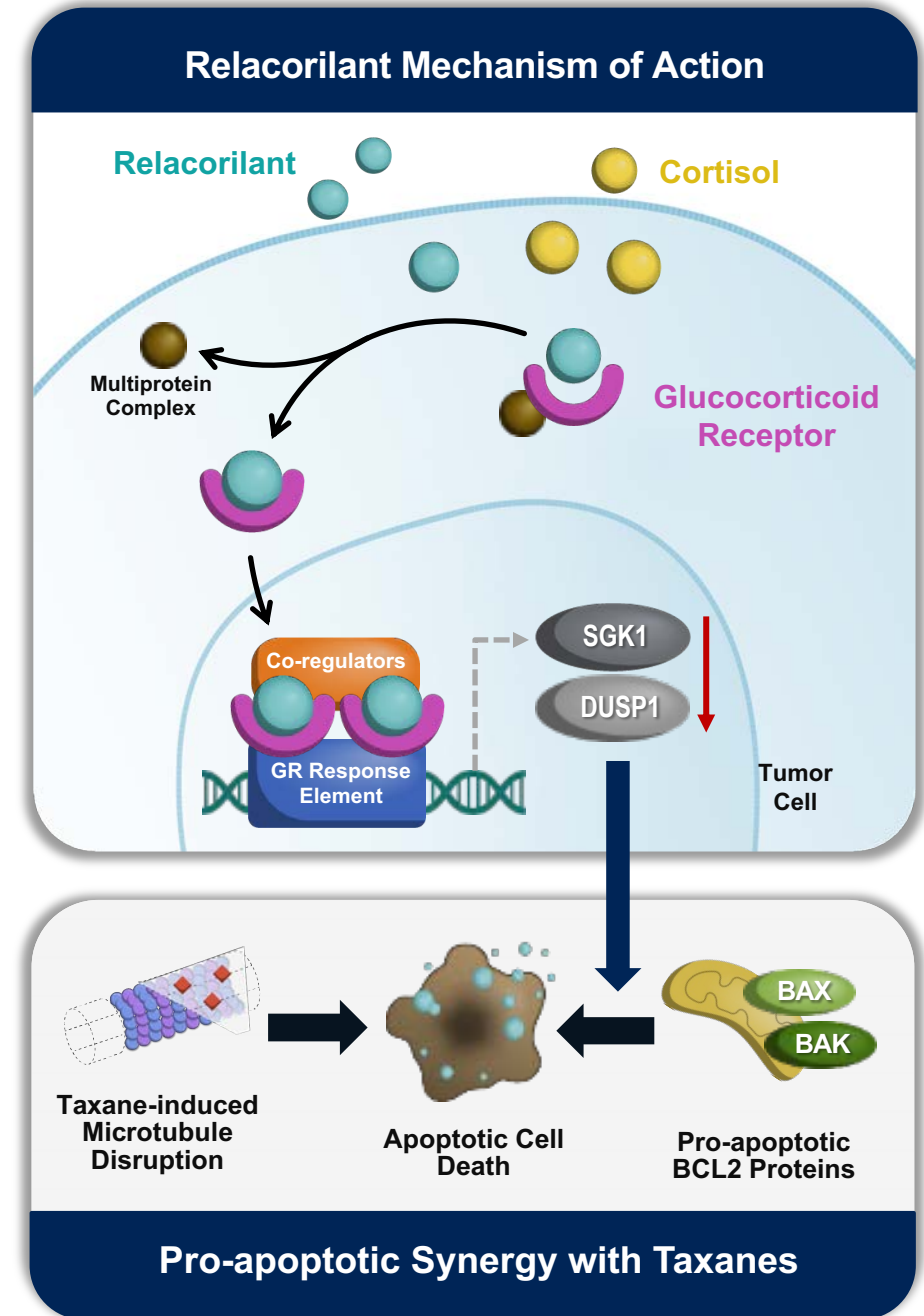
Strategies for Advanced OC Treatment

- ROSELLA (nab-paclitaxel +/- relacorilant)
- KEYNOTE-B96 (paclitaxel +/- Bev +/- pembro)
- Other promising novel agents (Other Than ADCs)

Background

- Patients with platinum-resistant ovarian cancer have an overall survival of ~1 year and need new treatments¹
- Ovarian cancers express the glucocorticoid receptor (GR), a marker of poor prognosis²
- GR signaling reduces sensitivity to chemotherapy^{3,4}
- Relacorilant is a novel, selective GR antagonist (SGRA) that restores the sensitivity of cancers to cytotoxic chemotherapy^{3,5,6}

1. Martorana, et al. *Int J Gynecol Cancer*. 2025;35(1):100009. 2. Veneris, et al. *Gynecol Oncol*. 2017;146(1):153-60.
3. Greenstein, et al. *Oncotarget*. 2021;12(13):1243-55. 4. Melhelm, et al. *Clin Cancer Res*. 2009;15(9):3196-3204.
5. Stringer-Reasor, et al. *Gynecol Oncol*. 2015;138(3):656-62. 6. Munster, et al. *Clin Cancer Res*. 2022;28(15):3214-24.

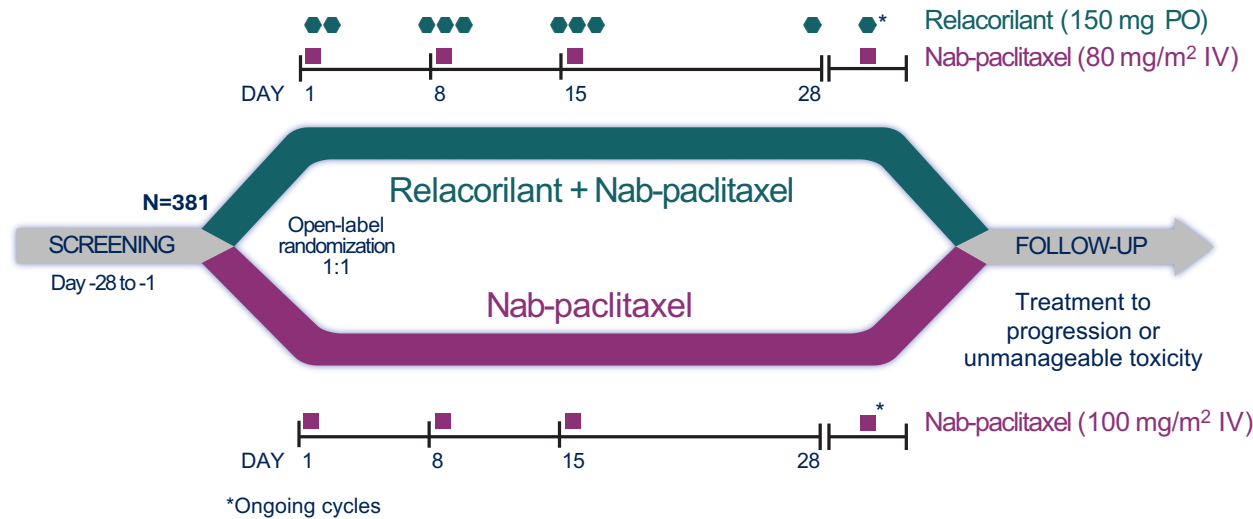


ROSELLA | Study Schema

Population

- Epithelial ovarian, primary peritoneal, or fallopian tube cancer
- ECOG performance status 0 or 1
- Progression <6 months after the last dose of platinum therapy (excluding no response to, or progression in <1 month of primary platinum)
- 1–3 prior lines of therapy
- Prior bevacizumab required

[NCT05257408](#)



Stratification Factors

- ▶ Prior lines of therapy (1 vs >1)
- ▶ Region (North America vs Europe vs Korea, Australia, & Latin America)

Dual Primary Endpoints

- Progression-free survival (PFS) by RECIST v1.1 per blinded independent central review
- Overall survival (OS)

Secondary Endpoints

- PFS by RECIST v1.1 per Investigator
- ORR, DoR, CBR (RECIST v1.1)
- Response by CA-125 GCIG criteria
- Combined response (RECIST v1.1 and CA-125 GCIG criteria)
- Safety

First patient enrolled: Jan 5, 2023
 Last patient enrolled: Apr 8, 2024
 Primary results data cutoff: Feb 24, 2025
 Final OS data cutoff: Jan 8, 2026
 Conducted at 117 sites in 14 countries.

CA, cancer antigen; CBR, clinical benefit rate; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; GCIG, Gynecologic Cancer Intergroup; IV, intravenous; ORR, objective response rate; PO, by mouth; RECIST, Response Evaluation Criteria in Solid Tumors.

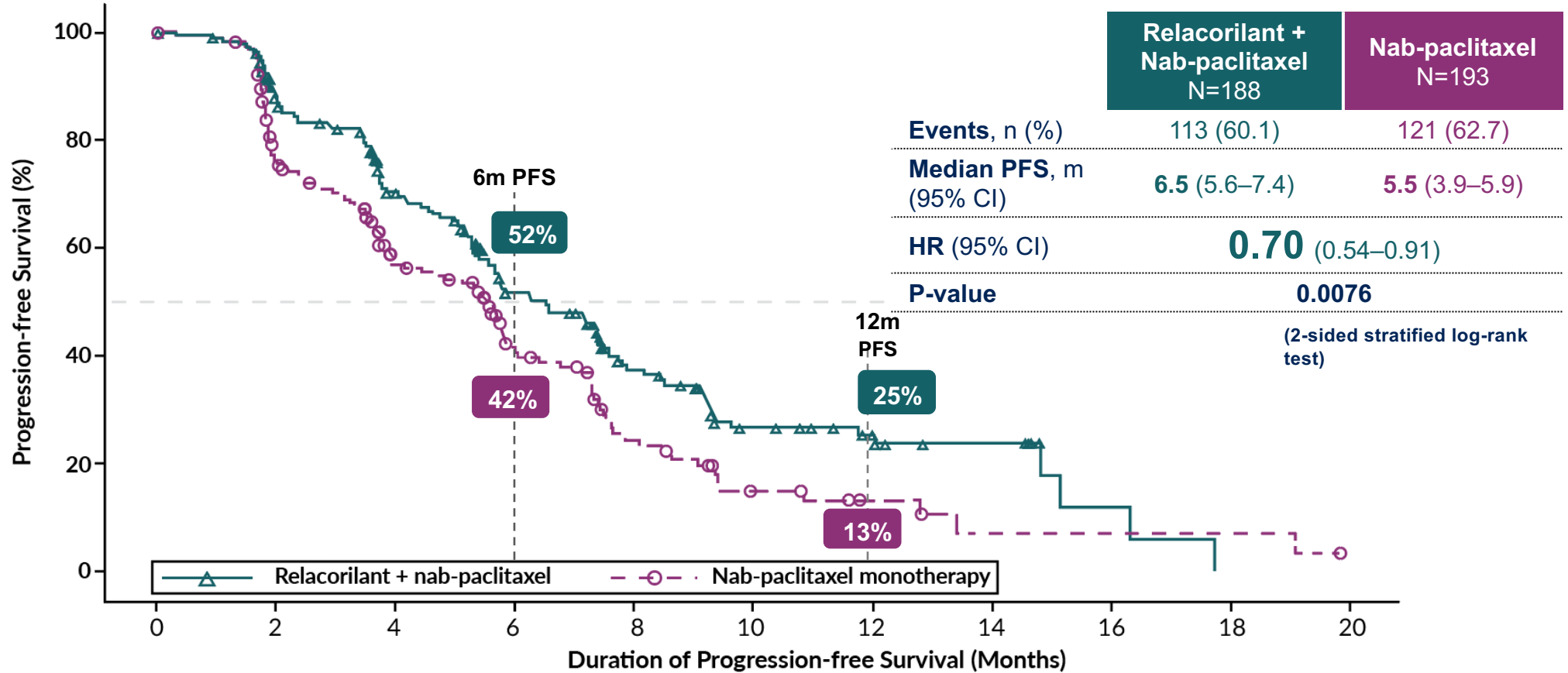
ROSELLA - Demographics

		Relacorilant + Nab-paclitaxel (N=188)	Nab-paclitaxel (N=193)
Age, median (range), years		61 (26–85)	62 (33–86)
Race, n (%)	White	136 (72.3)	135 (69.9)
	Black or African-American	3 (1.6)	2 (1.0)
	Asian (92% Korean)	22 (11.7)	26 (13.5)
	Other / Not Reported	27 (14.4)	30 (15.5)
Ethnicity, n (%)	Hispanic	16 (8.5)	17 (8.8)
Region	North America	45 (23.9)	45 (23.3)
	Europe	107 (56.9)	109 (56.5)
	Korea, Australia, and Latin America	36 (19.1)	39 (20.2)
ECOG Performance Status, n (%)*	1 or 2	53 (28.2)	63 (32.6)
BRCA1/2 Mutation, n (%)	Yes	23 (12.2)	24 (12.4)
Prior Lines of Therapy, n (%)	1	15 (8.0)	18 (9.3)
	2	92 (48.9)	89 (46.1)
	3	81 (43.1)	86 (44.6)
Primary Platinum Refractory, n (%)†	Yes	13 (6.9)	13 (6.7)
Prior Lines of Therapy in the Platinum-resistant Setting, n (%)	≥1	67 (35.6)	82 (42.5)
Prior Taxane in the Platinum-resistant Setting, n (%)	Yes	8 (4.3)	7 (3.6)
Prior Therapies, n (%)	Bevacizumab	188 (100)	193 (100)
	Taxanes	187 (99.5)	192 (99.5)
	Pegylated Liposomal Doxorubicin	121 (64.4)	125 (64.8)
	PARP Inhibitor	114 (60.6)	120 (62.2)

*In the nab-paclitaxel monotherapy arm, 1 patient had an ECOG performance status of 2. †Progressed within 3 months of the last dose of platinum from their first line platinum regimen. 97% of patients had high-grade serous carcinoma; 8 patients had high-grade endometrioid carcinoma and 2 patients had carcinosarcoma. BRCA, Breast Cancer Gene; ECOG, Eastern Cooperative Oncology Group; PARP, poly(ADP-ribose) polymerase.

Data cutoff: Feb 24, 2025

ROSELLA | Progression-Free Survival – BICR (Primary Analysis)

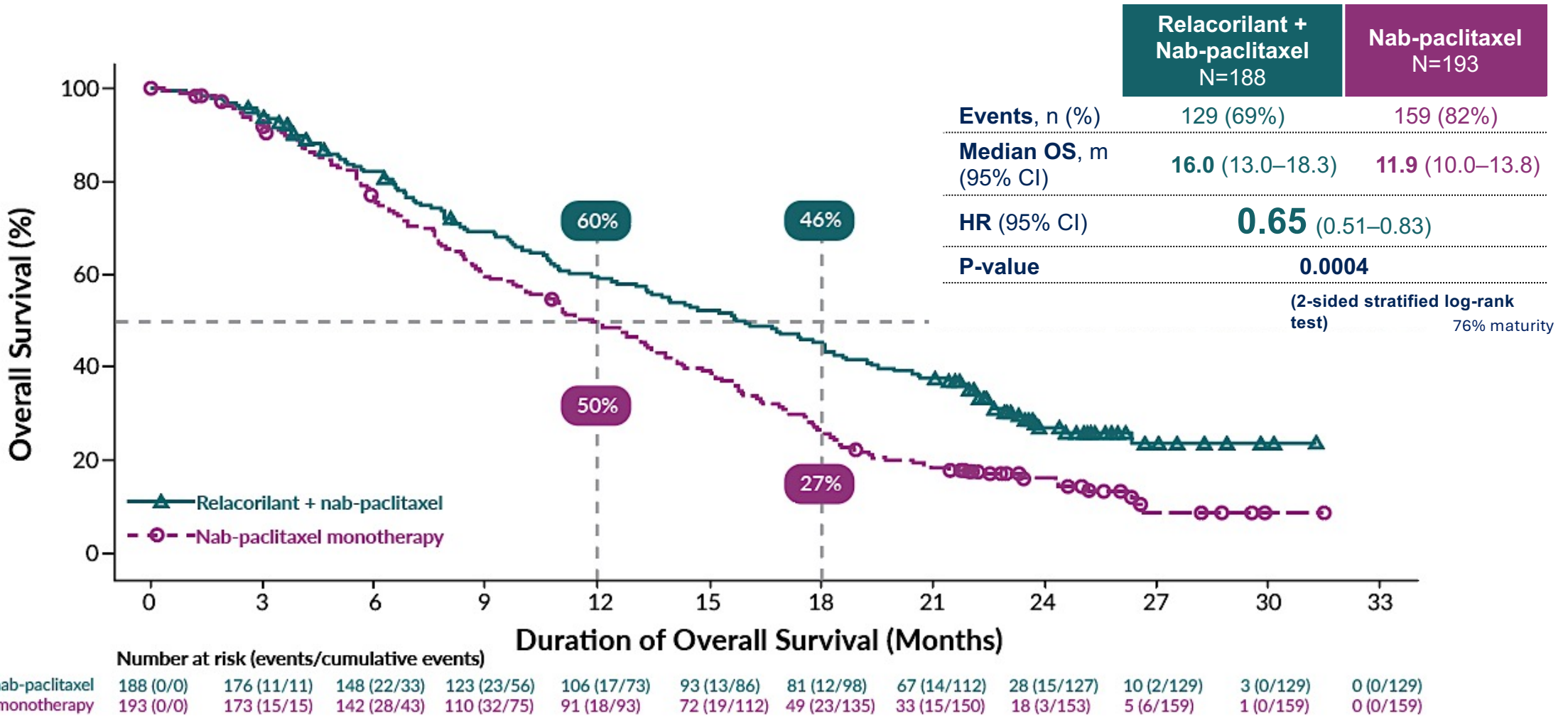


	No. at risk (events/cumulative events)										
Relacorilant + nab-paclitaxel	188 (0/0)	151 (22/22)	109 (29/51)	70 (27/78)	43 (18/96)	24 (11/107)	16 (1/108)	11 (1/109)	2 (2/111)	0 (2/113)	
Nab-paclitaxel monotherapy	193 (0/0)	129 (42/42)	85 (31/73)	47 (20/93)	21 (17/110)	9 (7/117)	5 (1/118)	2 (2/120)	2 (0/120)	2 (0/120)	0 (1/121)

Median follow-up time: 9.0 months; statistical significance threshold: $P \leq 0.04$. The Kaplan–Meier method was used to estimate the curves, median estimates and the 95% CIs for progression-free survival in each treatment arm. The HR and the associated 95% CI were estimated using a Cox regression model with treatment group as the main effect and stratification factors at randomization as covariates. CI, confidence interval; HR, hazard ratio; m, months; PFS, progression-free survival.

Data cutoff: Feb 24, 2025

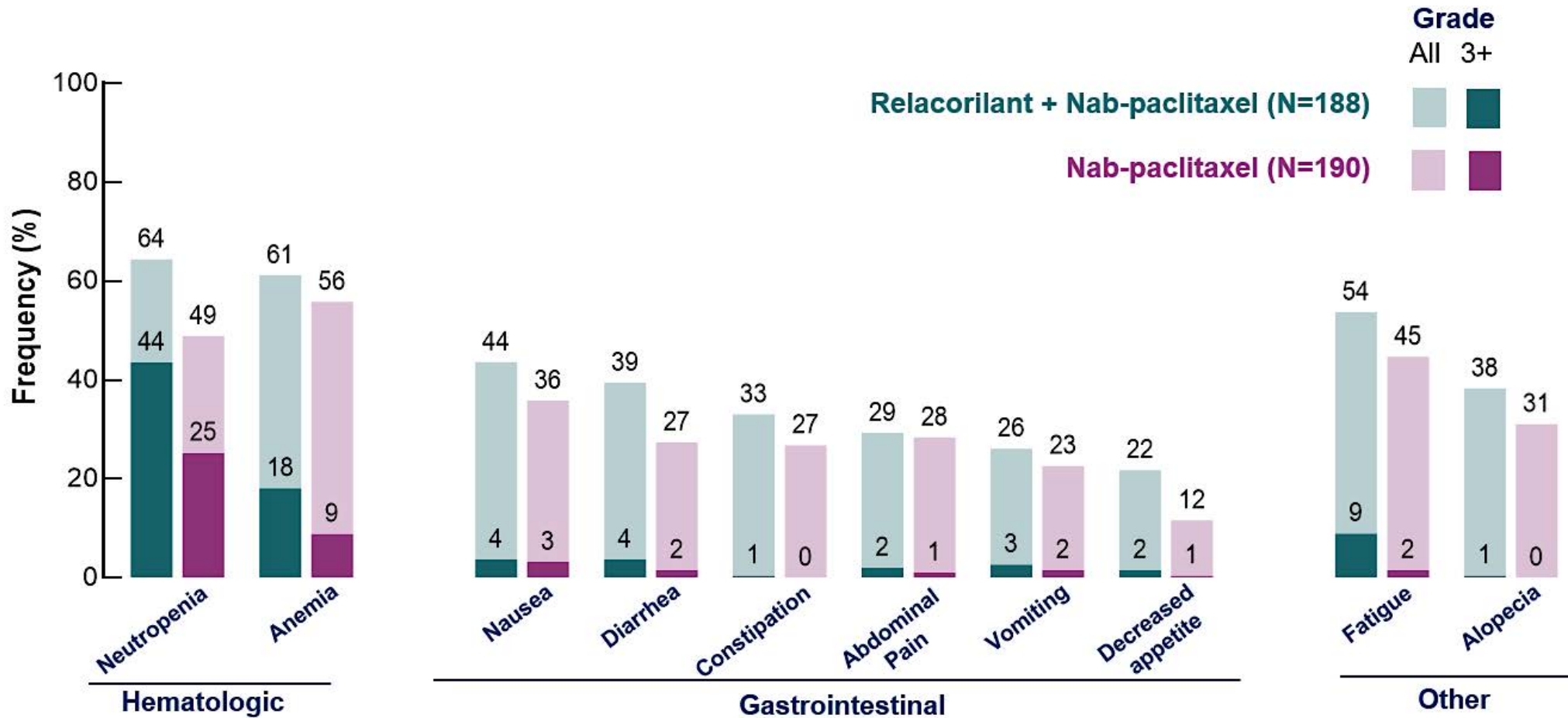
ROSELLA | Overall Survival - Final Analysis



Median follow-up time: 24.8 months; statistical significance threshold at the final analysis: $P \leq 0.0499$. The Kaplan–Meier method was used to estimate the curves, median estimates and the 95% CIs for OS in each treatment arm. The HR and the associated 95% CI were estimated using a Cox regression model with treatment group as the main effect and stratification factors at randomization as covariates. CI, confidence interval; HR, hazard ratio; m, months; OS, overall survival.

Data cutoff: Jan 8, 2026

ROSELLA | Common (>20%) Adverse Events



When adjusted for duration of exposure, the incidence rates of neutropenia and anemia were similar between study arms.
 Peripheral neuropathy occurred with similar frequency in both arms (19.1% and 17.4%).
 5 SAEs of febrile neutropenia: 4 (2.1%) vs 1 (0.5%).* 5 SAEs of sepsis: 3 (1.6%) vs 2 (1.1%).*

Treatment-emergent adverse events that occurred in >20% of patients. Assessed in the safety population of patients who received at least one dose of study drug, N=378. Combined terms are presented for neutropenia (neutropenia, reduced neutrophil count, and febrile neutropenia), anemia (anemia, reduced hemoglobin, and reduced red blood cell count) and fatigue (fatigue and asthenia). SAEs, serious adverse events. *Comparing the relacorilant combination arm to the nab-paclitaxel monotherapy arm, respectively.

Data cutoff: Jan 8, 2026

FDA Approves relacorilant with *nab* paclitaxel for platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer

Press Release: March 25, 2026

“On March 25, 2026, the Food and Drug Administration approved relacorilant, a glucocorticoid receptor antagonist, in combination with *nab*-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens, at least one of which included bevacizumab.

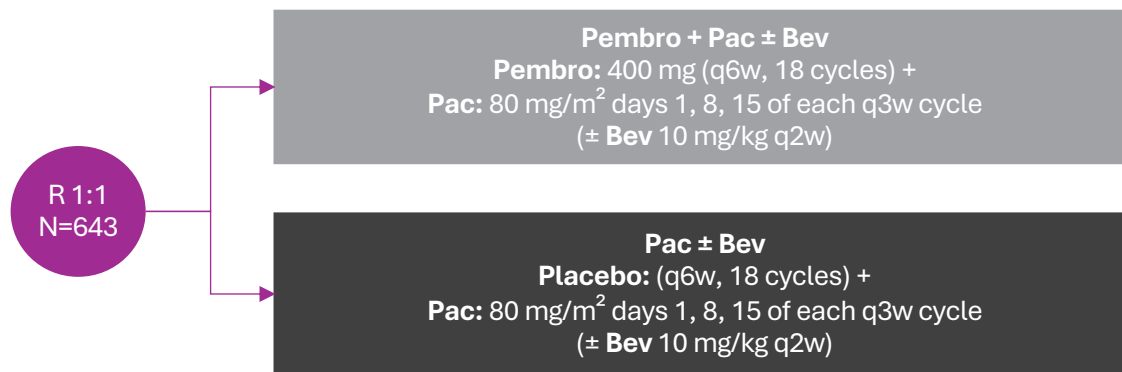
Efficacy was evaluated in ROSELLA (NCT05257408), a multicenter, open-label, trial in 381 patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. Patients were permitted to receive up to three prior lines of systemic therapy and prior bevacizumab was required. The trial excluded patients who required chronic or frequent use of glucocorticoids. Patients were randomized (1:1) to receive relacorilant in combination with *nab*-paclitaxel or *nab*-paclitaxel alone.”

KEYNOTE-B96: Phase 3 Trial of Pembro in PROC

Study Design and Patient Characteristics

Key Eligibility Criteria

- Histologically confirmed epithelial ovarian, fallopian tube, or primary peritoneal carcinoma
- 1 or 2 prior lines of therapy; at least 1 platinum-based Chemo
- Prior anti-PD-1 or anti-PD-L1, PARPi and Bev permitted
- Radiographic progression within 6 months after the last dose of platinum-based Chemo
- ECOG PS 0 or 1



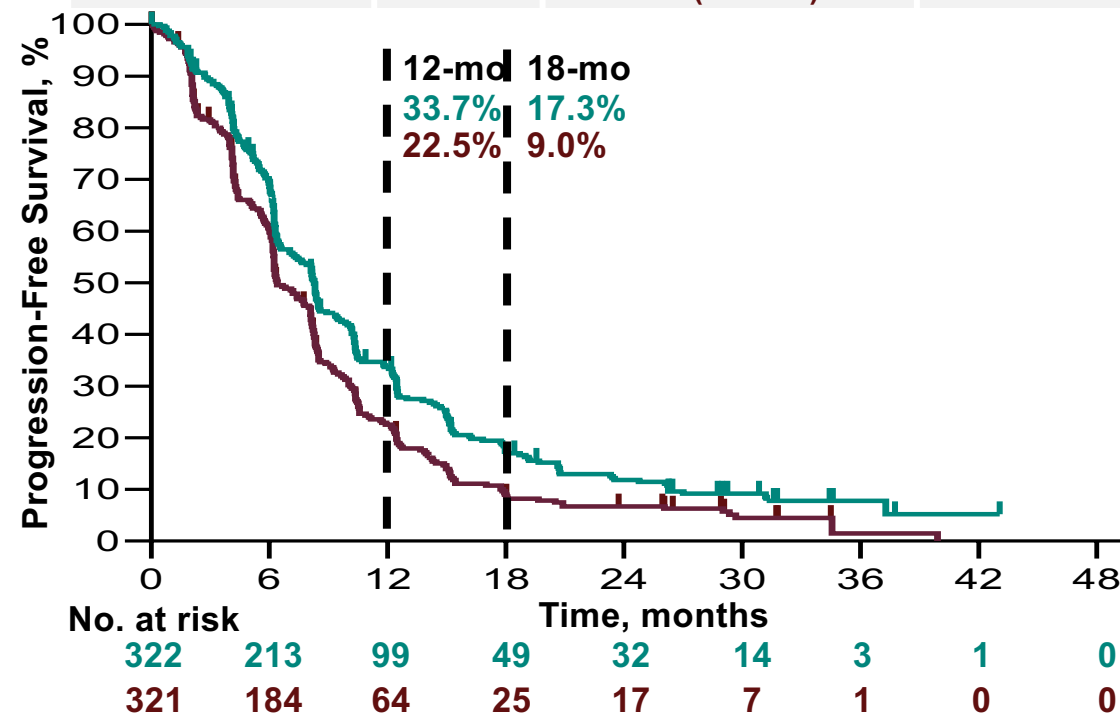
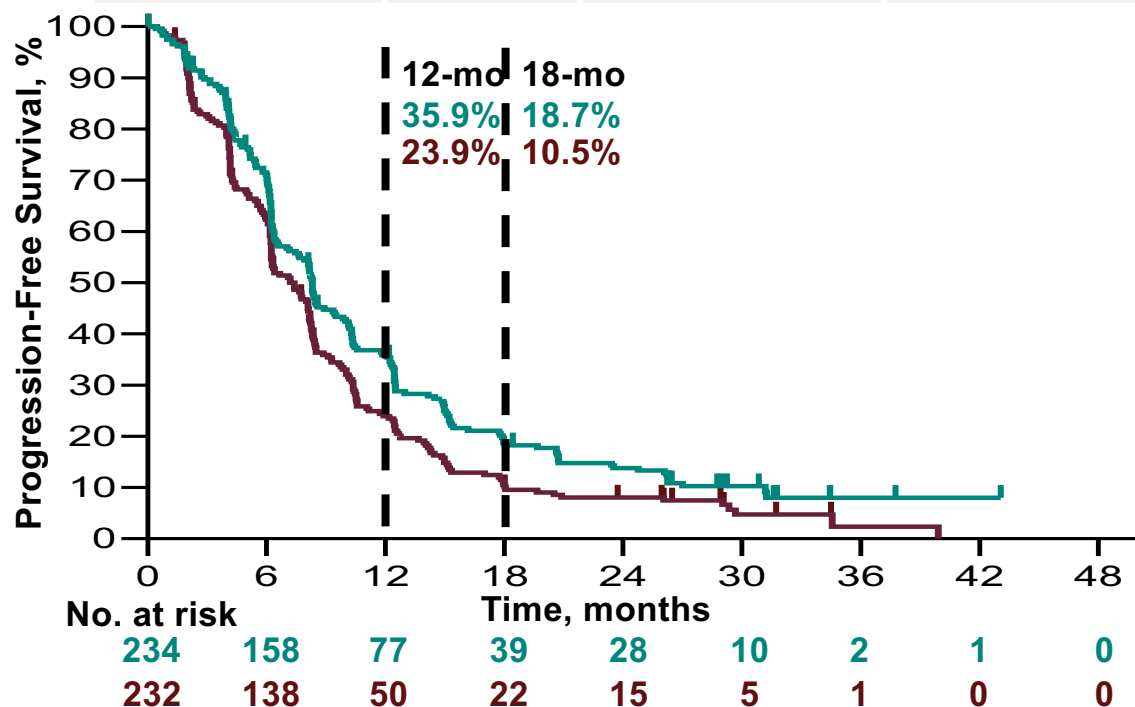
Primary endpoint: PFS per RECIST v1.1 by INV
Secondary endpoint: OS

Patient Characteristics	Pembro + Pac ± Bev (n=322)	Pac ± Bev (n=321)
Median age (range), years	62 (37-85)	61 (37-82)
Prior LOT, n (%)		
1	121 (38)	113 (35)
2	200 (62)	207 (65)
PD-L1 CPS, n (%)		
<1	88 (27)	89 (28)
1 to <10	133 (41)	132 (41)
≥10	101 (31)	100 (31)
Bev use, n (%)	235 (73)	236 (74)
Prior anticancer therapy, n (%)		
Anti-PD-1 or PD-L1	7 (2)	7 (2)
Bev	149 (46)	146 (46)
PARPi	112 (35)	123 (38)
ECOG PS 1, n (%)	142 (44)	144 (45)
Platinum-free interval, n (%)		
<3 months	137 (43)	162 (51)
≥3 to ≤6 months	183 (57)	154 (48)
>6 months	2 (1)	4 (1)

PFS in CPS ≥ 1 and ITT Populations at Final Analysis

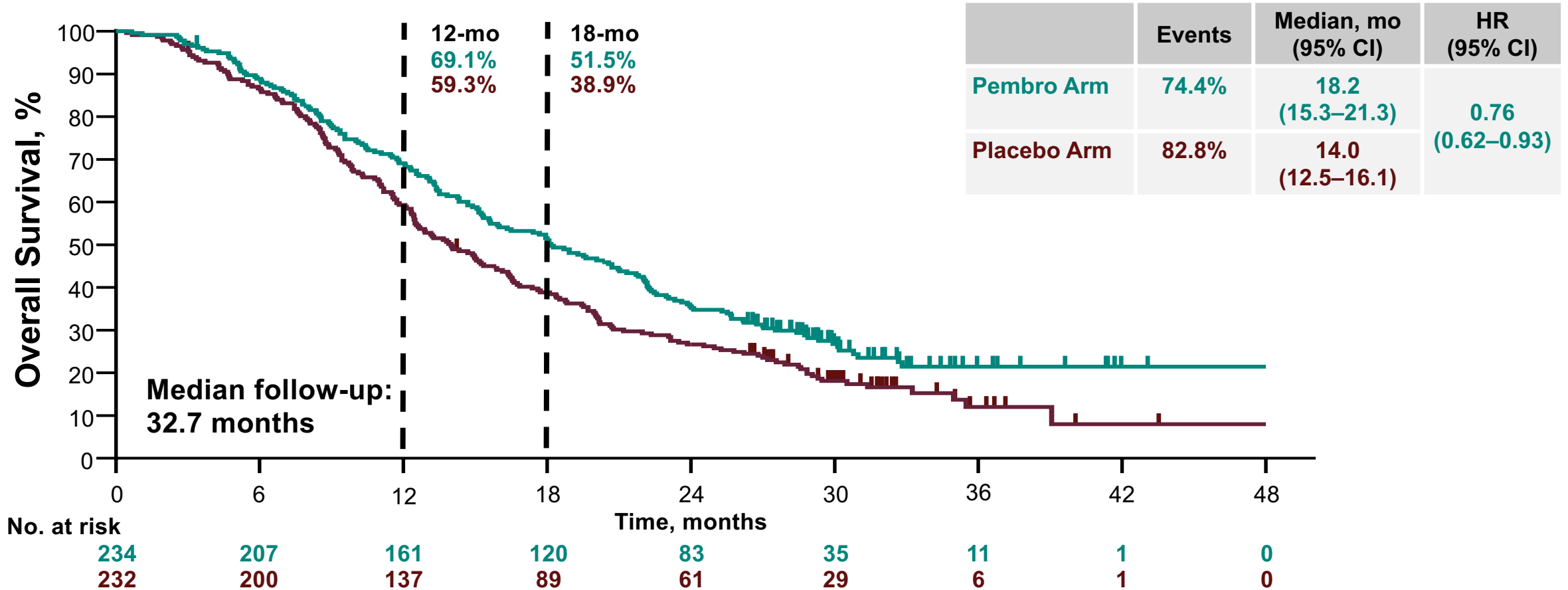
CPS ≥ 1 Population	Events	Median, mo (95% CI)	HR ^a (95% CI)
Pembro Arm	84.6%	8.3 (7.0–9.5)	0.76 (0.62–0.93)
Placebo Arm	88.8%	7.2 (6.2–8.1)	

ITT Population	Events	Median, mo (95% CI)	HR ^a (95% CI)
Pembro Arm	85.7%	8.3 (7.2–8.6)	0.73 (0.62–0.87)
Placebo Arm	89.1%	6.4 (6.2–8.1)	



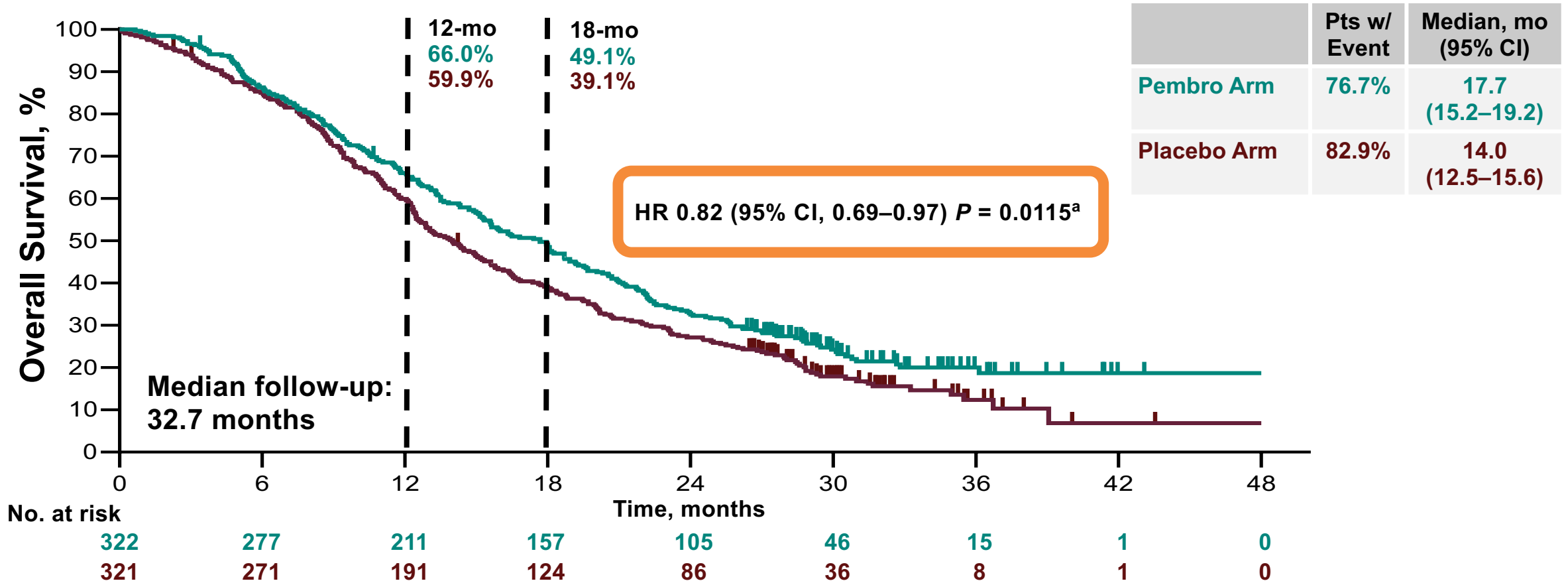
Median follow-up: 32.7 months

OS in CPS ≥ 1 Population at Final Analysis



^aHazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. Data cutoff date: September 5, 2025.

OS in ITT Population at Final Analysis

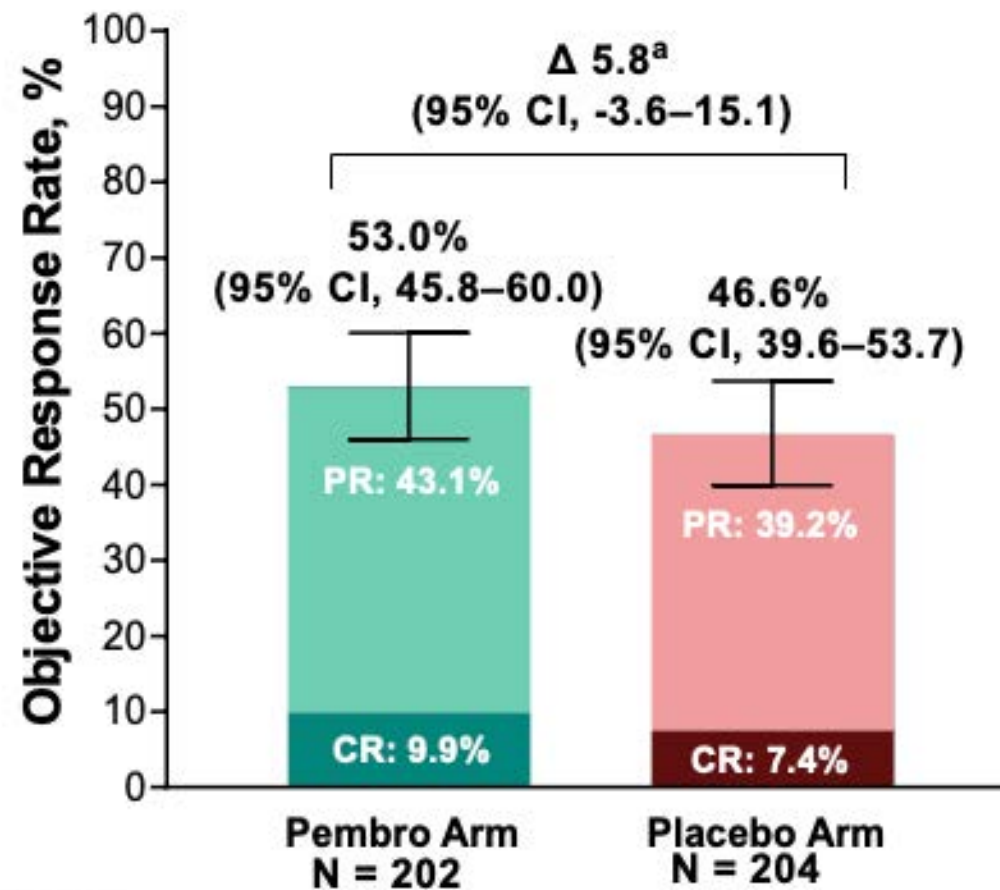
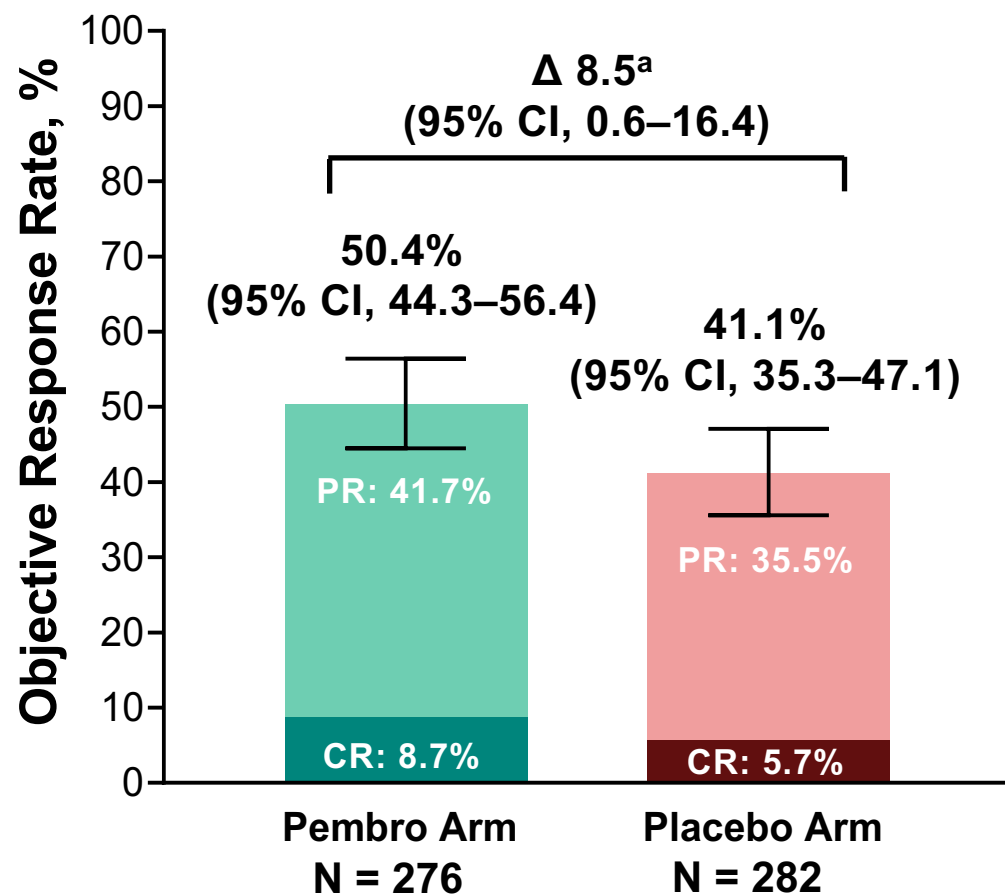


^aHazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. The observed p-value crossed the prespecified nominal boundary of 0.0242 at this planned final analysis. Data cutoff date: September 5, 2025.

FINAL ANALYSIS

ORR ITT Population

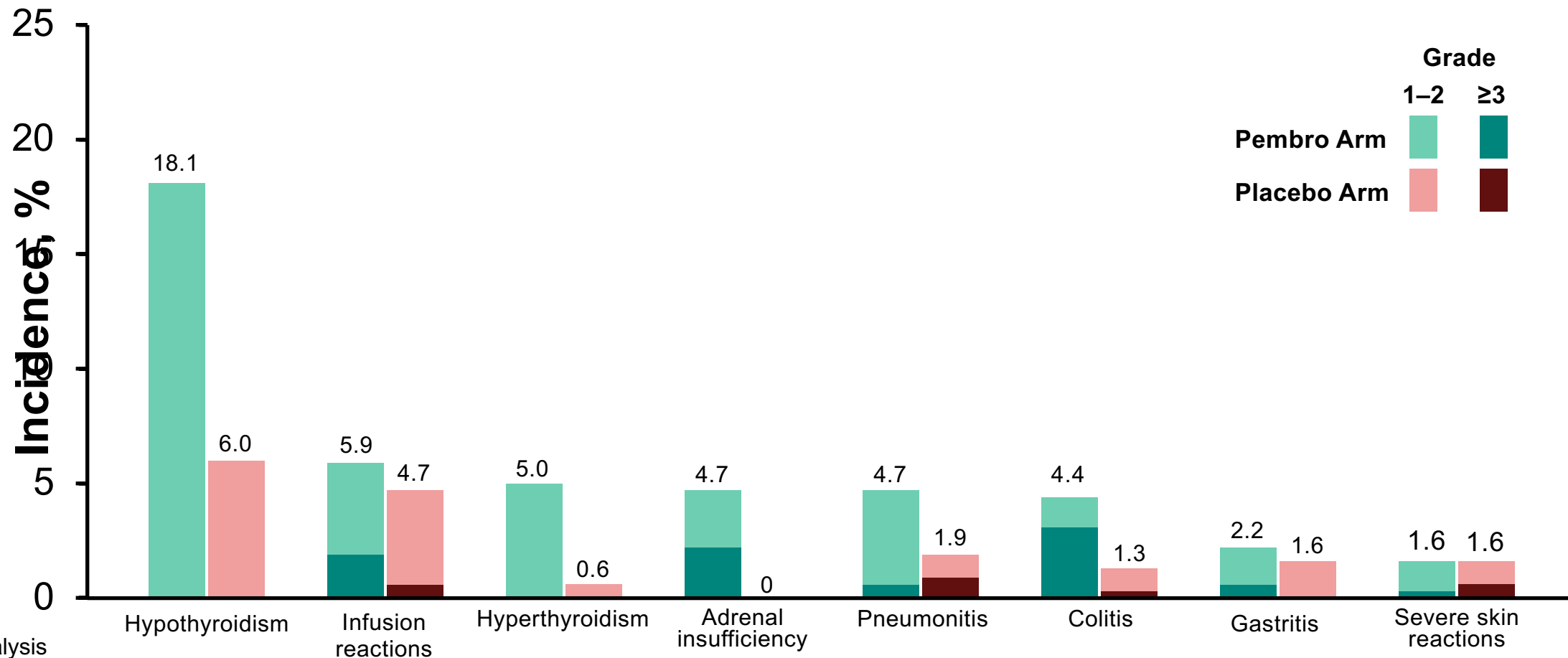
ORR CPS ≥ 1



- Final Analysis
- Monk SGO 2026

Monk SGO 2026

Immune-Mediated AEs and Infusion Reactions, Incidence ≥ 5 Participants in Either Arm*



- Final Analysis
- Monk SGO 2026

Monk SGO 2026

Events were based on a list of preferred terms intended to capture the known risks of pembrolizumab and considered regardless of attribution to treatment by the investigator. Data cutoff date: September 5, 2025.

FDA approves pembrolizumab with paclitaxel for platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma

Press Release: February 10, 2026

“On February 10, 2026, the Food and Drug Administration approved pembrolizumab as well as pembrolizumab and berahyaluronidase alfa-pmph in combination with paclitaxel, with or without bevacizumab, for adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS \geq 1) as determined by an FDA-authorized test, and who have received one or two prior systemic treatment regimens.

Efficacy was evaluated in KEYNOTE-B96 (NCT05116189), a multicenter, randomized, double-blind, placebo-controlled trial that enrolled 643 patients with platinum-resistant, epithelial ovarian, fallopian tube, or primary peritoneal carcinoma who received one or two prior lines of systemic therapy for ovarian carcinoma. Patients must have received at least one line of platinum-based chemotherapy for ovarian cancer with radiographic evidence of disease progression within six months after the last dose. Patients were randomized (1:1) to either pembrolizumab plus paclitaxel with or without bevacizumab or placebo plus paclitaxel with or without bevacizumab.”

Other Agents – non ADCs



Evolving Landscape: Non-ADC Options in the PROC space

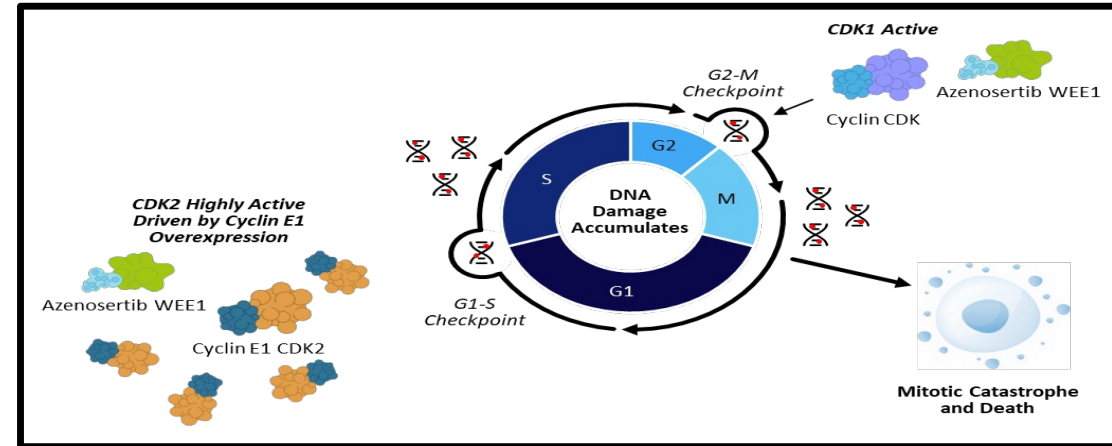
	GOG-3129/MAESTRA 1 (NCT07023627)¹	GOG-3066/DENALI² (NCT05128825)	GOG-3076/OnPrime³ (NCT05281471)
MOA	CDK2 inhibitor	Wee-1 inhibitor	Oncolytic vaccinia virus-based immunotherapy
Prior lines	2-4 prior lines of treatment	Up to 3 prior lines (4 prior lines permitted, if prior mirvetuximab)	Unlimited prior lines
Biomarker	Cyclin E1 overexpression	Cyclin E1 + overexpression	All comers

	PYNNACLE (NCT04585750)⁴	MUC16xCD3 Bispecific (NCT06787612)
MOA	P53 reactivator	MUC16xCD3 Bispecific
Prior lines	Unlimited prior lines	Not Reported
Biomarker	TP53 Y220C mutation	Elevated CA125

1. Thaker PH, et al. ESMO 2025; Abstract 1220TiP; 2. Leary A, et al. AACR-NCI-EORTC 2025; Abstract B013; 3. Holloway RW, et al. International Journal of Gynecological Cancer. 2023 Sep 1;33(9):1458-63; 4. Schram AM et al. ASCO 2025; Abstract TPS11581.

DENALI (GOG-3066): Phase 2, Open-Label, Multicenter Study of Azenosertib in PROC

- Cyclin E1 protein overexpression results in cells moving prematurely from G1 to S, thereby increasing reliance on the G2-M checkpoint to allow DNA repair^{1,2}
- WEE1 is a master regulator of the cell cycle acting as a brake at G1-S and G2-M to allow DNA repair³
- Targeting WEE1 with azenosertib ultimately leads to mitotic catastrophe⁴



Part 1b: Study design

Key eligibility criteria

- ✓ PROC
- ✓ 1-5 prior lines of therapy
- ✓ Prior bevacizumab
- ✓ **All comers** (irrespective Cyclin E1 status)

Enrollment
(N=102)

Azenosertib
400 mg QD 5:2

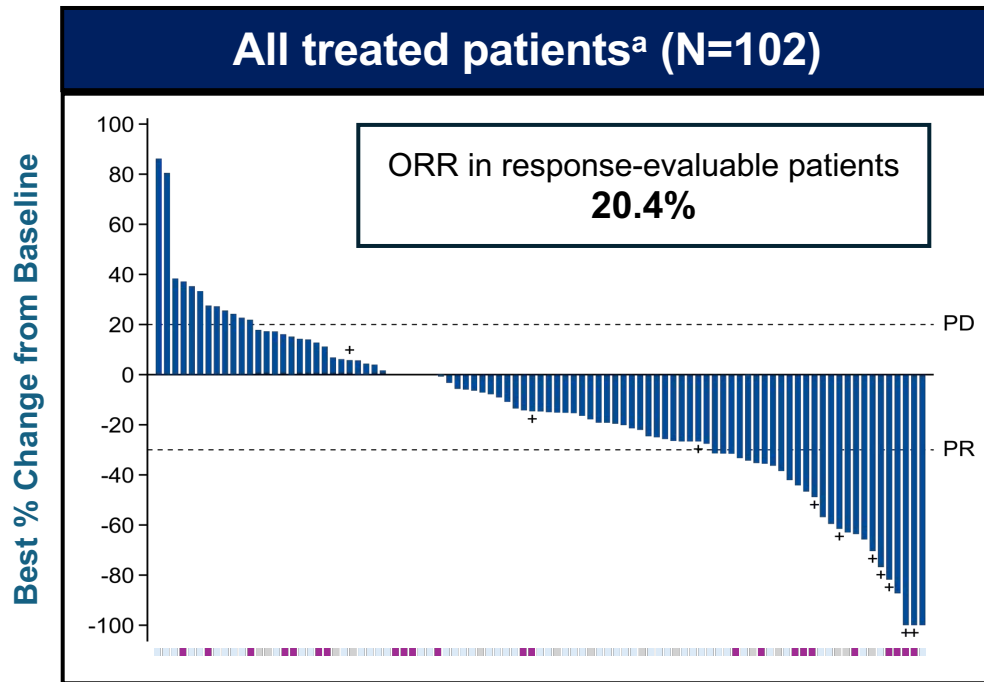
Endpoints

Safety and tolerability

ORR, DOR^a

PFS^b

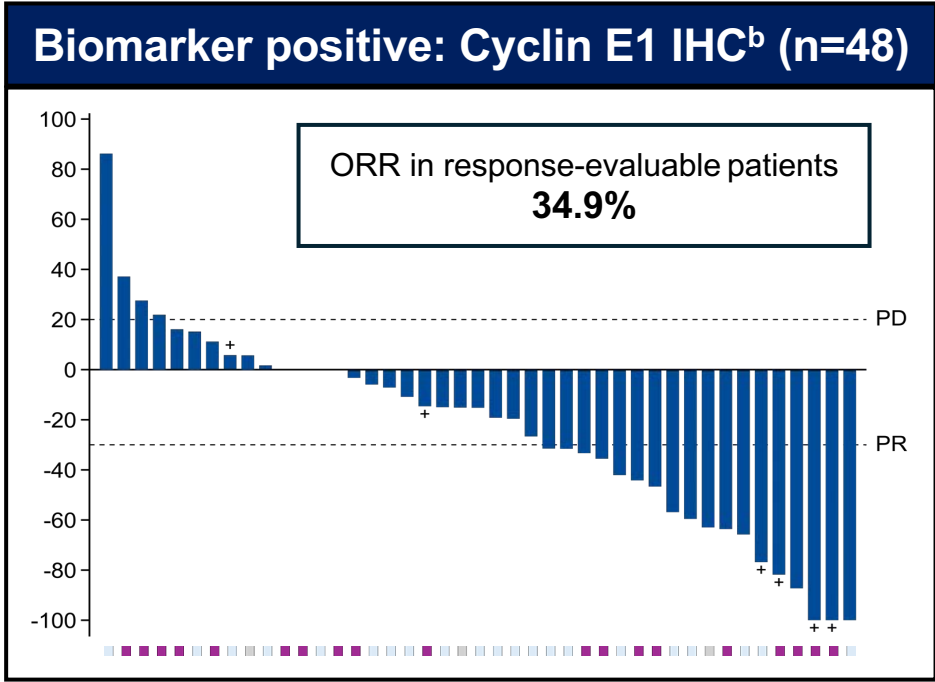
DENALI (GOG-3066) Part 1b: Cyclin E1+ by IHC is a Biomarker Predicting Response to Azenosertib



All treated patients (N=102)

ORR in response-evaluable^c patients, % (n/N; 95% CI) **20.4** (19/93; 12.8-30.1)

ORR, ITT % (n/N; 95% CI) **18.6** (19/102; 11.6-27.6)



Cyclin E1 IHC+ (n=48)

ORR in response-evaluable^c patients, % (n/N; 95% CI) **34.9** (15/43; 21.0-50.9)

ORR, ITT % (n/N; 95% CI) **31.3** (15/48; 18.7-46.3)

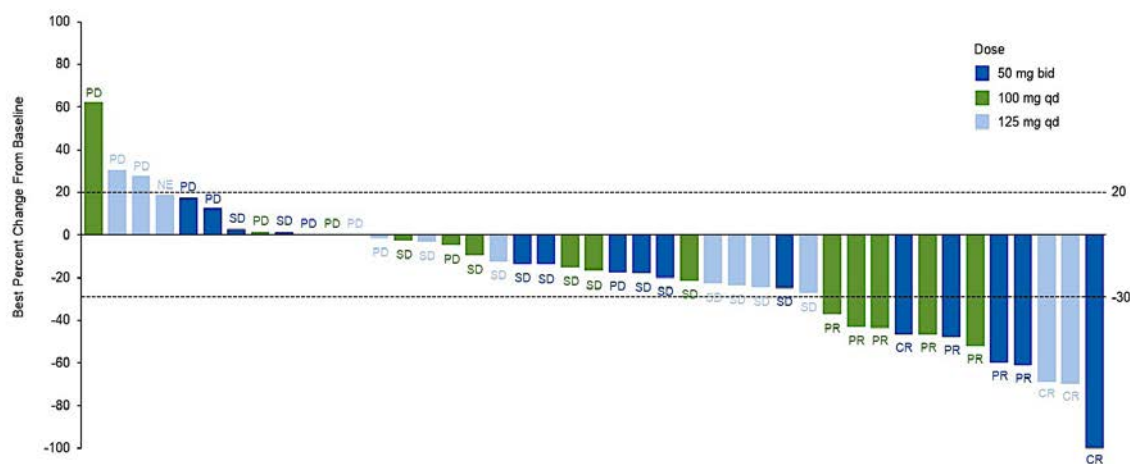
Data cutoff date: January 13, 2025. ^aFull analysis set: all treated patients. ^bBiomarker dataset: all treated patients with evaluable tissue and Cyclin E1 IHC status. ^cIncludes patients who received at least one post-treatment scan. Amp, amplified; IHC, immunohistochemistry; ORR, objective response rate; PD, progressive disease; PR, partial response.

GOG-3129 / MAESTRA 1 (NCT07023627)

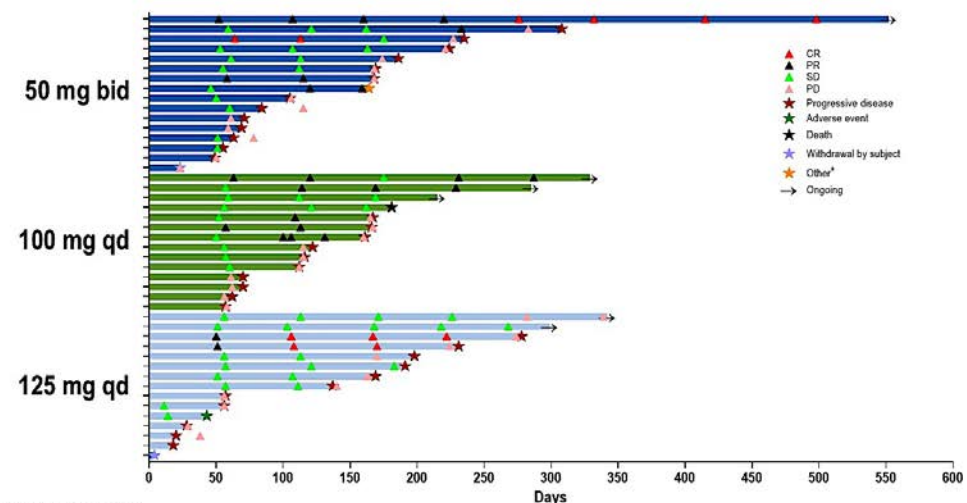
- CDK2 normally pairs with Cyclin E1 (CCNE1) to phosphorylate Rb and drive S-phase entry
- CCNE1 amplification (15–20% of HGSOC) leads to unchecked CDK2 activity, driving rapid replication and chemoresistance
- CDK2 inhibitors arrest the cell cycle at G1/S, inducing senescence or apoptosis preferentially in CCNE1-overexpressing cells
- Rationale: CCNE1-amplified tumors are distinctly resistant to platinum and PARP inhibitors — CDK2 is a compelling synthetic lethal target

Variable	50 mg bid (n=16)	100 mg qd (n=14)	125 mg qd (n=15)
Overall response rate, n (%) [95% CI]	5 (31.3) [11.0, 58.7]	5 (35.7) [12.8, 64.9]	2 (13.3) [1.7, 40.5]
Complete response	2 (12.5)	0 (0)	2 (13.3)
Partial response	3 (18.8)	5 (35.7)	0 (0)
Stable disease	7 (43.8)	5 (35.7)	6 (40.0)
Progressive disease	4 (25.0)	4 (28.6)	4 (26.7)
Not evaluable/missing, n (%)	0 (0)	0 (0)	3 (20.0)
Disease control rate, n (%) [95% CI]	12 (75.0) [47.6, 92.7]	10 (71.4) [41.9, 91.6]	8 (53.3) [26.6, 78.7]
Duration of response, median (95% CI), months	4.5 (1.7, NE)	3.6 (1.9, NE)	-
Progression-free survival, median (95% CI), months	5.5 (2.0, 7.3)	4.5 (2.0, 6.2)	5.4 (1.8, 9.0)

Median follow-up of 9.4 months.
bid, twice daily; CCNE1, cyclin E1; CI, confidence interval; DOR, duration of response; NE, not evaluable; ORR, overall response rate; PFS, progression-free survival; qd, daily.



bid, twice daily; CR, complete response; PD, progressive disease; PR, partial response; qd, daily; SD, stable disease.



*Sponsor decision after jejunostomy procedure.
bid, twice daily; CR, complete response; PD, progressive disease; PR, partial response; qd, daily; SD, stable disease.

GOG-3076/Olvi-Vec-022/OnPrime

A Randomized Phase 3 Study Assessing the Efficacy and Safety of Olvi-Vec followed by Platinum-doublet Chemotherapy and Bevacizumab Compared with Physician's Choice of Chemotherapy and Bevacizumab in Women with Platinum-Resistant/Refractory Ovarian Cancer (

- **Engineered Vaccinia Virus**

- Genetic modifications to attenuate the virus and enhance tumor targeting & replication in malignant cells
- Vaccinia is not a natural human pathogen.

- **Tumor immune modulation and immunogenic cell death**

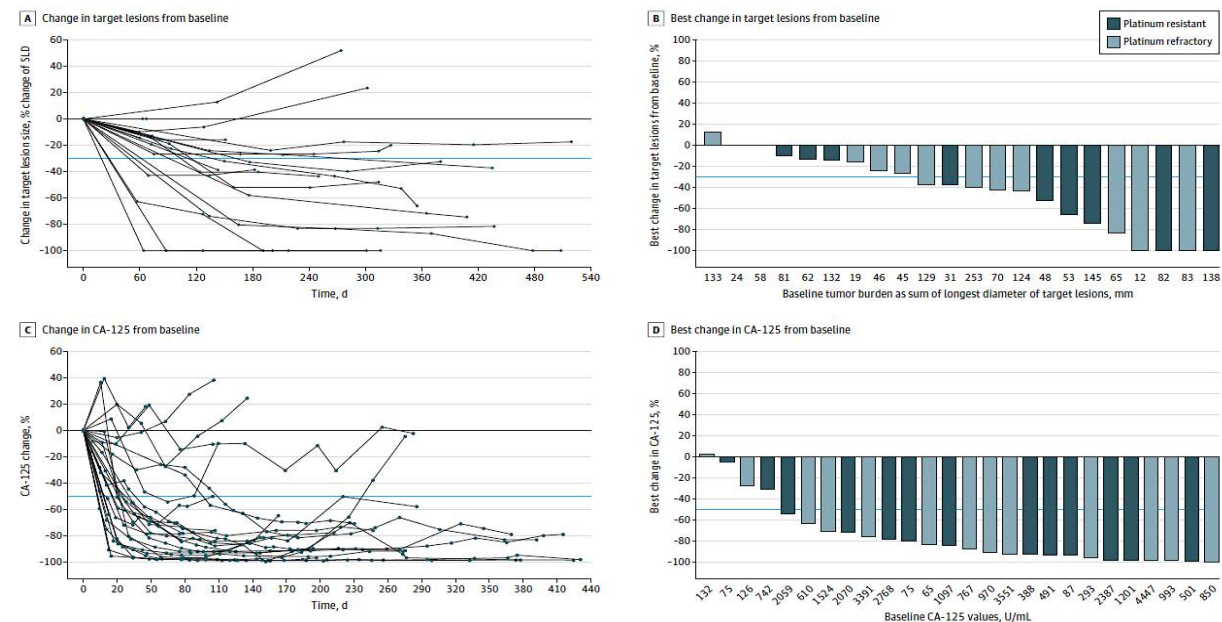
- Increased tumor vasodilation and permeability
- Innate Immune Response
 - Increase Type 1 IFN
 - Increase DAMPs/PAMPs
- Adaptive Immune Response
 - APCs present (neo)antigens
 - T-cell activation and cytotoxicity
 - Anti-tumor immune memory

- Blocks immune-suppression

NCT05281471

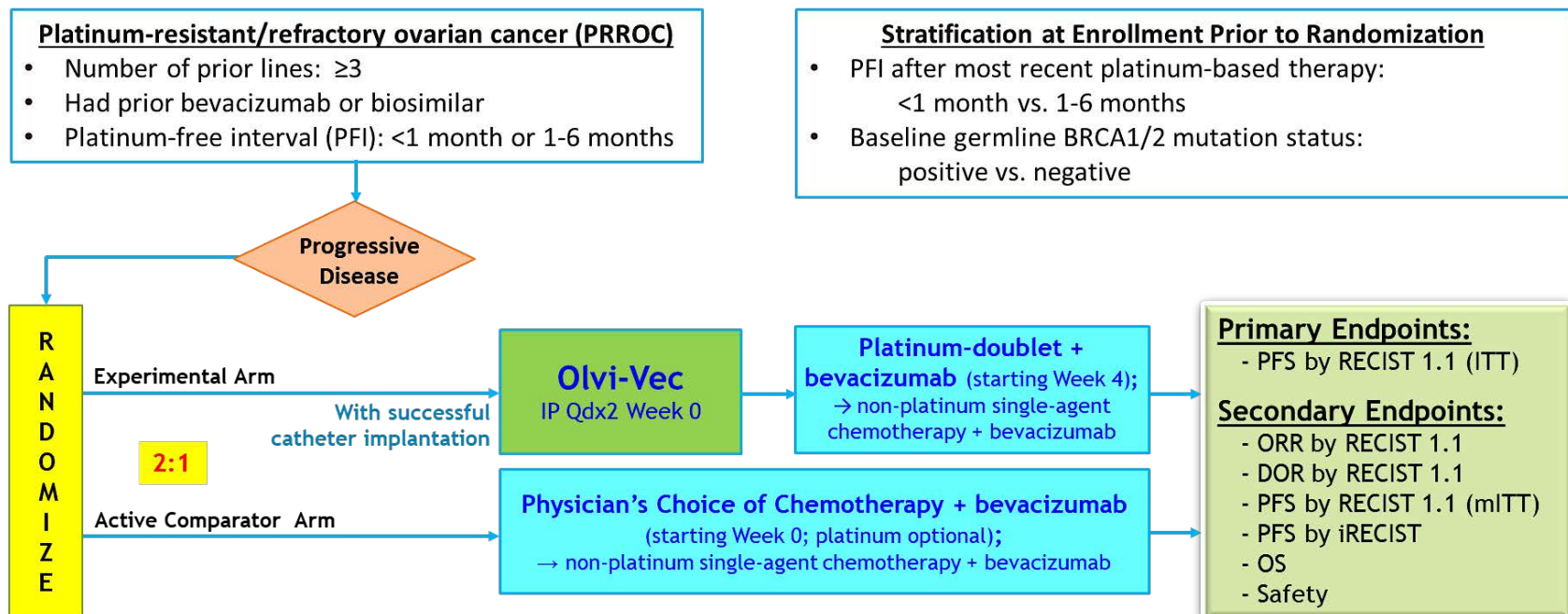
Holloway RW et al. JAMA Oncol. 2023;9(7):903-908.

Figure 2. Evaluations of Antitumor Activity



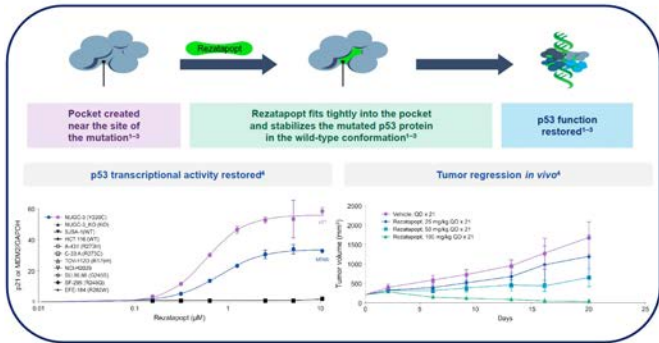
A. Assessment by the Response Evaluation Criteria in Solid Tumors (RECIST, version 1.1), showing a spider plot of radiographic change over time in target lesions (the dotted line at -30% indicates partial response). B. Waterfall plot of best change in target lesions from baseline. C. Assessment by the cancer antigen 125 (CA-125) assay.

showing a spider plot of CA-125 change over time (the dotted line at -50% indicates partial response). D. Waterfall plot of best change in CA-125 from baseline.



PYNNACLE

- TP53 Y220C is a key hotspot TP53 missense mutation present in about 1% of all solid tumors
 - Up to 3.6% of HGSOc³
- Rezatapopt – selective p53 reactivator specific to the TP53 Y220C mutation¹⁻³
- Rezatapopt stabilizes the mutated protein in the wtp53 conformation by binding to a pocket created by the tyrosine-to-cysteine substitution-restoring the p53 function

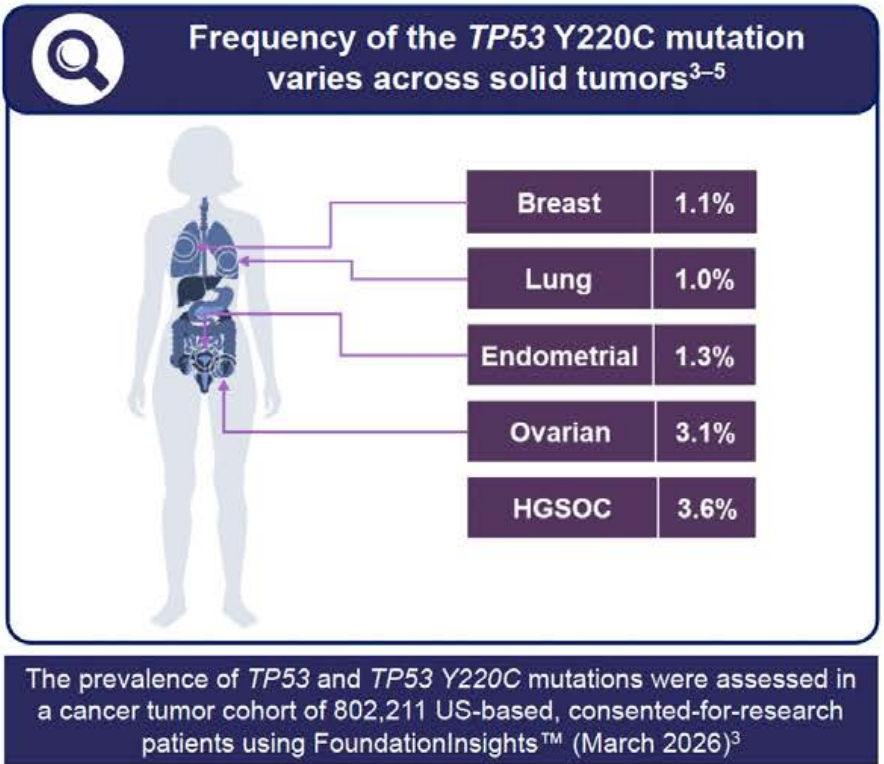


DOI: 10.1158/1078-0432.CCR-22-0100; DOI: 10.1158/1078-0432.CCR-22-0100; DOI: 10.1158/1078-0432.CCR-22-0100

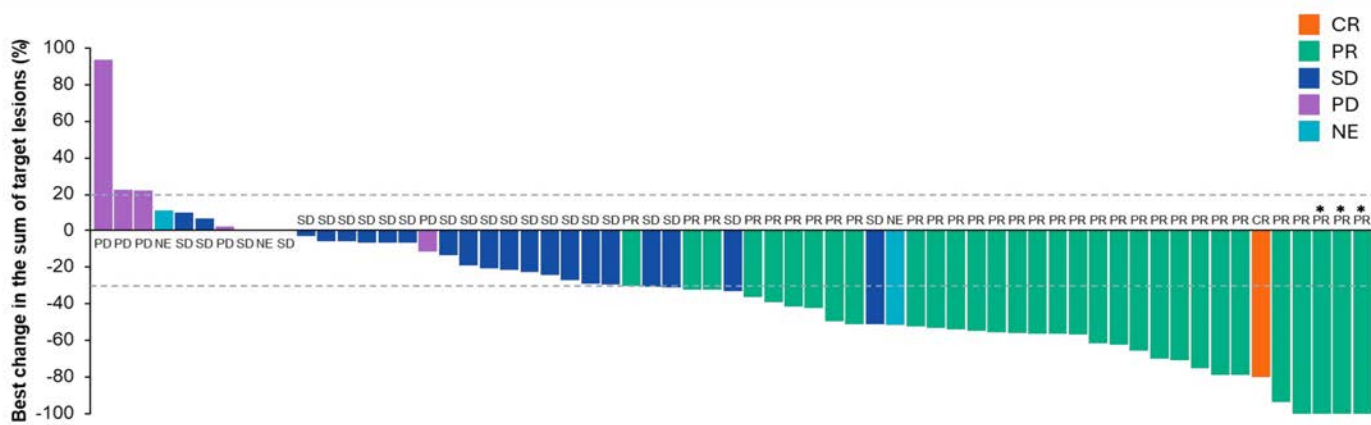
Schram A et al. SGO 2026 (NCT04585750)

HGSOC, high-grade serous ovarian cancer.

1. Baugh EH, et al. *Cell Death Differ.* 2018;25:154–160; 2. Hassan O, et al. *Nat Rev Drug Discov.* 2023;22:127–144; 3. FoundationInsights™. A proprietary database used under license with review and approval from Foundation Medicine®. Available at: <https://www.foundationmedicine.com/service/genomic-data-solutions>. Accessed March 2026; 4. de Andrade KC, et al. *Cell Death Differ.* 2022;29:1071–1073; 5. Dumbrava EE, et al. ASCO Annual Meeting. 2022; Oral presentation: abstract 3003.



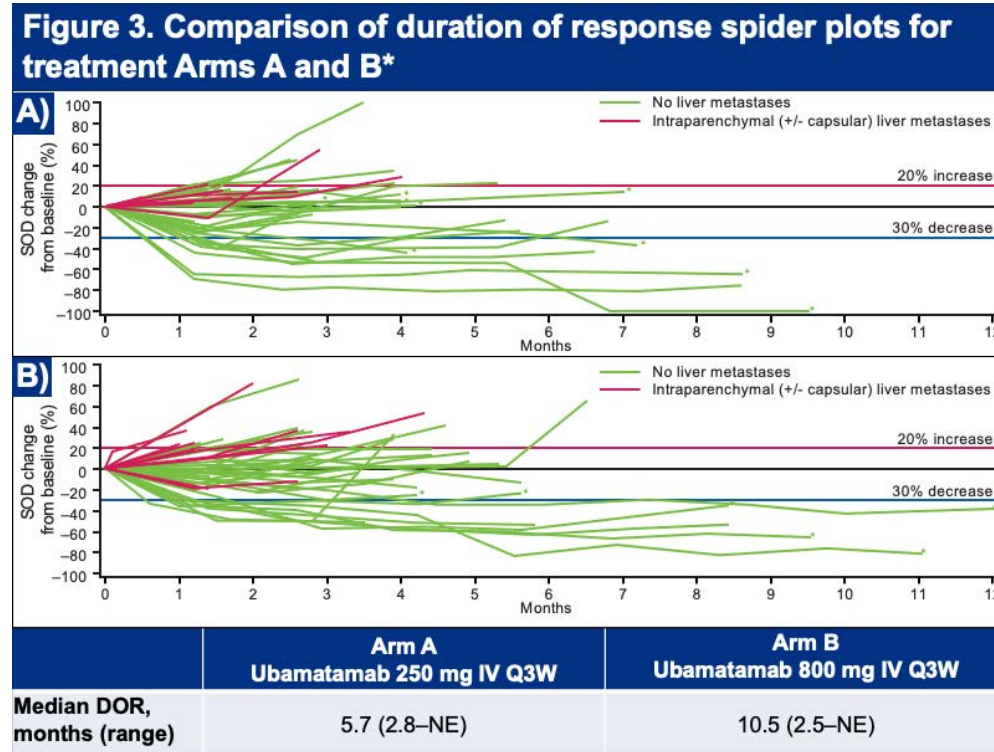
Target lesion reduction was observed in patients with ovarian cancer (n=63)^a



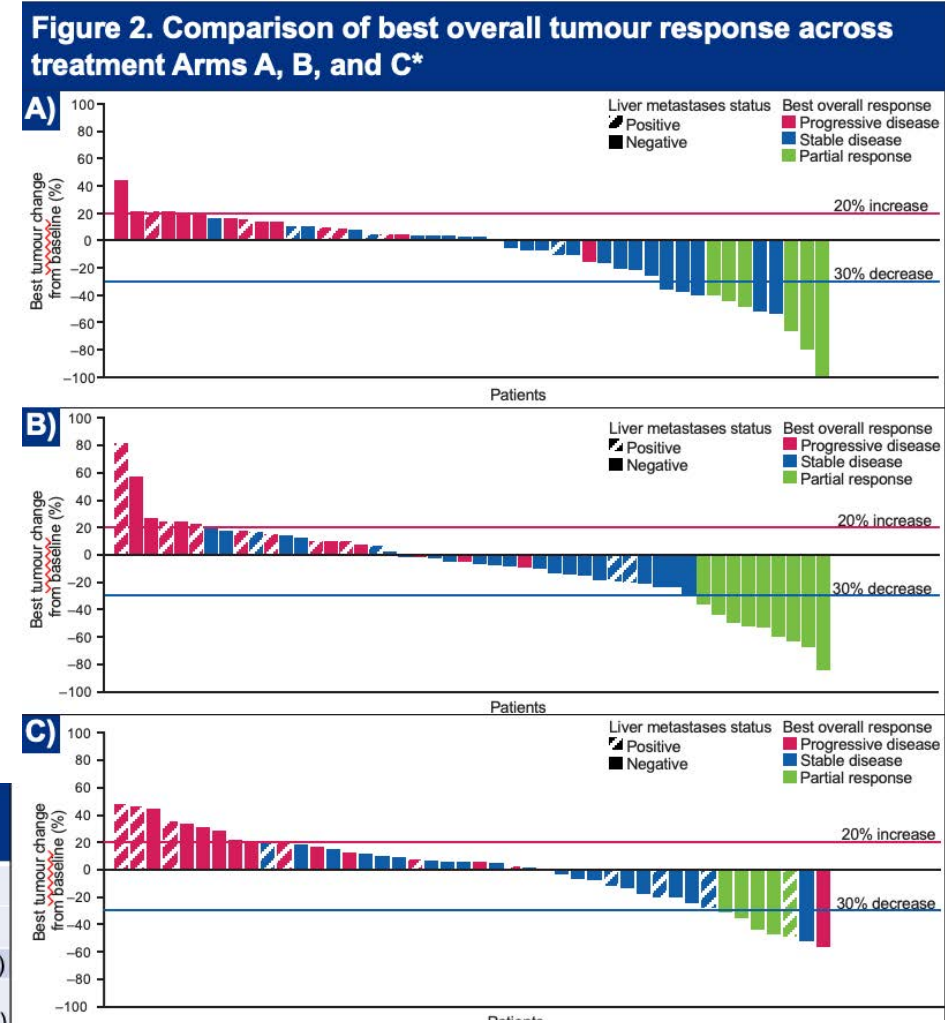
Data cutoff: March 29, 2026. Dotted line shows RECIST v1.1 criteria for PD (20%) and PR (-30%). A* denotes patients who achieved a confirmed PR as of the data cutoff and experienced unconfirmed CR at last scan. ^aIncludes patients with ovarian cancer and a post-baseline target tumor measurement (n=63). Best overall responses are noted in the figure. CR, complete response; NE, non-evaluable; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

Ubamatamab (REGN4018) - MUC16xCD3 Bispecific (NCT06787612)

- Ubamatamab (REGN4018) is a MUC16 × CD3 bispecific antibody that bridges MUC16 on tumour cells and CD3 on T cells to promote T-cell-mediated cytotoxicity
- Cemiplimab is a PD-1i



	Arm A Ubamatamab 250 mg			Arm B Ubamatamab 800 mg			Arm C Ubamatamab 250 mg + cemiplimab 350 mg		
	All	Yes	No	All	Yes	No	All	Yes	No
Liver metastases present, n	50	9	41	50	11	39	50	11	39
ORR, n (%)	8 [†] (16.0)	0	8 [†] (19.5)	9 (18.0)	0	9 (23.1)	6 [†] (12.0)	1 (9.1)	5 [†] (12.8)
mPFS (95% CI), months	2.9 (2.6-4.0)	1.6 (0.5-2.9)	2.9 (2.6-4.2)	2.9 (2.6-3.9)	1.5 (1.1-2.6)	3.5 (2.8-4.4)	2.8 (1.6-3.0)	1.7 (1.2-2.9)	2.9 (1.6-4.2)



Lee JY, ESMO 2025; Abstract 1078P

1. Burova E, et al. *Mol Cancer Ther* 2017;16(5):861-70.
2. Liu J, et al. *International Journal of Gynecologic Cancer* PO011LBA/#1512 2023;33:A9-A10

For a patient with advanced OC who is eligible to receive all 3 strategies, how would you generally sequence mirvetuximab soravtansine, relacorilant/*nab* paclitaxel and pembrolizumab/weekly paclitaxel?



Prof Eskander

Mirvetuximab soravtansine → pembrolizumab/weekly paclitaxel → relacorilant/*nab* paclitaxel



Dr Matulonis

Mirvetuximab soravtansine → pembrolizumab/weekly paclitaxel → relacorilant/*nab* paclitaxel



Dr Moore

I would not sequence these agents



Dr Olawaiye

Relacorilant/*nab* paclitaxel → mirvetuximab soravtansine → pembrolizumab/weekly paclitaxel



Dr O'Malley

Mirvetuximab soravtansine → relacorilant/*nab* paclitaxel → pembrolizumab/weekly paclitaxel*



Prof Colombo

Mirvetuximab soravtansine → pembrolizumab/weekly paclitaxel → relacorilant/*nab* paclitaxel

* Would only use either *nab*/paclitaxel or paclitaxel – not both

Would you employ pembrolizumab/weekly paclitaxel with or without bevacizumab for a patient with PD-L1-negative advanced OC under any circumstances?



Prof Eskander

Yes, I do not view this to be effective only in the PD-L1+ population based on the trial, although I understand the FDA label



Dr Matulonis

No



Dr Moore

No



Dr Olawaiye

No



Dr O'Malley

Yes, no marked difference in outcomes between biomarker-positive and -negative



Prof Colombo

No

In which situations are you currently adding bevacizumab when employing pembrolizumab/weekly paclitaxel for your patients with advanced OC?



Prof Eskander

In all situations, unless contraindicated



Dr Matulonis

If the patient hasn't received bevacizumab or received with evidence of benefit, unless contraindicated



Dr Moore

In all situations, unless contraindicated



Dr Olawaiye

I have not used this regimen



Dr O'Malley







If the patient is a candidate for bevacizumab



Prof Colombo

In all situations, unless contraindicated

Would you employ relacorilant in combination with any other chemotherapeutic agent beyond *nab* paclitaxel under any circumstances? Would you employ relacorilant/*nab* paclitaxel in combination with bevacizumab under any circumstances?

	In combination with other chemotherapy	In combination with bevacizumab
 Prof Eskander	No	No
 Dr Matulonis	No	No
 Dr Moore	No	Only on protocol
 Dr Olawaiye	Only on protocol	Only on protocol
 Dr O'Malley	No	Only on protocol
 Prof Colombo	No	No

Do you currently use glucocorticoid expression levels to inform how you sequence relacorilant/*nab* paclitaxel for your patients with advanced OC?



Prof Eskander

No



Dr Matulonis

No



Dr Moore

No



Dr Olawaiye

No



Dr O'Malley

No



Prof Colombo

No

Agenda

Module 1: Current Role of PARP Inhibitors in the Management of Advanced Ovarian Cancer (OC) — Prof Eskander

Module 2: Strategies Targeting Folate Receptor Alpha in Advanced OC — Dr Matulonis

Module 3: Other Approved and Promising Investigational Antibody-Drug Conjugates for Advanced OC — Dr Moore

Module 4: Other Novel Agents and Strategies for Advanced OC — Dr O'Malley

Module 5: Diagnosis and Management of Adverse Events Associated with Common Therapies for Advanced OC — Dr Olawaiye

Diagnosis and Management of Adverse Events Associated with Commonly Employed Therapies for Advanced Ovarian Cancer

Alexander B. Olawaiye, MD

Professor

University of Pittsburgh School of Medicine

Pittsburgh

Pennsylvania, USA



Outline

- ❖ **PARP Inhibitors**
- ❖ **ADCs (Mirvetuximab, T-DXd)**
- ❖ **Relacorilant**



Phase III PAOLA-1/ENGOT-ov25: maintenance olaparib with bevacizumab in patients with newly diagnosed, advanced ovarian cancer treated with platinum-based chemotherapy and bevacizumab as standard of care

Isabelle Ray-Coquard, Patricia Pautier, Sandro Pignata, David Pérol, Antonio González-Martin, Paul Sevela, Keiichi Fujiwara, Ignace Vergote, Nicoletta Colombo, Johanna Mäenpää, Frédéric Selle, Jalid Sehoui, Domenica Lorusso, Eva Maria Frederik Marmé, Eric Pujade-L

Niraparib Therapy in Patients With Newly Diagnosed Advanced Ovarian Cancer (PRIMA/ENGOT-OV26/GOG-3012)

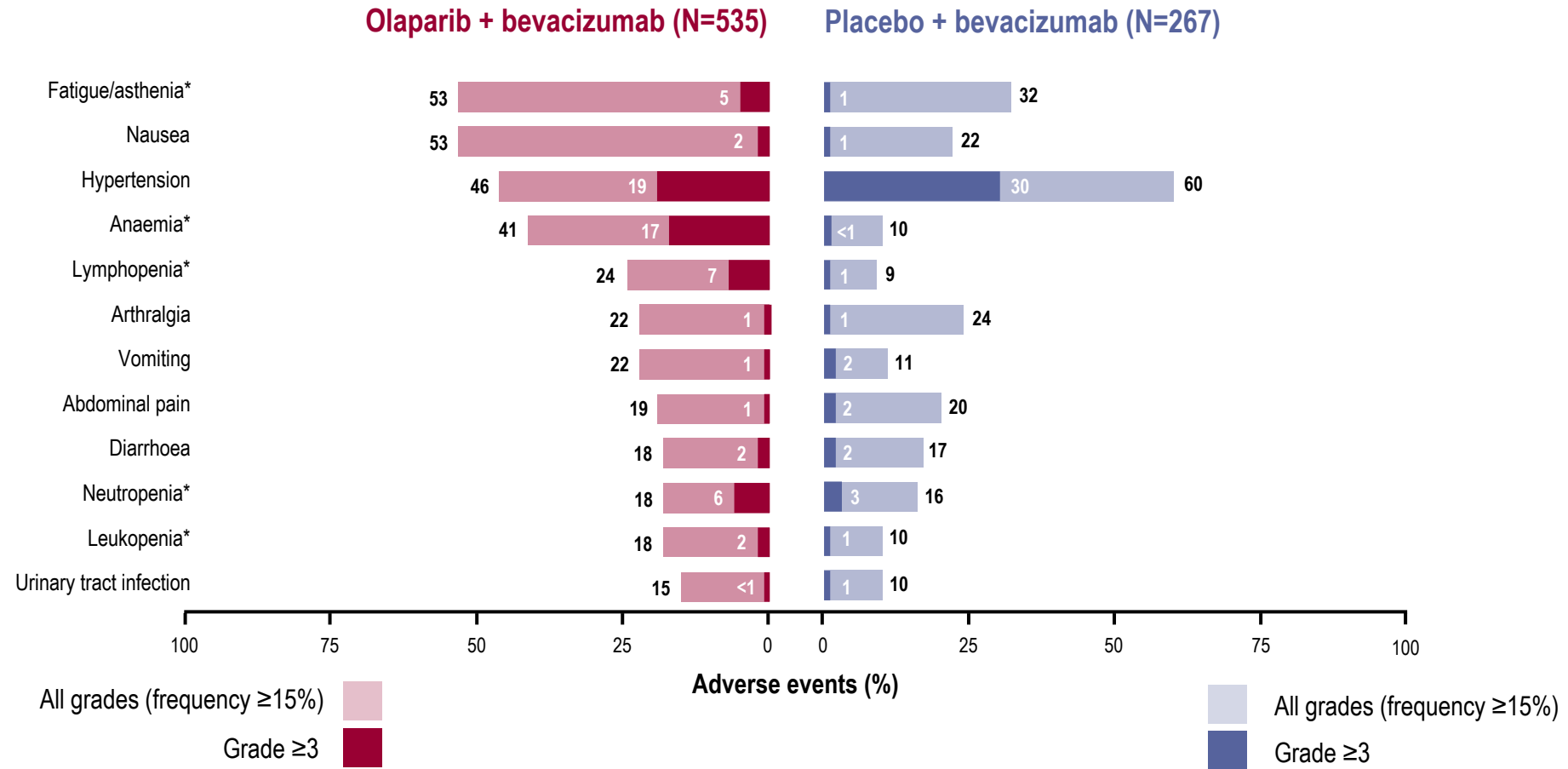
A. González-Martín,¹ B. Pothuri,² I. Vergote,³ R.D. Christensen,⁴ W. Graybill,⁵ M.R. Mirza,⁶ C. McCormick,⁷ D. Lorusso,⁸ P. Hoskins,⁹ G. Freyer,¹⁰ F. Backes,¹¹ K. Baumann,¹² A. Redondo,¹³ R. Moore,¹⁴ C. Vulsteke,¹⁵ R.E. O'Coirre,¹⁶ B. Lund,¹⁷ V. Li,¹⁸ D. Gupta,¹⁸ B. I. Monk¹⁹

SOLO1: Phase III trial of maintenance olaparib following platinum-based chemotherapy in newly diagnosed patients with advanced ovarian cancer and a *BRCA1/2* mutation

Kathleen Moore,¹ Nicoletta Colombo,² Giovanni Scambia,³ Byoung-Gie Kim,⁴ Ana Oaknin,⁵ Michael Friedlander,⁶ Alla Lisyanskaya,⁷ Anne Floquet,⁸ Alexandra Leary,⁹ Gabe S. Sonke,¹⁰ Charlie Gourley,¹¹ Susana Banerjee,¹² Amit Oza,¹³ Antonio González-Martín,¹⁴ Carol Aghajanian,¹⁵ William Bradley,¹⁶ Elizabeth S. Lowe,¹⁷ Ralph Bloomfield,¹⁸ Paul DiSilvestro¹⁹

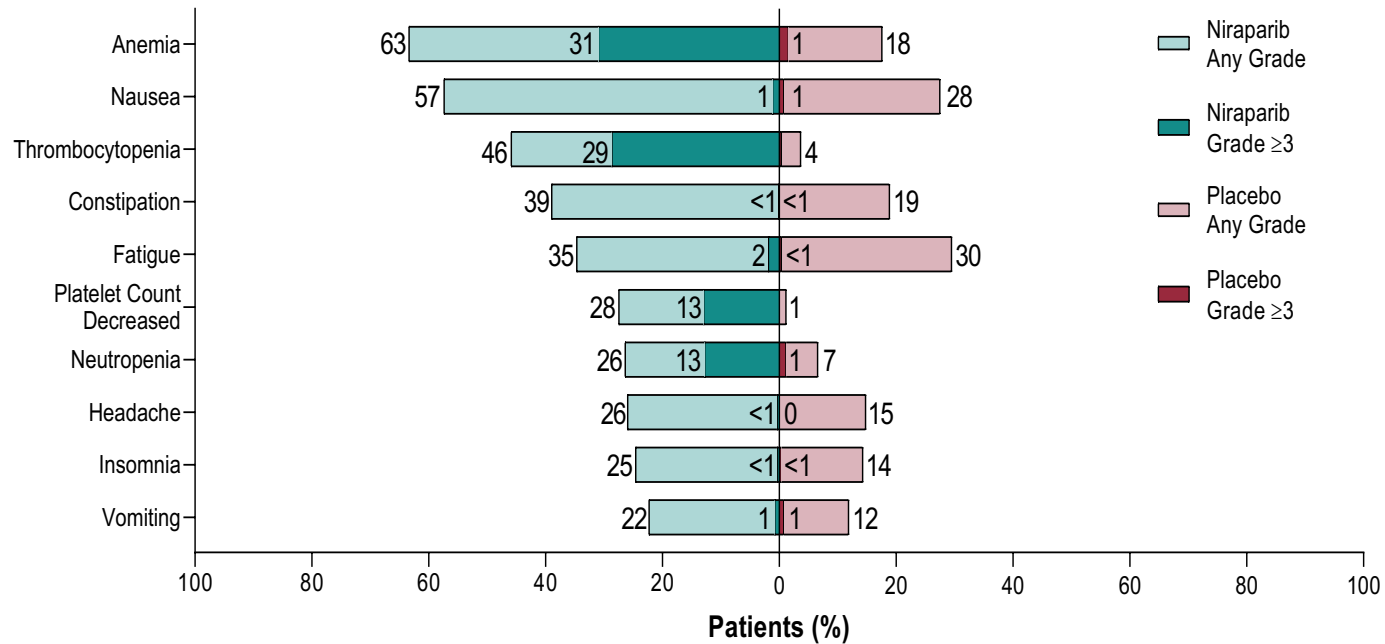


PAOLA-1: Most common AEs



*Grouped terms. All-grade thrombocytopenia (grouped term) occurred in 8% of patients in the olaparib group and 3% of patients in the placebo group, grade ≥3 thrombocytopenia occurred in 2% of patients in the olaparib group and <1% of patients in the placebo group

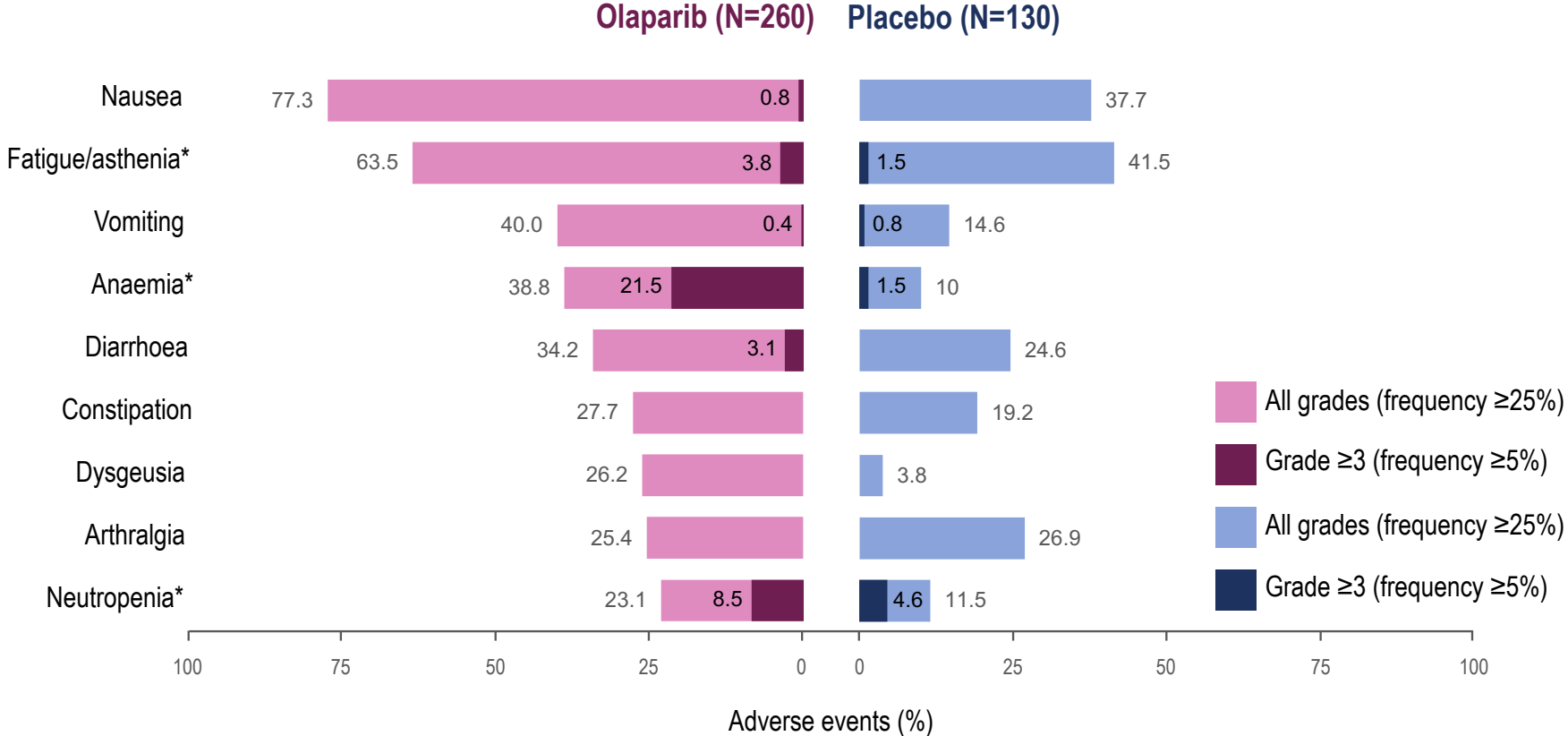
PRIMA Safety



- No new safety signals were identified for niraparib
- Most common TEAE was reversible myelosuppression
- One patient was diagnosed with MDS after 9 months of niraparib treatment

TEAEs ≥20% incidence in niraparib arm. Note: Hematologic TEAEs are not combined with laboratory results
MDS, myelodysplastic syndrome; TEAE, treatment-emergent adverse event.

SOLO1: Most common treatment-emergent adverse events



*Grouped terms. All-grade thrombocytopenia (grouped term) occurred in 11.2% of patients in the olaparib group and 3.8% of patients in the placebo group and grade ≥3 thrombocytopenia (grouped term) occurred in 0.8% and 1.5%, respectively.

Most Common Grade 3/4 Adverse Events

STUDY	1	2	3	4
PAOLA 1	Hypertension (19%)	Anemia (17%)	Lymphopenia (7%)	Fatigue/asthenia (5%)
PRIMA	Anemia (31%)	Thrombocytopenia (29%)	Neutropenia (13%)	Fatigue (2%)
SOLO 1	Anemia (21.5%)	Neutropenia (8.5%)	Fatigue/asthenia (3.8%)	Diarrhea (3.1%)



Managing Fatigue

Prior to treatment

Inform patients that fatigue is common - generally improves over time although can persist

Exclude other causes

Anaemia
Depression
Insomnia
Hypothyroid

Menopausal symptoms – hot flashes -which impact on sleep

Management

- Non-pharmacologic: e.g. afternoon nap
- Massage therapy
- Psychosocial interventions -CBT
- Exercise: referral to an exercise physiologist
- Ginseng / methylphenidate
- Dose interrupt and restart at a reduced dose

(< 2% stop a PARP inhibitor in trials due to fatigue)

Monitoring for Haematological toxicity

Prior to treatment

- Baseline testing of complete blood count (CBC)
- Ensure recovery (grade ≤ 1) from any existing haematological toxicity caused by previous chemotherapy

Monitoring

- Monthly CBC for the first 12 months (8-12 weekly thereafter) – Olaparib and Rucaparib
- Weekly CBC for the first month – Niraparib. Then monthly as above if CBC stable

Haematological toxicity –Anemia

GRADE 1

10-12g/dl

Continue and monitor

GRADE 2

8-10g/dl

Interrupt and monitor
Restart when G1 and Dose Reduce

GRADE 3 / 4

6.5-8g/dl / < 6.5 g/dl

Interrupt and Transfuse
Restart when G1 with dose reduction

Exclude other causes of anaemia where relevant
Check B12; Folate ; Iron

1.4- 3% cease for anaemia – depends on agent and setting

Haematological Toxicity –Thrombocytopenia

Platelets <100,000 u/l

G1 75-100,000 u/l
G2 50-75,000 u/l
G3 25-50,000 u/l
G4 < 25,000 u/l

- Interrupt treatment and monitor CBC weekly/ bi weekly until recovery
- Resume at the same/ reduced dose (G1)
- Reduced dose if < 75,000u/l (G2)
- Reduced dose if < 50,000 u/l (G3 /4)
- If not recovered to CTCAE ≤ grade 1 after 4 weeks, refer to a hematologist

MONITOR CBC WEEKLY X 4 AFTER RESTARTING

(Platelet transfusion if < 10,000u/l)

0.5 -4% cease due to thrombocytopenia varies by trial

Haematological Toxicity –Thrombocytopenia

Interrupt treatment if platelet count < 100,000 on Niraparib

Platelets <100,000 u/l

G1 75-100,000 u/l
G2 50-75,000 u/l
G3 25-50,000 u/l
G4 < 25,000 u/l

- Interrupt treatment and monitor blood counts weekly/ bi weekly until recovery
- Resume at the same/ reduced dose (G1)
- Reduced dose if < 75,000u/l (G2)
- Reduced dose if < 50,000 u/l (G3 /4)
- If not recovered to CTCAE ≤ grade 1 after 4 weeks, refer to a hematologist

Less stringent for olaparib or rucaparib – interrupt if platelets < Grade 3 or 4 (In practice – consider interrupt if grade 2 or monitor closely)

(Platelet transfusion if < 10,000u/l)

0.5 -4% cease due to thrombocytopenia varies by trial

Haematological toxicity –Neutropenia

GRADE 1

$1.5-2 \times 10^9 / l$

Continue and monitor

GRADE 2

$1.0-1.5 \times 10^9 / l$

Interrupt and monitor
Restart when G1 and Dose Reduce

GRADE 3 / 4

$0.5-1 \times 10^9 / l / <0.5 \times 10^9 / l$

Interrupt
Restart when G1 with dose reduction

If not recovered to \leq grade 1 after 4 weeks
refer to hematologist

0.8-1.9% cease due to neutropenia

MDS/AML

- Incidence of myeloid neoplasms has increased with introduction of PARP inhibitors
- Low risk (to date) in 1st line trials of maintenance therapy
- Higher risk (3.8-8%) in recurrent setting after multiple lines of chemotherapy
- **Risk factors include**
 - Older Age
 - Multiple lines of platinum based chemotherapy prior to PARPi
 - BRCA mutation
 - TP53 clonal hematopoiesis of indeterminate potential variants

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 (FR α) Expression

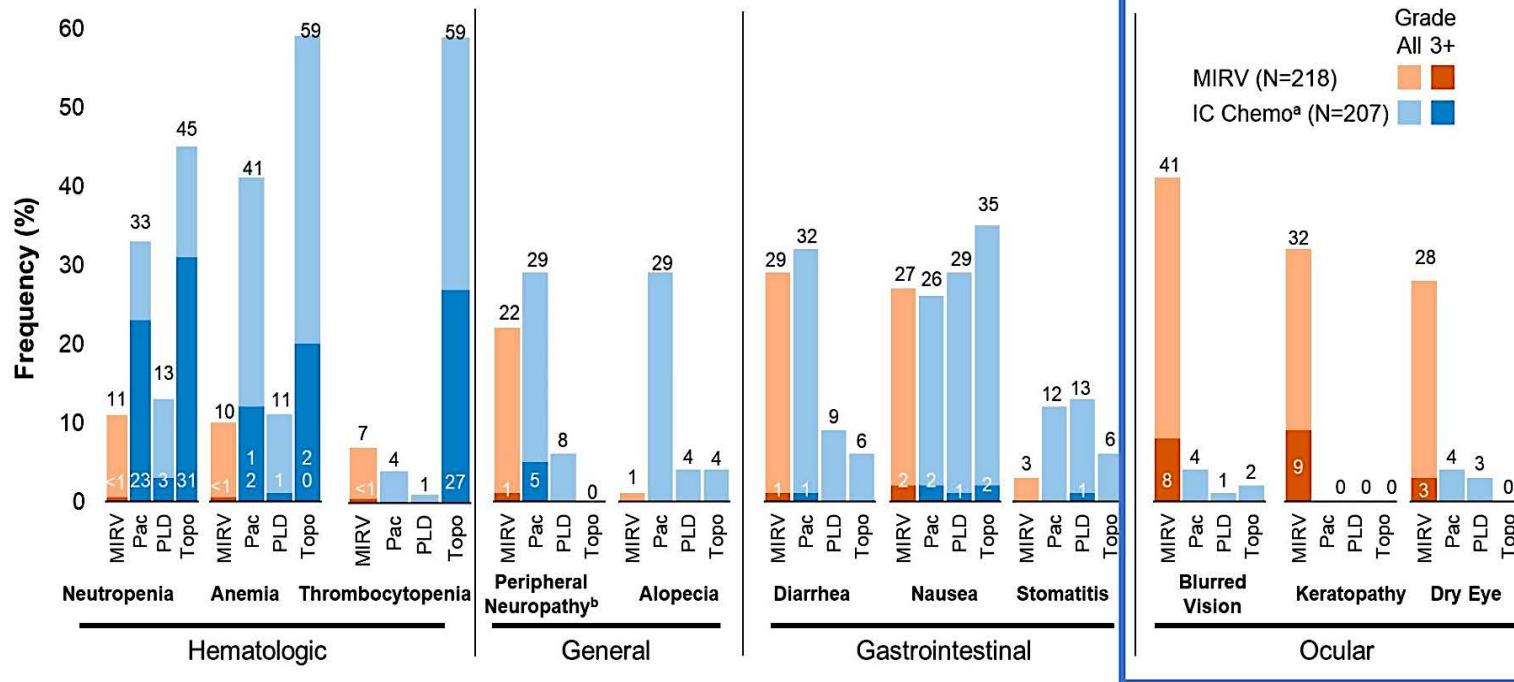
Kathleen N. Moore¹, Antoine Angelergues², Gottfried E. Konecny³, Susana Banerjee⁴, Sandro Pignata⁵, Nicoletta Colombo⁶, John Moroney⁷, Casey Cosgrove⁸, Jung-Yun Lee⁹, Andrzej Roszak¹⁰, Shani Breuer¹¹, Jacqueline Tromp¹², Diana Bello Roufai¹³, Lucy Gilbert¹⁴, Rowan Miller¹⁵, Tashanna Myers¹⁶, Yuemei Wang¹⁷, Anna Berkenblit¹⁷, Domenica Lorusso¹⁸, Toon Van Gorp¹⁹

¹Stephenson Cancer Center University of Oklahoma College of Medicine, Oklahoma City, OK, USA; ²Groupe Hospitalier Diaconesses Croix Saint Simon, Paris, France; ³UCLA Jonsson Comprehensive Cancer Center, Los Angeles, CA, USA; ⁴The Royal Marsden NHS Foundation Trust - Royal Marsden Hospital, London, UK; ⁵Istituto Nazionale Tumori- G. Pascale, Naples, Italy; ⁶European Institute of Oncology IRCCS, Milan, Italy and University of Milan-Bicocca, Milan, Italy; ⁷The University of Chicago, Chicago, IL, USA; ⁸The Ohio State University, Columbus, OH, USA; ⁹Severance Hospital, Seoul, South Korea; ¹⁰Wielkopolskie Centrum Onkologii, Poznan, Poland; ¹¹Hadassah Ein Kerem – Sharett, Jerusalem, Israel; ¹²Amsterdam UMC, Amsterdam, The Netherlands; ¹³Hopital Rene Huguenin, Institut Curie, Saint-Cloud, France; ¹⁴McGill University Health Centre, Montreal, Canada; ¹⁵University College London Hospital, London, UK; ¹⁶Baystate Medical Center, Springfield, MA, USA; ¹⁷ImmunoGen, Inc., Waltham, MA, USA; ¹⁸Fondazione Policlinico Universitario A. Gemelli, IRCCS and Catholic University of Sacred Heart, Rome, Italy; ¹⁹University Hospital Leuven Leuven Cancer Institute, Leuven, Belgium



Mirvetuximab Soravtansine

Safety MIRASOL trial

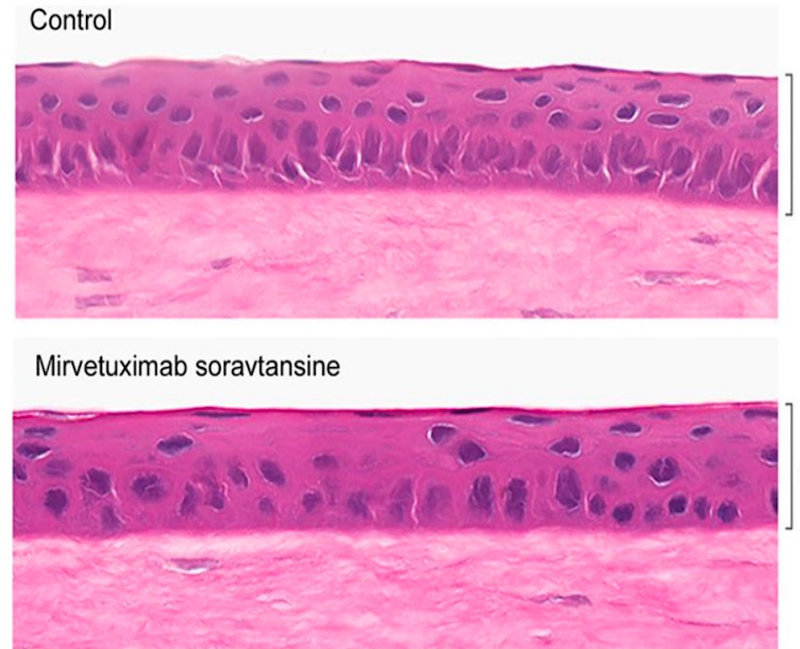
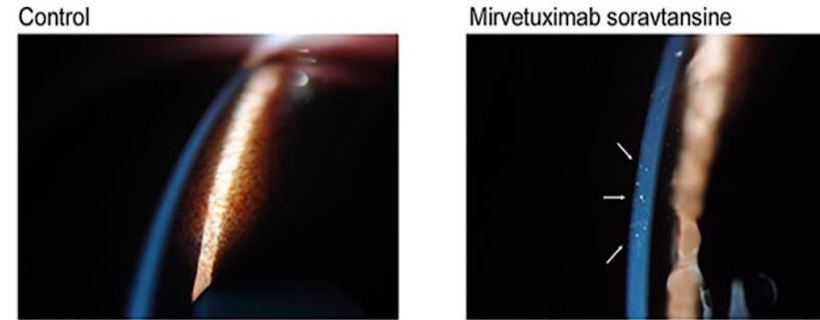
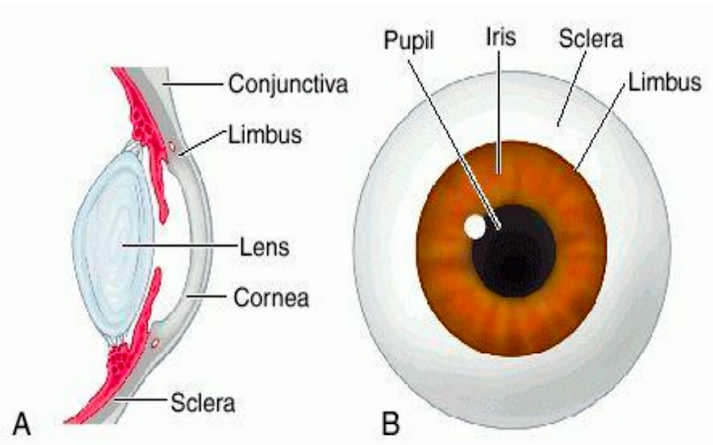


- **56% ocular AE**
- **Majority resolved to G≤1**
- **No G4**
- **Median time onset: 5.4 weeks**
- **4 pts (1.8%) discontinued due to ocular AE**
- **No corneal ulceration or perforations and no permanent alterations**

Manifestation of ocular toxicity

Mirvetuximab Soravtansine

- **FR α is expressed** in the retina but NOT in the non-retinal structures (cornea, conjunctiva, limbal region)
- **Off-target effect** of DM4 payload (endocytosis or passive diffusion)
- Transient corneal alterations, called “**microcystic-like epithelial changes**” due to anti-mitotic effect in the **limbal region of the cornea** (reservoir of stem cells)
- **Dose dependent and reversible**



Matulonis, CCR 2019



Mitigation strategies

	Mirvetuximab Soravtansine
Eye exam	Baseline, every other cycle up to 8 th
Medical history	Baseline
Lubricating eye drops	At least QID
Corticosteroid eye drops	1 drop 6 times/ day, D-1 to D4, 1 drop qid D5-8
Vasoconstrictor eye drops	Not recommended
Cold packs	Not recommended
Contact lens	Avoid use

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

Funda Meric-Bernstam

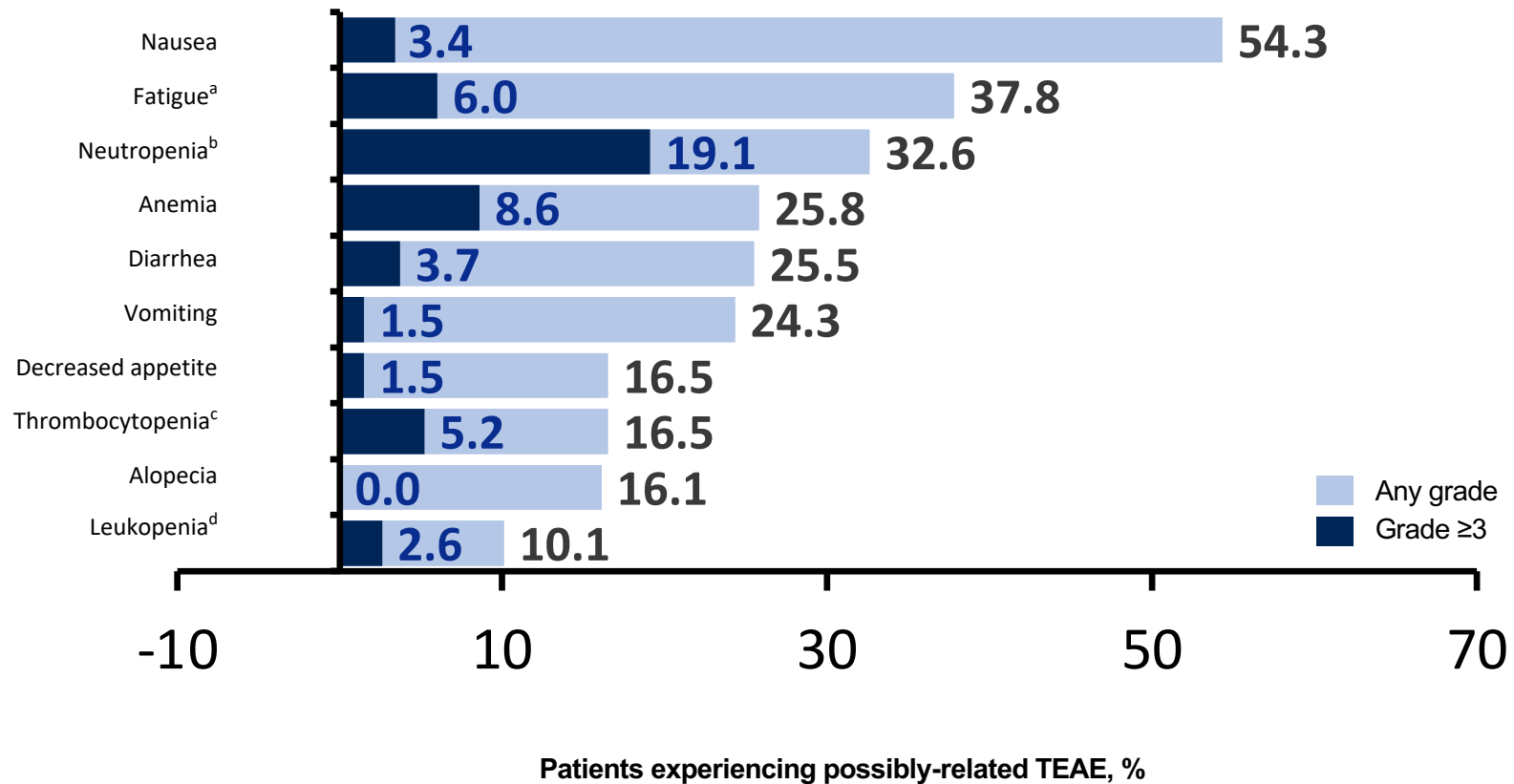
The University of Texas MD Anderson Cancer Center, Houston, TX, USA

June 5, 2023

Additional authors: Vicky Makker, Ana Oaknin, Do-Youn Oh, Susana Banerjee, Antonio González-Martín, Kyung Hae Jung, Iwona Ługowska, Luis Manso, Aránzazu Manzano, Bohuslav Melichar, Salvatore Siena, Daniil Stroyakovskiy, Chiedozie Anoka, Yan Ma, Soham Puvvada, Jung-Yun Lee

On behalf of the DESTINY-PanTumor02 investigators

Drug-Related TEAEs in $\geq 10\%$ of Patients



Analyses were performed in patients who received ≥ 1 dose of T-DXd (n=267). ^aThis category includes the preferred terms fatigue, asthenia, and malaise. ^bThis category includes the preferred terms neutrophil count decreased and neutropenia. ^cThis category includes the preferred terms platelet count decreased and thrombocytopenia. ^dThis category includes the preferred terms white blood cell count decreased and leukopenia. TEAE, treatment-emergent adverse event; T-DXd, trastuzumab deruxtecan.



Adverse Events of Special Interest

ILD/pneumonitis adjudicated as T-DXd–related

n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any grade
All patients (N=267)	6 (2.2)	12 (4.5)	1 (0.4)	0	1 (0.4)	20 (7.5)

Left ventricular dysfunction^a

n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any grade
Ejection fraction decreased						
All patients (N=267)	1 (0.4)	4 (1.5)	1 (0.4)	0	0	7 (2.6) ^b
Cardiac failure						
All patients (N=267)	0	0	1 (0.4)	0	0	1 (0.4)

Analyses were performed in patients who received ≥ 1 dose of T-DXd (n=267).

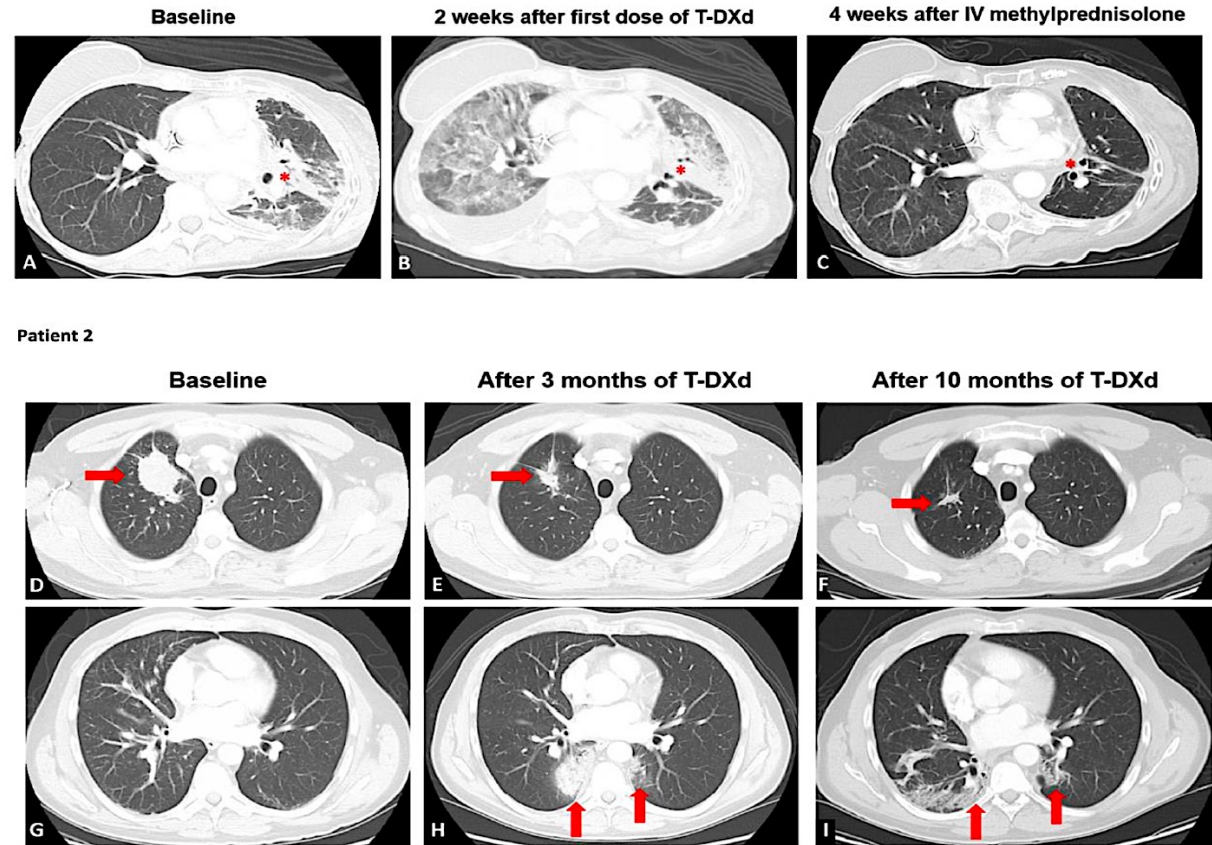
^aLeft ventricular dysfunction was reported in a total of 12 (4.5%) patients, of which 8 (3.0%) were considered possibly T-DXd–related. ^bOne patient had unknown grade of ejection fraction decrease.

ILD, interstitial lung disease; T-DXd, trastuzumab deruxtecan.

Interstitial Lung Disease (ILD)

Trastuzumab Deruxtecan

- **Inflammation and/or fibrosis** in the lungs
- T-DXd accumulation in **alveolar macrophages** → **off-target toxicity**
- Presentation with variable pulmonary **symptomatology or asymptotically** (radiographic opacities)
- **Symptoms:** dyspnea (most common), cough, malaise, chest pain, hypoxemia, and low-grade fever
- Can be **fulminant** and life-threatening



Swain, CTR 2022

Management of ILD

The 5 “S” rule



Pre-T-DXd treatment

Complete history and physical
HRCT
Baseline SpO₂
Consider pulmonary consult for patients with significant lung comorbidities
Provide patient education on risk and symptom identification

On T-DXd treatment

HRCT at least every 12 weeks, or every 6-9 weeks with baseline respiratory symptoms
Vitals signs including SpO₂ and symptom assessment with treatment visits

If ILD suspected

T-DXd-related ILD/pneumonitis should be suspected when
Radiographic changes potentially consistent with ILD/pneumonitis are seen
Patient experiences acute onset of new or worsening pulmonary signs/symptoms, such as dyspnea, cough, or fever

Immediately hold T-DXd therapy and proceed with diagnostic workup

Vitals and SpO₂ HRCT Blood tests

If clinically indicated, consider
PFTs
ABG
Bronchoscopy/BAL

**Consider early
Consultation of a
pulmonologist
Treatment with
corticosteroids as
clinically indicated**

Differential diagnostic workup and subsequent management should involve MDT including specialists as appropriate
Follow standard clinical practice as indicated for infectious, inflammatory, etc etiologies
For confirmed T-DXd-associated ILD, Tables 1 and 2 and T-DXd prescribing information

Final Overall Survival Results From the Phase 3 ROSELLA Trial: Relacorilant Plus Nab-Paclitaxel vs Nab-Paclitaxel Monotherapy in Patients With Platinum-Resistant Ovarian Cancer

(GOG-3073, ENGOT-ov72, APGOT-Ov10, LACOG-0223, and ANZGOG-2221/2023)

Alexander B Olawaiye,¹ Stanislas Quesada, Lucy Gilbert, Jae-Weon Kim, Mariana Scaranti, Elena Giudice, Elizabeth Hopp, Linda Mileskin, Toon Van Gorp, Michael E McCollum, Ana Oaknin, Aliza L Leiser, Philippe Follana, Chiara Cassani, Boglárka Balázs, Andrew Clamp, Hristina I. Pashova, Sachin G Pai, Nicoletta Colombo and Domenica Lorusso

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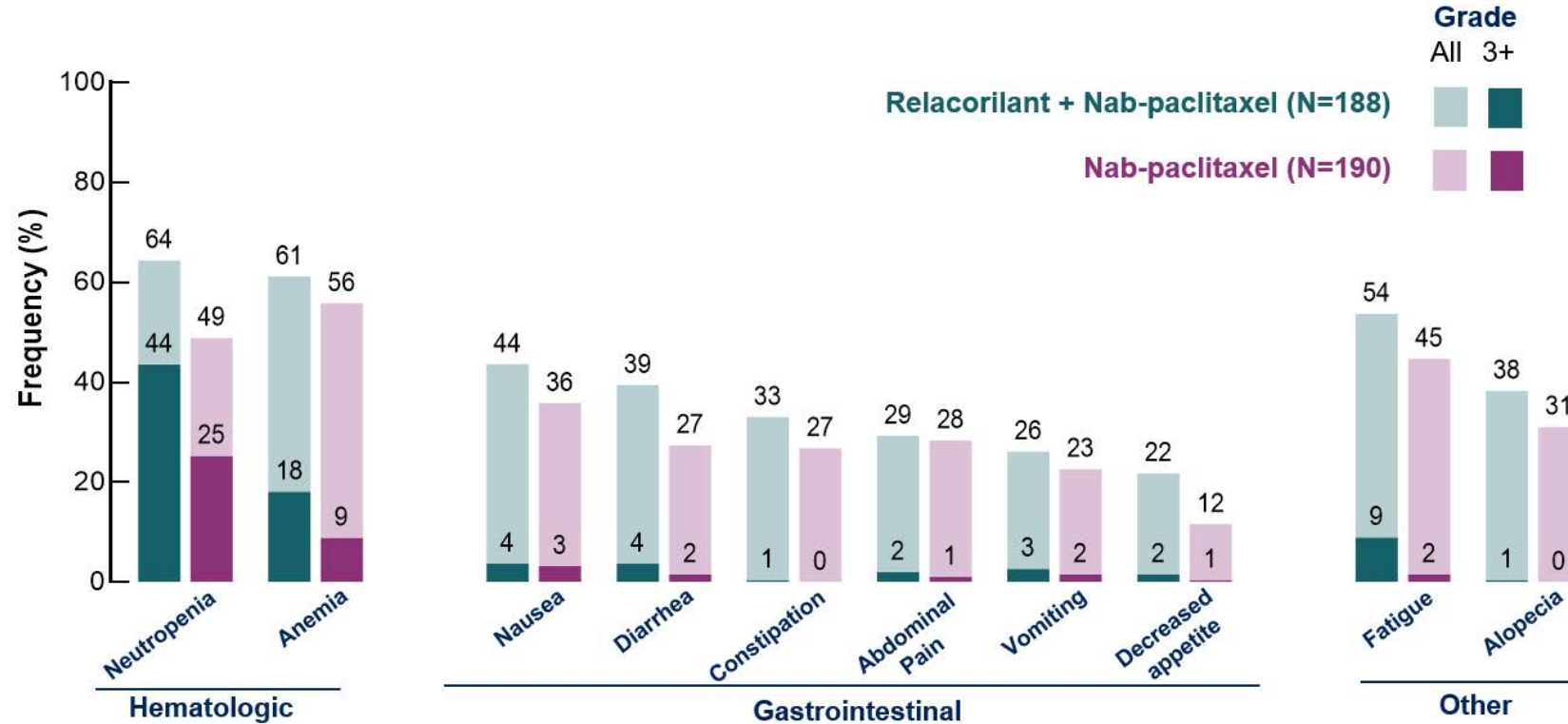
Plain Language
Summary



In collaboration with:



ROSELLA | Common (>20%) Adverse Events



When adjusted for duration of exposure, the incidence rates of neutropenia and anemia were similar between study arms.
 Peripheral neuropathy occurred with similar frequency in both arms (19.1% and 17.4%).
 5 SAEs of febrile neutropenia: 4 (2.1%) vs 1 (0.5%).* 5 SAEs of sepsis: 3 (1.6%) vs 2 (1.1%).*

Treatment-emergent adverse events that occurred in >20% of patients. Assessed in the safety population of patients who received at least one dose of study drug, N=378. Combined terms are presented for neutropenia (neutropenia, reduced neutrophil count, and febrile neutropenia), anemia (anemia, reduced hemoglobin, and reduced red blood cell count) and fatigue (fatigue and asthenia). SAEs, serious adverse events. *Comparing the relacorilant combination arm to the nab-paclitaxel monotherapy arm, respectively.

Data cutoff: Jan 8, 2026

Mitigations

- ❖ **Vigilance**
- ❖ **Monitor aggressively**
- ❖ **Prophylactic use of G-CSF in at-risk patients**
- ❖ **Reactive use of G-CSF in other patients**



Relacorilant USPI: Dose Modifications for Neutropenia

		Nab-paclitaxel	Relacorilant
ANC		Dosage Modification	
Day 1	1,000 to < 1,500/mm ³	Withhold until $\geq 1,500/\text{mm}^3$; resume at same dose	Withhold; Resume at the same dose once nab-paclitaxel resumes
	< 1,000/mm ³	Withhold until $\geq 1,500/\text{mm}^3$; resume at reduced dose	Withhold; Resume at the same dose once nab-paclitaxel resumes
Day 8 or 15	< 1,000/mm ³	Omit dose; resume at reduced dose or continue at the same dose with short acting G-CSF* If the delay in nab-paclitaxel dosing exceeds 7 days, omit the nab-paclitaxel dose.	Withhold; Resume at the same dose once nab-paclitaxel resumes
Febrile neutropenia	Grade 3 or 4	Withhold until fever resolves and ANC \geq 1,500/mm ³ ; resume at reduced dose	Withhold; Resume at the same dose once nab-paclitaxel resumes

* Supportive short acting G-CSF administered 24 hours after nab-paclitaxel for 2 days in accordance with clinical practice

Unless otherwise specified, Grade per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.

Conclusions

- ❖ **Adverse events are integral to cancer therapy**
- ❖ **Counseling and education of patients are important in mitigation**
- ❖ **Cancer care providers are duty-bound to familiarize themselves with therapy toxicities**
- ❖ **Vigilance can significantly reduce the impact of adverse events**



In general, do you initiate prophylactic steroid eye drops for your patients who are about to begin mirvetuximab soravtansine, or do you wait for ocular side effects to occur?



Prof Eskander

Wait for ocular side effects to occur



Dr Matulonis

Initiate prophylactic steroid eye drops



Dr Moore

Initiate prophylactic steroid eye drops



Dr Olawaiye

Initiate prophylactic steroid eye drops



Dr O'Malley

Initiate prophylactic steroid eye drops



Prof Colombo

Wait for ocular side effects to occur

Approximately what proportion of patients with advanced OC receiving mirvetuximab soravtansine develop new or worsening peripheral neuropathy?



Prof Eskander

40%-50% in clinical practice



Dr Matulonis

50%



Dr Moore

22%



Dr Olawaiye

20%



Dr O'Malley

20%-30%



Prof Colombo

20%

In your experience, what are the most commonly encountered treatment-related adverse events with relacorilant/*nab* paclitaxel?



Prof Eskander

Hematologic, nausea/emesis



Dr Matulonis

Myelosuppression, rash, fatigue, neuropathy, some hair loss



Dr Moore

Hematologic and gastrointestinal



Dr Olawaiye

Mostly side effects of *nab* paclitaxel, eg, anemia, neutropenia, nausea, vomiting



Dr O'Malley

Hematologic toxicity



Prof Colombo

Myelosuppression, nausea, fatigue

How would you indirectly compare the global tolerability of relacorilant/*nab* paclitaxel to that of pembrolizumab/weekly paclitaxel for patients with advanced OC?



Prof Eskander

Tolerability is about the same



Dr Matulonis

Pembrolizumab/weekly paclitaxel is more tolerable



Dr Moore

Relacorilant/*nab* paclitaxel is more tolerable



Dr Olawaiye

Relacorilant/*nab* paclitaxel is more tolerable



Dr O'Malley

Relacorilant/*nab* paclitaxel is more tolerable



Prof Colombo

Pembrolizumab/weekly paclitaxel is more tolerable

How would you indirectly compare the rates and severity of peripheral neuropathy with relacorilant/*nab* paclitaxel to those with mirvetuximab soravtansine for patients with advanced OC?



Prof Eskander

Peripheral neuropathy is worse with mirvetuximab soravtansine



Dr Matulonis

Peripheral neuropathy is worse with relacorilant/*nab* paclitaxel



Dr Moore

Peripheral neuropathy is worse with mirvetuximab soravtansine



Dr Olawaiye

Peripheral neuropathy is worse with mirvetuximab soravtansine



Dr O'Malley

Peripheral neuropathy is worse with relacorilant/*nab* paclitaxel



Prof Colombo

Peripheral neuropathy is worse with mirvetuximab soravtansine

Consensus or Controversy? Documenting and Discussing Investigators' Approaches to the Use of Oral SERDs and Agents Targeting the PI3K/AKT/mTOR Pathway in Breast Cancer

A CME Symposium Held Adjunct with the 2026 ASCO® Annual Meeting

Sunday, May 31, 2026

7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)

Faculty

Sara A Hurvitz, MD, FACP

Erica Mayer, MD, MPH, FASCO

Joyce O'Shaughnessy, MD

Nicholas Turner, MD, PhD

Moderator

Sara M Tolaney, MD, MPH

What Clinicians Want to Know: Addressing Community Oncologists' Questions About the Current and Future Management of Endometrial Cancer

A CME Symposium Held Adjunct with the 2026 ASCO® Annual Meeting

Sunday, May 31, 2026

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Faculty

Floor J Backes, MD

Brian M Slomovitz, MD

Moderator

Shannon N Westin, MD, MPH, FASCO, FACOG

**What Clinicians Want to Know: Addressing Community
Oncologists' Questions About the Roles of CAR T-Cell Therapy and
Bispecific Antibodies in the Management of Non-Hodgkin Lymphoma**

A CME Symposium Held Adjunct with the 2026 ASCO® Annual Meeting

Sunday, May 31, 2026

7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)

Faculty

Joshua Brody, MD

Manali Kamdar, MD, MBBS

Tysel Phillips, MD, FASCO

Jason Westin, MD, MS, FACP, FASCO

Moderator

Jeremy S Abramson, MD, MMSc

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