The GOG Highlight Reel
July 2025

A GOG Foundation, Inc. Educational Program

Date: Saturday, July 26, 2025
Time: 9:30 am – 12:00 pm ET
Location: National Press Club, Washington, DC

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GOG Highlight Reel

MODERATORS

Thomas Herzog, MD
University of Cincinnati
Cancer Center
Cincinnati, OH

Bradley Monk, MD
Florida Cancer Specialists &
Research Institute
West Palm Beach, FL

GOG Highlight Reel

GOG FOUNDATION®
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OUR MISSION

To conduct clinical and translational research that positively impacts patients through the prevention and treatment of gynecologic malignancies

OUR VISION

To be the premier collaborative network for transformative research in gynecologic malignancies

GOG Highlight Reel

FACULTY

Robert Coleman, MD
Texas Oncology
Austin, Texas

Ramez N. Eskander, MD
University of California San Diego
Moores Cancer Center
San Diego, California

Kathleen Moore, MD
University of Oklahoma
Stephenson Cancer Center
Oklahoma City, Oklahoma

David O'Malley, MD
The Ohio State University
James Comprehensive Cancer Center
Columbus, Ohio

Bhavana Pothuri, MD
NYU Langone
New York City, New York

Leslie Randall, MD
Inova Health
Fairfax, Virginia

Brian M. Slomovitz, MD
Mount Sinai Medical Center
Miami Beach, Florida

INVITED GUEST SPEAKERS

Linda Duska, MD, MPH
UVA Health
Charlottesville, Virgina

Alexander Olawaiye, MD
University of Pittsburgh,
Magee-Womens Hospital of UPMC
Pittsburgh, Pennsylvania

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GOG HIGHLIGHT REEL
PRE-TEST

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GOG Highlight Reel

LEARNING OBJECTIVES

Upon completion of the activities in this series, learners will demonstrate:

THE OVERALL OBJECTIVE FOR THIS SESSION IS TO SHOWCASE CLINICAL TRIALS AND OTHER NEWSWORTHY EDUCATION FROM MAJOR MEDICAL MEETINGS THROUGHOUT THE YEAR

Increased knowledge regarding:

- The current agents and regimens used in treating advanced, persistent, or recurrent cervical, endometrial, and ovarian cancers
- The key trial data for newly approved therapies in treating advanced, persistent, or recurrent cervical, endometrial, and ovarian cancers
- The current investigational agents and regimens under evaluation for the treatment of advanced, persistent, or recurrent cervical, endometrial, and ovarian cancers

Greater competence related to:

- Understanding the available therapies and selecting treatments for women with cervical, endometrial, and ovarian cancers
- Interpret and understand the application of recent data into clinical practice
- Learn about current clinical trials in gynecologic cancers and understand what opportunities exist in the public domain

GOG FACULTY DISCLOSURE INFORMATION

The GOG Highlight Reel: An Education Series Highlighting Newsworthy Data Distillation and Emerging Global Therapies in Clinical Trials
Saturday, July 26, 2025
Washington, D.C.

In accordance with the ACCME Accreditation Criteria, The GOG Foundation, Inc., as the accredited provider of this activity, must ensure that anyone in a position to control the content of the educational activity has disclosed all relevant financial relationships with any ineligible company *(formally known as commercial interests). All **Committee/Planning/Faculty members** were required to disclose all financial relationships and speakers were required to disclose any financial **relationship as it pertains to the content of the presentations.**

The ACCME does not consider providers of clinical service directly to patients to be an ineligible company. “Relevant” financial relationships are financial transactions (in any amount) occurring within the past 24 months that may create a conflict of interest.

Please note the presentations may include information and discussions on the use of a device, product, or drug that is not FDA approved or the off-label use of an approved device, product, or drug or unapproved usage. The requirement for disclosure is not intended to imply any impropriety of such relationships, but simply to identify such relationships through full disclosure, and to allow the audience to form its own judgments regarding the presentation.

All of the relevant financial relationships listed for these individuals have been mitigated. However, if you perceive a bias during a session, please report the circumstances on the session evaluation form.

NEW TERM *An “**ineligible company**” is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

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Name	Individual's Role(s) in Activity	Nothing To Disclose	Name of Ineligible Company(s)	Nature of Relevant Financial Relationship(s)
Planning Disclosures				
Herzog, Thomas, MD	**Planner/ Moderator**		Astra Zeneca; Caris; Clovis; Eisai; Epsilogen; Genentech; GSK; J&J; Merck; Mersana; Novocure; Seattle Genetics	Scientific Advisory Boards
Monk, Bradley, MD	**Planner/ Moderator**		Acrivon Adaptimmune ; Agenus; Akeso Bio; Amgen; AstraZeneca; Biohaven; BMS; Corcept; Easai; Eli Lilly; Genmab; Seagen; Pfizer; Genalux; GOG Foundation; Gradalis; GSK; HengRui; Immunogen; Abbvie; Karyopharm; Iovance; Merck; Mersana; Mural; Alkermes; Myriad; Novartis; Novocure; OncoC4; Panavance; Profound Bio; Regeneron; Roche; Genentech; Sutro; Verastem; Zentalis; Zymeworks	Consultant (Acrivon Adaptimmune ; Agenus; Akeso Bio; Amgen; AstraZeneca; Biohaven; BMS; Corcept; Easai; Eli Lilly; Genmab; Seagen; Pfizer; Genalux; GOG Foundation; Gradalis; GSK; HengRui; Immunogen; Abbvie; Karyopharm; Iovance; Merck; Mersana; Mural; Alkermes; Myriad; Novartis; Novocure; OncoC4; Panavance; Profound Bio; Regeneron; Roche; Genentech; Sutro; Verastem; Zentalis; Zymeworks) Speaker (AstraZeneca; Easai; GSK; Immunogen; Abbvie; Merck)
Speaker Disclosures				
Coleman, Robert, MD	**Speaker**		Mural; AstraZeneca; Pharma&; Eisai; Genentech USA Inc; GSK; Gradalis; Mersana; Novocure; Abbvie; Immunogen, Abbvie; Merck; Novrtis; Valero/Valbio; Seagen/Genmab/Pfizer; VBL; Eisai; GOG-Partners; Karyopharm	Consultant (Mural; AstraZeneca; Pharma&; Eisai; Genentech USA Inc; GSK; Gradalis; Mersana; Novocure; Seagen/Genmab/Pfizer) Grant Contract (Genentech USA Inc; Abbvie; Immunogen, Abbvie; Merck; Novrtis; Valero/Valbio; Seagen/Genmab/Pfizer; Karyopharm) Data & Safety Monitoring (VBL; Eisai; GOG-Partners)
Duska, Linda, MD, MPH	**Speaker**		Regeneron; Aadi Bioscience; Daiichi Sankyo; Agenus; NX Development Corp	Advisory Board (Regeneron; Aadi Bioscience; Daiichi Sankyo) Data Safety Monitoring -Money to institution (Agenus) NX Development Corp
Eskander, Ramez, MD	**Speaker**		AstraZeneca, MSD, Regeneron, PMV Pharmaceuticals, Daiichi Sanyo, GSK, Myriad, Seagen, Abbvie, Pfizer, Novocure, BioNTech, Eisai, Roche, Mersana; Nuvectis Pharma, Merck, Loxo @ Lilly, Genmab/Seagen, Clovis Oncology, Acrivon therapeutics, Zentalis, Eisai, Gilead, Roche	Consultant (AstraZeneca, MSD, Regeneron, PMV Pharmaceuticals, Daiichi Sankyo, GSK, Myriad, Seagen, Abbvie, Pfizer, Novocure, BioNTech, Eisai, Roche, Mersana) Research Funding (Nuvectis Pharma, GSK, Merck, Daiichi Sankyo, Loxo @ Lilly, AstraZeneca, Genmab/Seagen, Clovis Oncology, Acrivon Therapeutics, Zentalis, Eisai, Gilead, Roche)
Moore, Kathleen, MD	**Speaker**		Research To Practice; Company: Prime Oncology; Great Debates and Updates; Corcept; Abbvie; Nykode Therapeutics; third arc; Astellas Medivation; GOG Partners; NRG Ovarian Committee Chair; Genentech/Roche; Immunogen; AstraZeneca; Merck; Eisai; Verastem/Pharmacyclics; AADi; Caris Life Sciences; Iovance Biotherapeutics; Janssen Oncology; Regeneron; zentalis; Daiichi Sankyo Europe GmbH; Novacure; BioNTech SE; immunocore; Sanofi/Aventis; seagen; Takeda Science Foundation; zymeworks; profound bio; Mersana; Blueprint pharmacetuicals; GSK/Tesaro; Duality Biologics; Artios; Amgen; Schrodinger; Daiichi Sankyo/Lilly; Regeneron; Up to Date; BioNTech SE	Honoraria (Research To Practice; Company: Prime Oncology; Great Debates and Updates; Corcept; Abbvie; Nykode Therapeutics; third arc; Astellas Medivation Leadership (GOG Partners; NRG Ovarian Committee Chair) Consulting or Advisory Role (Genentech/Roche; Immunogen; AstraZeneca; Merck; Eisai; Verastem/Pharmacyclics; AADi; Caris Life Sciences; Iovance Biotherapeutics; Janssen Oncology; Regeneron; zentalis; Daiichi Sankyo Europe GmbH; Novacure; BioNTech SE; immunocore; Sanofi/Aventis; seagen; Takeda Science Foundation; zymeworks; profound bio; Mersana; Blueprint pharmacetuicals; GSK/Tesaro; Duality Biologics; Schrodinger) Research Funding (Merck; Regeneron; Verastem; AstraZeneca; Immunogen; Artios; Amgen; Daiichi Sankyo/Lilly; Immunocore) Patents, Royalties, Other Intellectual Property (Up to Date) Travel, Accommodations, Expenses (BioNTech SE)
Olawaiye, Alexander, MD	**Speaker**		AstraZeneca; GSK; Merck; Daiichi Sankyo	Advisory Board

GOG FACULTY DISCLOSURE INFORMATION (Cont.)

Name	Individual's Role(s) in Activity	Nothing To Disclose	Name of Ineligible Company(s)	Nature of Relevant Financial Relationship(s)
Speaker Disclosures				
O'Malley, David, MD	**Speaker**		AbbVie; AdaptImmune; Advaxis; Agenus,Inc; Alkermes; Aravive, Inc.; Arcus Biosciences, Inc.; Arquer Diagnostics; AstraZeneca; Atossa Therapeutics; BeiGene USA,Inc.; Boston Biomedical; Bristol Myers Squibb; Cardiff Oncology; Celcuity; Clovis Oncology; Corcept Therapeutics; Deciphera Pharma; Duality Bio; Eisai; Elevar; EMD Serono, Inc.; Exelixis; Genentech Inc; Genmab; Genelux; GlaxoSmithKline; GOG Foundation; Hoffmann-La Roche Inc; ImmunoGen, Inc; Imvax; InterVenn; INXMED; Incyte Corporation; IOVANCE Biotherapeutics; Jazz Pharmaceuticals; Karyopharm; Laekna; Leap Therapeutics, Inc.; Ludwig Institute for Ca; Luzsana Biotechology; Merck & Co; Merck Sharp & Dohme Corp.; Mersana Therapeutics,Inc.; Myriad; NCI; Novartis; NovoCure; NRG Oncology; OncoC4, Inc.; OncoQuest Inc.; Onconova; Pfizer Inc; Precision Therapeutics, Inc.; Prelude Therapeutics; Regeneron Pharmaceuticals, Inc; RTOG; Rubius Therapeutics; RepImmune; R Pharm; Roche Diagnostics; Seattle Genetics (SeaGen); Sorrento; Sutro Biopharma; SWOG; ; Tarveda Therapeutics; Toray; Trillium; Umoja; Verastem, Inc; VBL Therapeutics; Vincerx Pharma; Xencor; Zentalis	Institution Received Funds for research (AbbVie; Advaxis; Agenus,Inc; Alkermes; Aravive, Inc.; Arcus Biosciences, Inc.; AstraZeneca; BeiGene USA,Inc.; Boston; Biomedical; Bristol Myers Squibb; Clovis Oncology; Deciphera Pharma; Eisai; EMD Serono, Inc.; Exelixis; Genentech Inc; Genmab; GlaxoSmithKline; GOG Foundation; Hoffmann-La Roche Inc; ImmunoGen, Inc; Incyte Corporation; IOVANCE Biotherapeutics; Karyopharm; Leap Therapeutics, Inc.; Ludwig Institute for Ca; Merck & Co; Merck Sharp & Dohme Corp.; Mersana Therapeutics,Inc.; NCI; Novartis; NovoCure; NRG Oncology; OncoC4, Inc.; OncoQuest Inc.; Pfizer Inc; Precision Therapeutics, Inc.; Prelude Therapeutics; Regeneron Pharmaceuticals, Inc; RTOG; Rubius Therapeutics; Seattle Genetics (SeaGen); Sutro Biopharma; SWOG; Verastem, Inc) Ad Board/Consultant (AbbVie; AdaptImmune; Agenus,Inc; Arquer Diagnostics; Arcus Biosciences, Inc.; AstraZeneca; Atossa Therapeutics; Boston Biomedical; Cardiff Oncology; Celcuity; Clovis Oncology; Corcept Therapeutics; Duality Bio; Eisai; Elevar; Exelixis; Genentech Inc; Genelux; GlaxoSmithKline; GOG Foundation; Hoffmann-La Roche Inc; ImmunoGen, Inc; Imvax; InterVenn; INXMED; Jazz Pharmaceuticals; Laekna; Leap Therapeutics, Inc.; Luzsana Biotechology; Merck & Co; Merck Sharp & Dohme Corp.; Mersana Therapeutics,Inc.; Myriad; Novartis; NovoCure; OncoC4, Inc.; Onconova; Regeneron Pharmaceuticals, Inc; RepImmune; R Pharm; Roche Diagnostics; Seattle Genetics (SeaGen); Sorrento; Sutro Biopharma; Tarveda Therapeutics; Toray; Trillium; Umoja; Verastem, Inc; VBL Therapeutics; Vincerx Pharma; Xencor; Zentalis
Pothuri, Bhavana, MD, MS	**Speaker**		AstraZeneca; celsion/Immunon; Clovis Oncology, Inc.; Genentec; Eisai; GlaxoSmithKline; GOG foundation; Imab; Immunogen; Incyte Corporation; Karyopharm Therapeutics; Merck; Mersana; Seagen Inc.; Sutro; Toray Industriesc	Consultant (AstraZeneca; Eisai; GlaxoSmithKline; GOG foundation; Merck; Mersana; Seagen Inc.; Sutro) Grant/Contract (AstraZeneca; celsion/Immunon; Clovis Oncology, Inc.; Genentec; GlaxoSmithKline; Imab; Immunogen; Incyte Corporation; Karyopharm Therapeutics; Merck; Mersana; Seagen Inc.; Sutro; Toray Industries)
Randall, Leslie, MD	**Speaker**		AstraZeneca; Genmab; Pfizer; GSK; Eisai; Merck; AbbVie; GOG Foundation	Consultant (AstraZeneca; Genmab; Pfizer; GSK, Eisai; Merck; Abbvie; GOG Foundation) Research Funding (Merck; AbbVie; GOG Foundation)
Slomovitz, Brian, MD	**Speaker**		Seagen, Novocure; AstraZeneca; Aadi; Regeneron; Immunocore; Merck; Gilead, Eisai; Incyte	Consultant
Holley Engbert	**Staff**	**X**		
Heather Rush	**Staff**	**X**		
Kara Shumaker	**Reviewer/Staff**	**X**		
Michelle N Small, MPH	**Reviewer/Staff**	**X**		
Angeles Alvarez-Secord, MD	**Reviewer/Edu-Chair**		AZ, Abbvie; Aravive; Clovis, Eisai, Ellipses Pharma, Roche/Genentec ; GSK; I-MAB Biopharma; Immunogen; Karyopharm; Merck; Mersana; Seagen; VBL Therapeutics; Zentalis; Gilead; Oncoquest/Canaria Bio	Research funds to institution (AZ, Abbvie; Aravive; Clovis; Eisai; Ellipses Pharma; Roche/Genentec; GSK; I-MAB Biopharma; Immunogen; Karyopharm; Merck; Mersana; Seagen; VBL Therapeutics; Zentalis; Oncoquest/Canaria BIo) Adboard (Abbvie) Uncomp AdBoard (Gilead; Oncoquest/Canaria Bio; Aravive; VBL) SteeringCommitte (Aravive; VBL; Oncoquest/Canaria Bio) Stock (Amgen; Johnson&Johnson, Divested)
Linda Duska, MD	**Reviewer/Edu-Co-Chair**		Regeneron; Aadi Bioscience; Daiichi Sankyo; Agenus; NX Development Corp	Advisory Board (Regeneron; Aadi Bioscience; Daiichi Sankyo) Data Safety Monitoring -Money to institution (Agenus) NX Development Corp
Stephanie Blank, MD	**Reviewer**		AstraZeneca; Merck; Zentalis; Acrivon; Seattle Genetics; GSK	Research Funding to Institution
David Mutch, MD	**Reviewer**	**X**		
Susan Zweizig, MD	**Reviewer**	**X**		

GOG CONTINUING EDUCATION

In support of improving patient care, this activity has been planned and implemented by The GOG Foundation, Inc. (GOG).

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The GOG Foundation, Inc. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education for physicians.

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Method of Participation
There are no fees for participating in and receiving CME credit for this activity. Participants must: 1) read the educational objectives and faculty disclosures; 2) attend the educational activity; 3) complete the online evaluation that will be sent to all registered participants who provide a valid email address and attend the activity. Participants who complete the educational activity and evaluation will receive a certificate of credit.

Participants who complete the educational activity, pre- and post-test, and evaluation will receive a certificate of credit.

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AGENDA

9:30 AM – 9:35 AM **WELCOME & INTRODUCTIONS**
Thomas Herzog, MD, University of Cincinnati
Bradley Monk, MD, Florida Cancer Specialists and Research Institute

9:35 AM – 10:30 AM **PART 1: THE LANDSCAPE EVOLUTION OF ENDOMETRIAL CANCER: APPROVALS, EVIDENCE AND IMPACT**
The Evolving Therapeutic Landscape and State of the Science, Ramez N. Eskander, MD, University of California San Diego Moores Cancer Center
Implementing Clinical Trials Into Your Practice: A Case Series, Brian Slomovitz, MD, Mount Sinai Medical Center
Panel Discussion and Audience Q&A, All Faculty

10:32 AM – 10:55 AM **PART 2: TREATING CERVICAL CANCER: A ROADMAP TO UNDERSTAND THERAPY OPPORTUNITIES**
A Roadmap to Understand Therapy Opportunities, Leslie Randall, MD, Inova Health
A Roadmap to Understand Therapy Opportunities in Locally Advanced Disease, Linda Duska, MD, UVA Health
Panel Discussion and Audience Q&A, All Faculty

10:57 AM –11:40 AM **PART 3: ENHANCING OVARIAN CANCER CARE: NEW REGIMENS AND INNOVATIVE TREATMENT APPROACHES WHAT'S NEW IN OVARIAN CANCER**
Ovarian Cancer Highlights: Summary, Robert Coleman, MD, Texas Oncology
Ovarian Cancer: Updates, David O'Malley, MD, The Ohio State University
Rosella Data Highlights & Panel Discussion, Alexander Olawaiye, MD, University of Pittsburgh, Magee-Womens Hospital of UPMC
Innovations in Treatment for Ovarian Cancer, Kathleen Moore, MD, Stephenson Cancer Center, University of Oklahoma

11:40 AM –11:55 AM **PANEL DISCUSSION AND AUDIENCE Q&A**
All Faculty

11:55 AM – 12:00 PM **CLOSING REMARKS AND ANNOUNCEMENT OF THE WINTER 2026 GOG HIGHLIGHT REEL**
Thomas Herzog, MD, University of Cincinnati

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Endometrial Cancer: The Evolving Therapeutic Landscape and State of the Science

Ramez N. Eskander, MD
Professor of Gynecologic Oncology
UC San Diego Health
Rebecca & John Moores NCI Designated Comprehensive Cancer Center
La Jolla, CA

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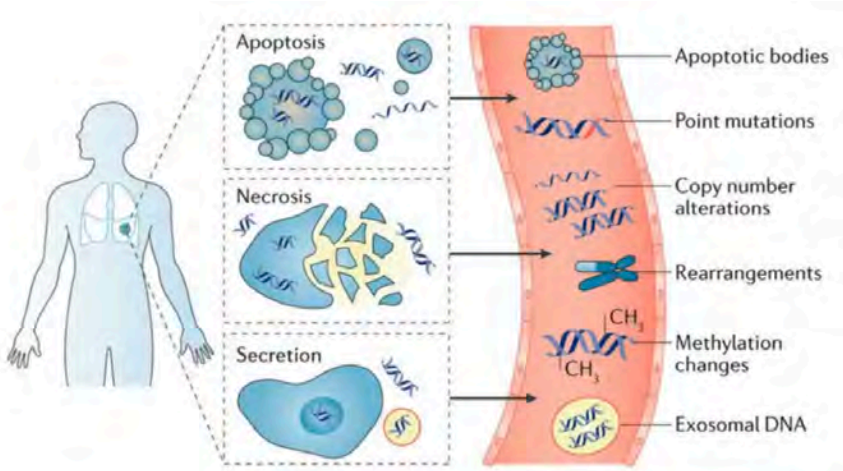
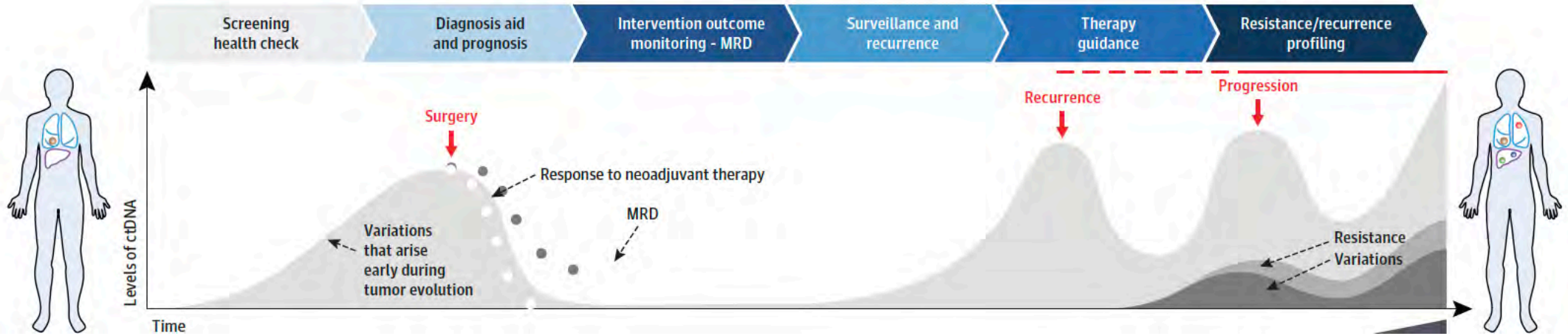
Role of ctDNA in EC

Defining ctDNA and its potential roles in cancer therapeutics



Wan, J., Massie, C., Garcia-Corbacho, J. *et al. Nat Rev Cancer* **17**, 223–238 (2017).

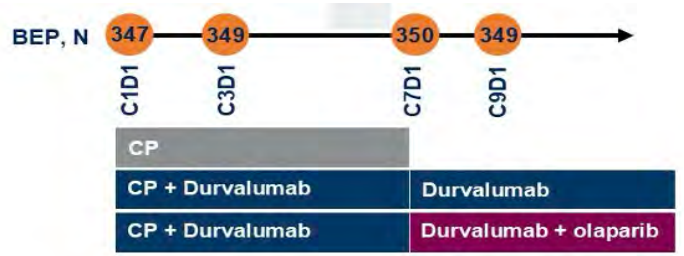


Krebs et al. JAMA Oncol Rev 2022

ctDNA in EC: DUO-E/GOG-3041/ENGOT-En10

(post-hoc exploratory, longitudinal ctDNA analysis)

N=718 in ITT
N=341 (47.5%) with ctDNA at all 4 time points



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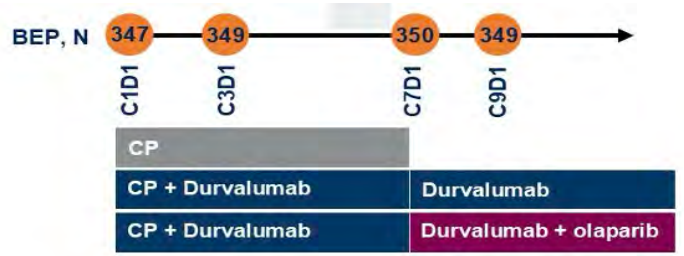


ctDNA in EC

How will this data inform clinical practice if at all?

Does prognostic data/information matter?

Are you using ctDNA in the management of your endometrial, ovarian, or cervical cancer patients?

What future clinical trials are needed to inform incorporation of ctDNA in gynecologic cancer care?

Limitations of ctDNA:

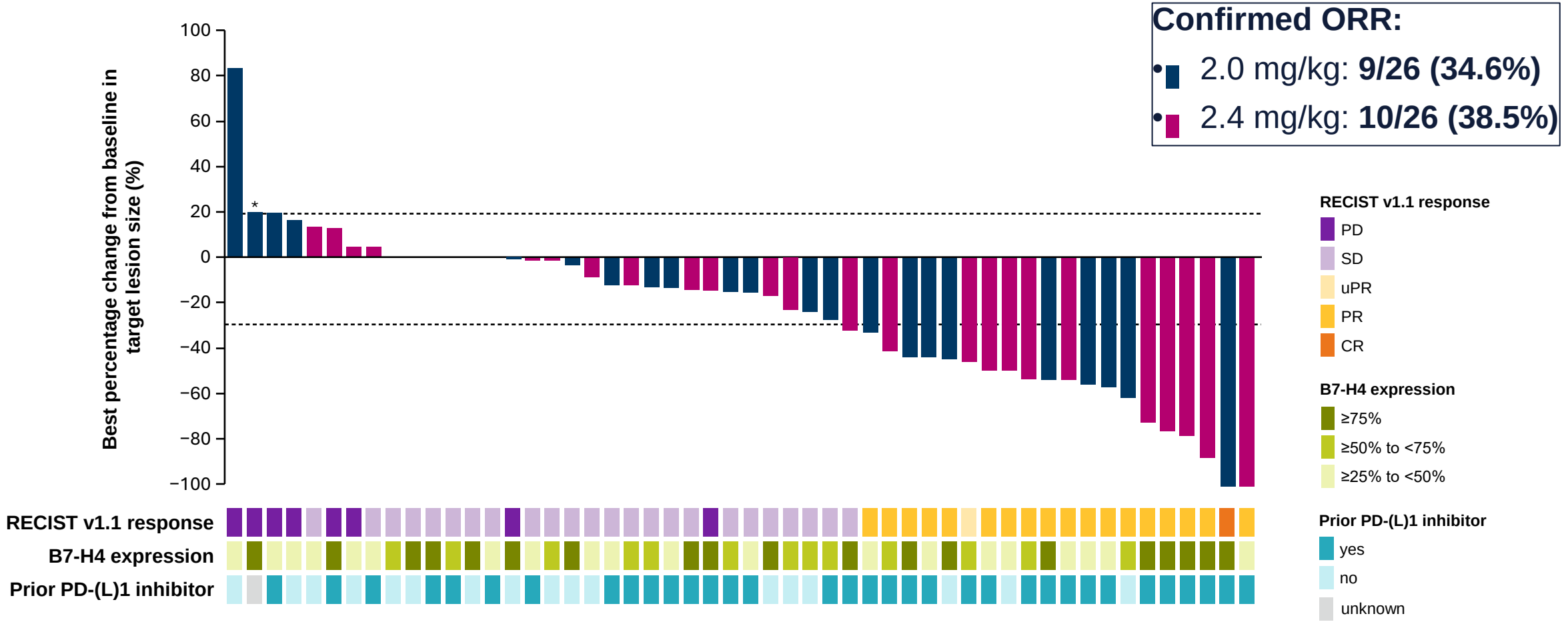
- Not all diseases ”shed” similarly
- Lead time bias, rather than impact on clinical outcomes
- Need to better understand/define actionable biomarkers
- Tissue is “gold-standard”
- Lack of proof to improve clinical management

ADC preliminary efficacy in EC

	Sacituzumab Govitecan (SG) TROPiCS-03	Datopotamab Deruxtecan (Dato-DXd) TROPION-PanTumor03	Sacituzuman Tirumotecan (sac-TMT)	Rinatabart Sesutecan (Rina-S)
Target	Trop-2	Trop-2	Trop-2	FR-alpha
Payload	SN-38 (metabolite of Topo-I inhibitor)	Deruxtecan (Topo-I payload)	Novel Topo-I inhibitor (KL610023)	Exatecan (Topo-I inhibitor)
DAR	7.6	4	7.4	8
Study Size	N=41	N=40	N=44	N=64
Patient Population	- 61% with ≥3 prior lines - 85% prior IO	- 73% with 1 prior line - 22.5% prior IO	- 48% with 1 prior line - 36% prior IO	- 95-100% with prior IO
Region Trial conducted	United States	- EU (45%) - Asia (45%)	- Almost entirely China	- ? Predominantly US
Efficacy	ORR 33%	ORR 27.5%	ORR 27.3% (41.7% H-score>200)	ORR 50% in the N=22 at 100mg/m2
SAEs	- Neutropenia - Diarrhea	- Stomatitis - Anemia - Amylase Increase	- Stomatitis - Anemia - Neutropenia	- Anemia - Neutropenia - Thrombocytopenia

Santin A et al J Clin Oncol 2024,A Oaknin et al ESMO 2024, Wang et al. ESMO 2024, Lee et al ESMO 2024; Winer et al ASCO 2025

Puxitatug samrotecan (P-Sam):B7-H4 targeting TOPO-1 ADC Efficacy observed in EC across B7-H4 expression



Includes patients who had the opportunity for ≥13 weeks of follow-up at data cut-off: January 30, 2025
*Patient was discontinued prior to first evaluation scan
CR, complete response; ORR, objective response rate; PD, progressive disease; PD-(L)1, programmed cell death (ligand) 1; PR, partial response; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; SD, stable disease; uPR, unconfirmed partial response

Presented at SGO Annual Meeting, 2025, Seattle, WA

Rina-S for patients with advanced stage/recurrent EC: RAINFOL-01

	Rinatabart Sesutecan (Rina-S)
Target	FR-alpha
Payload	Exatecan (Topo-I inhibitor)
DAR	8
Study Size	N=64
Patient Population	- 95-100% with prior IO
Region Trial conducted	- ? Predominantly US
Efficacy	ORR 50% in the N=22 at 100mg/m2
SAEs	- Anemia - Neutropenia - Thrombocytopenia

Table 2. Antitumor Activity With Rina-S

	Rina-S 100 mg/m^2 (n=22)	Rina-S 120 mg/m^2 (n=34)[a]
Median on-study follow-up[b], months (95% CI)	7.7 (7.2-8.4)	9.8 (7.9-11.8)
Confirmed ORR[c], % (95% CI)	50.0 (28.2-71.8)	47.1 (29.8-64.9)
Confirmed response, n (%)		
CR	2 (9.1)	0
PR	9 (40.9)	16 (47.1)
SD	11 (50.0)	13 (38.2)
NE	0	1 (2.9)
Disease control rate, % (95% CI)	100 (84.6-100.0)	85.3 (68.9-95.0)

- **Median time to response was 6 weeks**

Winer et al ASCO 2025

ADCs in EC…

What is your impression of this data?

Do you suspect that target expression levels will inform efficacy, long term?

How are we going to distinguish between multiple ADCs, if available, in the EC space

Sequencing…?

Evolution of Molecularly Directed Therapy in Endometrial Cancer

TP53

- Predictive biomarker of response to anti-angiogenic therapy
- **GOG-86P:**
  PFS HR 0.48 vs 0.87 in mutant TP53 vs. TP53wt
- **Selinexor:**
  - Inhibition of nuclear export of wild-type TP53
  - Median PFS: 28.4 months (TP53wt) vs 5.2 months (placebo).

Anti-HER2 (+ other ADC's)

- Evolving anti-HER2 treatment
- **DESTINY-Pan Tumor02**: ORR 57.5%; Median DOR: NR
- **US FDA Accelerated Approval in HER2 3+**
- **Other ADCs targets:** TROP-2, B7H4, FRalpha, etc…

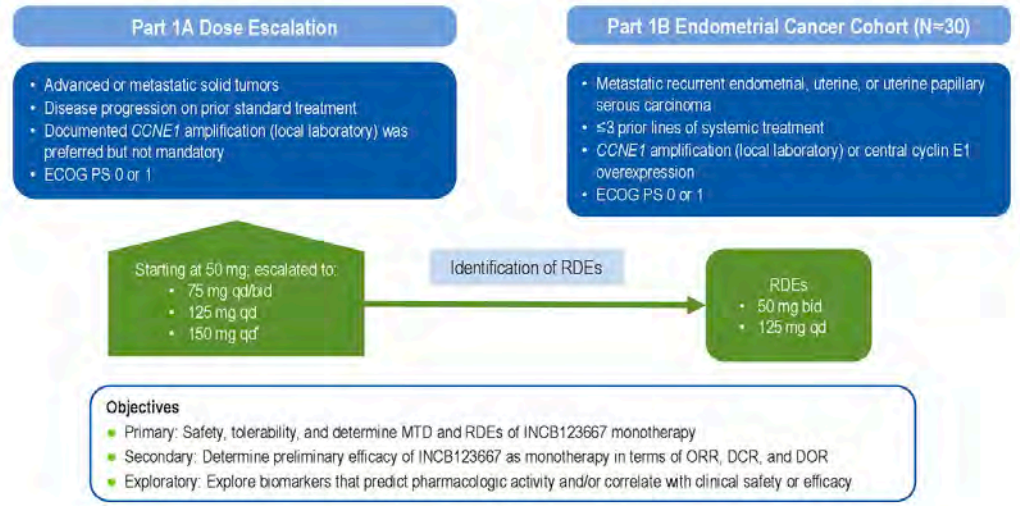
Hormonal Therapies

- May benefit copy-number low, TP53wt tumors.
- **PALEO Study (**Letrozole vs Palbocilcib + letrozole):
- HR 0.56; Median PFS 8.3 vs 3 mo
- Everolimus/Letrozole PFS:28 mths
- **Letrozole + Abemaciclib:** ORR 30%

Other Targets

- CDK 2 inhibitors
- Beta-catenin/CREB-BP interaction inhibition
- **CHK1 / 2 inhibition**
- CDK2 inhibition

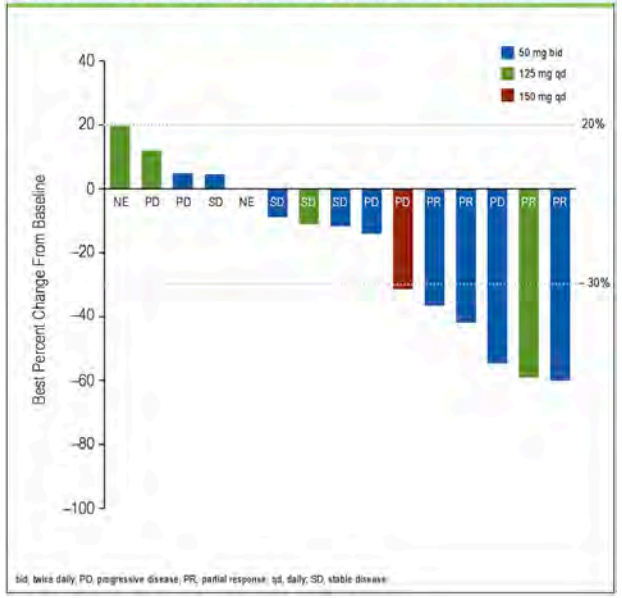
Phase 1 study of INCB123667 (selective CDK2 inhibitor) in patients with metastatic, recurrent EC



Variable	Total (N=19)
Age, median (range), years	62.0 (55, 76)
≥65, n (%)	5 (26.3)
Race, n (%)	
White	14 (73.7)
Black	1 (5.3)
Asian	2 (10.5)
Not reported/unknown	2 (10.5)
Histology, n (%)	
Endometrioid	6 (31.6)
Serous carcinoma	7 (36.8)
Carcinosarcoma	4 (21.1)
Clear cell carcinoma	1 (5.3)
Mixed serous and clear cell carcinoma	1 (5.3)
Cyclin E1 overexpression,* n (%)	17 (89.5)
CCNE1 amplification,* n (%)	10 (52.6)
Prior lines of systemic therapies, median (range)	3 (1-5)
Prior bevacizumab, n (%)	2 (10.5)
Prior anti–PD-1 mAbs, n (%)	11 (57.9)

*Overexpression as determined by central testing; *CCNE1* amplification determined by either local results or central testing.
CCNE1, cyclin E1; mAbs, monoclonal antibodies; PD-1, programmed cell death protein 1

Figure 3. Best Percent Decrease in Tumor Size for Individual Patients



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

Table 4. Treatment Response*

Variable	Total (n=17)
Best overall response, n (%)	
CR	0 (0)
PR	4 (23.5)
SD	4 (23.5)
PD	6 (35.3)
NE	2 (11.8)
Missing	1 (5.9)
ORR, n (%) [95% CI]	4 (23.5) [6.8, 49.9]
DCR, n (%) [95% CI]	8 (47.1) [23.0, 72.2]
PFS, median (95% CI), months	3.7 (1.9, 9.4)
DOR, median (95% CI), months	5.7 (3.6, NE)

*Part 1A and Part 1B combined.
CI, confidence interval; CR, complete response; DCR, disease control rate; DOR, duration of response; NE, not evaluable; ORR, objective response rate; PD, progressive disease; PFS, progression-free survival; PR, partial response; SD, stable disease.

3 of 4 responders had CCNE1 overexpression, including 2 with amplification

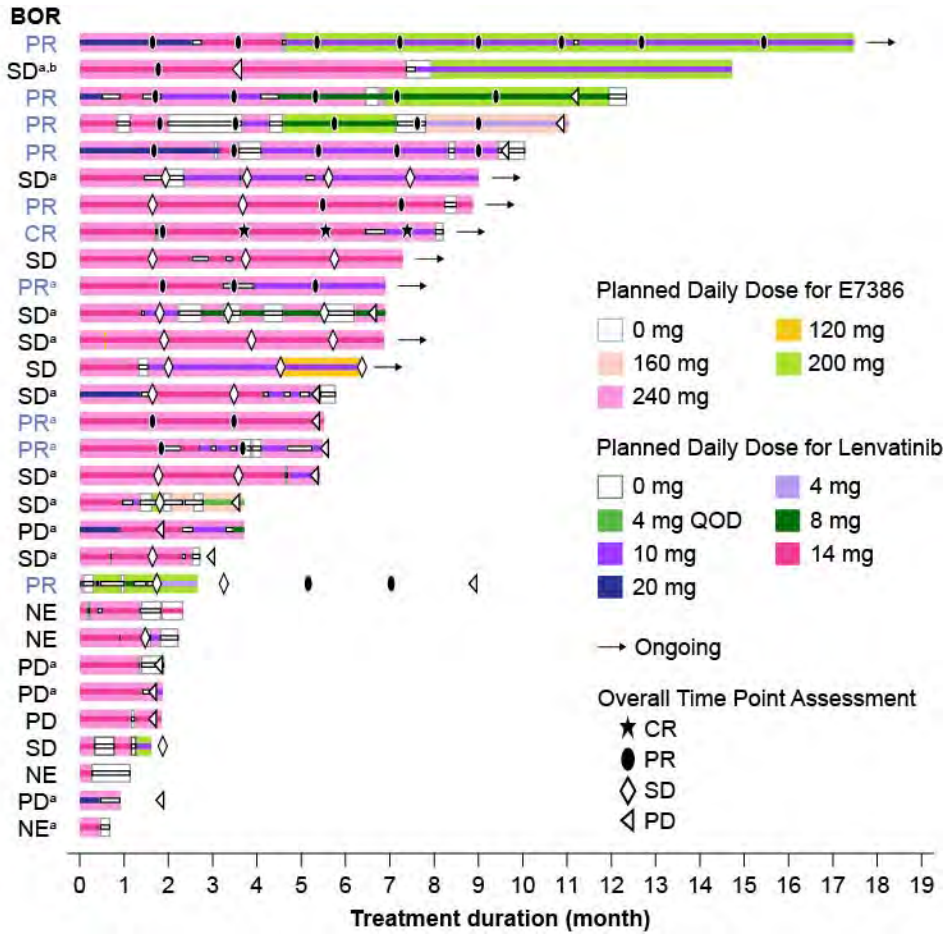
Lorusso et al. Presented at ASCO Annual Meeting, 2025

E7386: Wnt/Beta-Catenin and CREB binding Protein

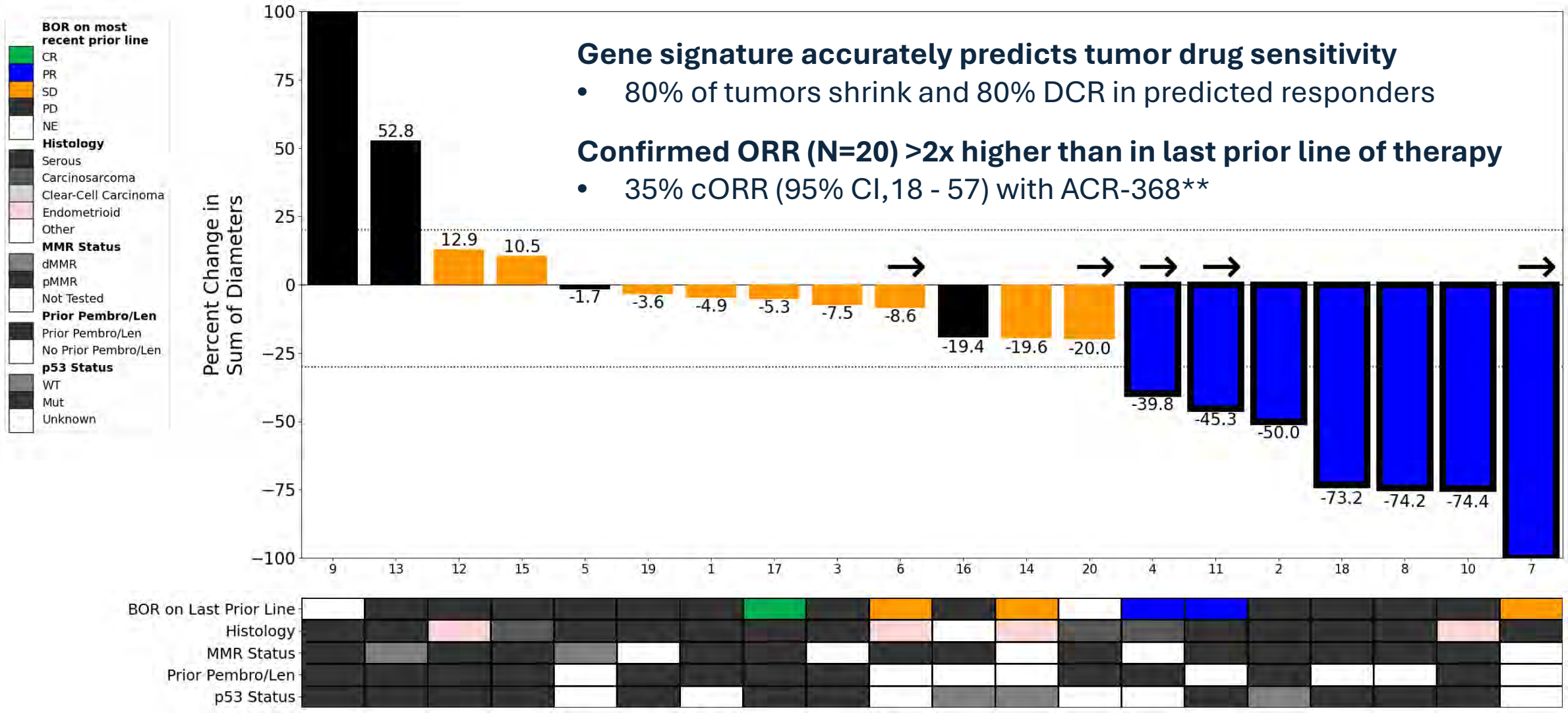
Category	Overall N = 30
Best overall response, n (%)	
Confirmed CR	1 (3.3)
Confirmed PR	9 (30.0)[a]
Stable disease	11 (36.7)
Progressive disease	5 (16.7)
Unknown/not evaluable[b]	4 (13.3)
ORR (CR + PR), % (95% CI)	33.3 (17.3–52.8)
ORR in patients who had not received prior lenvatinib (n = 14), n (%)	7 (50.0)[c]
ORR in patients who had received prior lenvatinib (n = 16), n (%)	3 (18.8)[d]
Median DOR, months (95% CI)	8.0 (3.7–9.5)
CBR (CR + PR + SD for ≥ 23 weeks), % (95% CI)	56.7 (37.4–74.5)
Median PFS, months (95% CI)	5.5 (3.0–9.6)

[a]Three patients with confirmed PR had received lenvatinib as prior therapy; [b]2 patients had no post-baseline tumor assessment, 1 patient had an early SD (< 7 weeks) and 1 patient had ≥ 1 lesion not evaluable; [c]Percent based on 14 patients who did not receive prior lenvatinib; [d]Percent based on the 16 patients who received prior lenvatinib.

Changes in sums of diameters of target lesions[a,b]



ACR-368: Phase 2 trial of CHK1/2 inhibitor in patients with recurrent EC



Gene signature accurately predicts tumor drug sensitivity

- 80% of tumors shrink and 80% DCR in predicted responders

Confirmed ORR (N=20) >2x higher than in last prior line of therapy

- 35% cORR (95% CI,18 - 57) with ACR-368**

*BOR of either BICR or INV

** cORR of ACR-368 is 37.5% versus 12.5% in the last prior line for the patients (N =16) with known BOR in last prior line (≥2nd line)

Agent	Most Commonly Reported AEs (all grade/Grade≥3)
INCB123667 (selective CDK2 inhibitor)	Best ORR at 100 mg daily dose: - Anemia (35.7%/7.1%) - Neutropenia (42.9%/0%) - Thrombocytopenia (35.7%/0%) - Nausea (71.4%/0%) No drug discontinuations due to TEAEs
E7386 (inhibits interaction between β-catenin and CREB-binding protein)	E7386 dosed at 120 mg PO BID + Lenvatinib 14 mg PO QD - Emesis (75.3%/3.3%) - Nausea (66.7%/6/7%) - Diarrhea (43.3%/12.3%) - PPE (36.7%/0%) - HTN (30%/6.7%) 6.7% discontinuation due to TEAEs
ACR-368 (CHK1/2 inhibitor)	Mixed BM+ and BM- population (% not clearly reported) - Anemia - Thrombocytopenia - Neutropenia - Febrile Neutropenia

Lee et al. ASCO 2025; Lorusso et al. ASCO 2025; J-M Lee et al ESMO 2024

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Implementing Clinical Trials Into Your Practice: A Case Series

Brian M. Slomovitz, MD, FACOG

Director, Gynecologic Oncology, Mount Sinai Medical Center
Professor, Obstetrics and Gynecology, Florida International University
Member, Board of Directors, GOG Foundation
Uterine Cancer Clinical Trial Lead, GOG Partners
Miami Beach, FL

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GOG Partners:
Trials Open or Under-Development

Adjuvant Therapy: 1

First-Line Therapy: 4 (3 ADC, 1 other)

Second Line: 8 (5 ADC, 3 other)

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Case 1

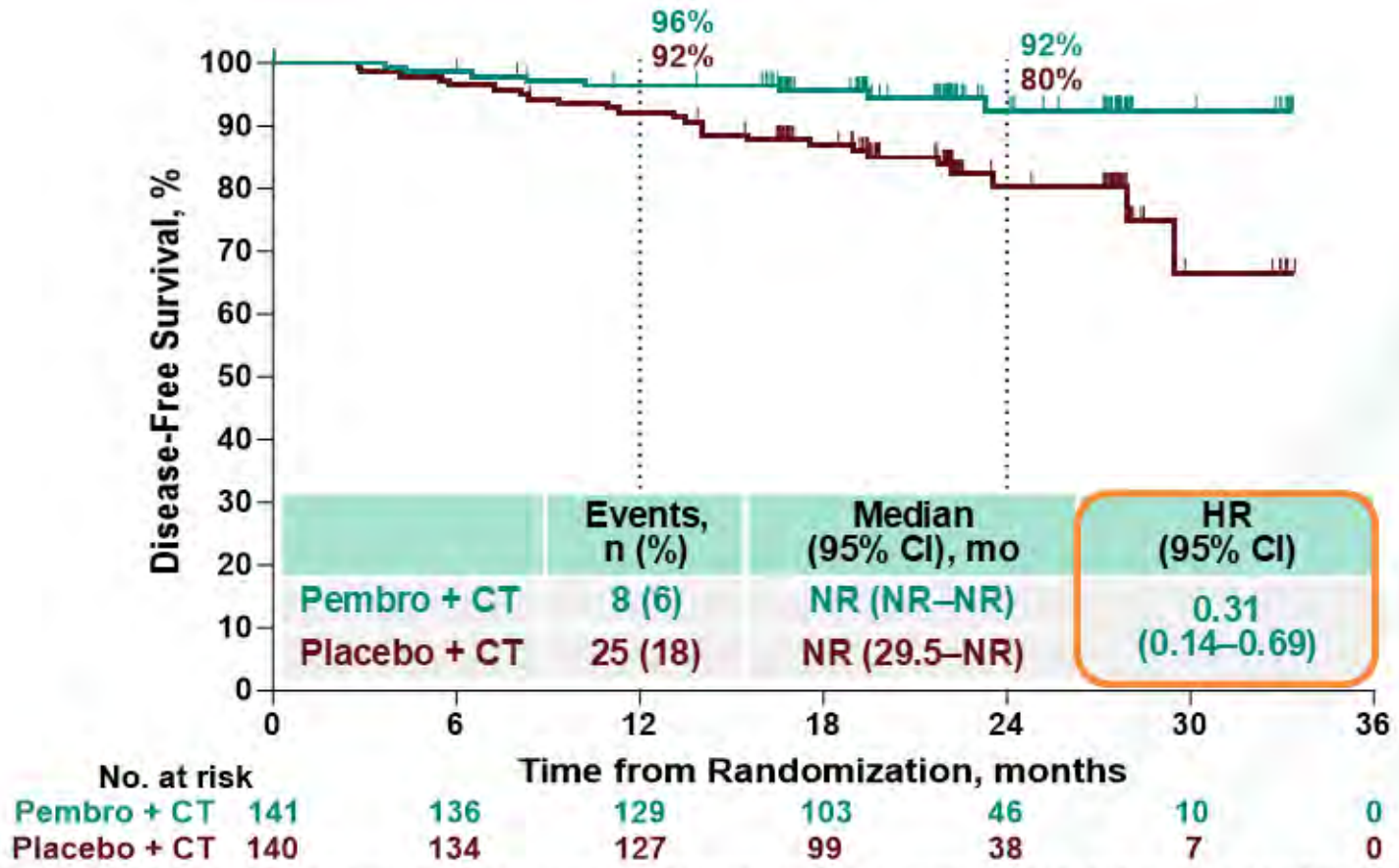
- 73-year-old with newly diagnosed uterine serous carcinoma
- s/p RA-TLH, SLNB
- Path: Stage IIC USC (FIGO 2023), nodes negative
- IHC: pMMR, p53 mutated, HER2 2+

Treatment Options:

- SOC: Carboplatin/paclitaxel +/- VB
- Role of I/O
- Clinical trials

What about IO in early stage completely resected EC?

ENGOT-EN11/GOG-3053/**KEYNOTE-B21: dMMR**



[a]DFS was defined as the time from randomization to local or distant recurrence of EC (assessed radiographically by the investigator or by histopathologic confirmation) or death from any cause. Data cutoff date: March 4, 2024.

Slomovitz et al. IGCS 2024

DESTINY-Endometrial02/ GOG-3122/ENGOT-en30/GINECO :

A Phase 3, Multicenter, Randomized, Open-label Trial of Trastuzumab Deruxtecan Versus Standard of Care Chemotherapy With or Without Radiotherapy as Adjuvant Treatment for HER2-Expressing (IHC 3+/2+) Endometrial Cancer

Tissue Screening

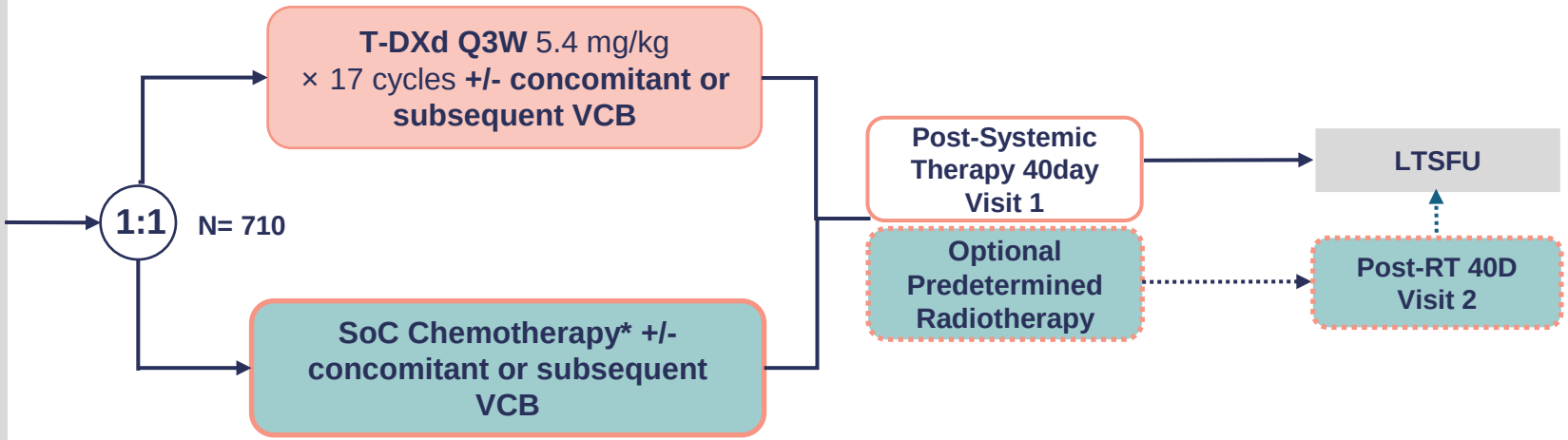
HER2 expression (IHC 3+/2+) per 2016 ASCO CAP gastric cancer IHC scoring guidelines by central confirmation

Main Screening

Key Patient Population

- Histologically confirmed diagnosis of endometrial cancer
- FIGO2023 Stage IIC or III
- NO evidence of disease post-surgery as per investigator and confirmed by BICR
- Treatment naïve (systemic therapy) in any setting including the neoadjuvant setting for endometrial cancer

Treatment



Follow-up

***SoC Chemotherapy +/- EBRT Options**

- 6 cycles of carboplatin AUC 5 or 6 and paclitaxel 175 mg/m2 Q3W followed by EBRT
- 4 cycles carboplatin AUC 5 or 6 and paclitaxel 175 mg/m2 Q3W followed by chemoradiotherapy (EBRT plus cisplatin 50 mg/m2 on days 1 and 29
- 6 cycles of carboplatin AUC 5 or 6 and paclitaxel 175 mg/m2 Q3W

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NCT07022483

ENGOT European Network of Gynaecological Oncological Trial groups

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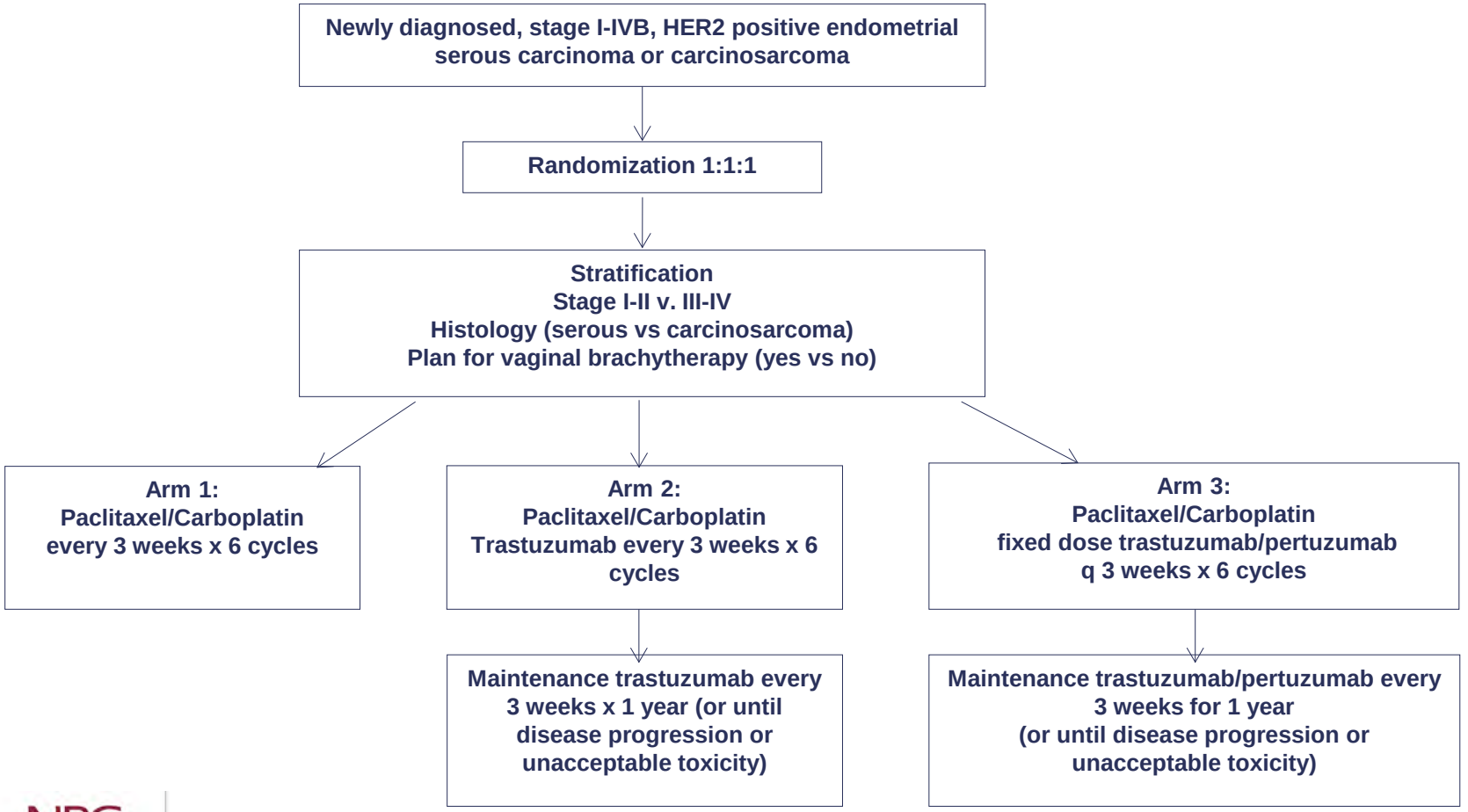
NRG-GY026

Phase II/III Study Of Paclitaxel/Carboplatin +/- Trastuzumab or Trastuzumab/ Pertuzumab in HER2 Positive, Stage I-IV Endometrial Serous Carcinoma or Carcinosarcoma

PI: Britt Erickson, MD | Co-PI: Amanda Nickles-Fader, MD



Key Inclusion

- Stage 1A-IVB (FIGO 2009) non-recurrent, chemo-naive, uterine serous or carcinosarcoma
- HER2 positive based in local testing (ASCO/CAP 2018 Breast guidelines recommended) or NGS
- OK for vaginal brachytherapy, pelvic radiotherapy not allowed.
- Patients must be within 8 weeks of primary surgery (or endometrial biopsy in patients who never undergo hysterectomy)

NCT05256225

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Case 1

- Patient Enrolled into GOG-3122
- Randomized to SOC (carboplatin and paclitaxel)
- 10 months had recurrent disease with liver metastasis, peritoneal carcinomatosis

Treatment Options:

- SOC: Carboplatin/paclitaxel + IO
- Clinical trial options:
  - GOG-3098
  - GOG-3119

Pivotal Phase III Trials of Immunotherapy in Advanced Endometrial Cancer

ORIGINAL ARTICLE

Dostarlimab for Primary Advanced or Recurrent Endometrial Cancer

M.R. Mirza, D.M. Chase, B.M. Slomovitz, R. dePont Christensen, Z. Novák, D. Black, L. Gilbert, S. Sharma, G. Valabrega, L.M. Landrum, L.C. Hanker, A. Stuckey, I. Boere, M.A. Gold, A. Auranen, B. Pothuri, D. Cibula, C. McCourt, F. Raspagliesi, M.S. Shahin, S.E. Gill, B.J. Monk, J. Buscema, T.J. Herzog, L.J. Copeland, M. Tian, Z. He, S. Stevens, E. Zografos, R.L. Coleman, and M.A. Powell, for the RUBY Investigators*

ORIGINAL ARTICLE

Pembrolizumab plus Chemotherapy in Advanced Endometrial Cancer

Ramez N. Eskander, M.D., Michael W. Sill, Ph.D., Lindsey Beffa, M.D., Richard G. Moore, M.D., Joanie M. Hope, M.D., Fernanda B. Musa, M.D., Robert Mannel, M.D., Mark S. Shahin, M.D., Guilherme H. Cantuaria, M.D., Eugenia Girda, M.D., Cara Mathews, M.D., Juraj Kavecansky, M.D., Charles A. Leath III, M.D., M.S.P.H., Lilian T. Gien, M.D., Emily M. Hinchcliff, M.D., M.P.H., Shashikant B. Lele, M.D., Lisa M. Landrum, M.D., Floor Backes, M.D., Roisin E. O'Cearbhaill, M.D., Tareq Al Baghdadi, M.D., Emily K. Hill, M.D., Premal H. Thaker, M.D., Veena S. John, M.D., Stephen Welch, M.D., Amanda N. Fader, M.D., Matthew A. Powell, M.D., and Carol Aghajanian, M.D.

Durvalumab Plus Carboplatin/Paclitaxel Followed by Maintenance Durvalumab With or Without Olaparib as First-Line Treatment for Advanced Endometrial Cancer: The Phase III DUO-E Trial

Shannon N. Westin, MD, MPH[1]; Kathleen Moore, MD[2]; Hye Sook Chon, MD[3]; Jung-Yun Lee, MD[4]; Jessica Thomes Pepin, MD[5]; Michael Sundborg, MD[6]; Ayelet Shai, MD, PhD[7]; Joseph de la Garza, MD[8]; Shin Nishio, MD[9]; Michael A. Gold, MD[10]; Ke Wang, MD[11]; Kristi McIntyre, MD[12]; Todd D. Tillmanns, MD[13]; Stephanie V. Blank, MD[14]; Ji-Hong Liu, MD[15]; Michael McCollum, MD[16]; Fernando Contreras Mejia, MD[17]; Tadaaki Nishikawa, MD[18]; Kathryn Pennington, MD[19]; Zoltan Novak, MD, PhD[20]; Andreia Cristina De Melo, MD[21]; Jalid Sehouli, MD[22]; Dagmara Klasa-Mazurkiewicz, MD[23]; Christos Papadimitriou, MD[24]; Marta Gil-Martin, MD[25]; Birute Brasiuniene, MD, PhD[26]; Conor Donnelly, PhD[27]; Paula Michelle del Rosario, MD[28]; Xiaochun Liu, MD, PhD[29]; and Els Van Nieuwenhuysen, MD[30]; on behalf of the DUO-E Investigators

DOI https://doi.org/10.1200/JCO.23.02132

Atezolizumab and chemotherapy for advanced or recurrent endometrial cancer (AtTEnd): a randomised, double-blind, placebo-controlled, phase 3 trial

*Nicoletta Colombo, Elena Biagioli, Kenichi Harano, Francesca Galli, Emma Hudson, Yoland Antill, Chel Hun Choi, Manuela Rabaglio, Frederic Marmé, Christian Marth, Gabriella Parma, Lorena Fariñas-Madrid, Shin Nishio, Karen Allan, Yeh Chen Lee, Elisa Piovano, Beatriz Pardo, Satoshi Nakagawa, John McQueen, Claudio Zamagni, Luis Manso, Kazuhiro Takehara, Giulia Tasca, Annamaria Ferrero, Germana Tognon, Andrea Alberto Lissoni, Mariacristina Petrella, Maria Elena Laudani, Eliana Rulli, Sara Uggeri, M Pilar Barretina Ginesta, and AtTEnd study group**

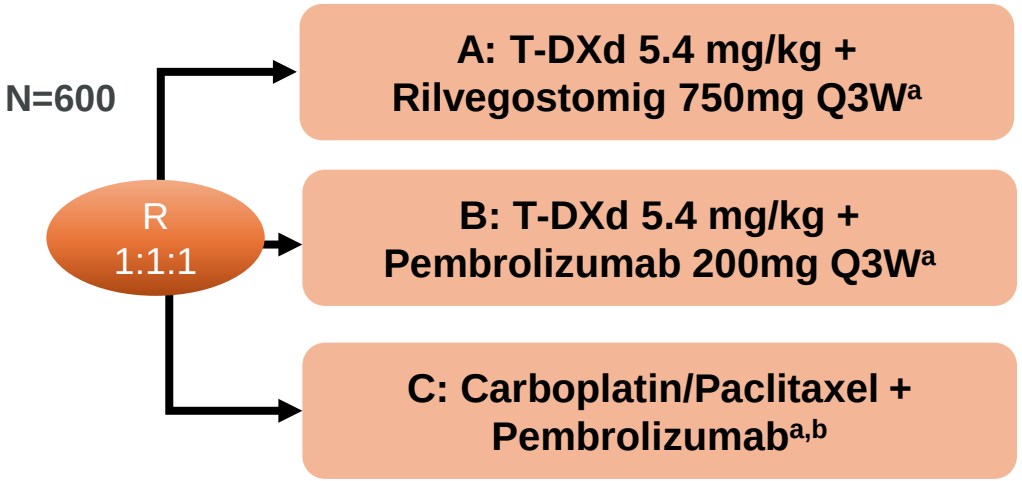
DESTINY-Endometrial01/ GOG-3098/ ENGOT-EN24:

A Phase III Study of Trastuzumab Deruxtecan Plus Rilvegostomig or Pembrolizumab as First-Line Treatment of HER2-Expressing (IHC 3+/2+), Mismatch Repair Proficient (pMMR) Endometrial Cancer

Patient Population

- HER2 expressing (IHC 3+/2+) EC by central test
- pMMR EC by central test
- Stage III, Stage IV, or recurrent, histologically-confirmed endometrial cancer
- Stage III must have measurable disease
- Any histological subtype except for sarcomas
- May have received 1 prior line of adjuvant/ neoadjuvant chemotherapy (chemotherapy and/ or chemoradiation) if recurrence ≥ 6 months after last dose of chemo
- No prior exposure to ADCs or ICIs
- ECOG PS 0 or 1

IHC 3+25%; IHC 2+ 75% (capped)



Stratification factors:
- HER2 IHC 3+ vs 2+
- PD-L1 TAP ≥1% vs TAP <1%
- Asia vs Non-Asia

Endpoints

Primary:
- PFS (BICR) in ITT

Secondary:
- OS (key secondary endpoint)
- PFS (Investigator)
- ORR
- PFS2
- HRQoL

[a] *Treatment will continue until objective disease progression according to RECIST v1.1 as assessed by the Investigator and confirmed by BICR or until other discontinuation criteria is met, whichever occurs first.*
[b] *Carboplatin AUC5, paclitaxel 175 mg/m2, and pembrolizumab 200 mg IV once Q3W x 6 cycles*, followed by maintenance with pembrolizumab 400 mg IV Q6W. Treatment with pembrolizumab will continue for up to 20 total cycles (approximately 24 months, accounting for combination and maintenance phases) or until other discontinuation criteria is met, whichever occurs first.*
** At the discretion of the treating Investigator, participants may continue to receive carboplatin, paclitaxel and pembrolizumab Q3W for up to 10 cycles.*

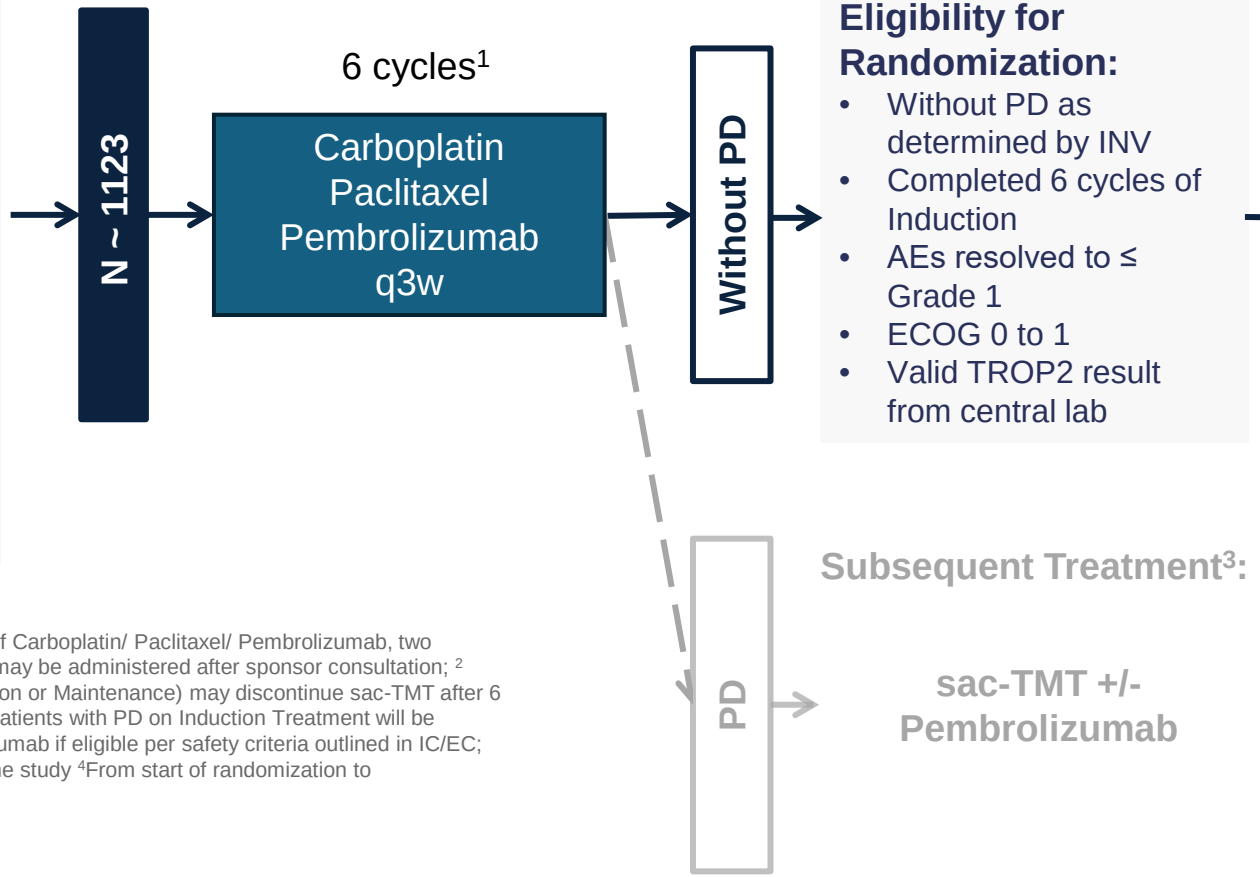
MK-2870-033/TroFuse-033/GOG-3119/ENGOT-en29

A Phase 3 Study to Compare Sacituzumab Tirumotecan in Combination With Pembrolizumab Vs Pembrolizumab Alone as Treatment in Participants With MMR-P Endometrial Cancer (TroFuse-033)

Key Eligibility Criteria

- Primary advanced/recurrent endometrial carcinoma
- pMMR
- No prior systemic therapy OR recurred after adjuvant (no PFI required)
- No prior anti-PD-1/PD-L1
- Radiologically apparent disease (measurable for St. III, measurable or non-measurable for St. IV & recurrent disease)
- Available tissue to test for TROP2 / MMR / p53
- ECOG 0 to 1

Induction



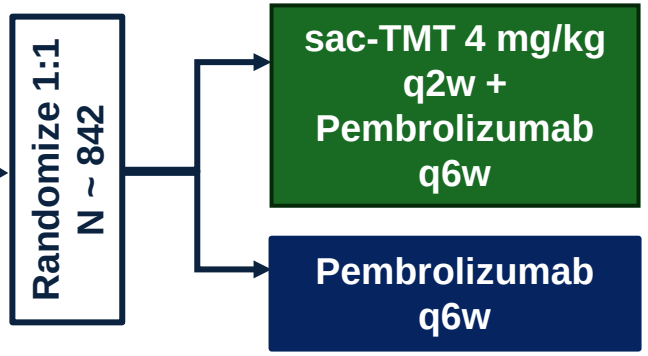
Eligibility for Randomization:

- Without PD as determined by INV
- Completed 6 cycles of Induction
- AEs resolved to ≤ Grade 1
- ECOG 0 to 1
- Valid TROP2 result from central lab

Subsequent Treatment[3]:

sac-TMT +/- Pembrolizumab

Maintenance



Treatment duration:
Treat until intolerable toxicities / PD or up to ~1.5 years (14 administrations of Pembrolizumab / 42 administrations of sac-TMT).[2]

Dual Primary Endpoints[4]
PFS (BICR) ; OS
(using a TROP2 enrichment strategy)

[1] If pt. needs more time to recover after 6 cycles of Carboplatin/ Paclitaxel/ Pembrolizumab, two additional cycles of pembrolizumab (cycle 7 + 8) may be administered after sponsor consultation; [2] Pts. with confirmed CR by BICR (following Induction or Maintenance) may discontinue sac-TMT after 6 months of sac-TMT after sponsor consultation; [3]Patients with PD on Induction Treatment will be randomized to sac-TMT vs. sac-TMT + pembrolizumab if eligible per safety criteria outlined in IC/EC; Subsequent Treatment is an exploratory part of the study [4]From start of randomization to Maintenance;

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Case 1

- Patient Enrolled into GOG-3098
- Randomized Carboplatin/Paclitaxel + Pembrolizumab
- 6 months had recurrent disease

Treatment Options:

- SOC chemotherapy
- Clinical trial options:
  - ➢GOG-3104
  - ➢GOG-3110

ASCENT-GYN-01/GOG-3104/ENGOT-en26

A Phase 3 Study of SG vs TPC in Patients With Endometrial Cancer Who Have Received Prior Platinum-Based Chemotherapy and Anti-PD-1/PD-L1 Immunotherapy

Key Eligibility Criteria

- Recurrent or persistent endometrial cancer (endometrial carcinoma or carcinosarcoma)
- Up to 3 prior lines of systemic therapy for endometrial cancer, including systemic platinum-based chemotherapy and anti-PD-1/PD-L1 therapy, either in combination or separately
- Radiologically evaluable disease (either measurable or nonmeasurable) per RECIST v1.1
- ECOG Performance Status of 0-1

N=520

R
1:1

Sacituzumab Govitecan (SG)
10 mg/kg on D1 and 8 of a 21-day cycle

Treatment of Physician's Choice (TPC)
Doxorubicin 60 mg/m^2 on D1 of a 21-day cycle, or
Paclitaxel 80 mg/m^2 on D1, 8, and 15 of a 28-day cycle

Treat until disease progression or unacceptable toxicity

Key Endpoints

Primary Endpoints

- PFS by BICR
- OS

Secondary Endpoints

- ORR, DOR, CBR
- PFS by INV
- Safety
- QOL

GOG Highlight Reel

ClinicalTrials.gov ID: NCT06486441

ENGOT European Network of Gynaecological Oncological Trial groups

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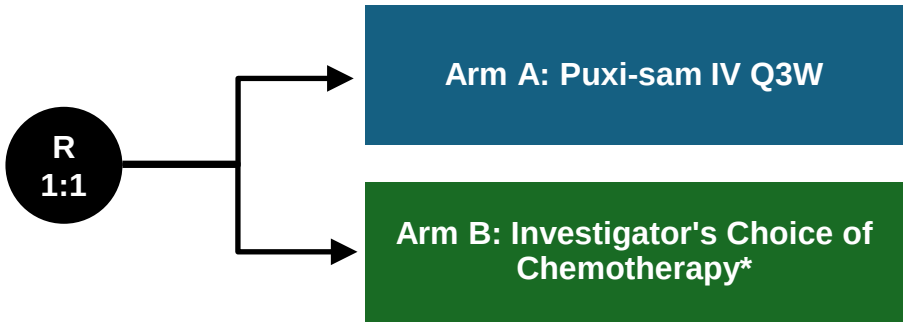
Bluestar-Endometrial01 / GOG 3110 / ENGOT-en28:

Puxitatug Samrotecan (Puxi-sam) Monotherapy vs Chemotherapy in B7-H4 Selected Advanced/Metastatic Endometrial Cancer Who Progressed On or After Platinum Based Chemotherapy and Anti-PD-1/Anti-PD-L1 Therapy

Key Eligibility Criteria

- Histologically confirmed endometrial cancer (EC) or carcinosarcoma
- Advanced or recurrent/metastatic EC
- B7-H4 expression
- Prior platinum-based chemotherapy and anti-PD-1/anti-PD-L1 therapy, either separately or in combination
- Has received no more than 2 prior lines of therapy in advanced/metastatic setting
- Neoadjuvant ± adjuvant platinum-based chemotherapy would count as 1 line of therapy if the recurrence occurred within 12 months after the date of the last platinum dose.
- WHO/ECOG 0 or 1
- At least 1 measurable lesion per RECIST 1.1
- No prior TOP1 inhibitors or B7-H4 agents



***Doxorubicin 60 mg/m^2 IV Q3W**
or
Paclitaxel 80 mg/m^2 IV on Days 1, 8, and 15 in a Q4W cycle

Dual primary endpoints

PFS, OS

Secondary endpoints

ORR, DoR, PFS2, TFST, TSST, TDT, Time to worsening, Safety

PFS, Progression Free Survival; OS, Overall Survival; ORR, Overall Response Rate; DoR, Duration of Response; TFST, Time until first subsequent anticancer therapy; TSST, Time until second subsequent anticancer therapy; TDT, Time until discontinuation of treatment; IV, intravenous

GOG Highlight Reel

ClinicalTrials.gov ID NCT07044336

ENGOT European Network of Gynaecological Oncological Trial groups

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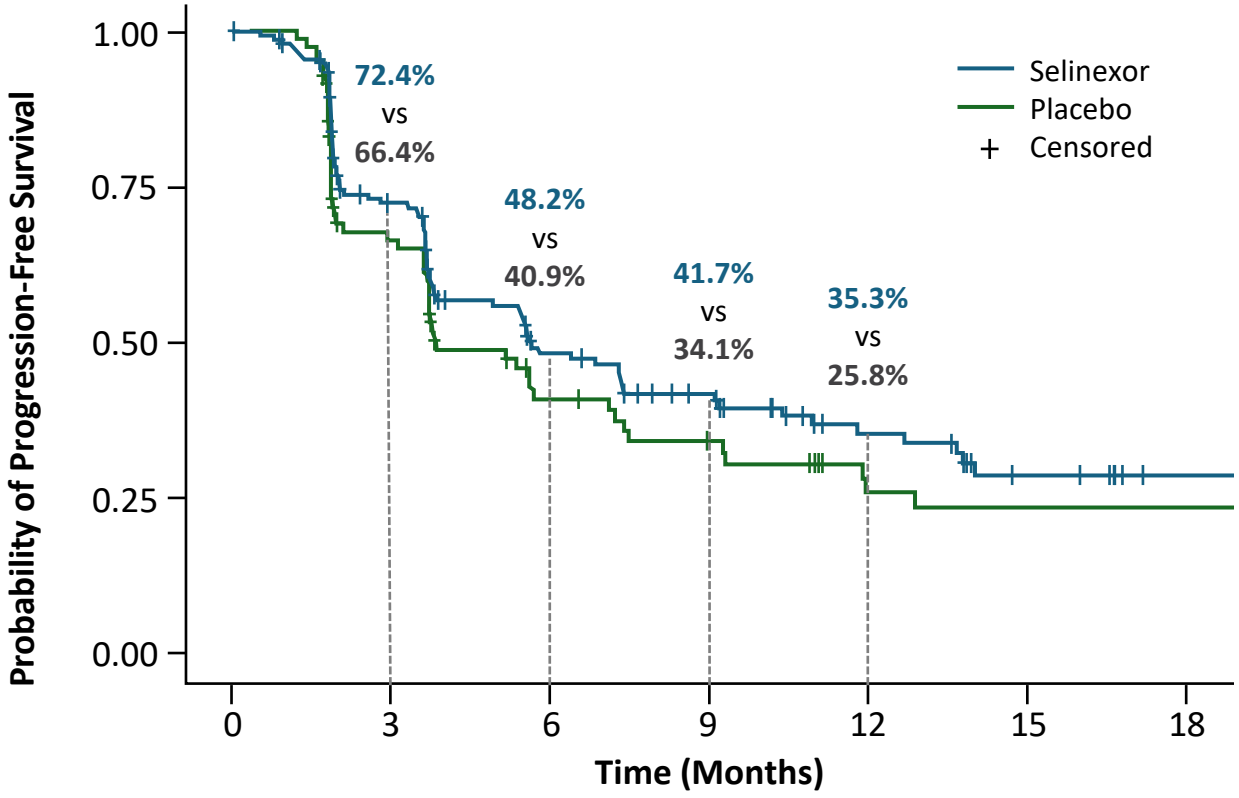
Case 2

- 68-year-old with newly diagnosed, stage IV endometrioid endometrial adenocarcinoma, b/l lung metastasis
- s/p RA-TLH,
- IHC: p53 wild type, ER/PR +, Her2 = 0, PIK3CA mutation

Treatment Options:

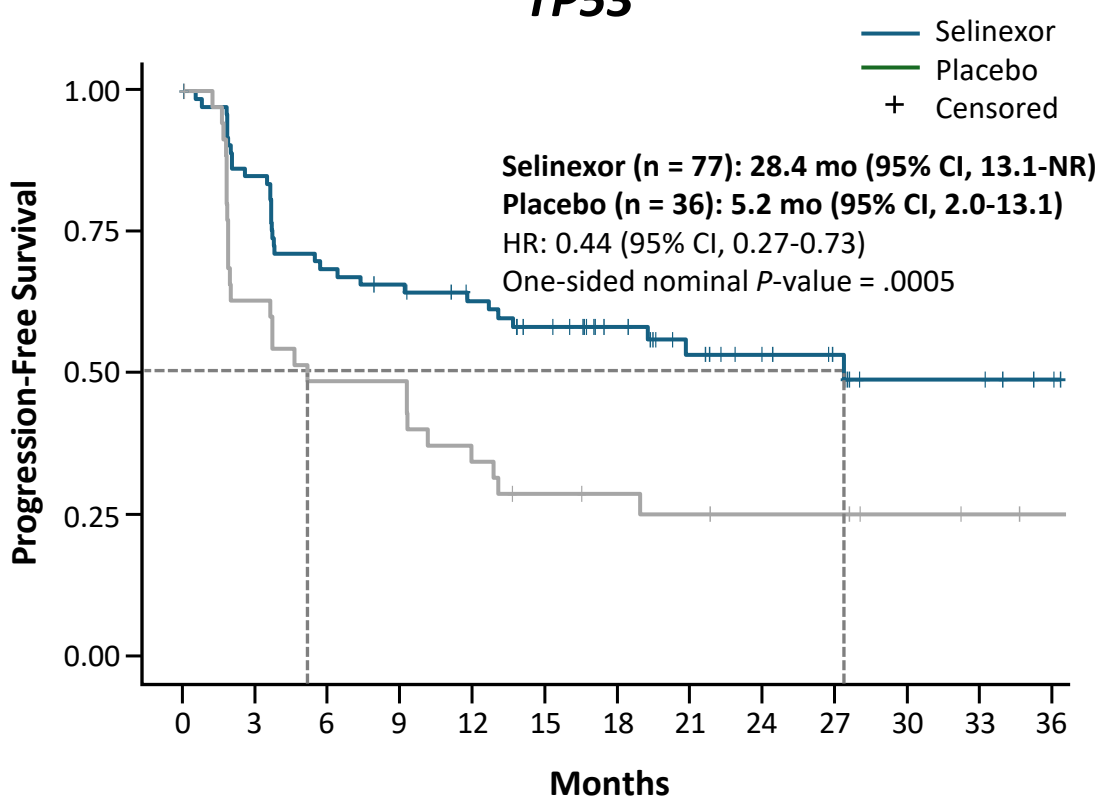
- Carboplatin/paclitaxel +/- IO
- Clinical trials

Selinexor Is a Targeted Oral XPO1 Inhibitor
ENGOT-EN5/GOG-3055/SIENDO



Median follow-up: 10.2 months (95% CI 8.97, 13.57)

***TP53*^{WT}**



Median follow-up: 36.8 months

Vergote I, et al. J Clin Oncol. 2023; Makker V, et al. Gynecol Oncol. 2024; Slomovitz BM, et al. J Clin Oncol. 2023

XPORT-EC-042/GOG-3083

A Phase 3 of Selinexor in Maintenance Therapy After Systemic Therapy for Patients With TP53 Wild-type, Advanced, or Recurrent EC

Prescreening Consent
Tissue Sent to Foundation

Study Consent

Key Eligibility

- ***TP53* wild-type endometrial cancer testing by FMI**
- Primary stage IV or first recurrent EC
- Received at least 12 weeks of platinum-based chemotherapy +/- immunotherapy
- Carcinosarcomas allowed; clear cell/small cell carcinoma excluded

N=220

PR/CR per RECIST v1.1

R 1:1

Stratification:
- Primary Stage IV vs recurrent disease after platinum-based treatment
- PR vs CR

Selinexor 60mg PO QW until PD
n = 110

Treat until progression or intolerability

Placebo weekly until PD
n = 110

Primary Endpoint
- PFS assessed by Investigator

Key Secondary Endpoint
- OS

Secondary Endpoints
- Safety
- TFST
- TSST
- PFS2
- PFS as assessed by BICR
- HR-QoL

Exploratory Endpoints
- PFS per histology subtypes
- PFS per other molecular features
- CR rate among patients with PR as best response
- Duration of CR among patients who enter study as PR and achieve CR during study
- analysis of tumor biomarkers
- PK analysis

*118 PFS events needed to provide 90% power to detect a HR of 0.55 with a 2-sided alpha of 0.05.

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Case 2

- Patient Enrolled into GOG-3083
- Randomized to maintenance therapy with selinexor
- 15 months had recurrent disease

Treatment Options:

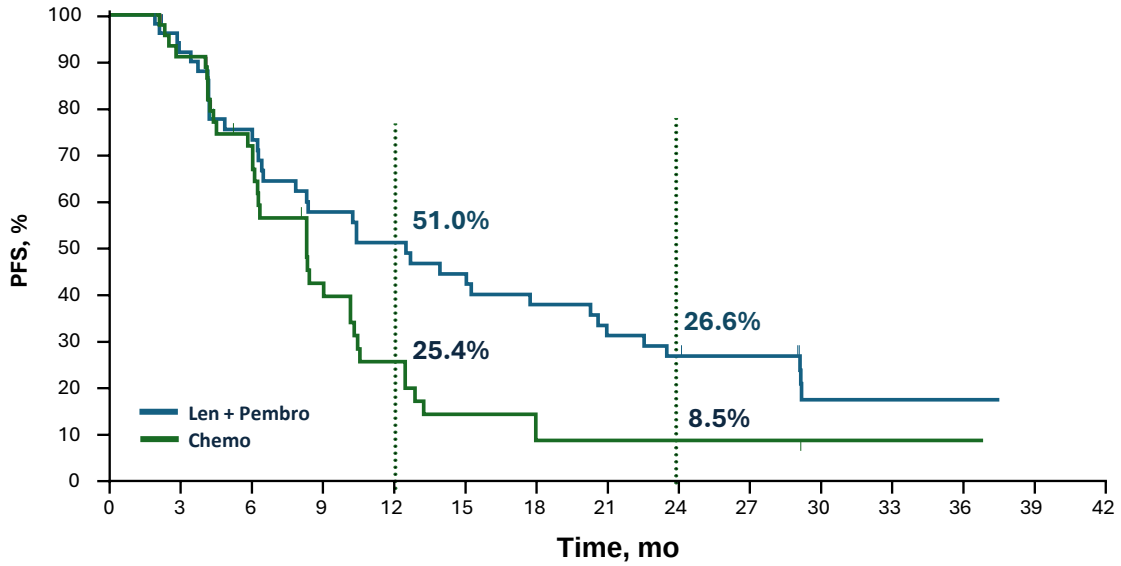
- Carboplatin/Paclitaxel +/- IO
- Lenvatinib/Pembrolizumab
- Clinical Trial Options:
  - GOG-3069
  - GOG-3111

ENGOT-en9/LEAP-001

Lenvatinib + Pembrolizumab vs Chemotherapy – PFS in Patients with Prior Neoadjuvant/Adjuvant Chemotherapy

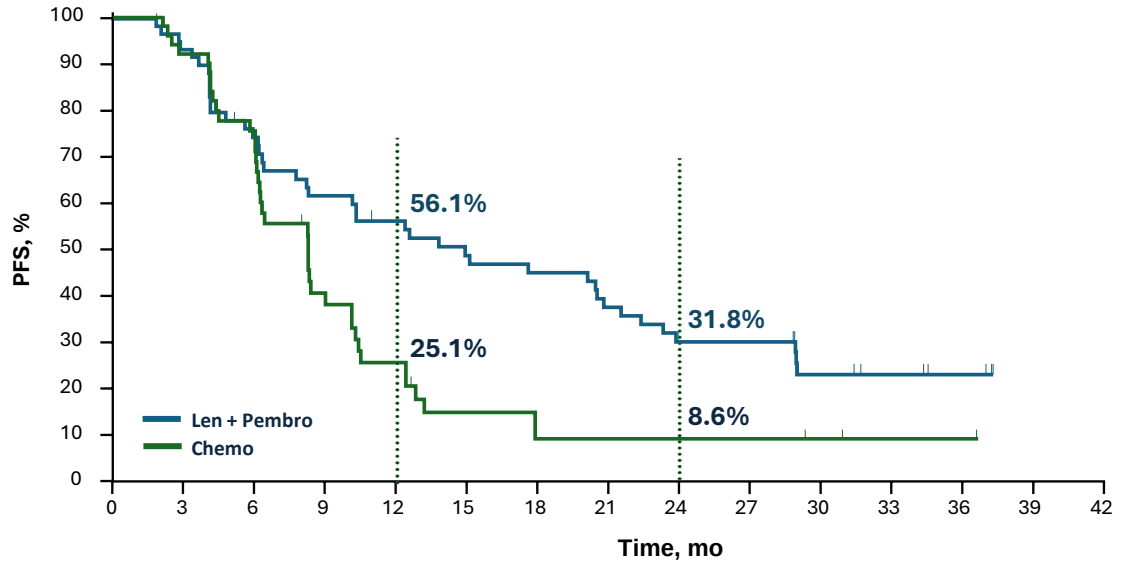
pMMR

Treatment Arm	Events, n/N	Median, mo (95% CI)	HR (95% CI)
Len + Pembro	37/53	12.5 (6.5-20.3)	**0.60** (0.37-0.97)
Chemo	35/51	8.3 (6.1-10.2)	



All-Comers

Treatment Arm	Events, n/N	Median, mo (95% CI)	HR (95% CI)
Len + Pembro	42/63	15.0 (8.3-21.0)	**0.52** (0.33-0.82)
Chemo	39/58	8.3 (6.2-10.2)	



Frontline Lenvatinib + pembrolizumab improved PFS vs chemotherapy in patients with prior neoadjuvant/adjuvant treatment.

GOG-3069

A Phase 2 Study of Alpelisib and Fulvestrant for PIK3CA-mutated Estrogen Receptor (ER)-positive Endometrioid Endometrial Cancers

(PI: Stéphanie Gaillard, MD PhD)

SCAN ME

BACKGROUND

- The PI3K/PTEN/PIK3CA pathway is altered in 93% of endometrioid endometrial cancer with PIK3CA activating mutations in 53%[1]
- Recent data have shown promising responses in patients with ER positive endometrial cancer treated with endocrine therapy plus mTOR inhibitors or CDK4/6 inhibitors[2-5].
- The combination of alpelisib and fulvestrant was FDA approved for treatment of ER+ PIK3CA-mutated Breast Cancer on May 24, 2019, based on the SOLAR-1 study[6].
- GOG3069 is evaluating the efficacy of alpelisib and fulvestrant for the treatment of ER+ PIK3CA-mutated Endometrioid Endometrial Cancer

METHODS

- Conditional stratified Phase 2 study
- Stratified by prior chemotherapy exposure
- Target accrual 50 patients

Screening/Registration

⬇

TREATMENT
Alpelisib 300mg orally daily
+
Fulvestrant 500mg IM Day 1 and Day 15 of Cycle 1, then Day 1 each 28-day cycle

⬇

Disease evaluations every 8 weeks for the first 3 evaluations then every 12 weeks until PD

Primary Outcome:
ORR
Secondary Outcomes:
safety/toxicity, PFS, OS, DoR

Eligibility

- Advanced, persistent, recurrent endometrial cancer
- Endometrioid histology
- PIK3CAmutated (CLIA-certified testing)
- ER+ (≥ 1% of tumor cells)
- Measurable disease by RECISTv1.1
- Prior endocrine therapy allowed
- No prior mTOR, PIK3CA, PI3K, or AKT inhibitors allowed

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NCT05154487

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GOG-3111

Sapanisertib and Serabelisib (PIKTOR) With Paclitaxel and a Substudy With Diet in Patients With Advanced/Recurrent Endometrial Cancer

Background

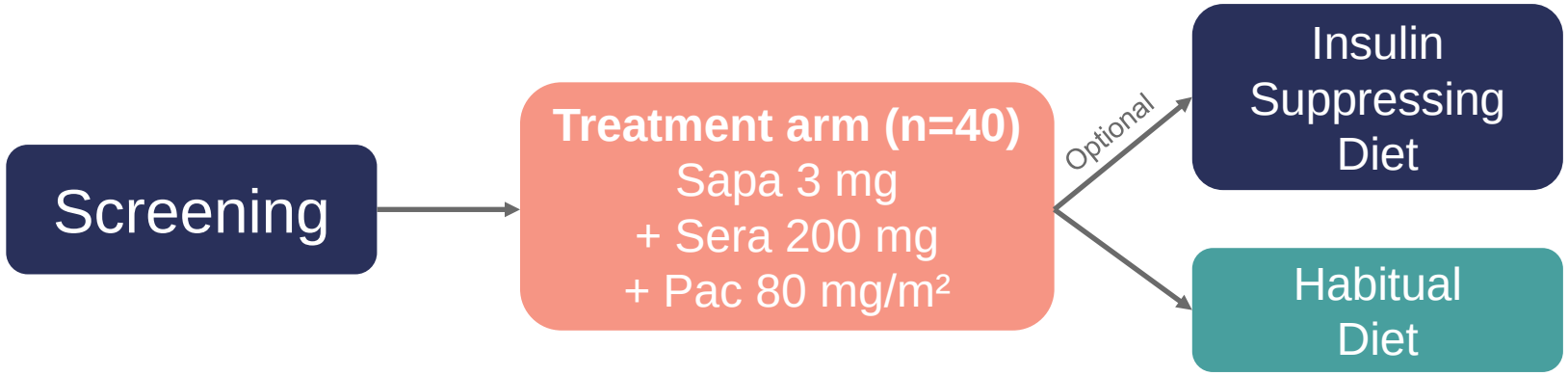
- PIKTOR is a multi-node PI3K-pathway inhibitor targeting mTORC1, mTORC2, and PI3K.
- Investigated in combination with **Paclitaxel** ± a dietary intervention.

Phase 1b Results

- 47% overall response rate (ORR) in all-comers
- In the endometrioid EC subset (n=5): 80% ORR (3 complete responses [CRs], 1 partial response [PR])

Eligibility

- Endometrial-endometrioid cancer
- 2nd line or later
- Post Pembrolizumab
- Must have PI3K pathway mutation



NCT06463028

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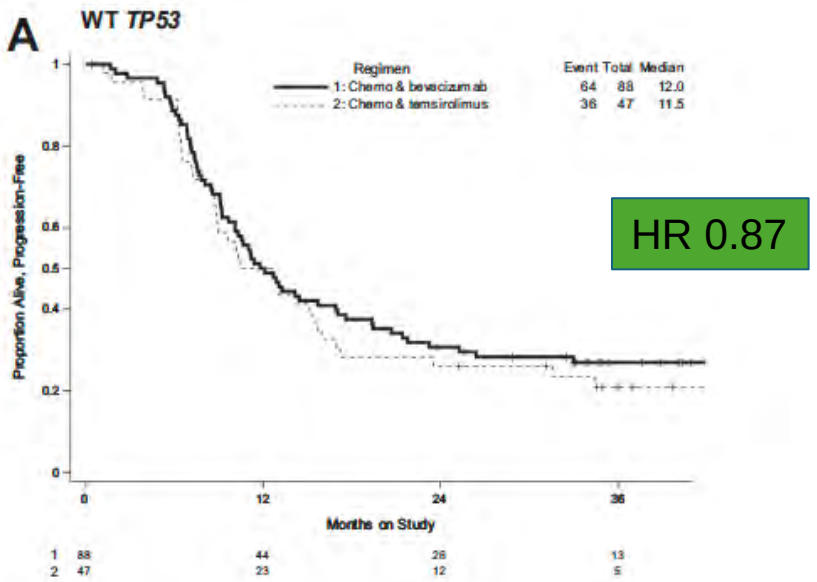
Case 3

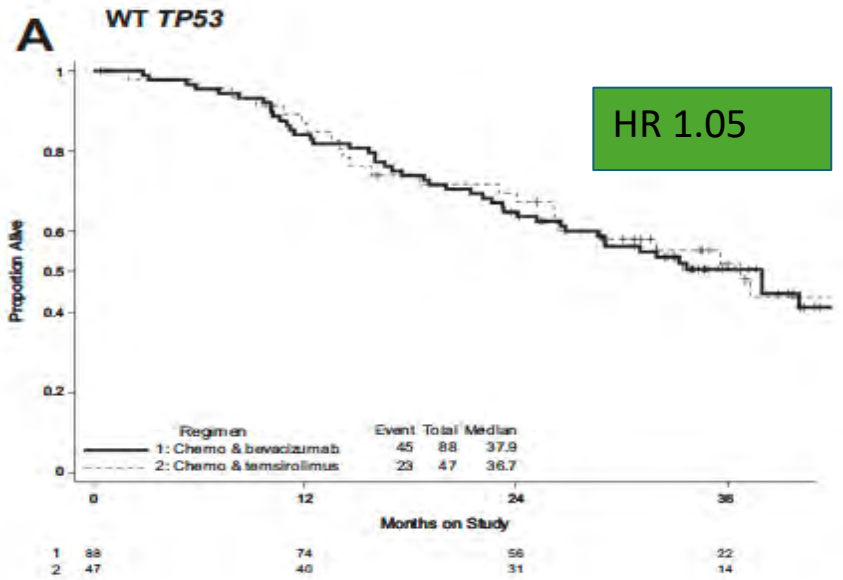
- 78-year-old with newly diagnosed, stage IV uterine serous carcinoma
- s/p RA-TLH, omentectomy (pre-op CT omental disease)
- IHC: p53 mutation, ER/PR -, Her2 = 1+

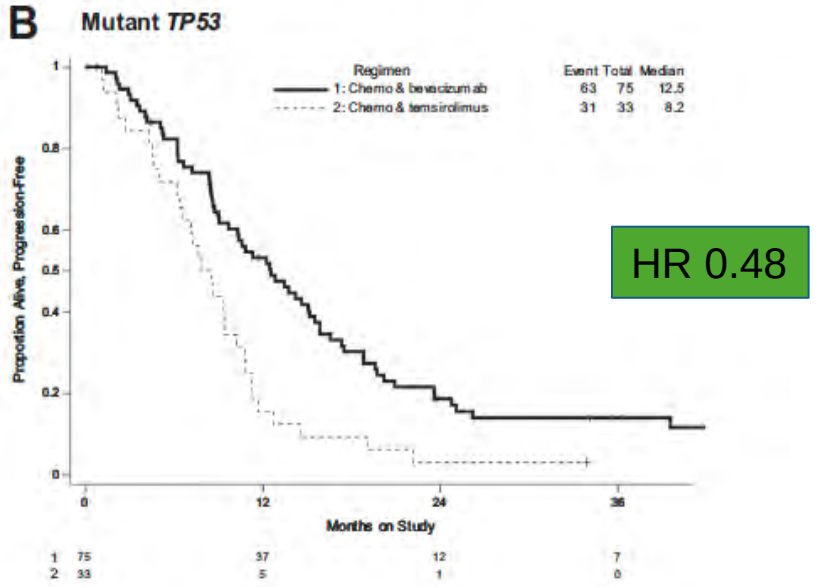
Treatment Options:

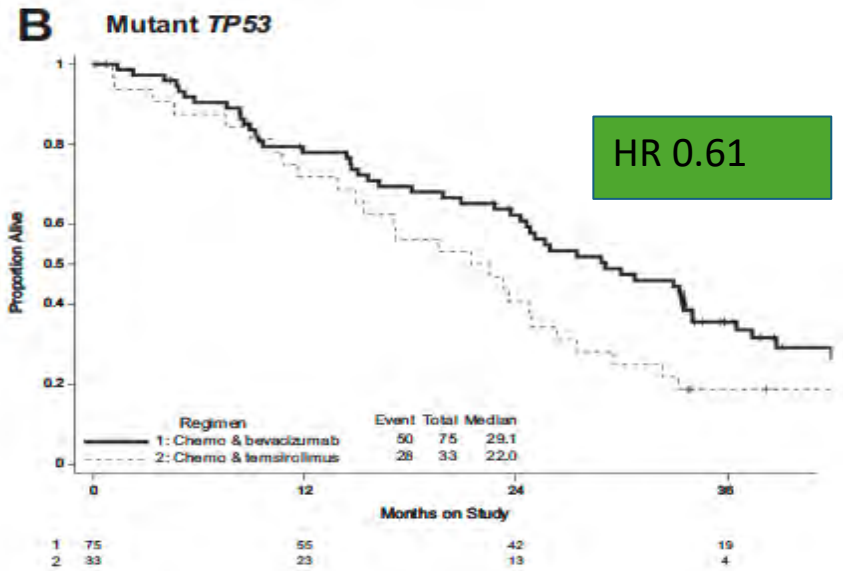
- Carboplatin/paclitaxel +/- IO
- Clinical trials

TP53 mutation as a "biomarker" for response to Bevacizumab in Endometrial Cancer: Ancillary Investigation of GOG 86P









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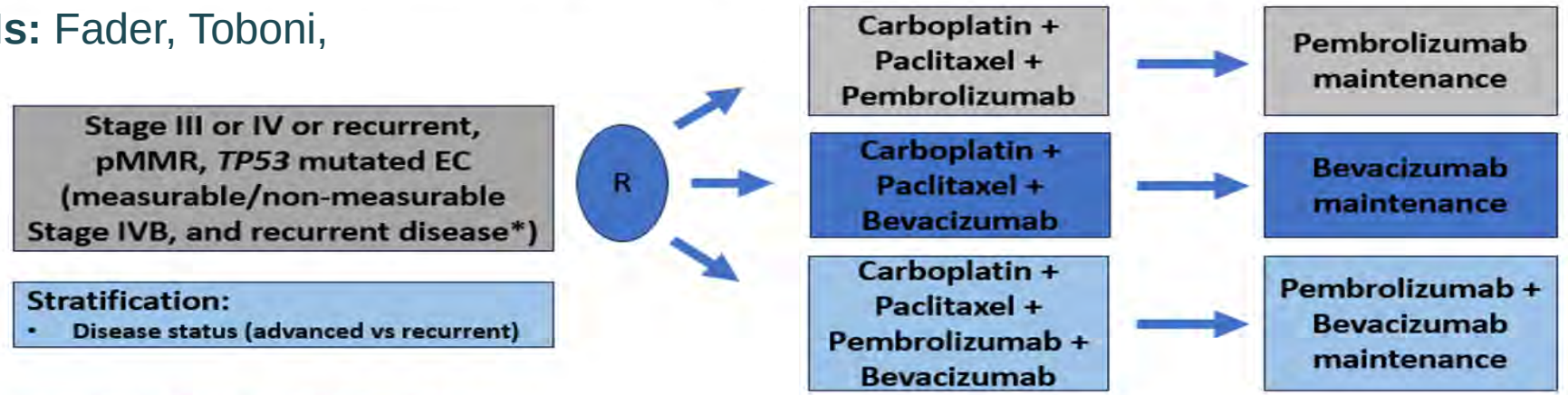
Leslie K. et al. Gyncol Oncol 2021

GY035 (UC2323)

Prelim trial design building on results of GY018 & GOG86P in TP53 mutated Endometrial cancer patients: approved by GCSC

Randomized Phase II/III Study of Carboplatin + Paclitaxel + Pembrolizumab vs. Carboplatin + Paclitaxel + Bevacizumab vs. Carboplatin + Paclitaxel + Pembrolizumab + Bevacizumab in Patients with Advanced or Recurrent, pMMR and *TP53* mutated Endometrial Cancer

PIs: Fader, Toboni,



*Primary Phase II endpoint: PFS by RECIST V1.1
*Primary Phase III endpoint: OS

Treatment Plan:
Arm 1: IV carboplatin AUC 5 + IV paclitaxel 175 mg/m^2 + IV pembrolizumab 200 mg on day 1 every 3 weeks x 6-10 cycles followed by 14 additional cycles of pembrolizumab 400 mg IV maintenance every 6 weeks.
Arm 2: IV carboplatin AUC 5 + IV paclitaxel 175 mg/m^2 + bevacizumab 15 mg/kg on day 1 every 3 weeks x 6-10 cycles followed by 28 additional cycles of bevacizumab 15 mg/kg maintenance every 3 weeks.
Arm 3: IV carboplatin AUC 5 + IV paclitaxel 175 mg/m^2 + IV pembrolizumab 200 mg + bevacizumab 15 mg/kg on day 1 every 3 weeks x 6-10 cycles followed by 14 additional cycles of pembrolizumab 400 mg IV maintenance every 6 weeks and 28 additional cycles of bevacizumab 15 mg/kg IV maintenance every 3 weeks.
*Patients with recurrent disease who have received prior adjuvant therapy must have a platinum-free interval of >/=12 months.

Courtesy B. Monk

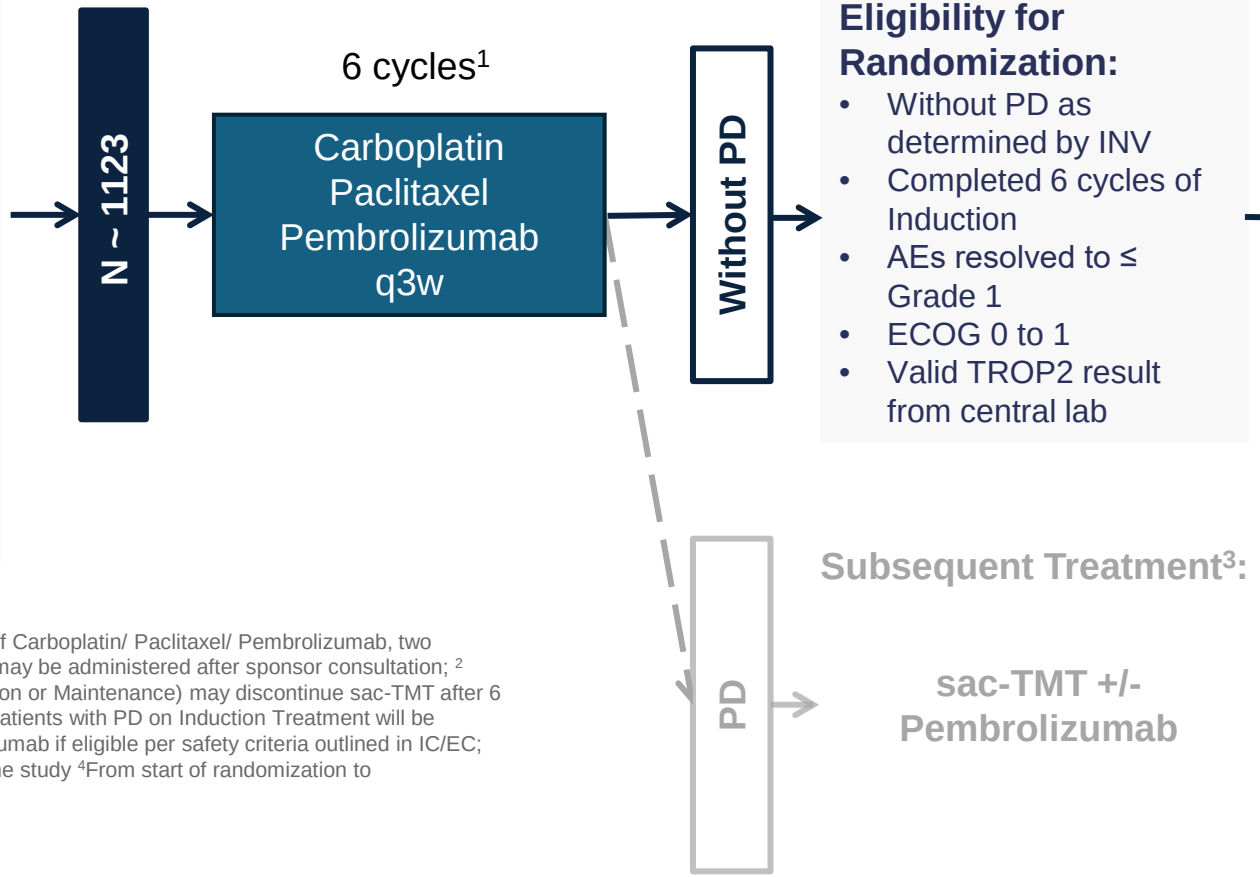
MK-2870-033/TroFuse-033/GOG-3119/ENGOT-en29

A Phase 3 Study to Compare Sacituzumab Tirumotecan in Combination With Pembrolizumab Vs Pembrolizumab Alone as Treatment in Participants With MMR-P Endometrial Cancer (TroFuse-033)

Key Eligibility Criteria

- Primary advanced/recurrent endometrial carcinoma
- pMMR
- No prior systemic therapy OR recurred after adjuvant (no PFI required)
- No prior anti-PD-1/PD-L1
- Radiologically apparent disease (measurable for St. III, measurable or non-measurable for St. IV & recurrent disease)
- Available tissue to test for TROP2 / MMR / p53
- ECOG 0 to 1

Induction



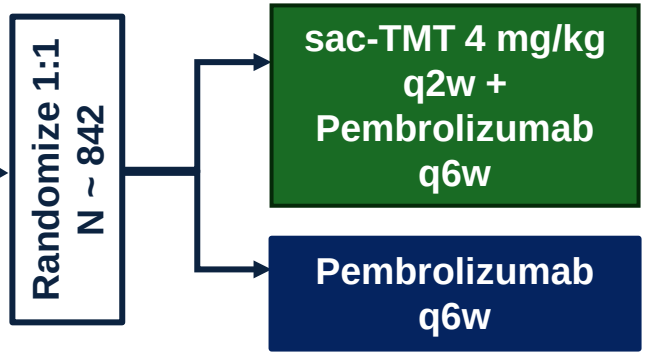
Eligibility for Randomization:

- Without PD as determined by INV
- Completed 6 cycles of Induction
- AEs resolved to ≤ Grade 1
- ECOG 0 to 1
- Valid TROP2 result from central lab

Subsequent Treatment[3]:

sac-TMT +/- Pembrolizumab

Maintenance



Treatment duration:
Treat until intolerable toxicities / PD or up to ~1.5 years (14 administrations of Pembrolizumab / 42 administrations of sac-TMT).[2]

Dual Primary Endpoints[4]
PFS (BICR) ; OS
(using a TROP2 enrichment strategy)

[1] If pt. needs more time to recover after 6 cycles of Carboplatin/ Paclitaxel/ Pembrolizumab, two additional cycles of pembrolizumab (cycle 7 + 8) may be administered after sponsor consultation; [2] Pts. with confirmed CR by BICR (following Induction or Maintenance) may discontinue sac-TMT after 6 months of sac-TMT after sponsor consultation; [3]Patients with PD on Induction Treatment will be randomized to sac-TMT vs. sac-TMT + pembrolizumab if eligible per safety criteria outlined in IC/EC; Subsequent Treatment is an exploratory part of the study [4]From start of randomization to Maintenance;

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ENGOT European Network of Gynaecological Oncological Trial groups

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Case 3

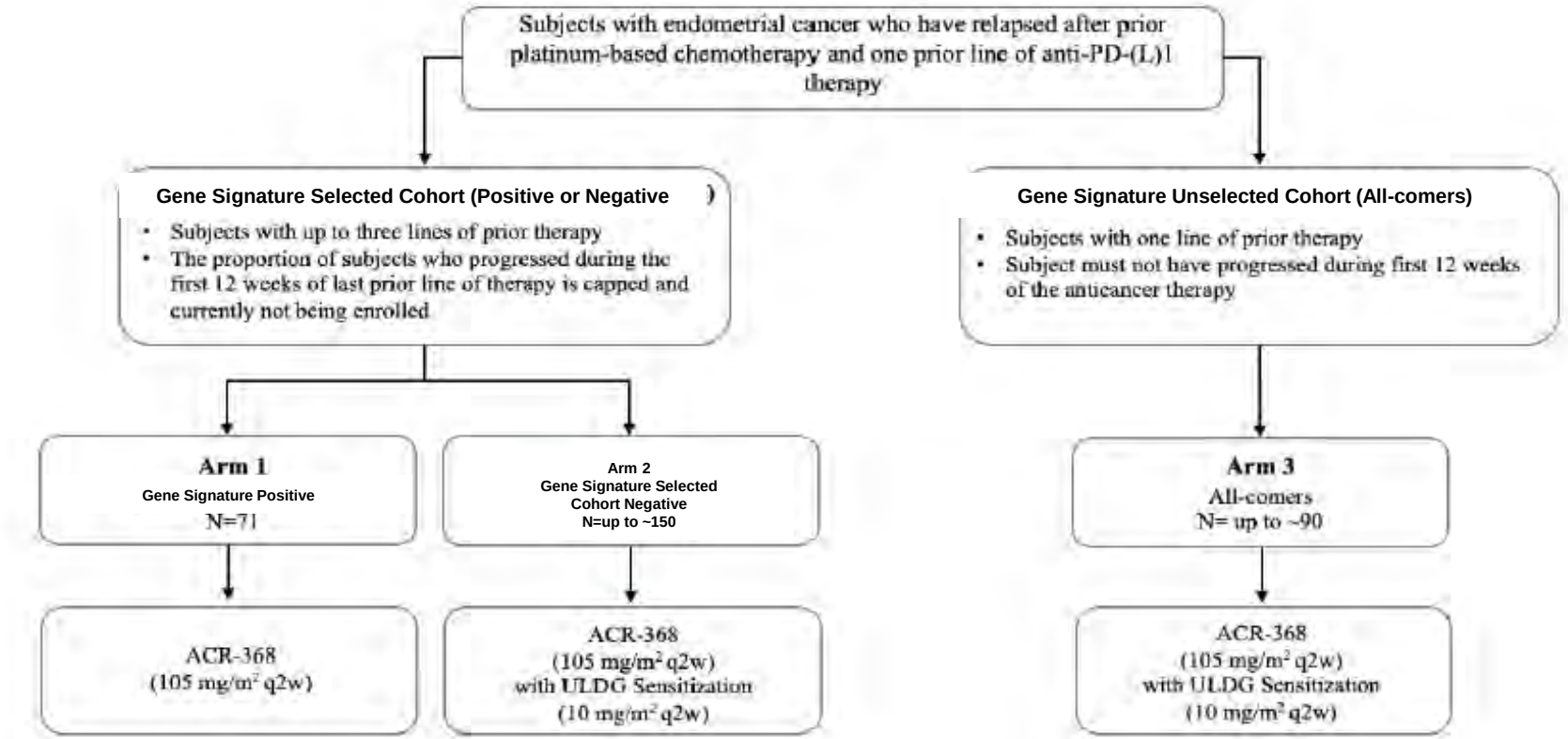
- Patient Enrolled into GOG-3119
- Randomized to Sac-TMT and pembrolizumab maintenance
- 9 months had recurrent disease

Treatment Options:

- Weekly paclitaxel or doxorubicin
- Clinical trial
  - ➢ GOG-3082

GOG-3082 / ACR-368-201

A PHASE 1B/2 BASKET STUDY OF ACR-368 AS MONOTHERAPY AND IN COMBINATION WITH GEMCITABINE IN ADULT SUBJECTS WITH PLATINUM-RESISTANT OVARIAN CARCINOMA, ENDOMETRIAL ADENOCARCINOMA, AND UROTHELIAL CARCINOMA BASED ON ACRIVON GENE SIGNATURE STATUS



ULDG, ultra-low-dose gemcitabine

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IDEA Commitment

Collaborating to make an **I**mpact, **D**rive our mission to transform the standard of care in women's cancers forward, **E**mpower physicians and patients to improve **A**ccess to clinical trials and tomorrow's drugs today.

Bhavana Pothuri, MD

Professor, NYU Grossman School of Medicine
Medical Director, Clinical Trials Office (CTO)
Director, Gynecologic Oncology Clinical Trials
Laura & Isaac Perlmutter Cancer Center, NCI Designated Comprehensive Cancer Center

Associate Clinical Trial Advisor, GOG Partners
Director of Clinical Trials Access, GOG Foundation

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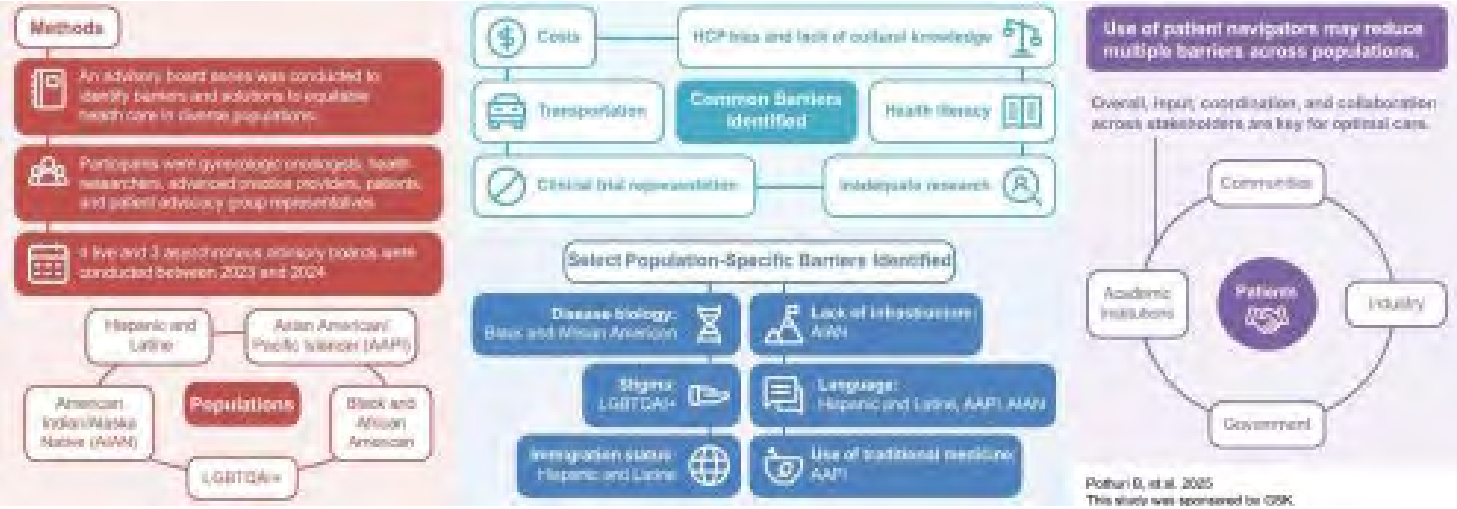
Identifying and breaking racial and ethnic barriers: enhancing access and equity in the care of patients with gynecologic malignancies



	Barrier	Black and African American	Hispanic and Latinx	AAPI	AIAN	Proposed solution(s)
Common across all populations	**Costs of accessing and receiving care**	☑	☑	☑	☑	• Cost subsidies • Vouchers for groceries or meals • Assistance for patients with accessing insurance
	Transportation	☑	☑	☑	☑	• Telemedicine • Financial support, including parking vouchers • Reduced travel distance
	Health literacy	☑	☑	☑	☑	• Education by PAGs and peers • Engagement of **patient navigators**
	HCP bias or cultural competence	☑	☑	☑	☑	• Cultural competency training • Involvement of family in treatment decisions • Recognition of the importance of community structure (eg, tribal identity)
	Inadequate research among diverse populations	☑	☑	☑	☑	• Research to disaggregate racial and ethnic subgroups
	Representation in clinical trials	☑	☑	☑	☑	• Modified trial eligibility criteria (ie, remove unnecessary language requirements, ensure accrual represents the real-world setting) • Removal of trial enrollment barriers
Shared by some but not all populations	**Language**	–	☑	☑	☑	• Documented translation or transcreation • In-person or virtual interpreters • Additional clinical visit time as needed
	Discrimination and implicit bias	☑	☑	–	–	• Sensitivity or cultural competency training for HCPs
	Mistrust of healthcare systems	☑	–	☑	☑	• Outreach and use of **patient navigators**
	Chronic diseases	☑	–	–	☑	• Engagement with **patient navigators** to assist in treating patients
Population specific	**Disease biology differences**	☑	–	–	–	• Engagement with **patient navigators** to increase clinical trial participation • Identify efficacy/safety of treatments by biomarkers
	Immigration status/ lack of insurance	–	☑	–	–	• Outreach/engagement with **patient navigators**
	Use of traditional medicines	–	–	☑	–	• Recognition of the importance of alternative medicine • Education and resources for HCPs to assist in shared decision-making
	Belief system juxtaposing mainstream health care	–	–	–	☑	• Outreach/engagement with **patient navigators** • Infrastructure in the community

Identifying and breaking barriers: Addressing disparities in the care of patients with gynecologic cancers

SCAN ME

Bhavana Pothuri [a], Michele Muir [b], Jean Hurteau [b], John Farley [c], Michelle D.S. Lightfoot [a], Summer Dewdney [d], Tara Castellano [e], John K. Chan [f], Sharad Ghamande [g], Al Asante-Facey [h], Marina Stasenko [a], B.J. Rimel [i], Electra D. Paskett [j]

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Pothuri, et al SGO 2025

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Race and Utilization of Immunotherapy for U.S. Food and Drug Administration Approved Indications in Recurrent Endometrial Cancer

Factors Associated with Immunotherapy Use (N=889)

Demographics	Univariate Odds Ratio	Multivariate Odds Ratio
Age at diagnosis	1.00 (0.98-1.01)	--
Charlson Comorbidity Index	1.10 (0.99-1.17)	--
Race	0.58 (0.43-0.81)	0.66 (0.47-0.92)
dMMR/MSI-H disease	2.43 (1.75-3.36)	2.19 (1.57-3.06)

Concerted efforts needed to avoid perpetuating racial inequities in treatment and outcomes

- Cohort: Endometrial Cancer Molecularly Targeted Therapy Consortium and Repository (ECMT2)
- Patients: screened for eligibility for immunotherapy using FDA approval guidelines in recurrent endometrial cancer
- Overall only 566/889 (64%) pts received immunotherapy

GOG IDEA Resources

SCAN ME

Inclusion, diversity, equity, and access (IDEA) in gynecologic cancer clinical trials: A joint statement from GOG foundation and Society of Gynecologic Oncology (SGO)

B. Pothuri [a,*], S.V. Blank [b], T.K. Myers [c], J.F. Hines [d], L.M. Randall [e], R.E. O'Cearbhaill [f], B.M. Slomovitz [g], R.N. Eskander [h], A. Alvarez Secord [i], R.L. Coleman [j], J.L. Walker [k], B.J. Monk [l], K.N. Moore [k], D.M. O'Malley [m], L.J. Copeland [m], T.J. Herzog [n]

https://www.gog.org/idea-commitment/

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Panel Discussion and Audience Q&A

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Treating Cervical Cancer: A Roadmap to Understand Therapy Opportunities

Leslie Randall, MD
Inova Health
Fairfax, Virginia

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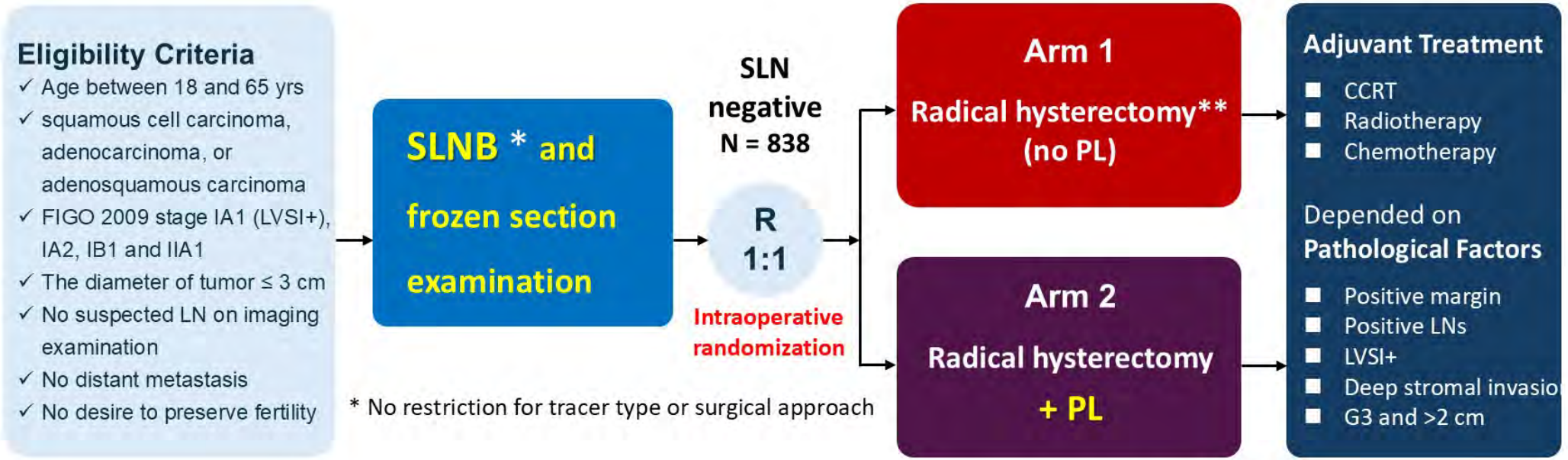
PHENIX-I Schema

Sentinel Lymph Node Biopsy Versus Pelvic Lymphadenectomy in Early-stage Cervical Cancer



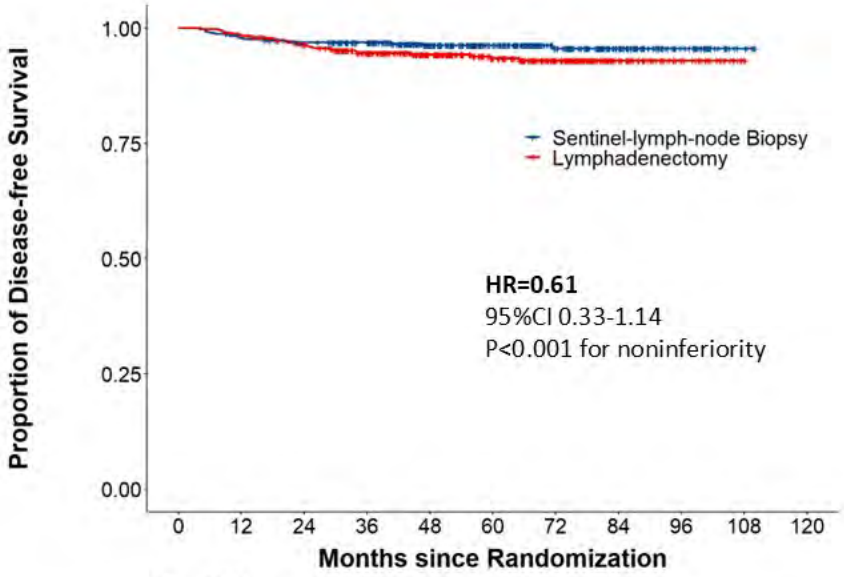
Side-specific PL were performed in cases of **unilateral SLN detection

Primary Endpoint: **Disease-free survival**

Secondary Endpoints: **Rate of retroperitoneal LN recurrence, Cancer-specific survival**, Surgical outcomes and morbidity

FIGO, International Federation of Gynecology and Obstetrics; **PL**, pelvic lymphadenectomy; **SLNB**, sentinel lymph node biopsy; **SLN**, sentinel lymph node; **LN**, lymph node; **CCRT**, concurrent radiochemotherapy; **LVSI**, lymphovascular space involvement; **QoL**, quality of life; **G**, histological grade.

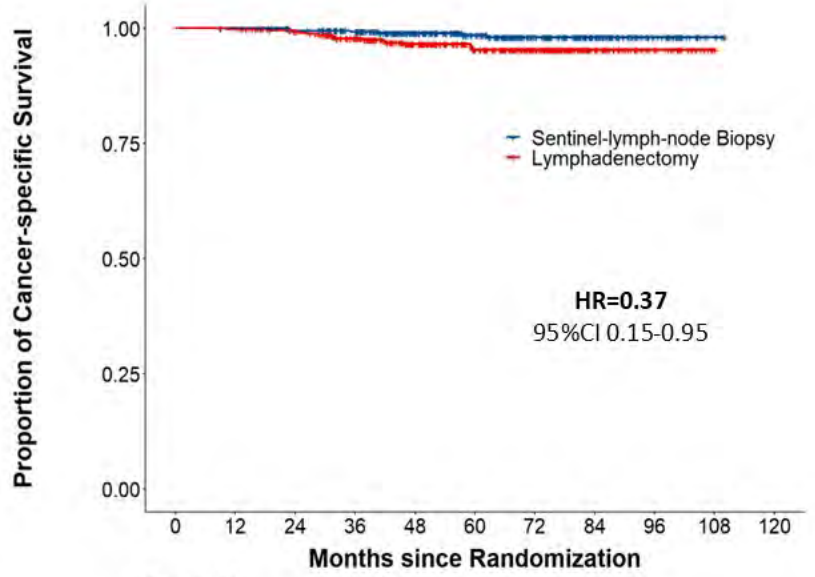
PHENIX-I: Survivals for ITT Population



No. at risk

Sentinel-lymph-node Biopsy	420	410	396	363	284	219	145	85	34	5	0
Lymphadenectomy	418	411	394	353	276	212	149	67	28	2	0

	DFS Events	3-year DFS rate	HR and P-value
Arm1	16	96.9%	HR=0.61 95%CI 0.33-1.14
Arm2	26	94.6%	P<0.001 for noninferiority

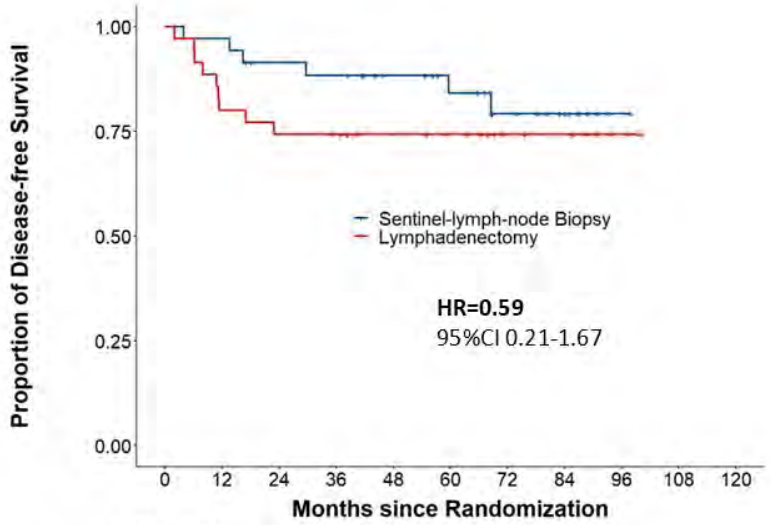


No. at risk

Sentinel-lymph-node Biopsy	420	419	405	370	290	223	148	87	34	5	0
Lymphadenectomy	418	416	406	366	284	219	156	72	30	2	0

	CSS Events	3-year CSS rate	HR
Arm1	6	99.2%	HR=0.37 95%CI 0.15-0.95
Arm2	16	97.8%	

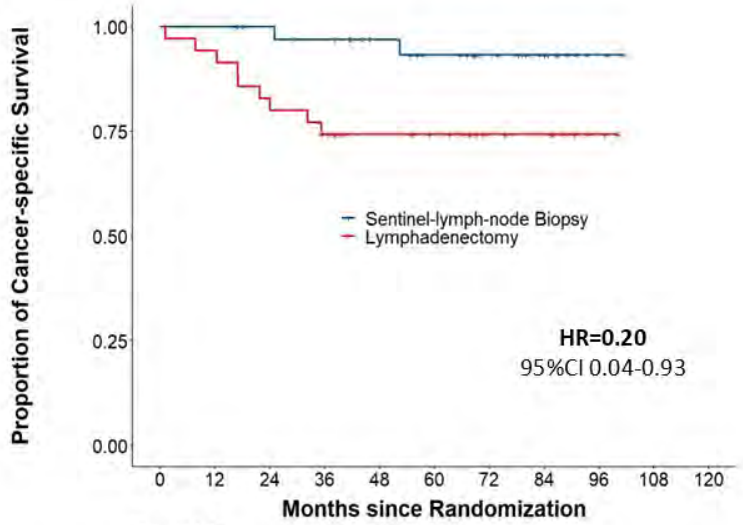
PHENIX-II: Survivals for ITT Population



No. at risk

Sentinel-lymph-node Biopsy	35	34	30	29	24	20	14	9	1	0	0
Lymphadenectomy	35	28	26	25	20	17	10	8	2	0	0

	DFS Events	3-year DFS rate	HR
Arm1	6	88.4%	HR=0.59
Arm2	9	74.3%	95%CI 0.21-1.67



No. at risk

Sentinel-lymph-node Biopsy	35	35	33	31	26	22	16	10	2	0	0
Lymphadenectomy	35	33	29	25	20	17	10	8	2	0	0

	CSS Events	3-year CSS rate	HR
Arm1	2	97.0%	HR=0.20
Arm2	9	74.3%	95%CI 0.04-0.93

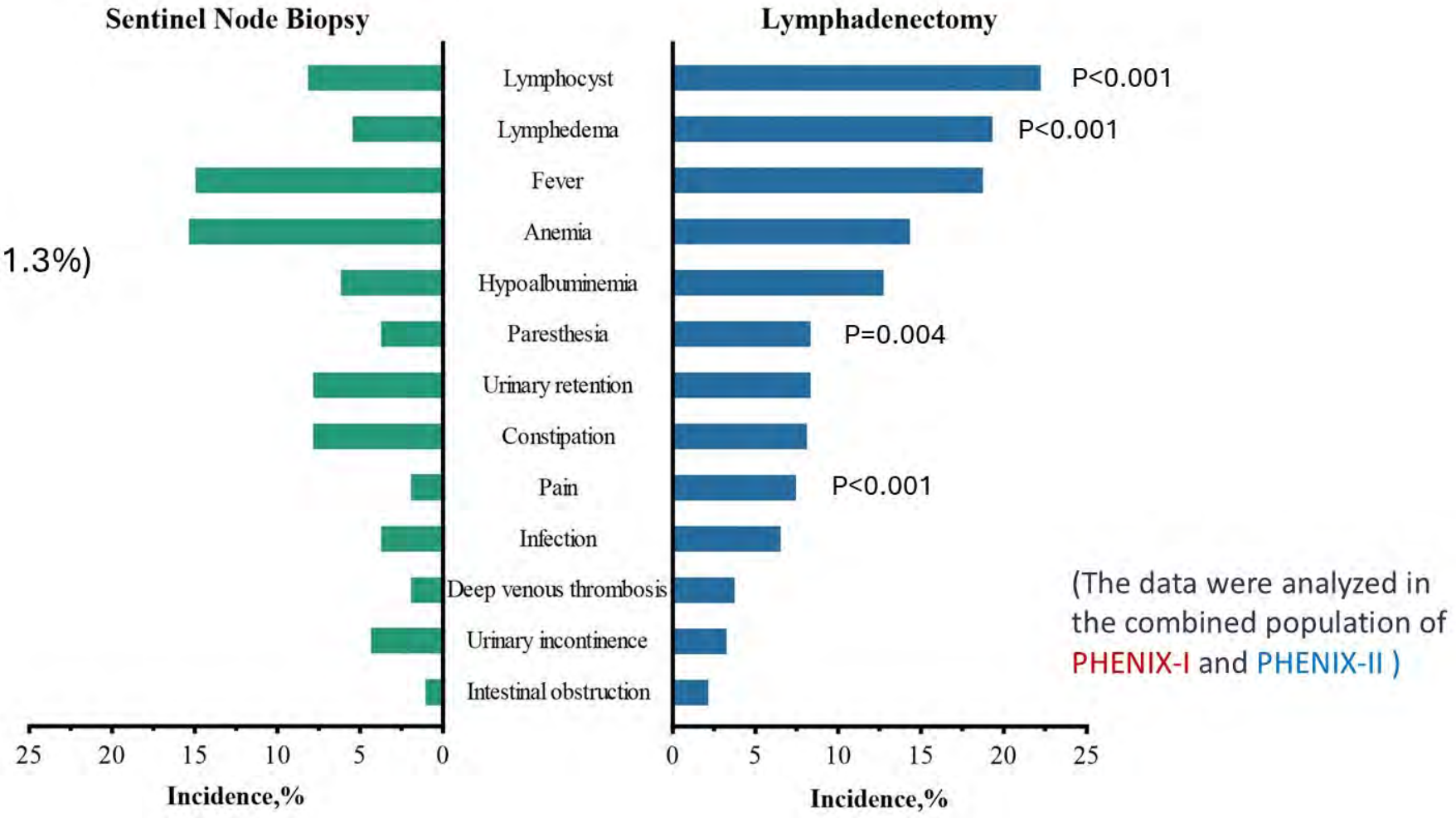
Due to the premature termination, the **PHENIX-II** part lacked sufficient statistical power
Nevertheless, preliminary analysis appeared to indicate trends consistent with those observed in PHENIX-I

Postoperative Adverse Events

Any Adverse Events:

263 (57.8%) **vs** 323 (71.3%)

p<0.001



(The data were analyzed in the combined population of PHENIX-I and PHENIX-II)

GOG-3043/ROCC

A Randomized Controlled Trial of Robotic versus Open Radical or Simple Hysterectomy for Early-Stage Cervical Cancer

PI: Kristin Bixel, MD | Co-PI: Mario Leitao, MD, Leslie Randall MD, Colleen McCormick MD, Dana Chase MD, Allison Quick MD

IA2–IB2 (FIGO 2018)
- Histology: SCC, adeno, adenosquamous
- MRI required
- Uterus <12 cm and amenable to vaginal delivery of specimen

Randomized 1:1

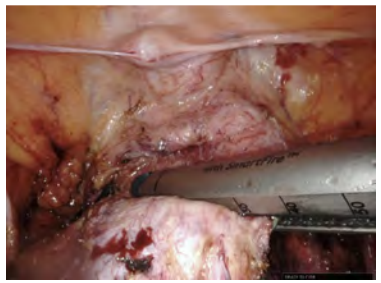
- Open radical or simple hysterectomy + LN Assessment (N=420)
- Robotic radical or simple hysterectomy + LN Assessment (N=420)

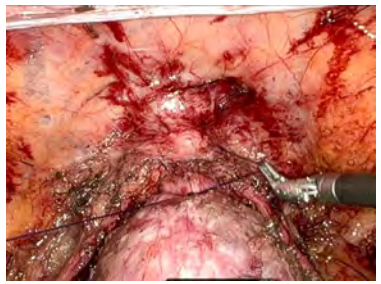
Primary outcome:
- 3-year DFS

Secondary outcomes:
- DSS/OS
- Patterns of recurrence
- Intra-op/Post-op complications
- PROs
- Lymphedema

SCAN ME

Minimization factors:
1/T<2 cm vs >2 cm
2/Simple vs radical
3/Sentinel vs full LND





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KGOG Korean Gynecologic Oncology Group

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Treating Cervical Cancer: A Roadmap to Understand Therapy Opportunities in Locally Advanced Disease

Linda Duska, MD, MPH
UVA Health
Charlottesville, Virgina

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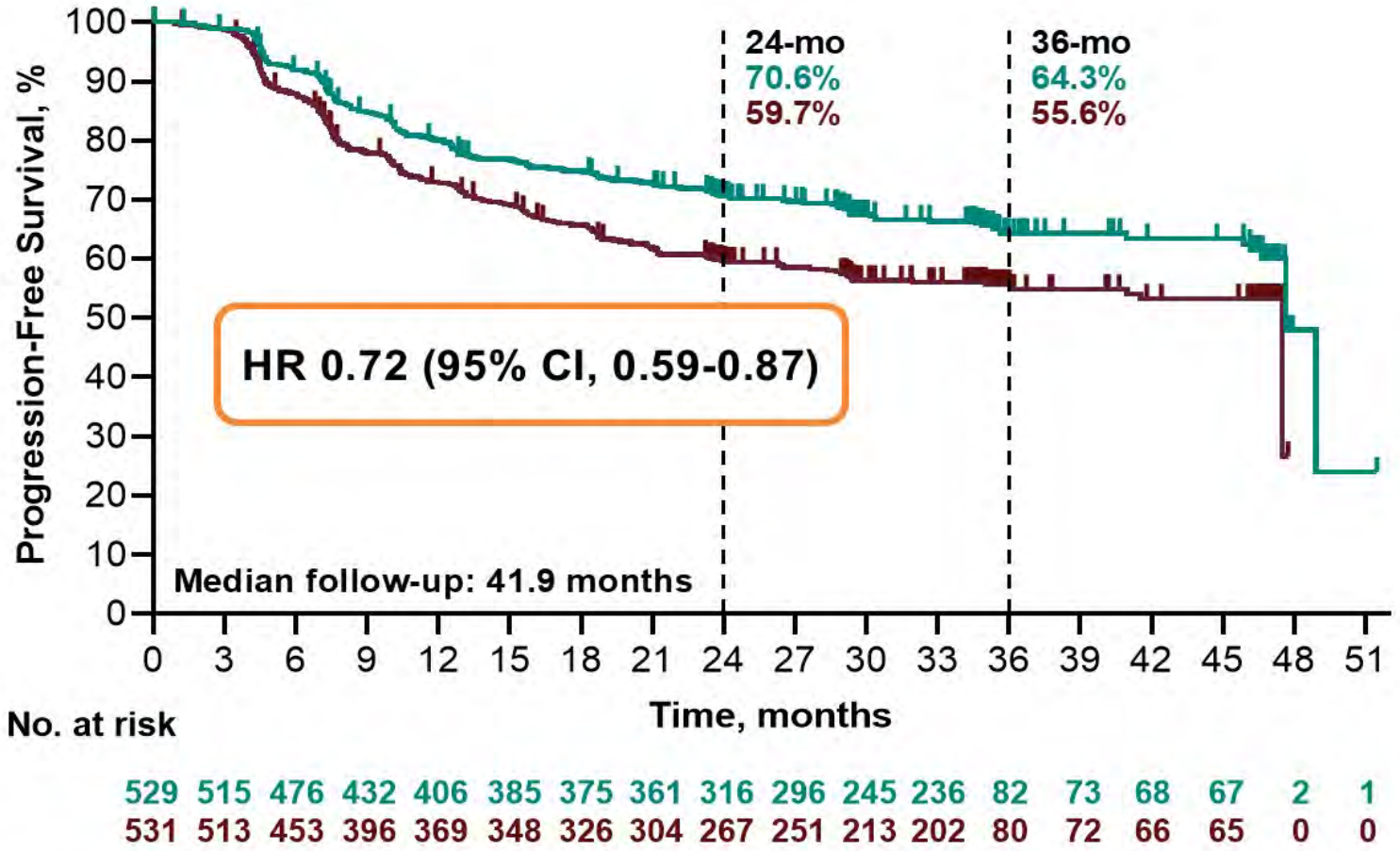
2025 ASCO ANNUAL MEETING

Pembrolizumab with Concurrent Chemoradiotherapy in Participants with High-Risk Locally Advanced Cervical Cancer: A Descriptive Analysis of Final Survival from the Phase 3, Randomized, Double-Blind ENGOT-cx11/GOG-3047/KEYNOTE-A18 Study

Linda R. Duska,[1] Yang Xiang,[2] Kosei Hasegawa,[3] Pier Ramos-Elias,[4] Paolo Rodolfo Valdez Barreto,[5] Alejandro Acevedo,[6] Felipe José Silva Melo Cruz,[7] Valeriya Saevets,[8] Rudolf Lampé,[9] Limor Helpman,[10] Jalid Sehouli,[11] Flora Zagouri,[12] Yong Man Kim,[13] Peng Liu,[14] Karin Yamada,[14] Sarper Toker,[14] Sandro Pignata,[15] Domenica Lorusso,[16] on behalf of the ENGOT-cx11/GOG-3047/KEYNOTE-A18 investigators

[1]University of Virginia School of Medicine, Charlottesville, VA, USA; [2]Department of Obstetrics and Gynecology, National Clinical Research Center for Obstetric & Gynecologic Diseases, Peking Union Medical College Hospital, Beijing, China; [3]Saitama Medical University International Medical Center, Hidaka, Saitama, Japan; [4]Integra Cancer Institute, Edificio Integra Medical Center, Guatemala City, Guatemala; [5]Hospital de Alta Complejidad de La Libertad Virgen de La Puerta, Trujillo, Peru; [6]Oncocentro, Valparaiso, Chile; [7]Instituto Brasileiro de Controle do Câncer, São Paulo, Brazil; [8]Chelyabinsk Regional Clinical Center of Oncology and Nuclear Medicine, Chelyabinsk, Russia; [9]University of Debrecen, Faculty of Medicine, Department of Obstetrics and Gynecology, Debrecen, Hungary; [10]Sheba Medical Center, Tel Aviv University Faculty of Medical and Health Sciences, Ramat Gan, Israel; [11]Charite Universitaetsmedizin, Berlin, Germany and North-Eastern German Society of Gynecological Oncology (NOGGO); [12]Alexandra Hospital, Athens, Greece; [13]Asan Medical Center, University of Ulsan, Seoul, South Korea; [14]Merck & Co., Inc., Rahway, NJ, USA; [15]Department of Urology and Gynecology, Istituto Nazionale Tumori IRCCS Fondazione G. Pascale, Napoli, Italy; [16]Gynaecology Oncology Unit, Fondazione Policlinico Universitario A Gemelli IRCCS, Rome and Humanitas San Pio X, Milan, Italy

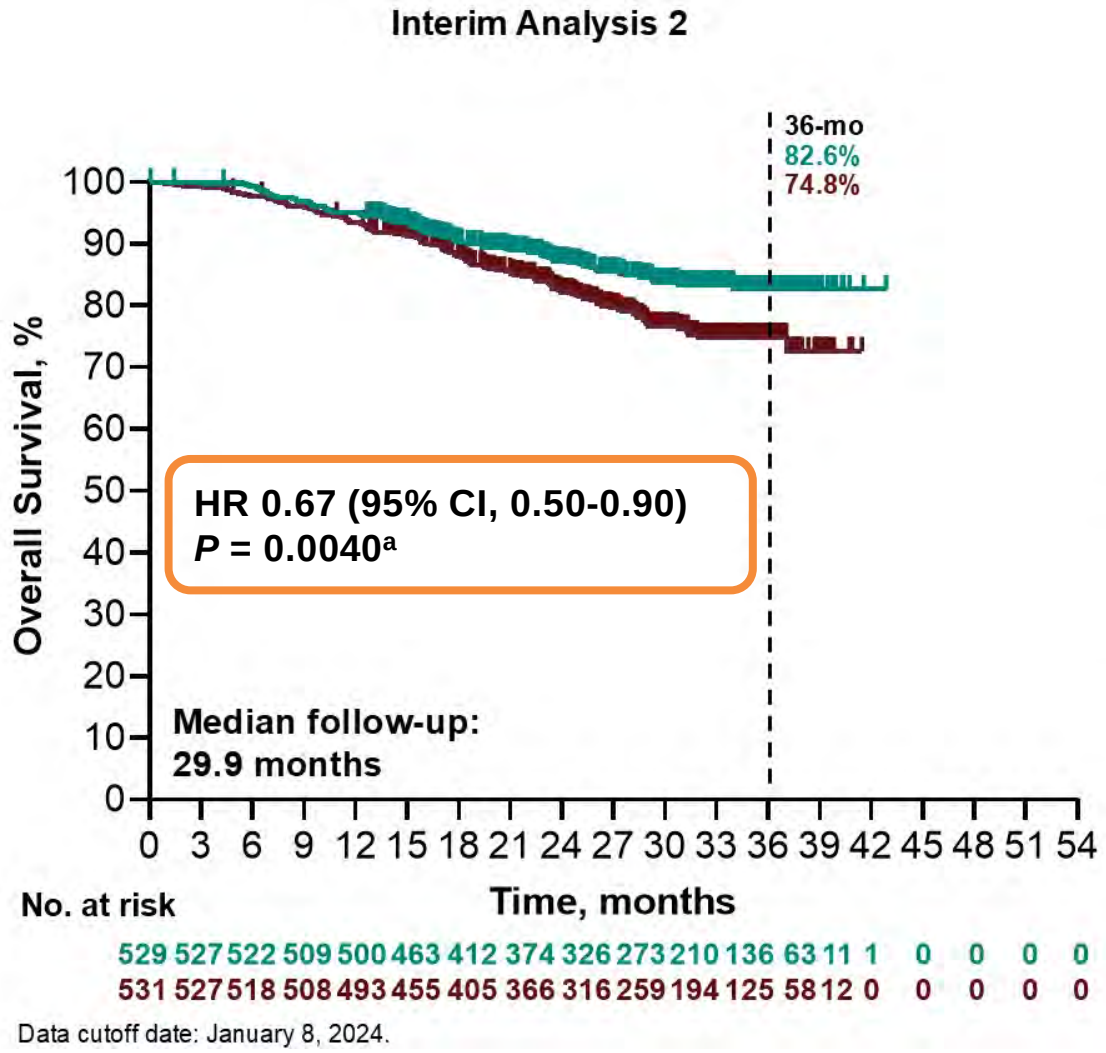
Descriptive Progression-Free Survival at Final Analysis

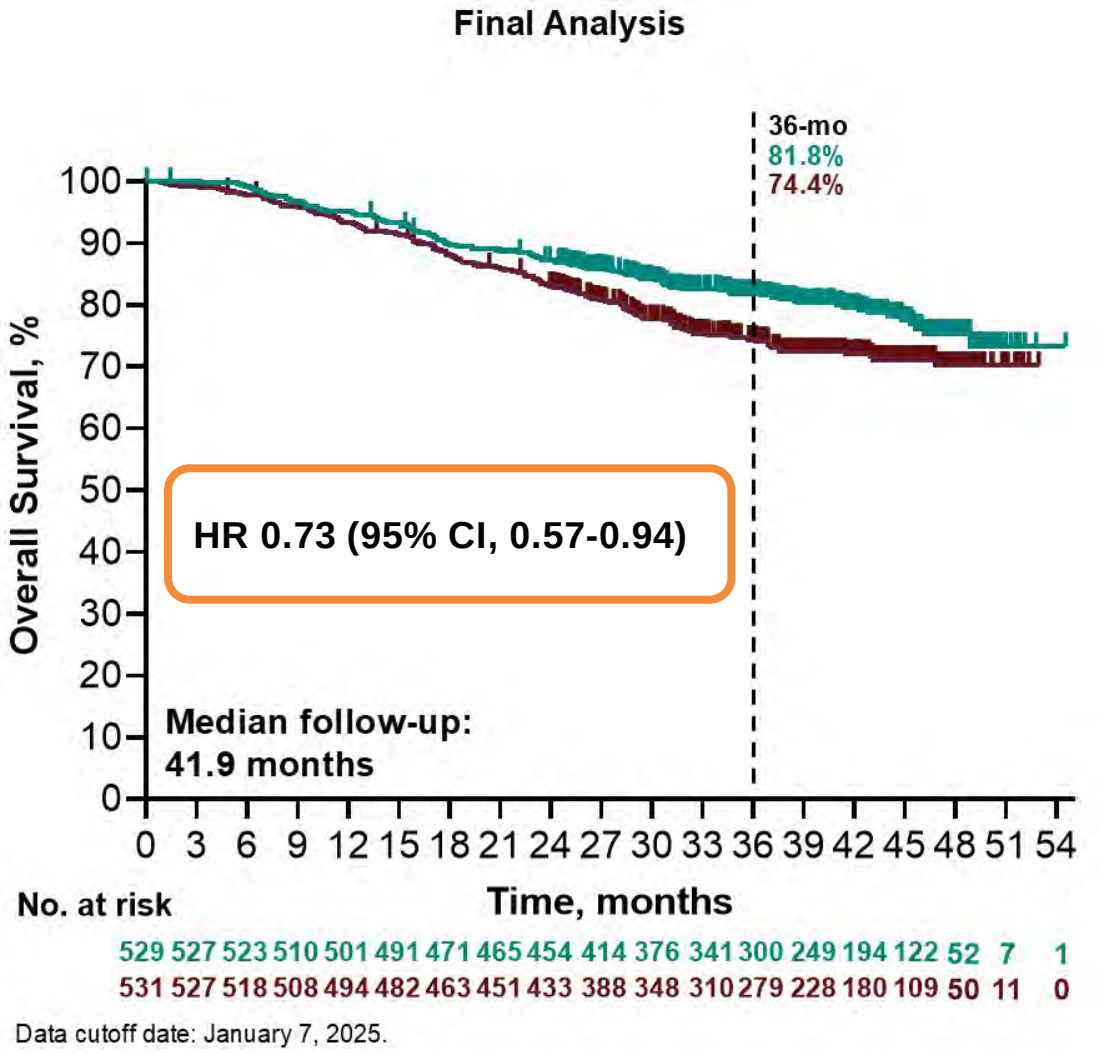


	Pts w/ Event	Pts Censored
Pembro Arm	33.5%	66.5%
Placebo Arm	42.4%	57.6%

Response assessed per RECIST v1.1 by investigator review or histopathologic confirmation. Data cutoff date: January 7, 2025.

Overall Survival at Interim Analysis 2 and Final Analysis





Summary of Post-Progression Therapy at Interim Analysis 2 and Final Analysis

Interim Analysis 2

Post-Progression Therapy[a]	Pembro Arm (N = 138)	Placebo Arm (N = 193)
Immunotherapy, n (%)	15 (10.9%)	51 (26.4%)
Pembrolizumab, n (%)	10 (7.2%)	41 (21.2%)
Antibody-drug conjugates[b]	3 (2.2%)	1 (0.5%)

Data cutoff date: January 8, 2024.

Final Analysis

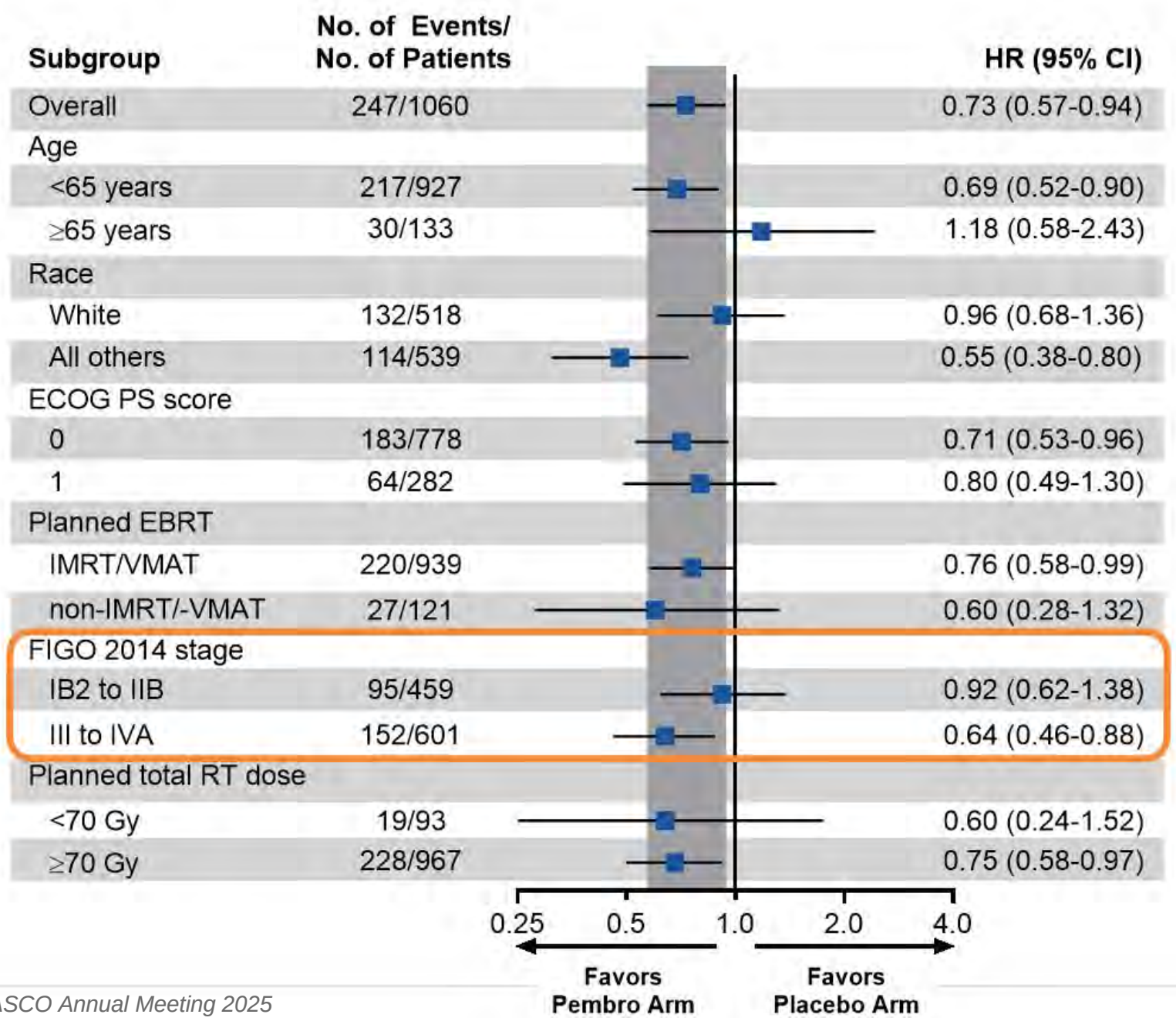
Post-Progression Therapy[a]	Pembro Arm (N = 154)	Placebo Arm (N = 204)
Immunotherapy, n (%)	18 (11.7%)	68 (33.3%)
Pembrolizumab, n (%)	12 (7.8%)	52 (25.5%)
Antibody-drug conjugates[b]	4 (2.6%)	5 (2.4%)

Data cutoff date: January 7, 2025.

[a]All lines of post-progression therapy. [b]Includes other monoclonal antibodies and antibody-drug conjugates and tisotumab vedotin.

Overall Survival in Protocol-Specified Subgroups at Final Analysis

Data cutoff date: January 7, 2025



GOG 3092: eVOLVE-Cervical-Phase 3 Study of Volrustomig in High-Risk Locally Advanced Cervical Cancer

Screening period FIGO 2018 IIIA-IVA cervical cancer (LN involvement)	Randomization	Treatment period (post-CRT maintenance)	Endpoints

Part I: Diagnosis/CRT

Patient consenting process step 1:

- Tumor sample submission and analysis
  - PD-L1 expression by VENTANA PD-L1 (SP263) Assay
- **Initial staging procedures** completed prior to any component of definitive treatment

Part II: Post CRT

Patient consenting process step 2:

- After completion of SOC CCRT (≥4 cycles), CCRT dose requirement
- No progression after SOC CCRT, persistent disease must not be amenable to other available therapies with curative intent
- Grade > 1 toxicities resolved prior to randomization
- ECOG 0 or 1

N=800

R 1:1

Arm A

Volrustomig 750mg IV Q3W for 24 months

Arm B

Placebo IV Q3W for 24 months

Stratification factors

- PD-L1 expression (PD-L1 high expression vs. low/negative)
- T1/T2 v T3/T4
- Region (Asia vs. non-Asia)

Primary Endpoint: PFS in PD-L1 high population (Inv)

Secondary Endpoint:

Key: PFS in ITT (Inv), OS in PD-L1 high population/ITT

Others: PFS (BICR), 12mons-PFS, 24mons-PFS, 36mons-OS, ORR, DOR, PFS2, TFST, incidence of local progression and distant disease progression, PK, ADAs, safety and tolerability, ePROs

Exploratory Endpoint: ctDNA, T cell proliferation/clonal expansion, baseline tumor immune and genomic profile, ePROs

NCT 06079671

2025 ASCO ANNUAL MEETING

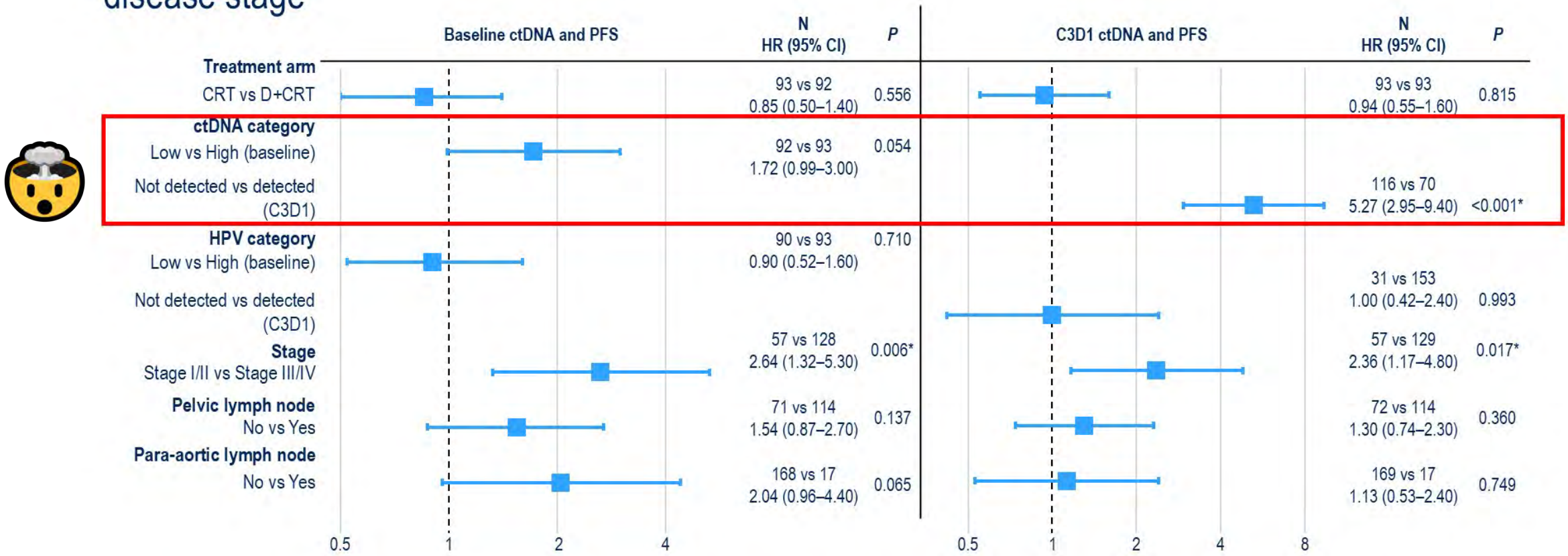
Ultrasensitive detection and tracking of circulating tumor DNA (ctDNA) and association with relapse and survival in locally advanced cervical cancer (LACC): phase 3 CALLA trial analyses

Jyoti Mayadev,[1] Juan Carlos Vázquez Limón,[2] Francisco J. Ramírez Godinez,[3] Manuel Leiva,[4] Lucely del Carmen Cetina-Pérez,[5] Szilvia Varga,[6] Alejandro Molina Alavez,[7] Ashley E. Alarcon Rozas,[8] Natalia Valdiviezo,[9] Xiaohua Wu,[10] Masaki Mandai,[11] Ronnie Shapira-Frommer,[12] Maria del Pilar Estevez-Diz,[13] Sewanti Limaye,[14] Wenjing Xin,[15] Hannah Dry,[16] Maria A.S. Broggi,[17] Daniel Y. Yuan,[17] Ross Stewart,[18] Bradley J. Monk[19]

[1]University of California San Diego Medical Center, San Diego, CA; [2]Antiguo Hospital Civil de Guadalajara "Fray Antonio Alcalde" University of Guadalajara, Guadalajara, Mexico; [3]Hospital Civil de Guadalajara, Guadalajara, Mexico; [4]Instituto de Oncologia y Radioterapia de la Clinica Ricardo Palma, San Isidro, Peru; [5]Clinical Research Department, Instituto Nacional de Cancerologia, Ciudad de México, México; [6]National Institute of Oncology, Budapest, Hungary; [7]Centro de Atención e Investigación Clinica en Oncologia, Mérida, Mexico; [8]Clinica Santa Beatriz, Lima, Peru; [9]Nacional de Enfermedades Neoplásicas, Lima, Peru; [10]Fudan University Shanghai Cancer Center, Shanghai, China; [11]Kyoto University Graduate School of Medicine, Kyoto, Japan; [12]Chaim Sheba Medical Center, Ramat Gan, Israel; [13]Instituto do Câncer do Estado de São Paulo and Universidade de São Paulo, São Paulo, Brazil; [14]Sir H N Reliance Foundation Hospital, Mumbai, India; [15]AstraZeneca, Gothenburg, Sweden; [16]AstraZeneca, Waltham, MA; [17]AstraZeneca, Gaithersburg, MD; [18]AstraZeneca, Cambridge, UK; [19]Florida Cancer Specialists and Research Institute, West Palm Beach, FL

CALLA Multivariate Analysis: C3D1 ctDNA+ Was The Most Significant Prognostic Factor for Progression and Independent of Disease Stage

Baseline ctDNA high was the second most significant prognostic factor for progression after disease stage



The prognostic impact of ctDNA levels, adjusting for other clinical covariates, was assessed via multivariate Cox proportional hazard models with Efron approximation tie handling. All comparisons are text vs reference. *Indicates significance. C, cycle; CI, confidence interval; ctDNA, circulating tumor DNA; CRT, chemoradiotherapy; D+CRT, durvalumab + chemoradiotherapy; OS, overall survival; PFS, progression-free survival.

2025 ESMO GYNAECOLOGICAL CANCERS
Annual Congress

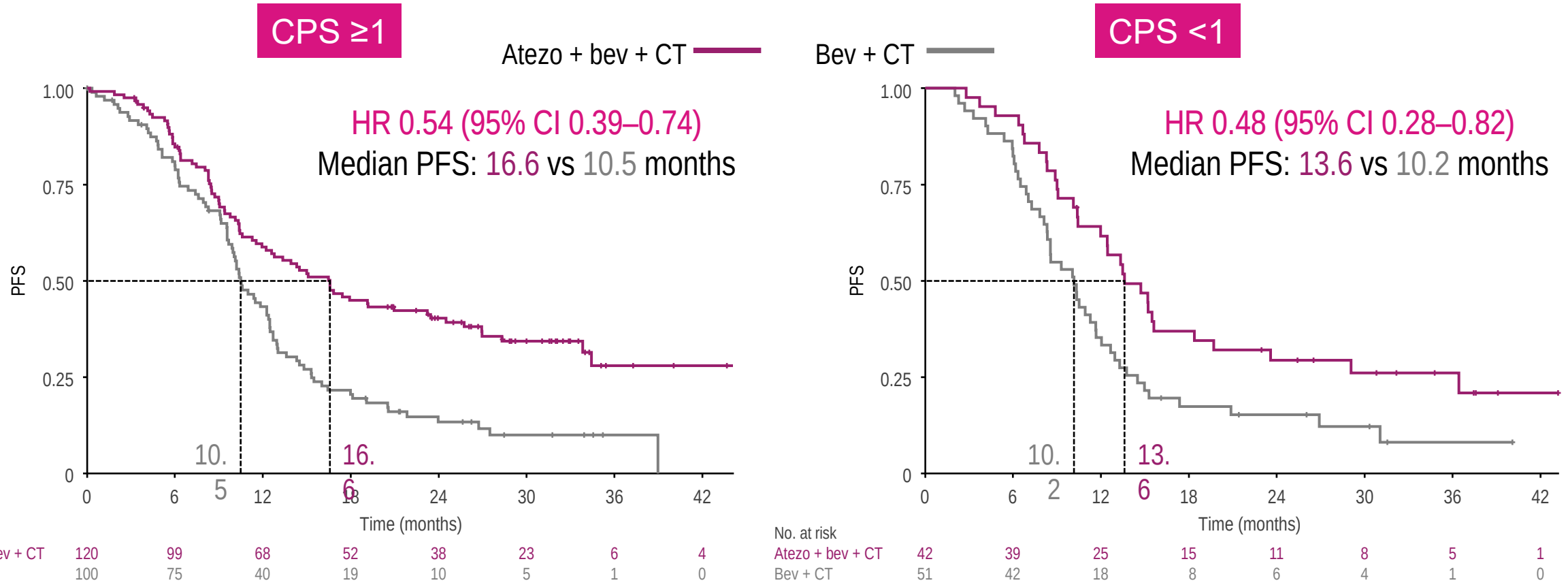
Efficacy according to PD-L1 status in the BEATcc (ENGOT-Cx10/GEICO 68-C/JGOG1084/GOG-3030) randomised phase 3 trial of first-line atezolizumab, chemotherapy and bevacizumab for metastatic, persistent or recurrent cervical cancer

Prof. Kristina Lindemann, MD, PhD
NSGO-CTU, Oslo University Hospital and University of Oslo, Oslo, Norway
On behalf of U De Giorgi, L Mansi, J Martinez-Garcia, G Villacampa, M Takekuma, K Lindemann, L Woelber, D Black, D Katsaros, B You, A Godoy Ortiz, A Yabuno, A-C Hardy-Bessard, MJ Rubio Pérez, S Abadie-Lacourtoisie, L Fariñas Madrid, W Mina, D Lorusso, H Dahlstrand and A Oaknin

19 June, 2025

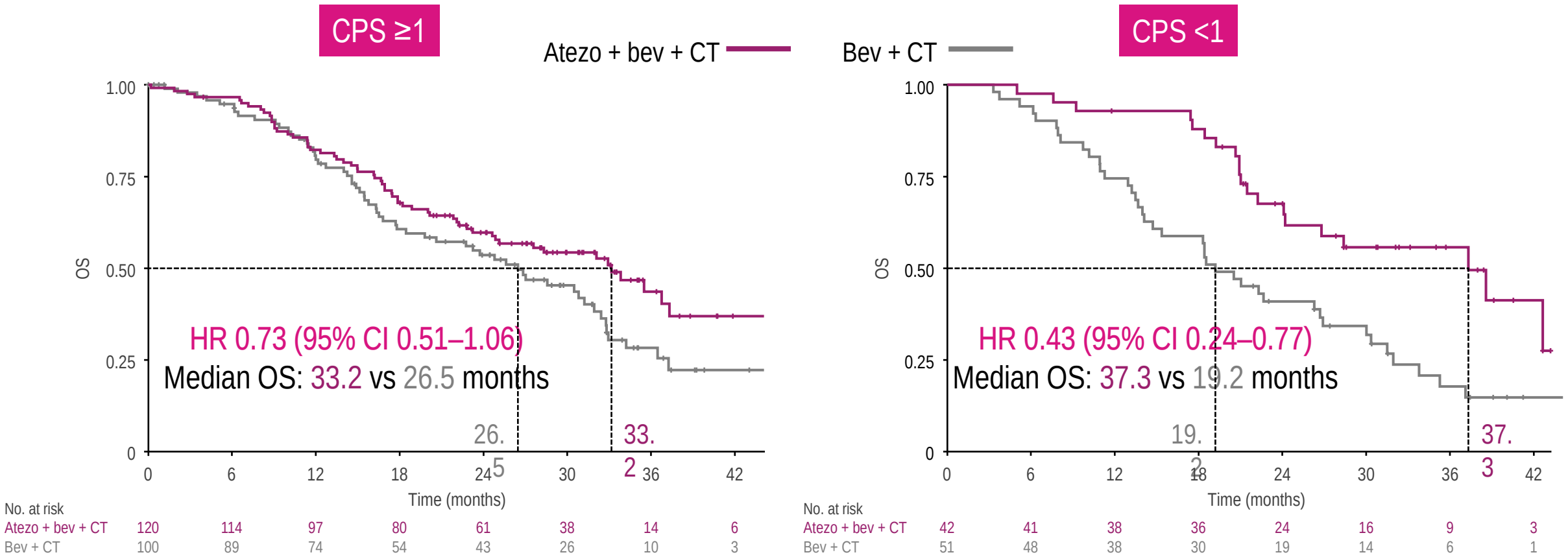
PFS according to PD-L1 CPS <1 vs ≥1

Median follow-up: 32.8 months (95% CI 31.5–34.6)



Interaction p=0.73

Interim OS according to PD-L1 CPS <1 vs ≥1



Interaction p=0.12

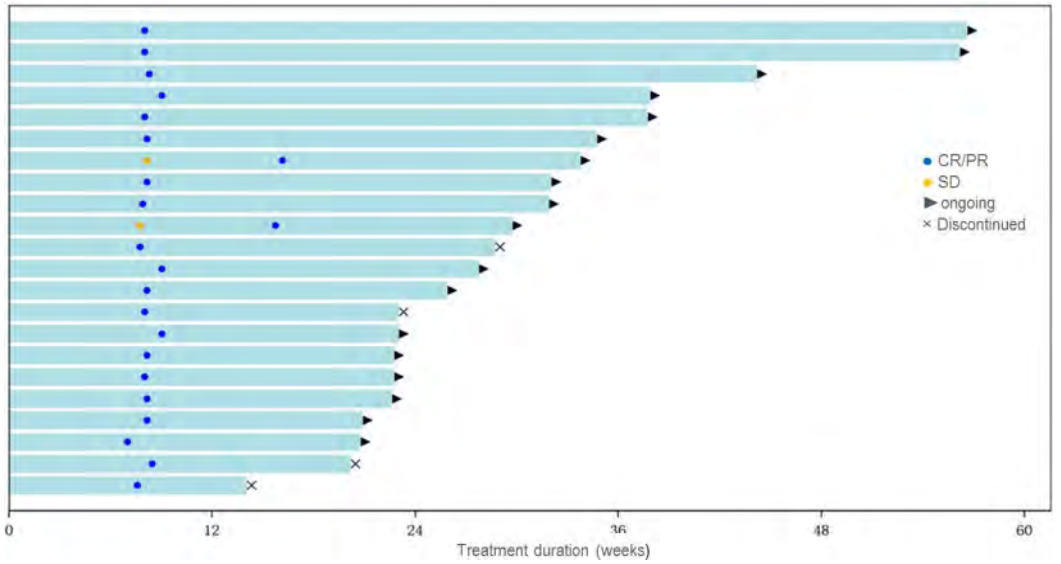
BARCELONA 2024 ESMO congress

Efficacy and Safety of Sacituzumab Tirumotecan (sac-TMT) Plus Pembrolizumab in Patients with Recurrent or Metastatic Cervical Cancer

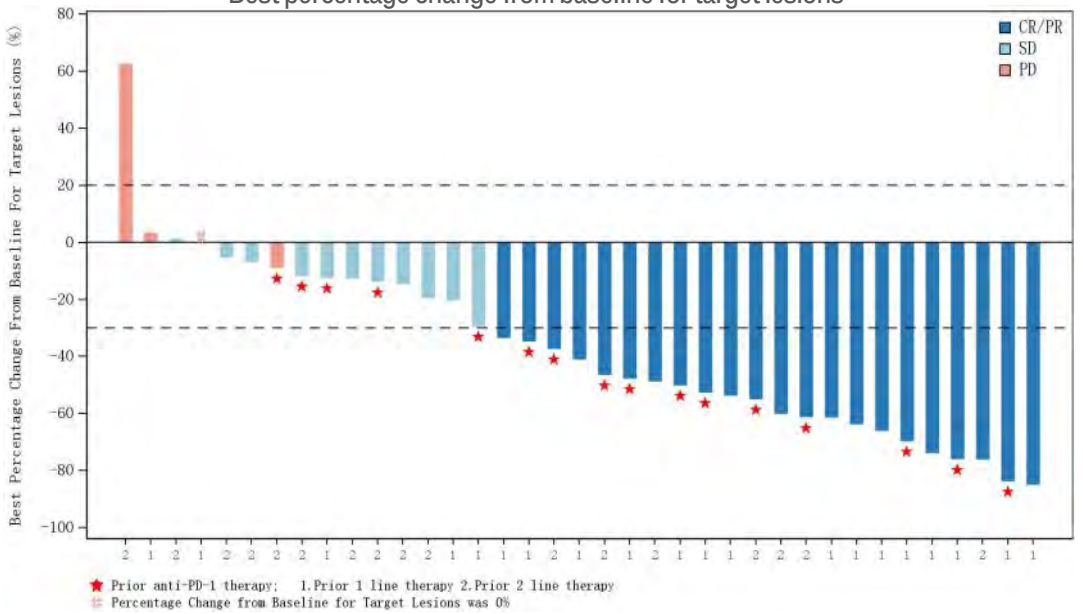
Xiaohua Wu[1], Jing Wang[2], Ruifang An[3], Yi Huang[4], Jieqing Zhang[5], Jeffrey C. Goh[6], Kui Jiang[7], Guohua Yu[8], Liang Chen[9], Diane Provencher[10], Ying Tang[11], Guiling Li[12], Hui Qiu[13], Omobolaji·O. Akala[14], Elliot Chartash[14], Yiting Zhou[15], Xiaoping Jin[15], Junyou Ge[15]

				(95% CI)
CPS status	CPS ≥ 1	14	7 (50.0)	68.8 (35.7, 87.3)
	CPS < 1	15	9 (60.0)	74.9 (39.1, 91.5)
	Unknown	9	6 (66.7)	43.8 (10.1, 74.2)
Prior anti-PD-1 based therapy	Yes	16	11 (68.8)	78.6 (47.2, 92.5)
	No	22	11 (50.0)	58.0 (32.4, 76.8)
Prior bevacizumab	Yes	20	12 (60.0)	67.1 (40.9, 83.7)
	No	18	10 (55.6)	67.5 (38.2, 85.2)
No. of prior systemic therapy	1	20	15 (75.0)	73.1 (46.7, 87.9)
	2	18	7 (38.9)	54.3 (21.8, 78.3)
therapy	2	18	7 (38.9)	54.3 (21.8, 78.3)

Time to response and duration of treatment for responders



Best percentage change from baseline for target lesions



GOG FOUNDATION

GOG-3101/TroFuse-020/ENGOT-cx20

A Phase 3 Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of Physician's Choice as Second-line Treatment for Participants with Recurrent or Metastatic Cervical Cancer

US PI: Ritu Salani, MD

Eligibility

- Squamous, adenosquamous, adenocarcinoma cervical cancer
- Recurrent or metastatic:
  - Progressed on or after treatment with 1 prior line of systemic platinum doublet chemotherapy (with or without bevacizumab) NOTE: may have also received prior chemoradiotherapy in the LACC setting

  AND
  - Received anti-PD-1/anti-PD-L1 therapy as part of prior cervical cancer regimens
- Measurable disease per RECIST 1.1
- ECOG PS 0-1
- <Grade 2 PN

Safety run-in

Sac-TMT 4 mg/kg IV q2 wk

ORR
Safety/Tolerability

R 1:1

Sac-TMT 4 mg/kg IV q2 wk

Physician's choice chemo
Tisotumab vedotin, pemetrexed, topotecan, vinorelbine, gemcitabine, or irinotecan

Primary Endpoint

- OS

Secondary Endpoints

- PFS
- ORR
- DOR
- Safety/Tolerability
- PROs
  - Time to first deterioration EORTC-QLQ-C30
  - Change baseline C30
    - Health status
    - QOL
    - Physical functioning
    - Role functioning

GOG Highlight Reel

NCT06459180

GOG FOUNDATION

GOG-3116/C5721005

PI: Scott Jordan, MD

Single-arm, prospective, low-interventional study of tisotumab vedotin in adult participants in the US with r/mCC who have received prior systemic therapy for recurrent or metastatic disease

Patient Population

r/m CC with disease progression on or after chemotherapy, following prior systemic therapy

No active ocular disease at baseline

No prior TV treatment

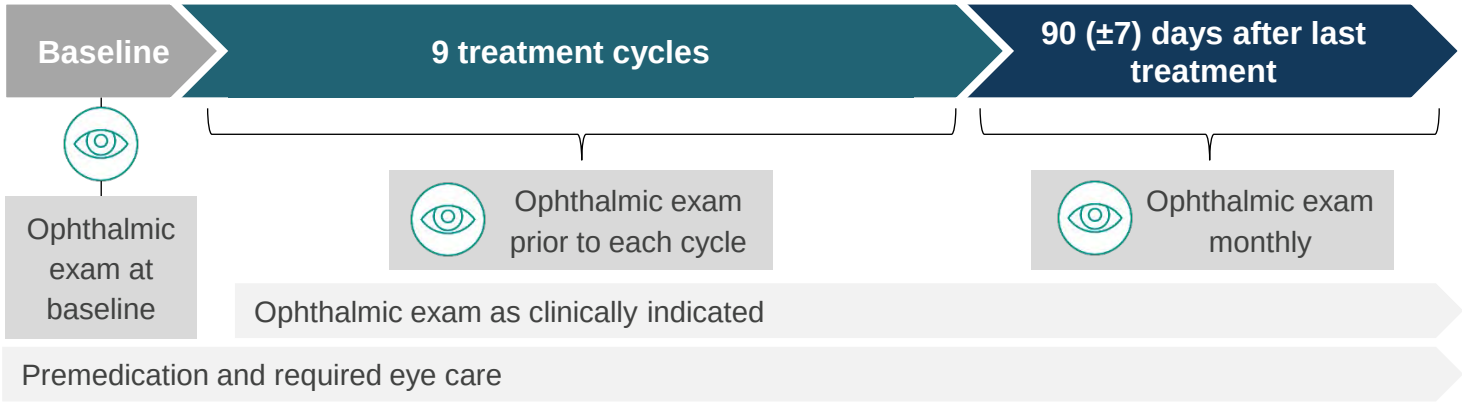
Tisotumab vedotin
2.0 mg/kg IV on Day 1 of a 21-day cycle (Q3W)

N=100

Intervention

Scheduled ocular assessments conducted by eye care providers

- Slit lamp exam of the anterior segment of the eye
- Visual acuity
- Assessment of normal eye movement
- Elicitation of visual symptoms



Endpoints

Primary endpoint

- Type, incidence and severity of ocular AEs

Secondary endpoints

- Time to onset, time to resolution, and outcome of ocular AEs
- Incidence of serious AEs
- AEs leading to dose modifications including treatment discontinuation

Objective: to further characterize the incidence and severity of tisotumab vedotin-related ocular events with prospectively pre-specified, scheduled ocular assessments in patients receiving tisotumab vedotin for r/mCC

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Panel Discussion and Audience Q&A

Bradley Monk, MD
Florida Cancer Specialists & Research Institute
West Palm Beach, Florida

GOG Highlight Reel

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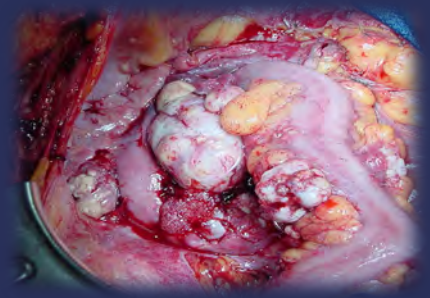
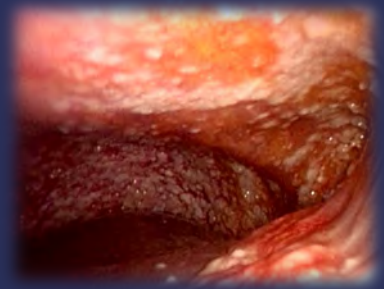
Ovarian Cancer Highlights: Summary

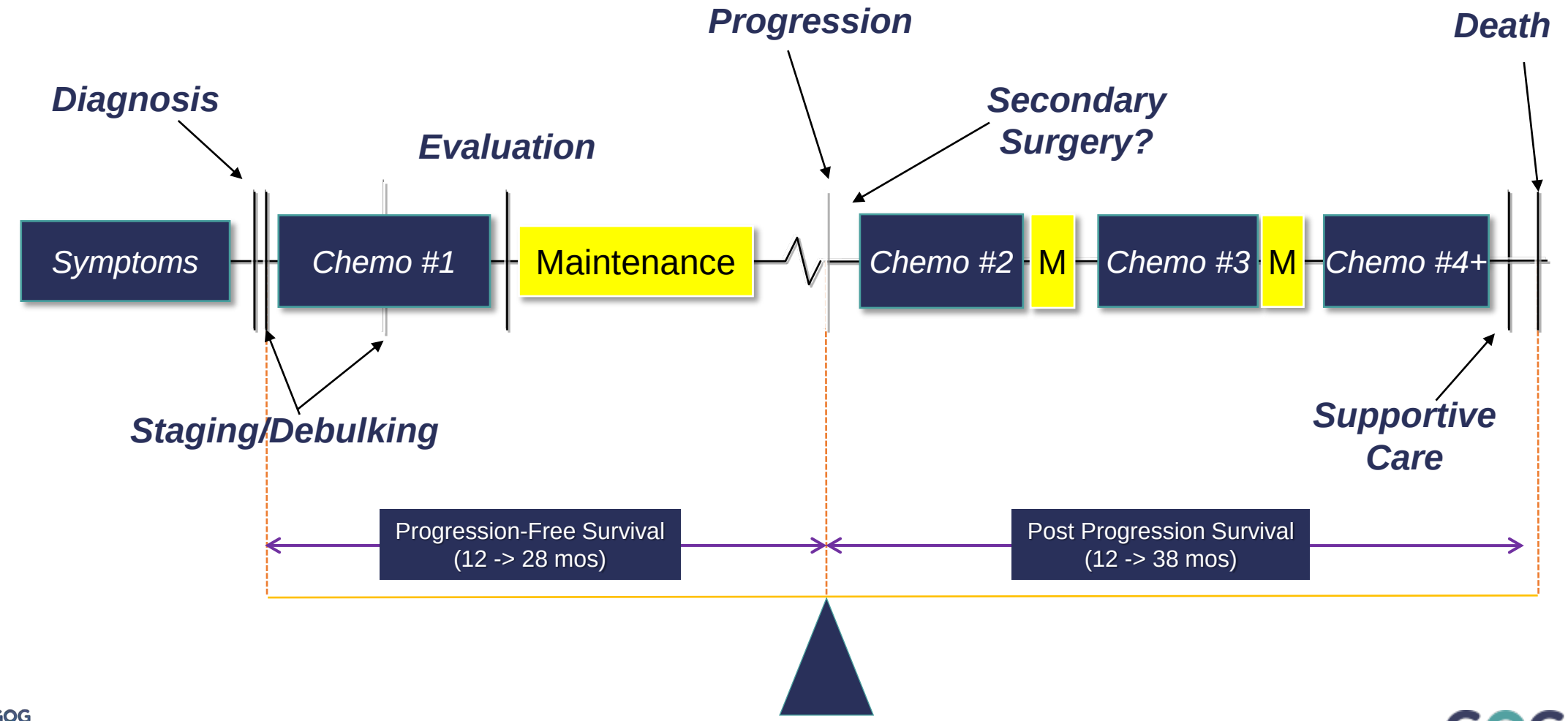




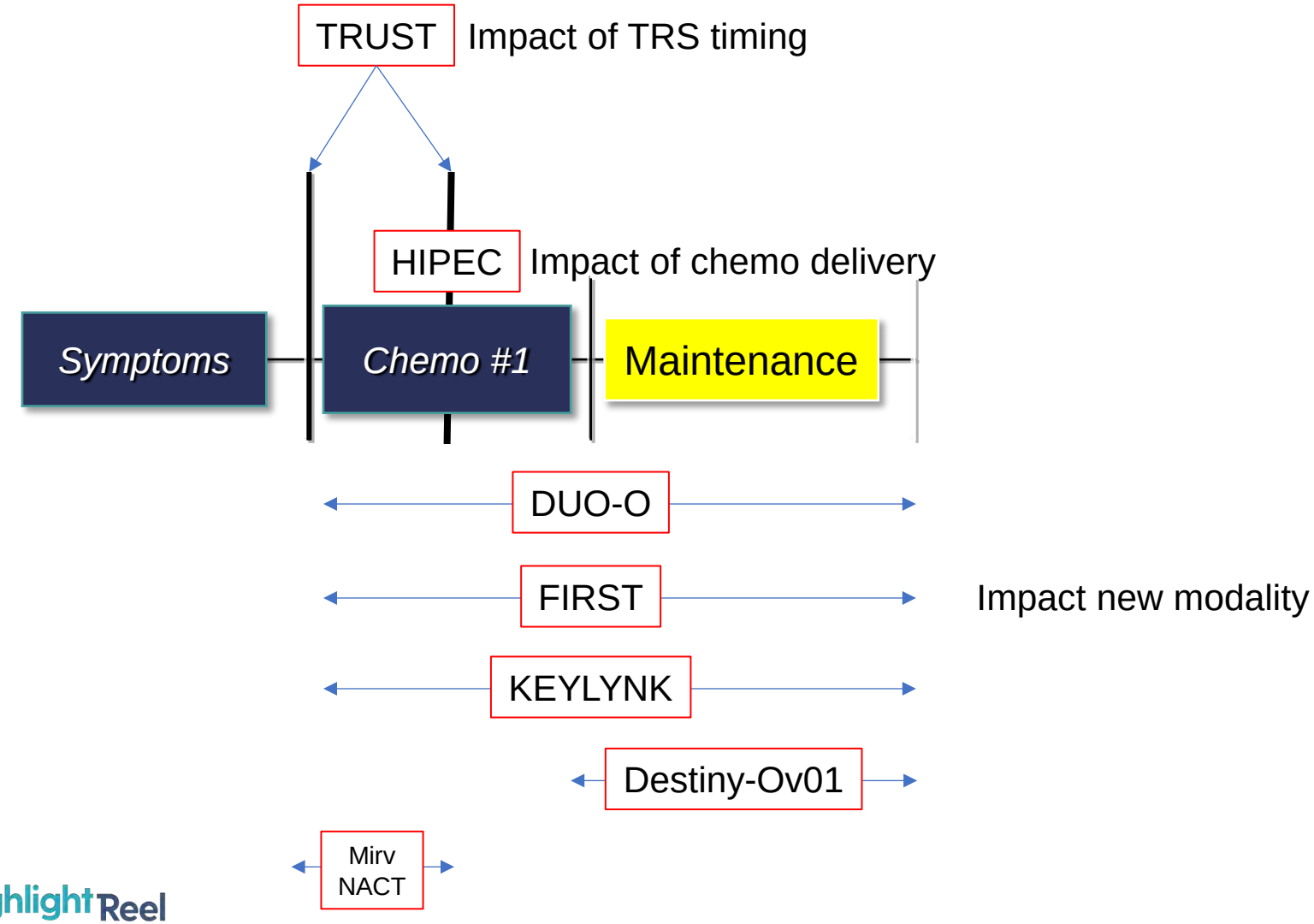
Robert Coleman, MD
Gynecologic Oncologist, Texas Oncology
Special Advisor, GOG-Partners
VP, GOG Foundation
The Woodlands, TX USA

GOG Highlight Reel

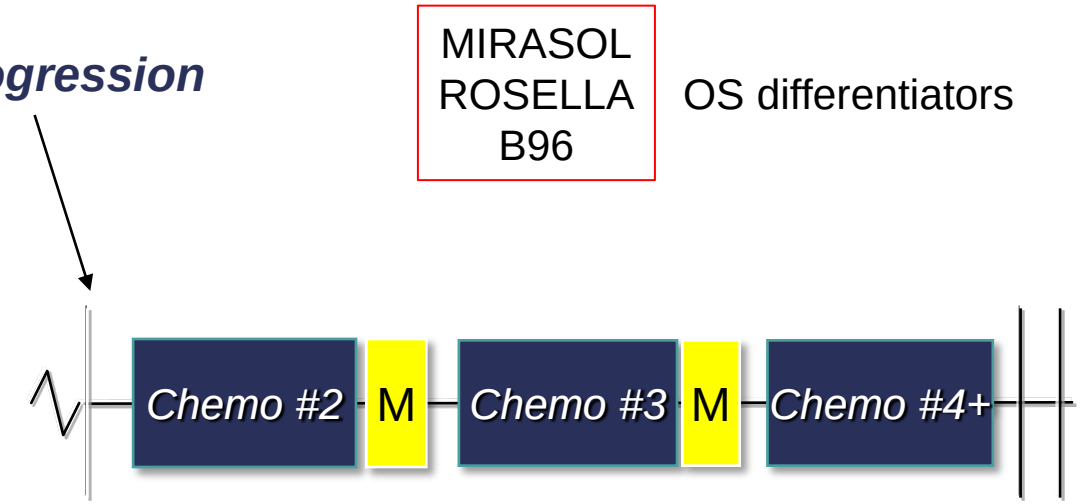
Ovarian Cancer: Innovative Treatment



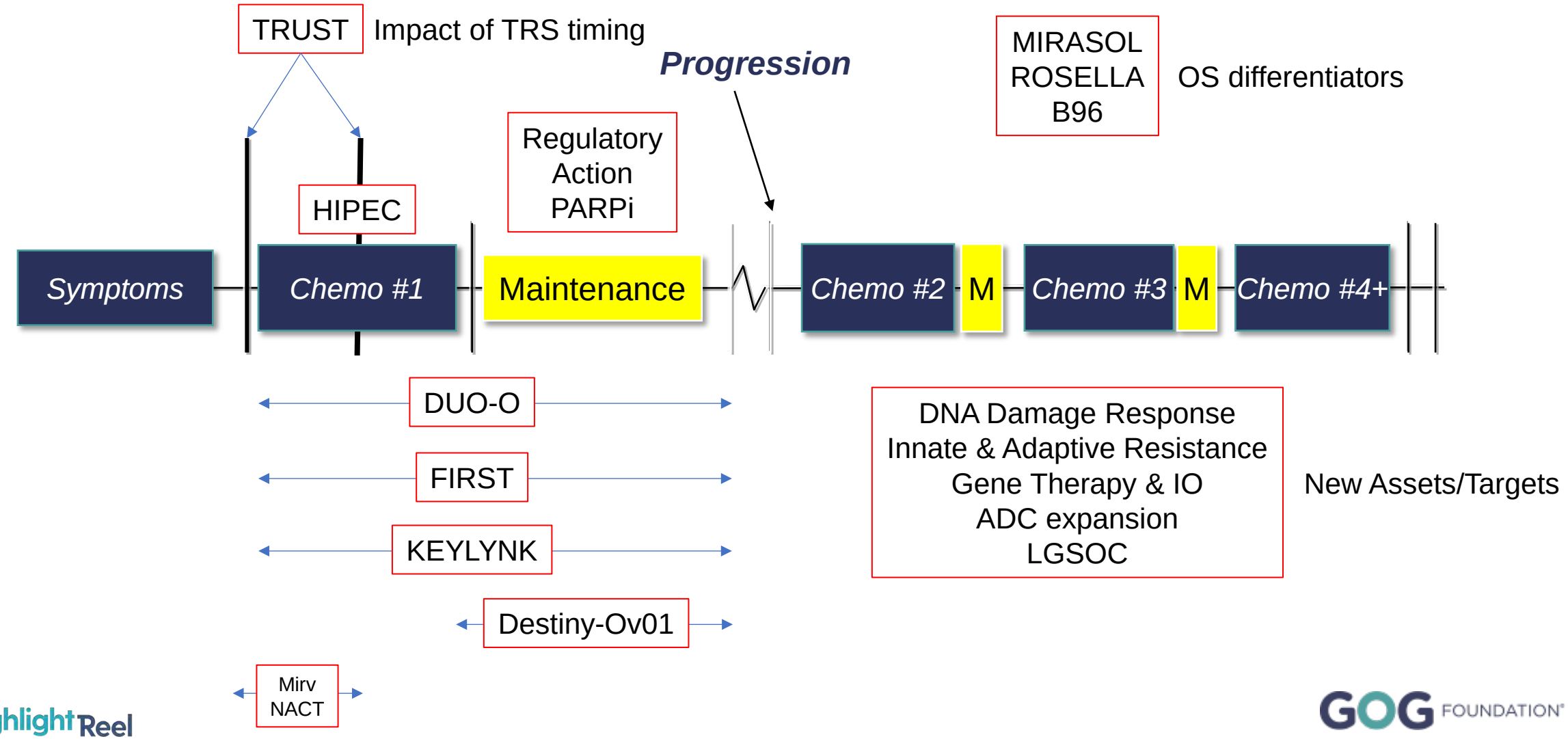
Ovarian Cancer Innovation: Primary Setting



Ovarian Cancer Innovation: Recurrent Setting



Ovarian Cancer Innovation Landscape



Key Issues for Development & Discussion

- How do we best characterize patients with recurrent disease?
  - PFI 6 month meaningful? What else can we justify?
  - Is “One and done” a real phenomenon?
    - For ADC: if same warhead class? If the same targeting antibody? If no on-treatment PD? Is there a sequence that matters?
    - For immunotherapy: Is there an IO-free interval?
- Should we support development of assets without a predictive biomarker?
- What are the most appropriate available therapies in the investigative setting?
  - What is the most appropriate control arm?

Key Issues for Development & Discussion

- How do we identify and adapt treatment to tumor modification?
- What are the most informative endpoints?
  - PFS, OS, second PFS, PFS2, Landmark risk?
  - Hierarchical designs?
  - Biomarker expression efficacy and safety differentiators?
- What is the best strategy to build a clinical trial portfolio?
  - Phase Ib/II and phase III strategy
  - Multiple phase III's in the same setting
  - Strategic planning based on targeted opening/closing targets

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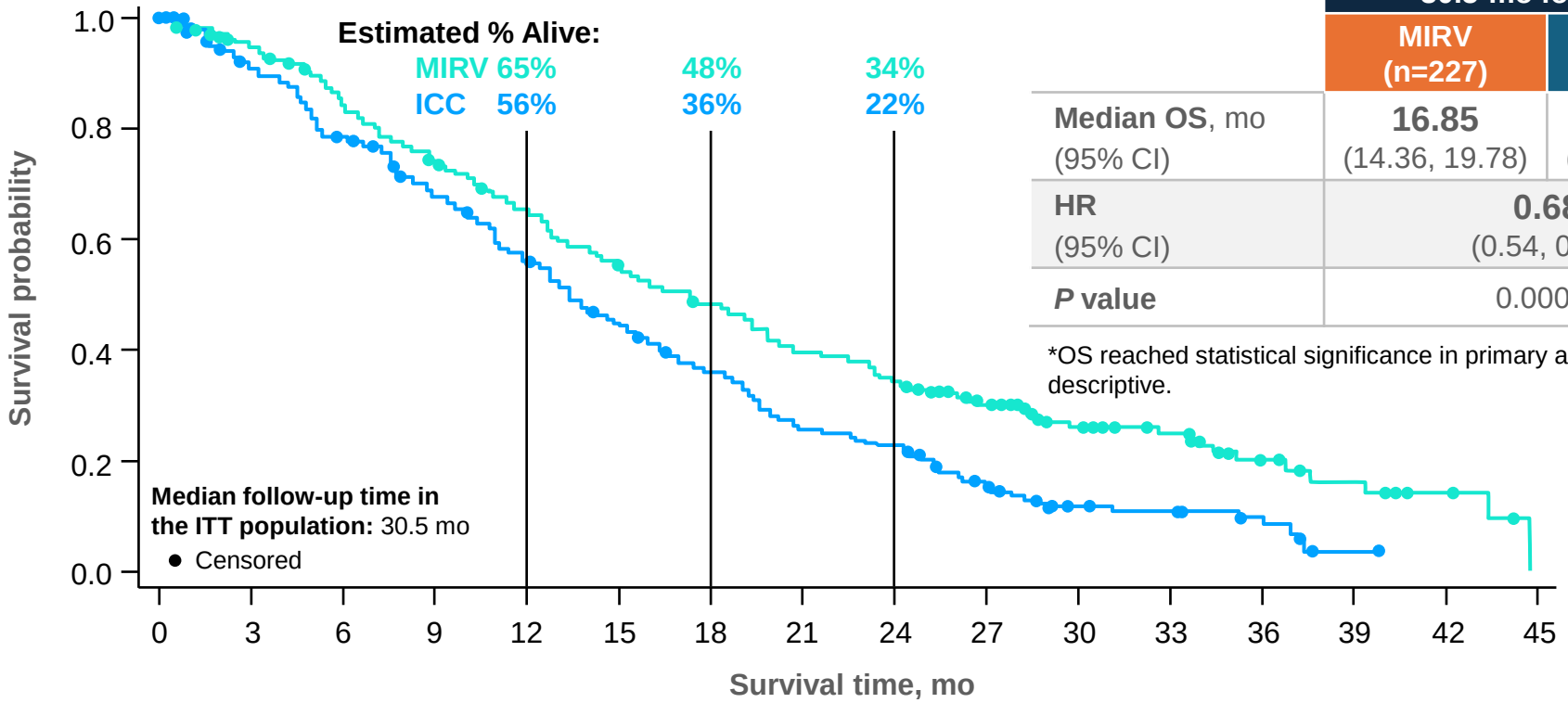
Ovarian Cancer: Updates

David O'Malley, MD
Director & Professor, Division of Gynecologic Oncology in Ob/Gyn
John G. Boutselis Chair in Gynecologic Oncology
The Ohio State University and the James Comprehensive Cancer Center
GOG Partners - Ovarian Cancer Clinical Trial Advisor
GOG Foundation Board of Directors

GOG Highlight Reel

MIRASOL Final Overall Survival



	Final analysis[a] 30.5-mo follow-up		Primary analysis[b] 13.1-mo follow-up	
	MIRV (n=227)	ICC (n=226)	MIRV (n=227)	ICC (n=226)
Median OS, mo (95% CI)	**16.85** (14.36, 19.78)	**13.34** (11.37, 15.15)	16.46 (14.46, 24.57)	12.75 (10.91, 14.36)
HR (95% CI)	**0.68** (0.54, 0.84)		0.67 (0.50, 0.89)	
***P* value**	0.0004*		0.0046	

*OS reached statistical significance in primary analysis. The *P* value at the final analysis is descriptive.

At the final analysis, the HR for OS (0.68) **continued to favor MIRV** over ICC, with patients treated with MIRV exhibiting a **32% reduction in risk of death**

Number of patients at risk:

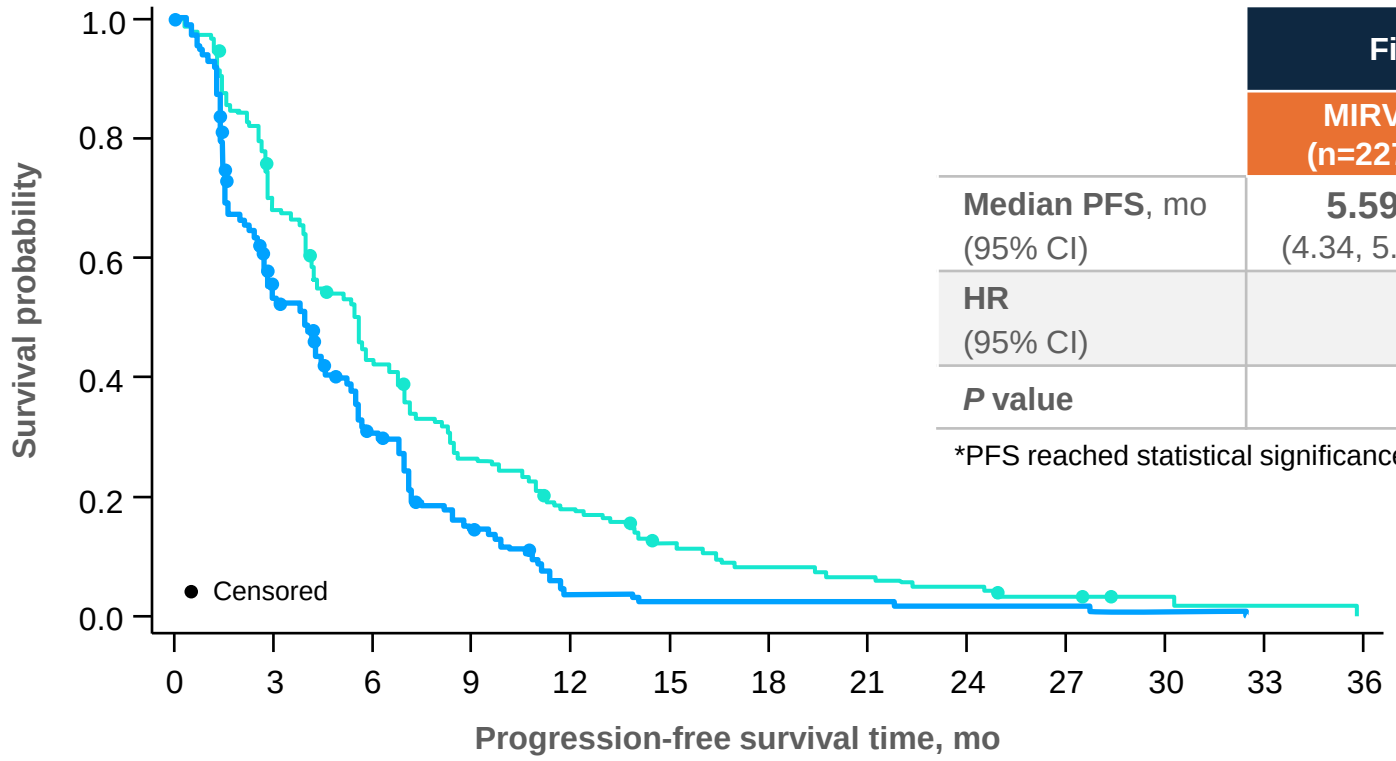
MIRV	227	204	178	156	135	114	98	80	70	50	33	25	12	8	4	0
ICC	226	186	159	134	110	85	67	48	42	25	13	11	7	1	0	

HR, hazard ratio; ICC, investigator's choice chemotherapy; ITT, intent-to-treat; MIRV, mirvetuximab soravtansine-gynx; OS, overall survival; PFS, progression-free survival.

[a]Data cutoff: September 26, 2024. [b]Data cutoff: March 6, 2023.

Moore KN, et al. *N Engl J Med.* 2023;389(23):2162-2174.

MIRASOL Final PFS by Investigator



	Final analysis[a]		Primary analysis[b]	
	MIRV (n=227)	ICC (n=226)	MIRV (n=227)	ICC (n=226)
Median PFS, mo (95% CI)	**5.59** (4.34, 5.88)	**3.98** (2.86, 4.47)	5.62 (4.34, 5.95)	3.98 (2.86, 4.47)
HR (95% CI)	**0.63** (0.51, 0.79)		0.65 (0.52, 0.81)	
***P* value**	<0.0001*		<0.0001	

*PFS reached statistical significance in primary analysis. The *P* value at the final analysis is descriptive.

At the final analysis, the HR for PFS (0.63) **continued to favor MIRV** over ICC, with patients treated with MIRV exhibiting a **37% reduction in risk of progression**

HR, hazard ratio; ICC, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine-gynx; PFS, progression-free survival.

[a]Data cutoff: September 26, 2024. [b]Data cutoff: March 6, 2023.

Moore KN, et al. N Engl J Med. 2023;389(23):2162-2174.

MIRASOL Efficacy Summary

Endpoints	Final analysis[a]		Primary analysis[b]	
	MIRV (n=227)	ICC (n=226)	MIRV (n=227)	ICC (n=226)
ORR by INV, n (%) (95% CI)	**95 (41.9)**[c] (35.4, 48.6)	**36 (15.9)** (11.4, 21.4)	**96 (42.3)** (35.8, 49.0)	**36 (15.9)** (11.4, 21.4)
Odds ratio (95% CI)	**3.75** (2.4, 5.85)		**3.81** (2.44, 5.94)	
Best overall response, n (%)				
Complete response	**13 (5.7)**	**0**	**12 (5.3)**	**0**
Partial response	**82 (36.1)**	**36 (15.9)**	**84 (37.0)**	**36 (15.9)**
Stable disease	87 (38.3)	91 (40.3)	86 (37.9)	91 (40.3)
Progressive disease	31 (13.7)	63 (27.9)	31 (13.7)	62 (27.4)
Not evaluable	14 (6.2)	36 (15.9)	14 (6.2)	37 (16.4)
Median DOR, mo (95% CI)	**6.93** (5.78, 8.84)	**4.44** (4.17, 5.75)	**6.77** (5.62, 8.31)	**4.47** (4.17, 5.82)
Median PFS2, mo (95% CI)	**11.01** (9.30, 12.02)	**7.59** (6.60, 8.84)	**11.04** (9.36, 12.45)	**8.05** (6.74, 9.36)
HR (95% CI)	**0.59** (0.480, 0.728)		**0.63** (0.497, 0.803)	

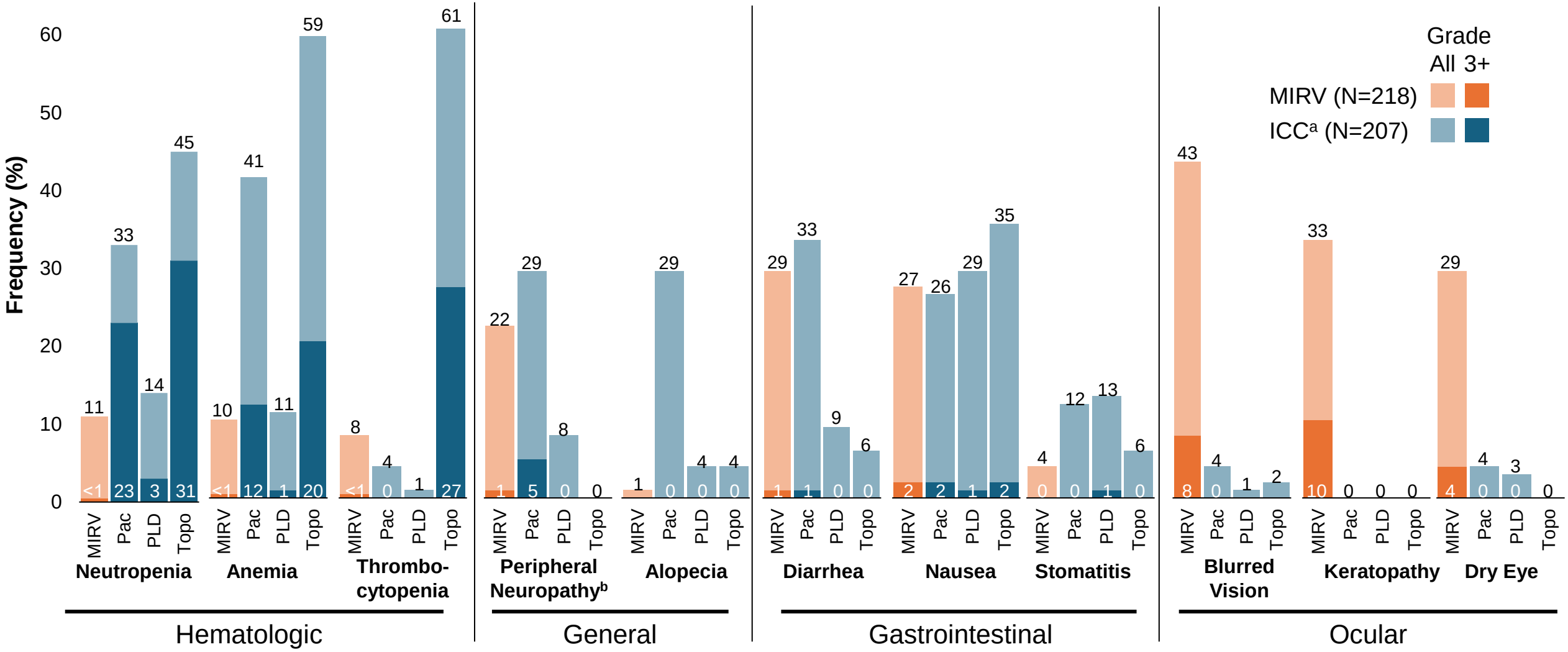
- At final analysis, MIRV maintained a **higher ORR (13 CRs vs none)** and **longer DOR** compared to ICC
- **PFS benefit for MIRV** over ICC was maintained **beyond the first progression** (PFS2 analysis) with an HR of 0.59

CR, complete response; DOR, duration of response; HR, hazard ratio; ICC, investigator's choice chemotherapy; INV, investigator; MIRV, mirvetuximab soravtansine-gynx; ORR, objective response rate, PFS2, time from randomization until second disease progression or death, regardless of initiation of next line of anticancer treatment .

[a]Data cutoff: September 26, 2024. [b]Data cutoff: March 6, 2023. [c]In the final analysis, 1 patient had best objective response change from stable disease to partial response, 2 patients had best objective response change from partial response to stable disease, and 1 patient had best objective response change from partial response to complete response.

Moore KN, et al. *N Engl J Med.* 2023;389(23):2162-2174.

MIRASOL Treatment-Emergent Adverse Events: No New Safety Signals at Final Analysis



Toon Van Gorp SGO 2025

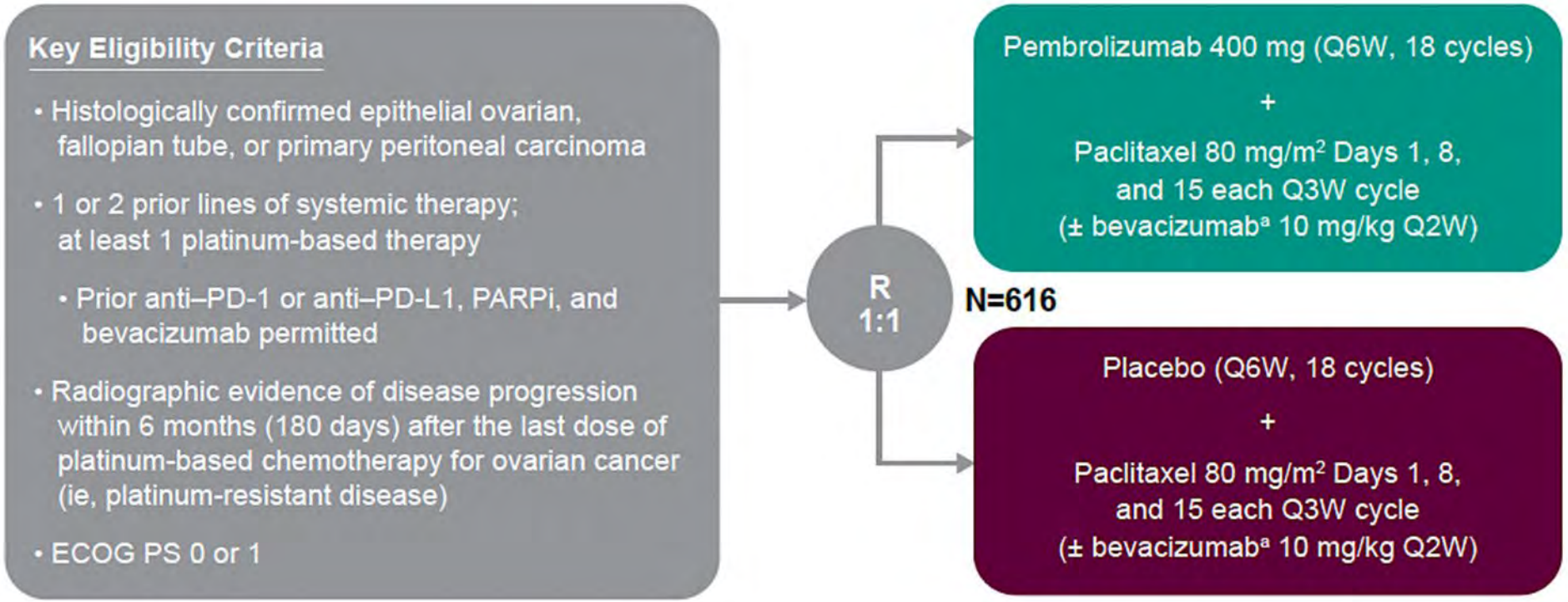
Data cutoff: September 26, 2024

ICC, investigator's choice chemotherapy; MIRV, mirvetuximab soravtansine-gynx; Pac, paclitaxel; PLD, pegylated liposomal doxorubicin; Topo, topotecan.
[a]Pac, n=82 (40%); PLD, n=76 (37%); Topo, n=49 (24%). [b]Grade 2+ peripheral neuropathy events were observed in 12%, 16%, and 3% of patients that received MIRV, PAC, or PLD, respectively.

ENGOT-ov65/KEYNOTE-B96

Phase 3, Randomized, Double-Blind Study of Pembrolizumab Versus Placebo Plus Paclitaxel With Optional Bevacizumab for Platinum-Resistant Recurrent Ovarian Cancer

A road for IO in PROC?



N. Colombo, ESGO 2022

A road for IO in PROC?

Merck Announces Phase 3 KEYNOTE-B96 Trial Met Primary Endpoint of Progression-Free Survival (PFS) in Patients With Platinum-Resistant Recurrent Ovarian Cancer Whose Tumors Expressed PD-L1 and in All Comers

https://www.merck.com/news/merck-announces-phase-3-keynote-b96-trial-met-primary-endpoint-of-progression-free-survival-pfs-in-patients-with-platinum-resistant-recurrent-ovarian-cancer-whose-tumors-expressed-pd-l1-and-in-all-c/

GOG FOUNDATION®
Transforming the standard of care

Rosella Data Highlights & Panel Discussion

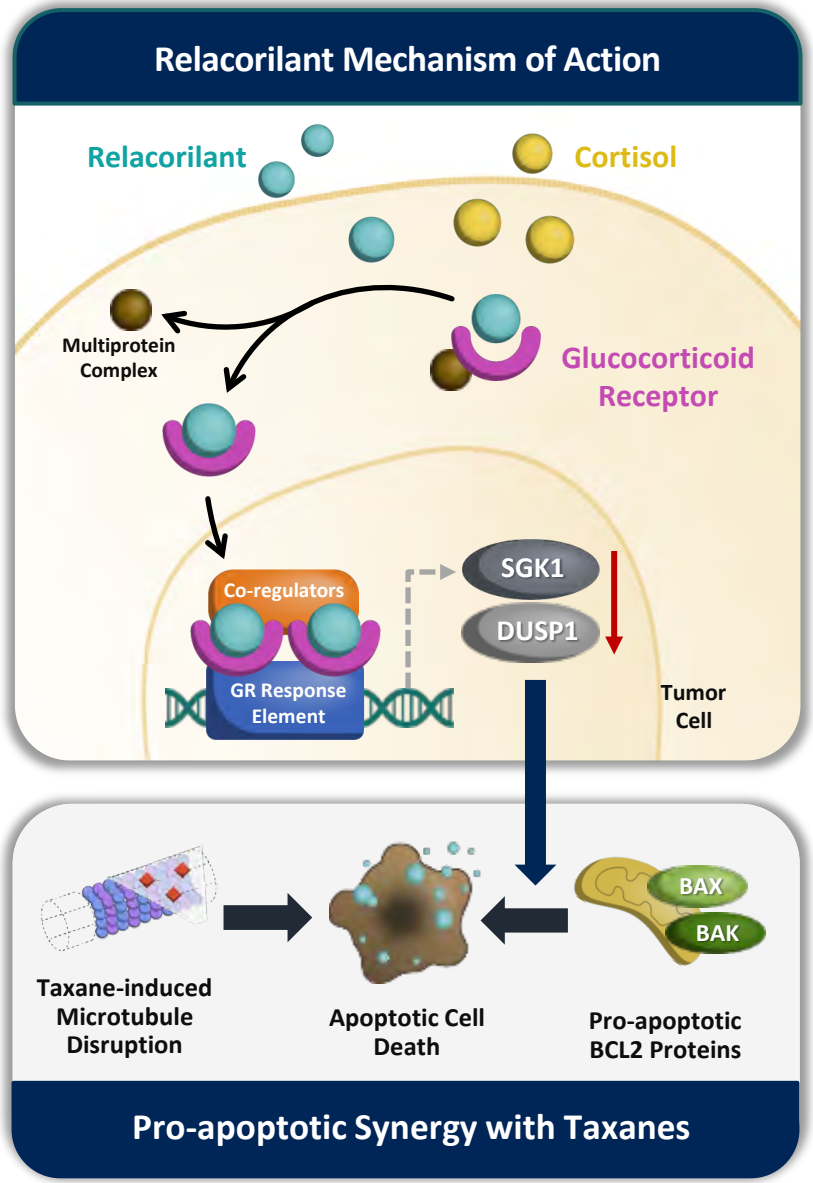
Alexander Olawaiye, MD
University of Pittsburgh,
Magee-Womens Hospital of UPMC
Pittsburgh, Pennsylvania

GOG Highlight Reel

ROSELLA | GOG-3073 Background

A Phase 3 Study of Relacorilant in Combination with Nab-Paclitaxel versus Nab-Paclitaxel Monotherapy in Advanced, Platinum-Resistant, High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian-Tube Cancer

- Patients with platinum-resistant ovarian cancer have an overall survival of ~1 year and need new treatments[1]
- Ovarian cancers express the glucocorticoid receptor (GR), a marker of poor prognosis[2]
- 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]



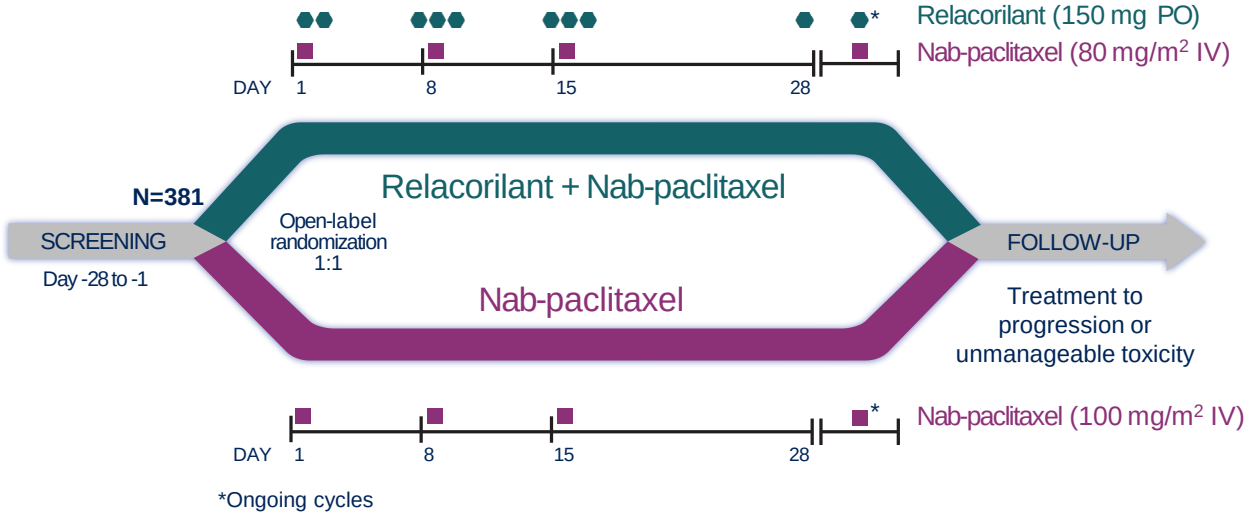
1. Martorana, et al. Int J Gynecol Cancer. 2025;35(1):100009. 2. Veneris, et al. Gynecol Oncol. 2017;146(1):153-60. 3. Greenstein, et al. Oncotarget. 2021;12(13):1243-55. 4. Melhelm, et al. Clin Cancer Res. 2009;15(9):3196-3204. 5. Stringer-Reasor, et al. Gynecol Oncol. 2015;138(3):656-62. 6. Munster, et al. Clin Cancer Res. 2022;28(15):3214-24. 7. Colombo, et al. J Clin Oncol. 2023;41(30):4779-89.

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

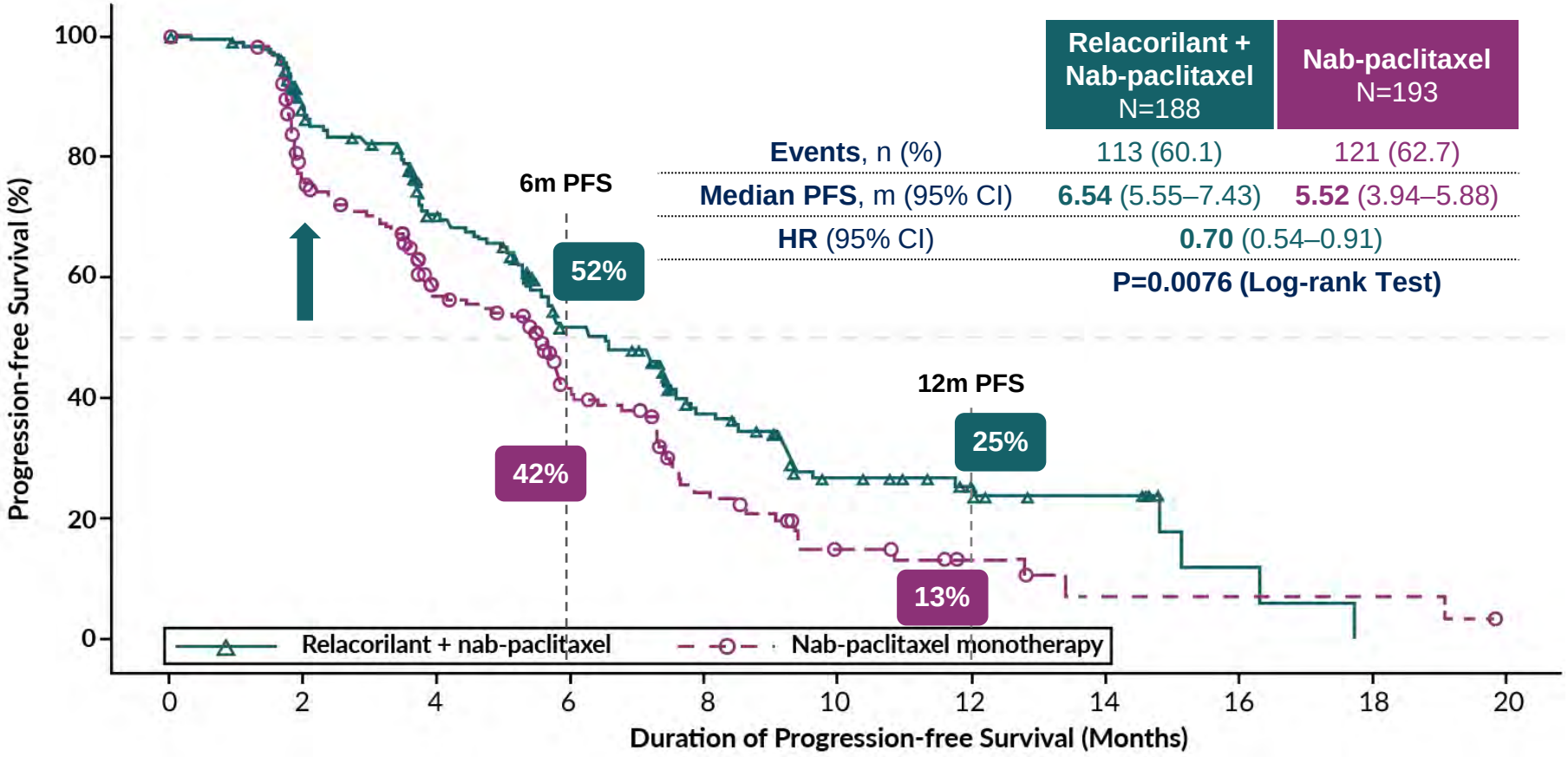
Secondary Endpoints

- 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: 5th January 2023
Last patient enrolled: 8th April 2024
Data cutoff: 24th February 2025
Conducted at 117 sites in 14 countries.

Additional Study Identifiers: APGOT-Ov10, LACOG-0223, and ANZGOG-2221/2023.
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; PFS, progression-free survival; PO, by mouth; RECIST, Response Evaluation Criteria in Solid Tumors.

ROSELLA | Relacorilant Significantly Improved Progression-Free Survival Assessed by Blinded Review



	Relacorilant + Nab-paclitaxel N=188	Nab-paclitaxel N=193
Events, n (%)	113 (60.1)	121 (62.7)
Median PFS, m (95% CI)	**6.54** (5.55–7.43)	**5.52** (3.94–5.88)
HR (95% CI)	**0.70** (0.54–0.91)	
	P=0.0076 (Log-rank Test)	

No. at risk (events/cumulative events)

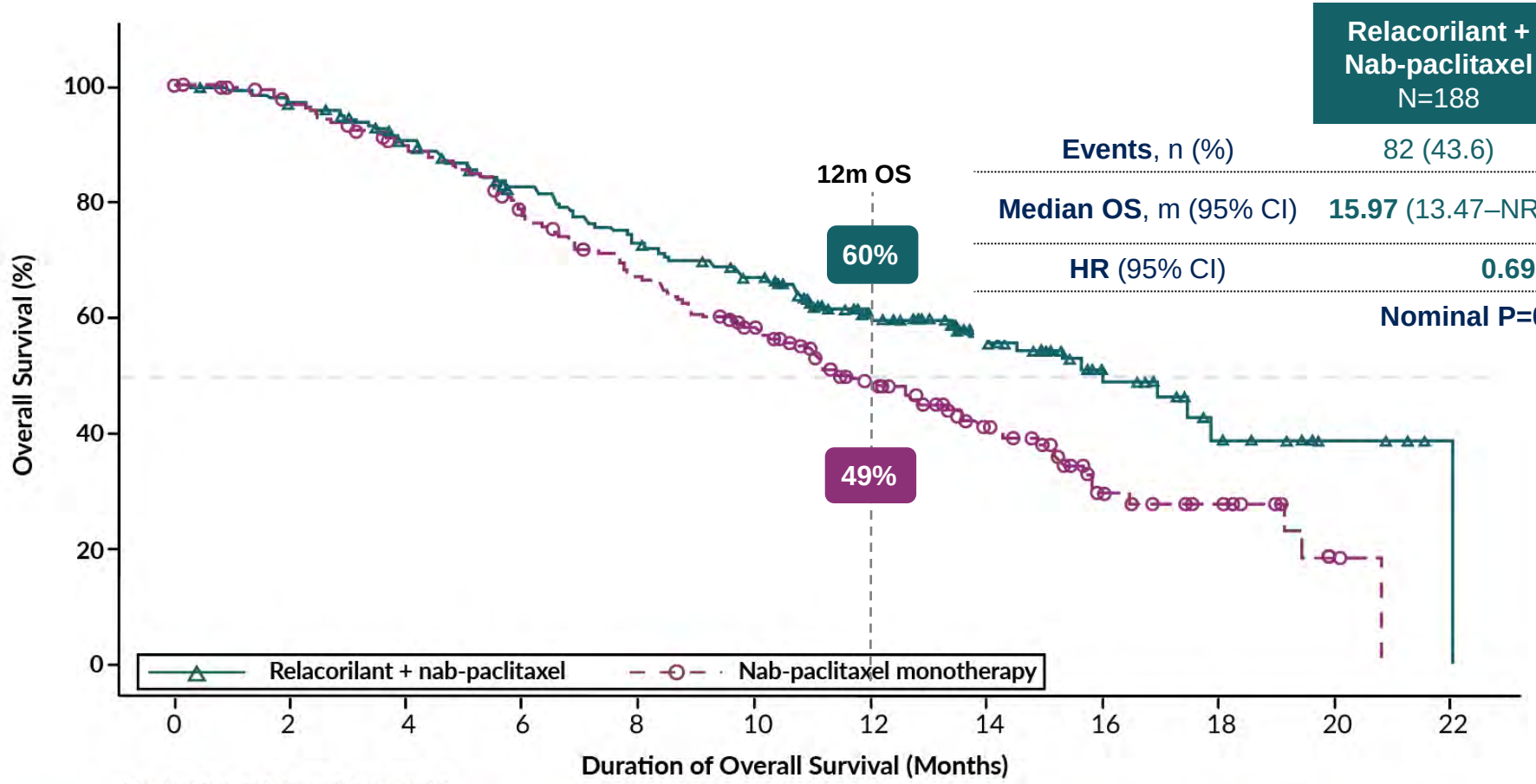
Relacorilant + nab-paclitaxel	188 (0/0)	151 (22/22)	109 (29/51)	70 (27/78)	43 (18/96)	24 (11/107)	16 (1/108)	11 (1/109)	2 (2/111)	0 (2/113)
Nab-paclitaxel monotherapy	193 (0/0)	129 (42/42)	85 (31/73)	47 (20/93)	21 (17/110)	9 (7/117)	5 (1/118)	2 (2/120)	2 (0/120)	2 (0/120)	0 (1/121)

Data cutoff: Feb 24, 2025

Median follow-up time: 9.0 months; statistical significance threshold: P≤0.04. The Kaplan–Meier method was used to estimate the curves, median estimates and the 95% confidence intervals (CI) 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. BICR, blinded-independent central review; CI, confidence interval; HR, hazard ratio; m, months; PFS, progression-free survival.

Presented by Alexander B. Olawaiye, MD ASCO 2025

ROSELLA | Interim Analysis for Overall Survival



	Relacorilant + Nab-paclitaxel N=188	Nab-paclitaxel N=193
Events, n (%)	82 (43.6)	110 (57.0)
Median OS, m (95% CI)	**15.97** (13.47–NR)	**11.50** (10.02–13.57)
HR (95% CI)	**0.69** (0.52–0.92)	

Nominal P=0.0121 (Log-rank Test)

No. at risk (events/cumulative events)

Relacorilant + nab-paclitaxel	188 (0/0)	180 (6/6)	162 (12/18)	143 (14/32)	126 (17/49)	111 (10/59)	77 (10/69)	49 (5/74)	24 (4/78)	10 (3/81)	4 (0/81)	0 (1/82)
Nab-paclitaxel monotherapy	193 (0/0)	179 (6/6)	160 (13/19)	137 (20/39)	115 (20/59)	93 (15/74)	65 (14/88)	40 (9/97)	16 (9/106)	11 (1/107)	3 (2/109)	0 (1/110)

Data cutoff: Feb 24, 2025

Median follow-up time: 13.9 months; statistical significance threshold at the interim analysis: P≤0.0001; statistical significance threshold at the final analysis: P≤0.0499. The Kaplan–Meier method was used to estimate the curves, median estimates and the 95% confidence intervals (CI) for overall 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; NR, not reached; OS, overall survival.

Presented by Alexander B. Olawaiye, MD ASCO 2025

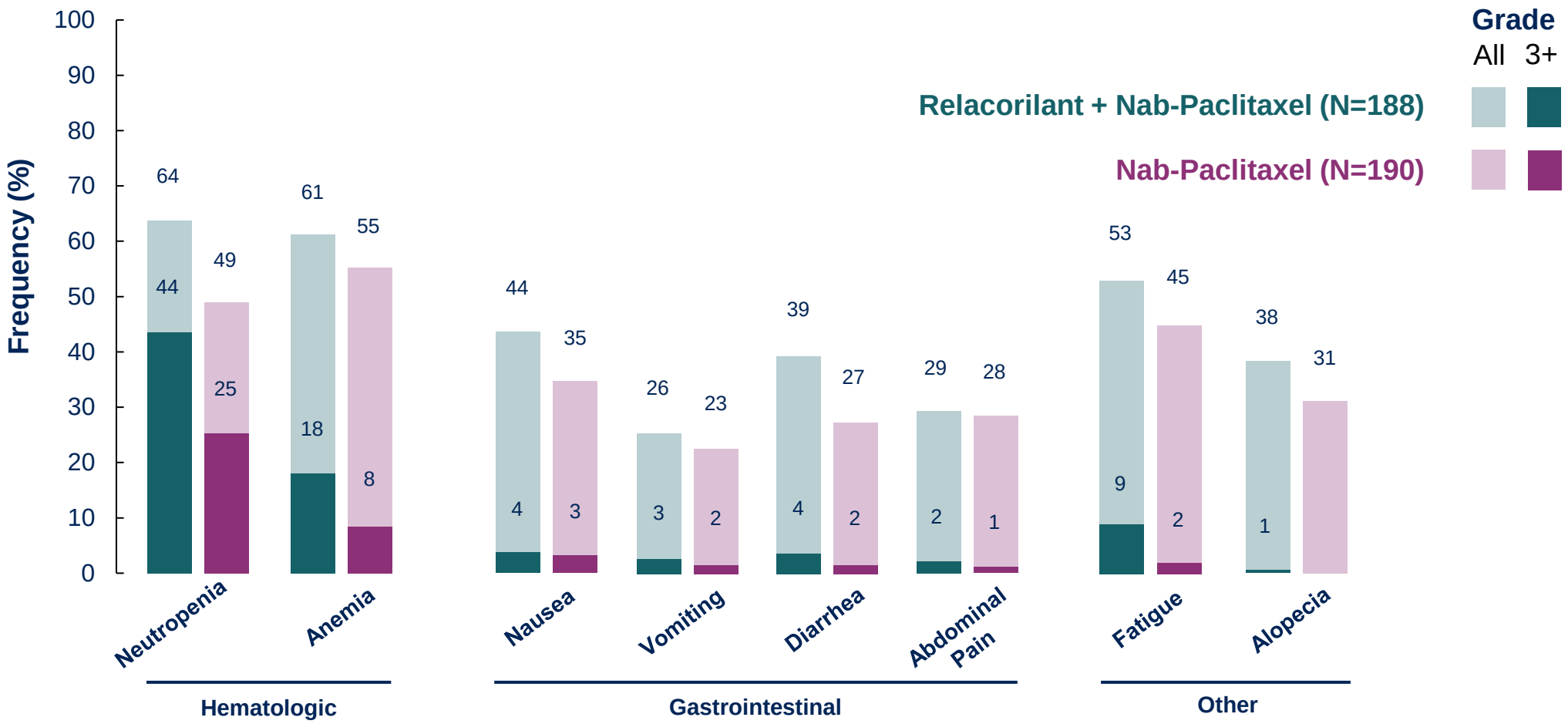
ROSELLA | Key Subgroups

Subgroup		Patients, n	Events, n	Hazard Ratio for PFS (BICR), (95% CI)	Events, n	Hazard Ratio for OS, (95% CI)
All Patients		381	234	0.70 (0.54–0.91)	192	0.69 (0.52–0.92)
Age	<65 years	229	140	0.76 (0.54–1.08)	119	0.83 (0.57–1.20)
	≥65 years	152	94	0.61 (0.40–0.94)	73	0.55 (0.34–0.89)
Region	North America	90	56	0.62 (0.36–1.07)	45	0.69 (0.38–1.27)
	Europe	216	130	0.73 (0.52–1.04)	111	0.67 (0.46–0.98)
	Korea, Australia, Latin America	75	48	0.70 (0.39–1.26)	36	0.76 (0.39–1.48)
ECOG Performance Status	0	262	154	0.72 (0.52–1.00)	118	0.72 (0.50–1.05)
	1	115	80	0.62 (0.39–0.98)	74	0.59 (0.36–0.97)
Prior Lines of Therapy	1	33	21	0.88 (0.35–2.22)	21	0.80 (0.32–1.97)
	2	181	119	0.63 (0.43–0.91)	91	0.74 (0.49–1.12)
	3	167	94	0.71 (0.47–1.08)	80	0.66 (0.42–1.04)
Prior PARP Inhibitor	Yes	234	138	0.60 (0.42–0.85)	116	0.77 (0.53–1.13)
	No	147	96	0.84 (0.55–1.28)	76	0.66 (0.42–1.05)
Primary Platinum-free Interval	≤6 months	112	73	0.50 (0.30–0.84)	62	0.52 (0.31–0.89)
	>6 months	269	161	0.78 (0.57–1.06)	130	0.82 (0.58–1.16)
BRCA1/2 Mutation	Positive	47	32	1.08 (0.49–2.37)	23	0.82 (0.33–2.07)
	Negative / Unknown	334	202	0.65 (0.49–0.87)	169	0.70 (0.52–0.96)
Largest Target Lesion	<5 cm	299	181	0.68 (0.51–0.92)	141	0.65 (0.46–0.91)
	≥5 cm	45	30	0.50 (0.23–1.09)	25	0.58 (0.25–1.34)

BICR, blinded independent central review; BRCA, Breast Cancer Gene; CI, confidence interval; ECOG, Eastern Cooperative Oncology Group; OS, overall survival; PFS, progression-free survival.

Data cutoff: Feb 24, 2025

ROSELLA | Common (>20%) Adverse Events



5 SAEs of febrile neutropenia were reported, 4 (2.1%) with relacorilant + nab-paclitaxel and 1 (0.5%) with nab-paclitaxel monotherapy.
5 SAEs of sepsis were reported, 3 (1.6%) with relacorilant + nab-paclitaxel and 2 (1.1%) with nab-paclitaxel monotherapy.

TEAEs 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; TEAEs, treatment-emergent adverse events.

Data cutoff: Feb 24, 2025

Presented by Alexander B. Olawaiye, MD ASCO 2025

Platinum until “platinum not an option”
Platinum combinations in PROC

Trial	Regimen	ORR	PFS/TTP
Nagourney RA[1] (P)	D1 cisplatin (30 mg/m^2) and D1/8 gem (600-750 mg/m^2) on 21-day cycle	8/14 (57%)	6
Penson RT[2] (P)	D1 carbo and D1/8 gem, and iniparib on 21-day cycle	11/45 (26%)	6.8
Nasu H[3] (P)	D1 carbo (AUC4) & D1/8 gem (1000 mg/m^2) & bev on 21-day cycle D1 carbo (AUC4) & D1/8 gem (1000 mg/m^2) on 21-day cycle	12/20 (60%) 2/7 (28%)	8.8 5.6
GOG 126L (P) Brewer CA[4]	D1/8 gem (750 mg/m^2) & D1/8 cis (30 mg/m^2) on **28-day cycle*** *Limited to primary platinum resistant	9/57 (16%)	5.4
Walsh CS[5] (P)	D1/8 cis (30 mg/m^2) & D1/8 gem (750 mg/m^2) & D1 pembro on 21-day cycle	11/18 (61%)	5.2
Rose PG[6] (R)	D1/8 cis (30 mg/m^2) & D1/8 gem (750 mg/m^2) on 21-day cycle	13/33 (43%)	6.0
Richardson DL[7] (R)	D1/15 platinum/gem/bev on a 28-day cycle	7/12 (58%)	NR
Havrilesky LJ[8] (P)	D1, 8, 15, paclitaxel (80 mg/m^2) & carbo (AUC 2) on 28-day cycle	3/8 (38%)	3.2
Sharma R[9] (R)	D1, 8, 15, paclitaxel (70 mg/m^2) & carbo (AUC 3) on 28-day cycle	12/20 (60%)	7.9
Tatsuki S[10] (R)	platinum “rechallenge” (paclitaxel; docetaxel; Gem; PLD; CPT-11)	26/47 (55%)	8.5
Holloway (P)	Olvi-Vec IP x 2 followed by platinum-doublet chemotherapy +/- bevacizumab	13/24 (54%)	11.0

AUC, area under the curve; bev, bevacizumab; cis, cisplatin; carbo, carboplatin; gem, gemcitabine; NR, not reported; ORR, objective response rate; P, prospective; PFS, progression-free survival; PLD, pegylated liposomal doxorubicin; PROC, platinum-resistant ovarian cancer; R, retrospective; TTP, time to progression.

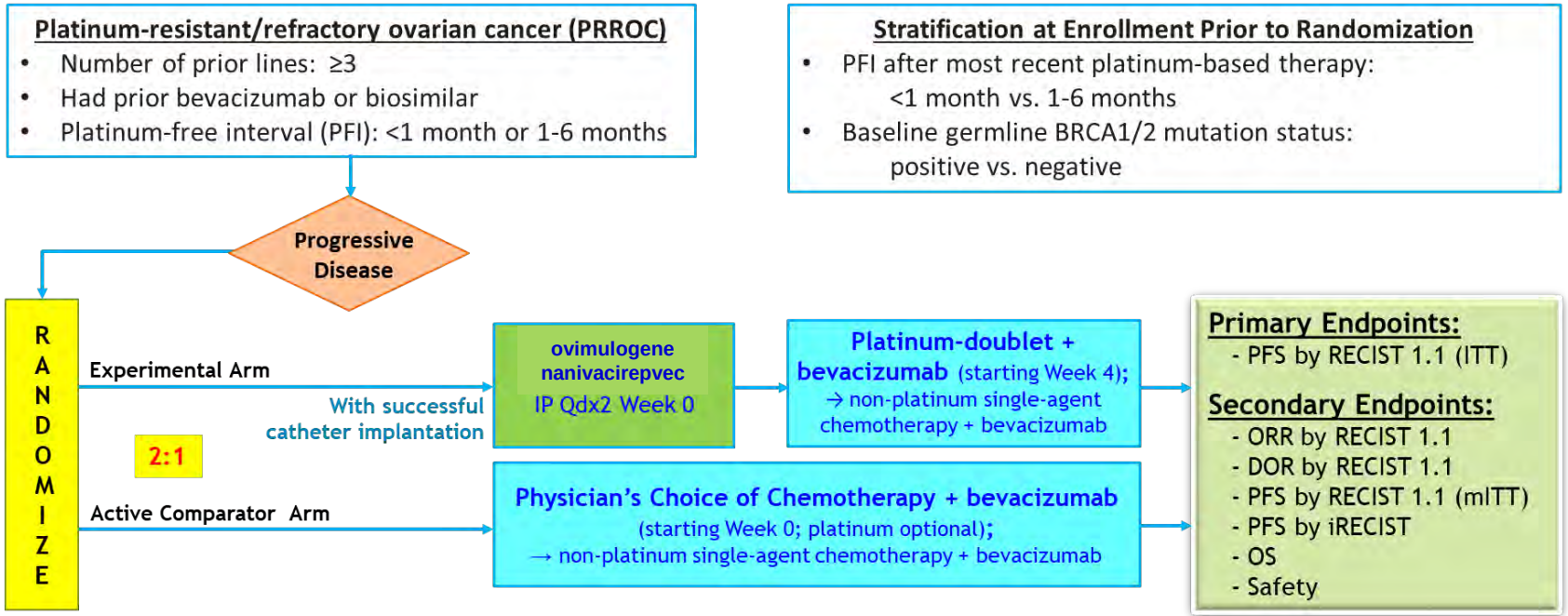
1. Nagourney RA et al. *Gynecol Oncol*. 2003;88(1):35–39. 2. Penson RT et al. *Oncologist*. 2023;oyac275. 3. Nasu H et al. *J Clin Oncol*. 2022;27(4):790–801. 4. Brewer CA et al. *Gynecol Oncol*. 2006;103(2):446–450. 5. Walsh CS et al. *PLoS One*. 2021;16(6):e0252665. 6. Rose PG et al. *Gynecol Oncol*. 2003;88(1):17–21. 7. Richardson DL et al. *Gynecol Oncol* 2008; 111(3):461–466. 8. Havrilesky LJ et al. *Gynecol Oncol*. 2003;88(1):51–57. 9. Sharma R et al. *Br J Cancer*. 2009;100(5):707–712. 10. Tatsuki S et al. *Anticancer Res*. 2022;42(9):4603–4610.

GOG-3076/ovimulogene nanivacirepvec-022/OnPrime

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

SCAN ME

(NPI: Robert Holloway, MD;
Co-NPIs: Premal Thaker, MD, Ramez Eskander, MD, Erin Crane, MD)



- Olvimulogene nanivacirepvec: oncolytic vaccinia virus-based immunotherapy
- virus-mediated immune activation
- re-sensitization of tumor cells to chemotherapy
- No maximal limit on the number of prior lines
- Temporary intraperitoneal dialysis catheter can be placed either through laparoscopy or interventional radiology (requires backup surgical option available if IR placement fails)
- Institutional BioSafety Committee, BSL-1 practice, -70C ± 10 freezer required

PLEASE ENROLL

GOG Highlight Reel

NCT05281471

Olvi-Vec = ovimulogene nanivacirepvec (o-v)

Key Issues for Development & Discussion

- How do we best characterize patients with recurrent disease?
  - PFI 6 month meaningful? What else can we justify?
  - Is “One and done” a real phenomenon?
    - For ADC: if same warhead class? If the same targeting antibody? If no on-treatment PD? Is there a sequence that matters?
    - For immunotherapy: Is there an IO-free interval?
- Should we support development of assets without a predictive biomarker?
- What are the most appropriate available therapies in the investigative setting?
  - What is the most appropriate control arm?

Right When You Thought IO Was Done in 1L OC...

FIRST Study Design

20 December 2024

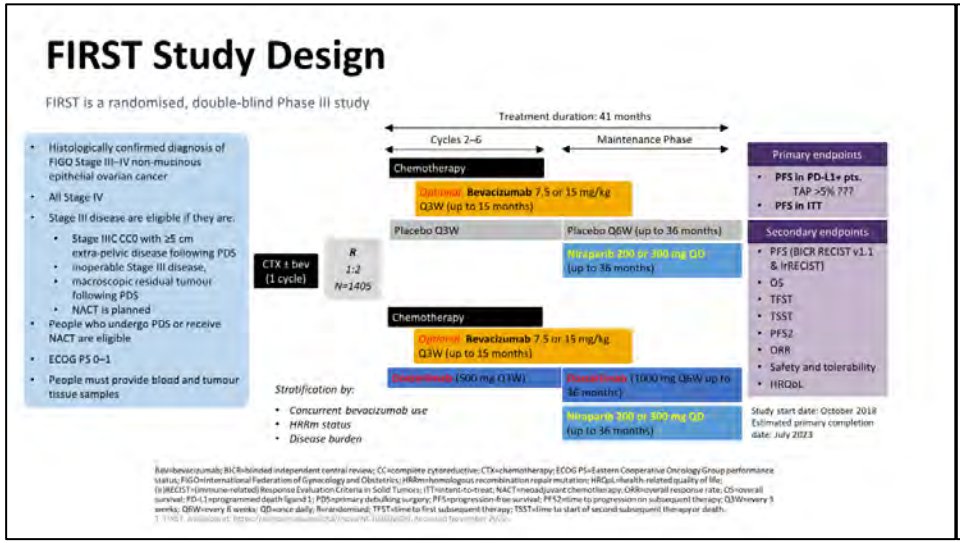
Issued: London, UK

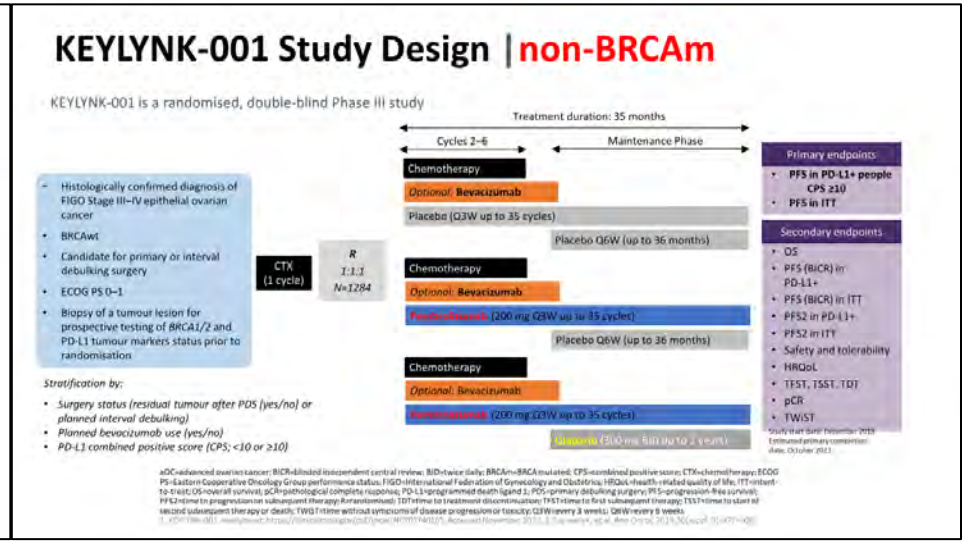
For media and investors only

GSK announces FIRST trial met its primary endpoint of progression free survival in first line advanced ovarian cancer

KEYLYNK-001 Study Design | non-BRCAm

Merck Announces Phase 3 KEYLYNK-001 Trial Met Primary Endpoint of Progression-Free Survival (PFS) in Patients With Advanced Epithelial Ovarian Cancer





ENGOT-OV43/GOG-3036/KEYLYNK-001 Study Design

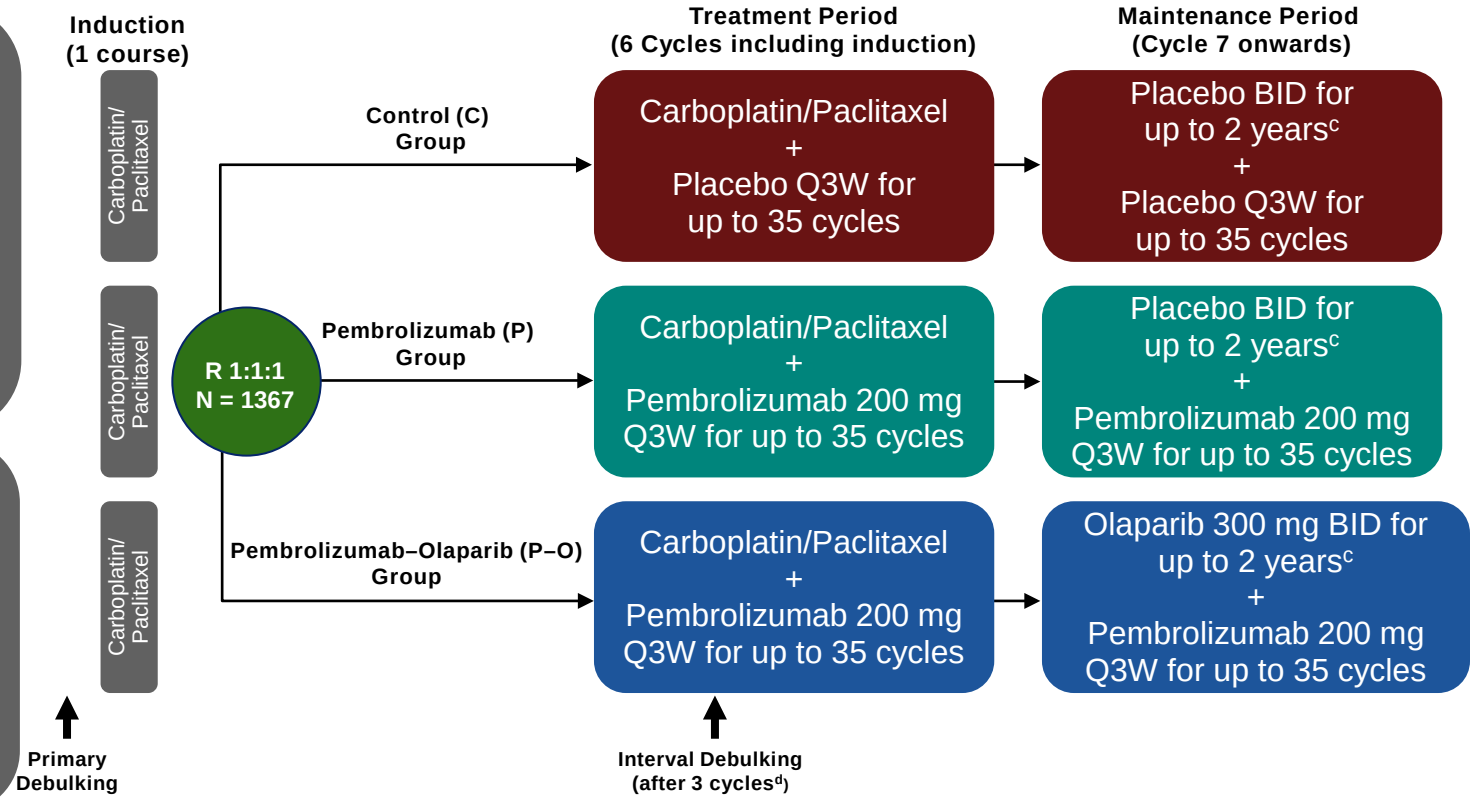
A Randomized Phase 3, Double-Blind Study of Chemotherapy With or Without Pembrolizumab Followed by Maintenance With Olaparib or Placebo for the First-Line Treatment of BRCA Non-mutated Advanced Epithelial Ovarian Cancer

Key Eligibility Criteria

- Advanced (FIGO Stage ≥III) epithelial ovarian cancer
- *BRCA1/2*-nonmutated
- No prior systemic therapy
- Candidate for carboplatin + paclitaxel[a] as adjuvant or neoadjuvant therapy
- Bevacizumab permitted per investigator discretion

Stratification Factors

- PD-L1 expression[b] (CPS ≥10 vs <10)
- Planned bevacizumab use (yes vs no)
- Surgery status (residual tumor after primary debulking surgery [yes vs no] or planned interval debulking)



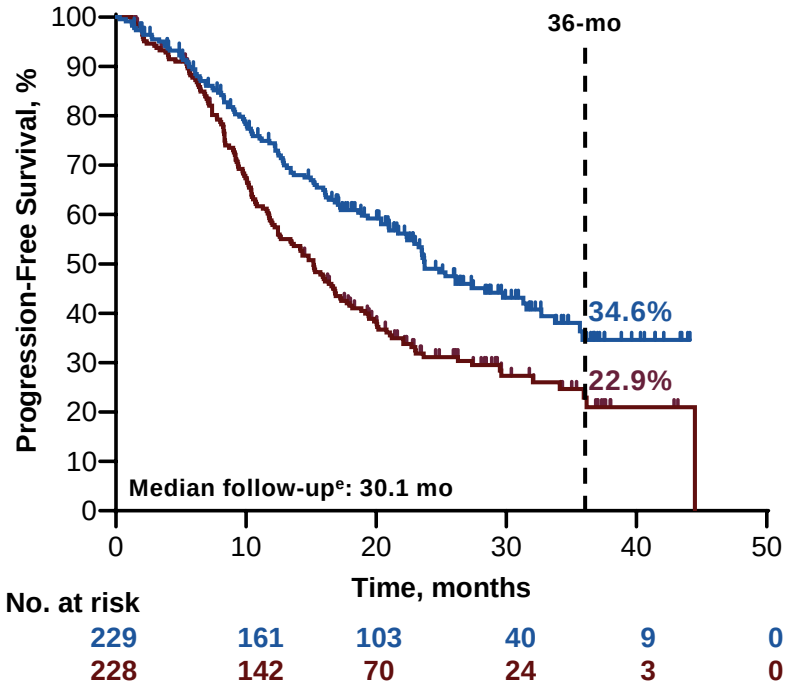
[a]Docetaxel may be considered for participants who experience either a severe hypersensitivity reaction to paclitaxel or an adverse event requiring discontinuation of paclitaxel. [b]Assessed at a central laboratory using PD-L1 IHC 22C3 pharmDx and measured using the combined positive score (CPS; number of PD-L1–positive tumor cells, lymphocytes, and macrophages divided by total number of tumor cells x 100). [c]Only participants with no evidence of disease at start of maintenance and no progression stopped after 2 years. [d]Including induction cycle.

NCT03740165

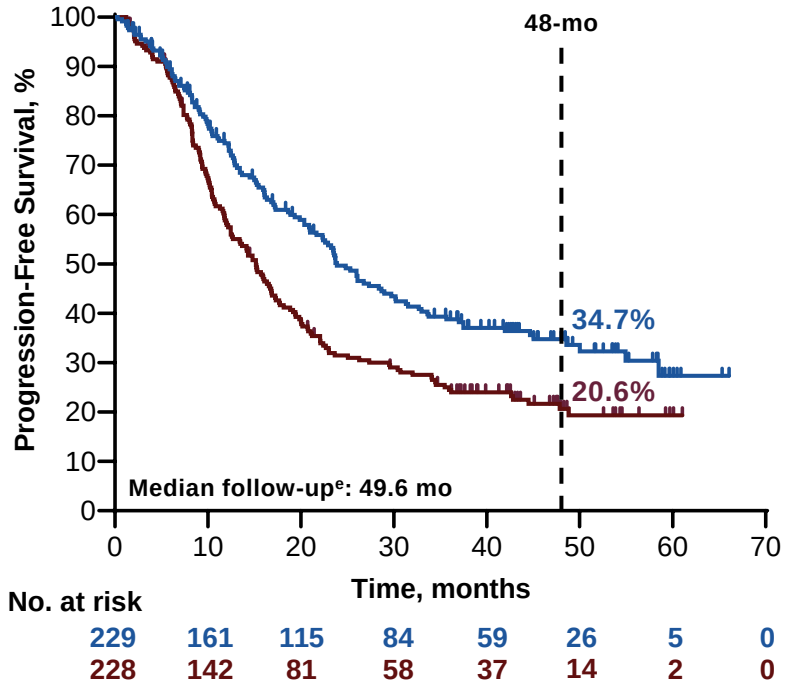
Vergote et al, ESGO 2025

Progression-Free Survival P–O vs C, CPS ≥10 Population

IA1[a]	Median, months	Events	HR (95% CI)	*P*-value
P–O Group	23.7	48.9%	0.63[c] (0.49-0.80)	<0.0001[d]
C Group	15.2	66.2%		



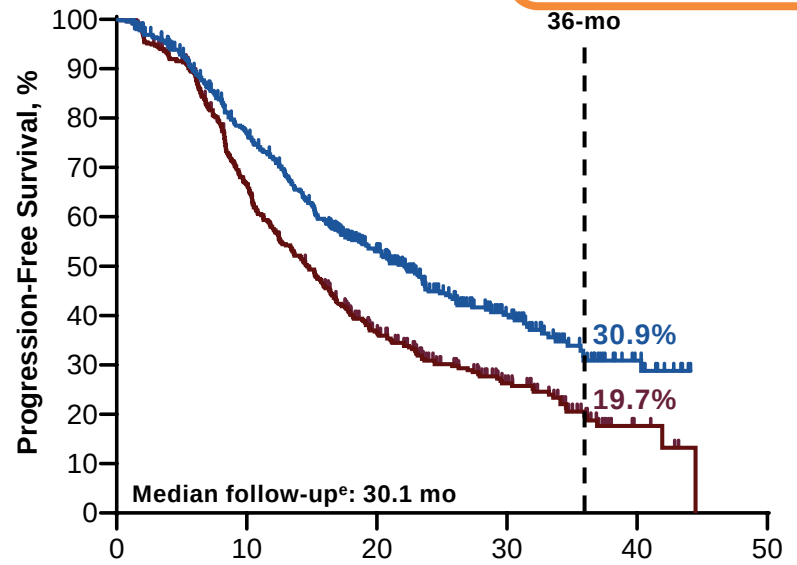
FA[b]	Median, months	Events	HR (95% CI)
P–O Group	23.9	58.5%	0.66[c] (0.53-0.83)
C Group	15.2	72.4%	



Response assessed per RECIST v1.1 by investigator review. [a]Data cutoff date: January 9, 2023. [b]Data cutoff date: August 26, 2024. [c]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. [d]Prespecified P-value boundary met. [e]Defined as the time from randomization to the data cutoff date.

Progression-Free Survival P–O vs C, Total ITT Population

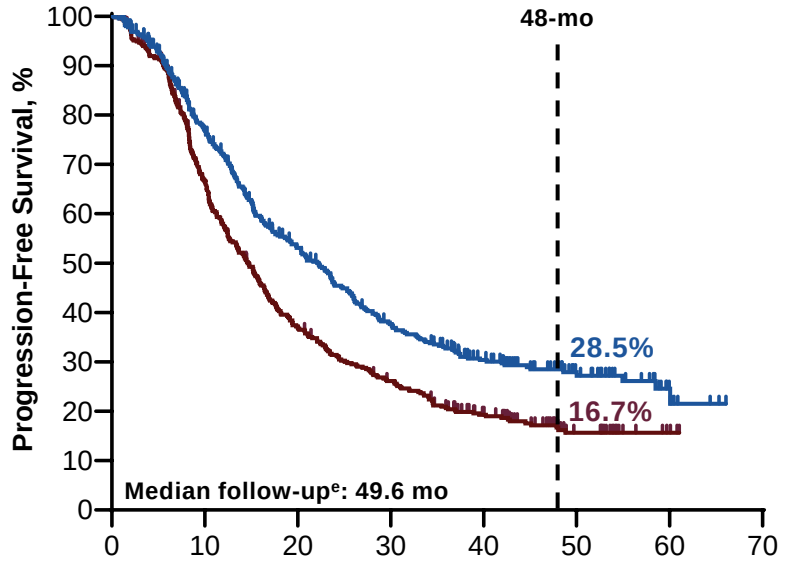
IA1[a]	Median, months	Events	HR (95% CI)	*P*-value
P–O Group	22.1	53.0%	0.68[c] (0.58-0.81)	<0.0001[d]
C Group	14.6	69.2%		



No. at risk

455	317	186	72	15	0	
454	285	134	52	5	0	

FA[b]	Median, months	Events	HR (95% CI)
P–O Group	22.2	64.0%	0.71[c] (0.61-0.84)
C Group	14.6	77.5%	



No. at risk

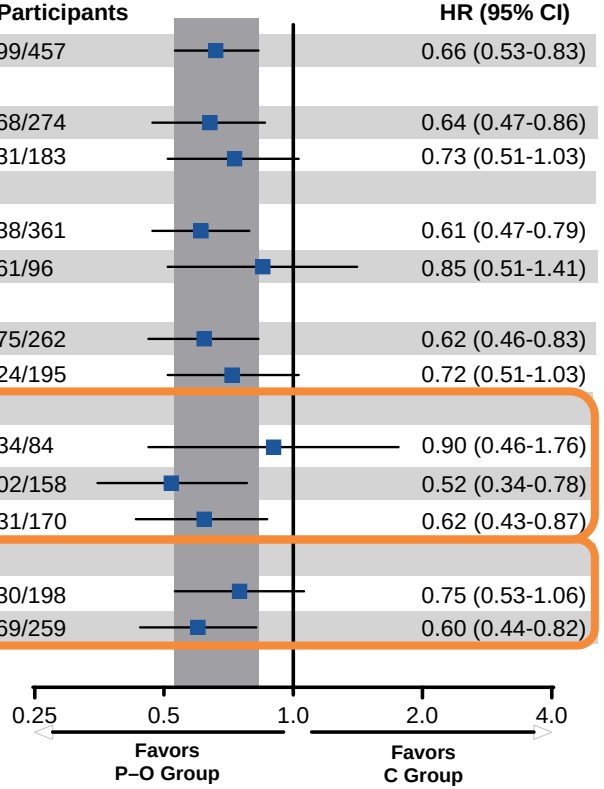
455	317	209	145	93	40	8	0
454	285	157	106	64	26	3	0

Response assessed per RECIST v1.1 by investigator review. [a]Data cutoff date: January 9, 2023. [b]Data cutoff date: August 26, 2024. [c]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. [d]Prespecified P-value boundary met. [e]Defined as the time from randomization to the data cutoff date.

Progression-Free Survival in Subgroups P–O vs C at FA

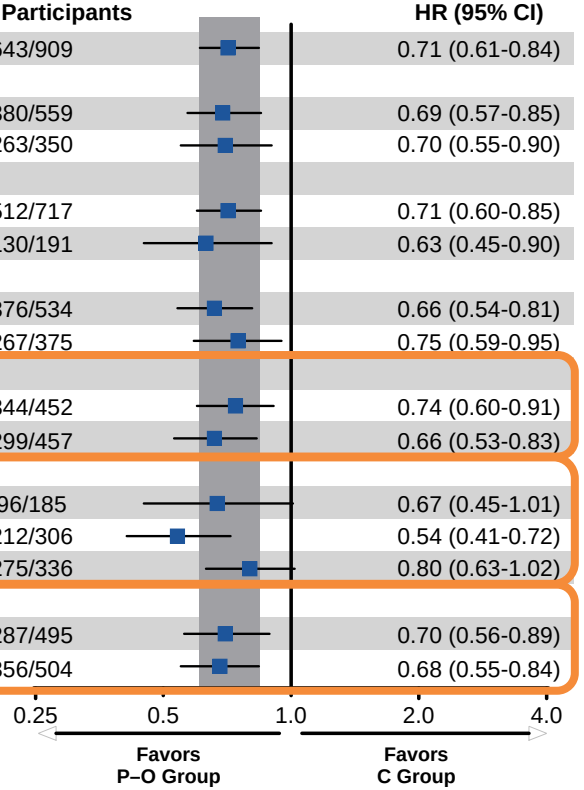
CPS ≥10 Population

Subgroup	No. of Events/ No. of Participants	HR (95% CI)
Overall	299/457	0.66 (0.53-0.83)
Age		
<65 years	168/274	0.64 (0.47-0.86)
≥65 years	131/183	0.73 (0.51-1.03)
Race		
White	238/361	0.61 (0.47-0.79)
All others	61/96	0.85 (0.51-1.41)
ECOG PS score		
0	175/262	0.62 (0.46-0.83)
1	124/195	0.72 (0.51-1.03)
Debulking surgery		
R0 primary	34/84	0.90 (0.46-1.76)
R1 primary	102/158	0.52 (0.34-0.78)
Interval	131/170	0.62 (0.43-0.87)
Bevacizumab use		
Yes	130/198	0.75 (0.53-1.06)
No	169/259	0.60 (0.44-0.82)



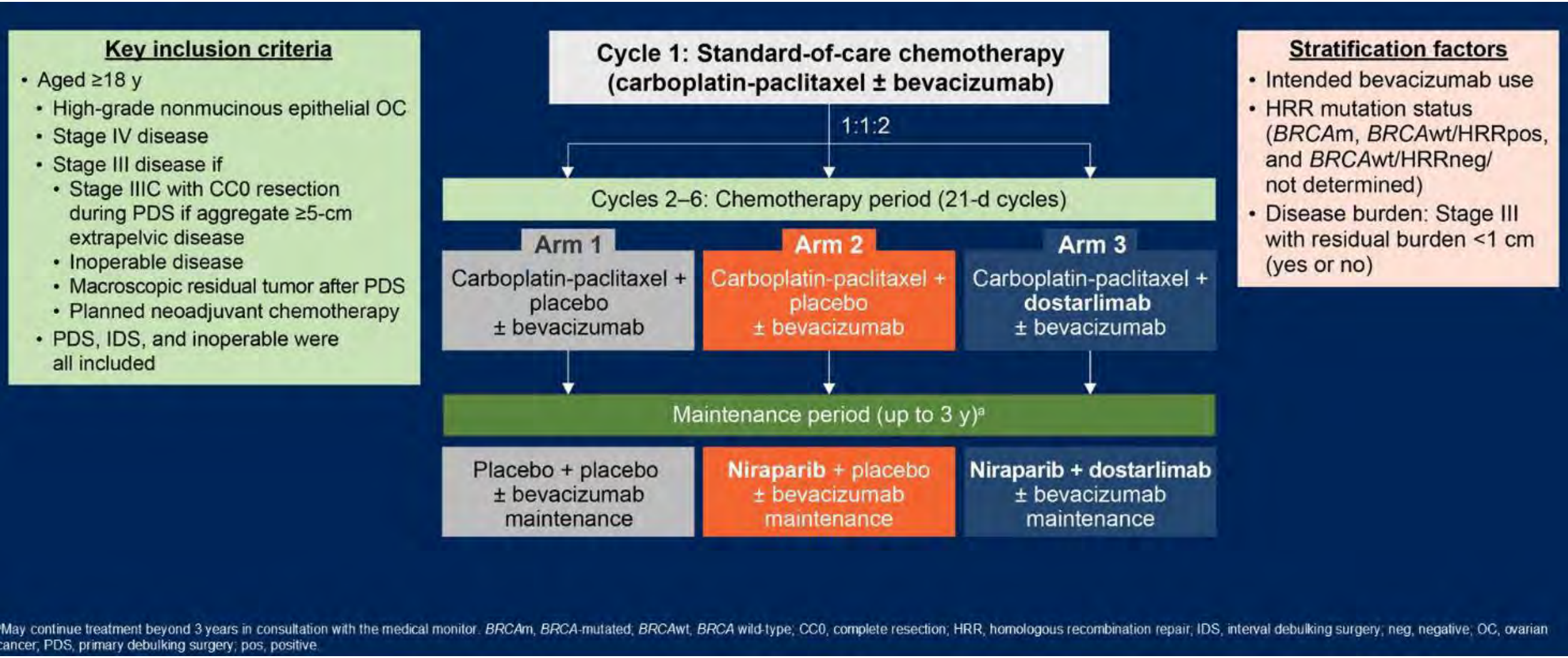
Total ITT Population

Subgroup	No. of Events/ No. of Participants	HR (95% CI)
Overall	643/909	0.71 (0.61-0.84)
Age		
<65 years	380/559	0.69 (0.57-0.85)
≥65 years	263/350	0.70 (0.55-0.90)
Race		
White	512/717	0.71 (0.60-0.85)
All others	130/191	0.63 (0.45-0.90)
ECOG PS score		
0	376/534	0.66 (0.54-0.81)
1	267/375	0.75 (0.59-0.95)
PD-L1 status[a]		
CPS <10	344/452	0.74 (0.60-0.91)
CPS ≥10	299/457	0.66 (0.53-0.83)
Debulking surgery		
R0 primary	96/185	0.67 (0.45-1.01)
R1 primary	212/306	0.54 (0.41-0.72)
Interval	275/336	0.80 (0.63-1.02)
Bevacizumab use		
Yes	287/495	0.70 (0.56-0.89)
No	356/504	0.68 (0.55-0.84)



Response assessed per RECIST v1.1 by investigator review. [a]The subgroup results shown in the forest plot were based on an unstratified Cox model, so the results for CPS ≥10 may differ slightly compared with those of the primary analysis, which were based on a stratified Cox model. Data cutoff date: August 26, 2024.

FIRST Trial Design

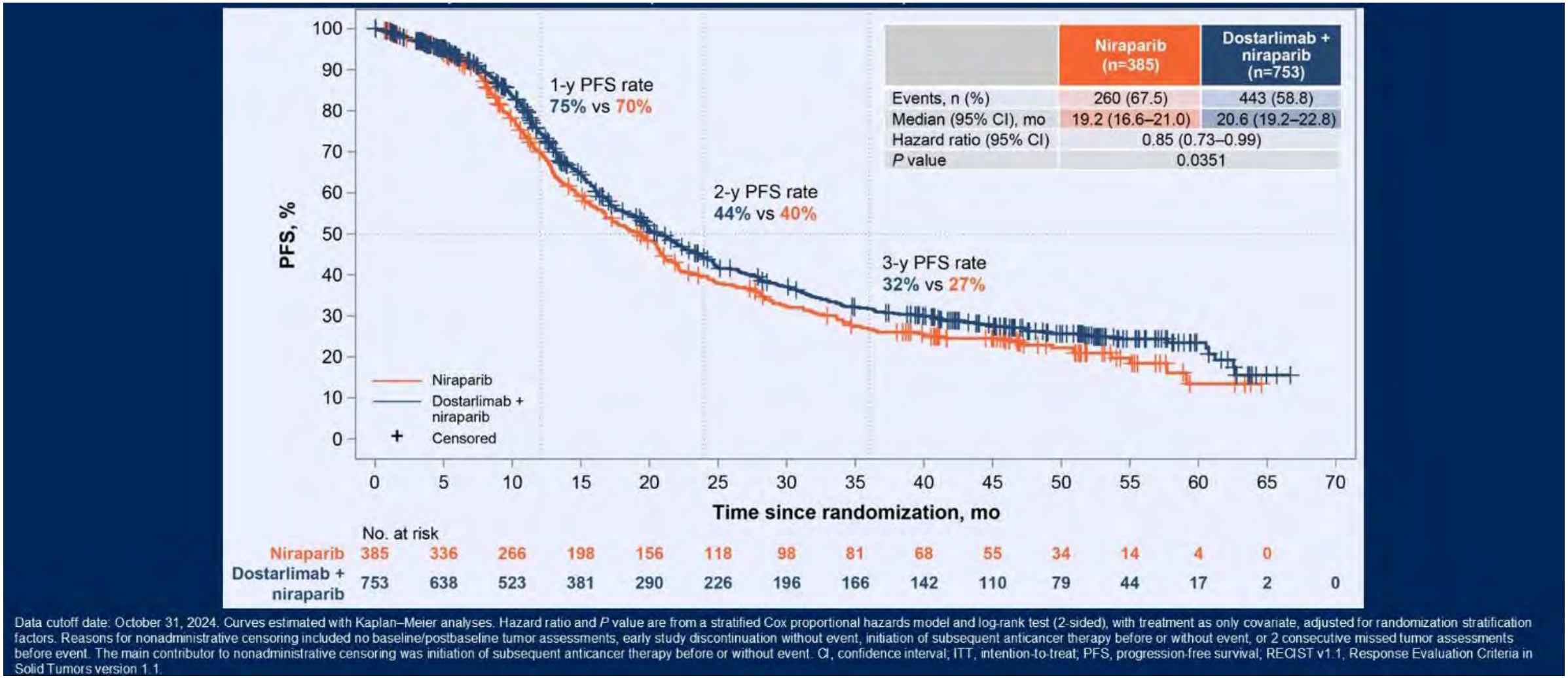


[a]May continue treatment beyond 3 years in consultation with the medical monitor. *BRCAm*, *BRCA*-mutated; *BRCAwt*, *BRCA* wild-type; CC0, complete resection; HRR, homologous recombination repair; IDS, interval debulking surgery; neg, negative; OC, ovarian cancer; PDS, primary debulking surgery; pos, positive.

Hardy-Bessard et al, ASCO 2025

PFS per RECIST v1.1 in the ITT Population

Median duration of follow-up was 53.1 mo (IQR, 47.5-59.7 mo).

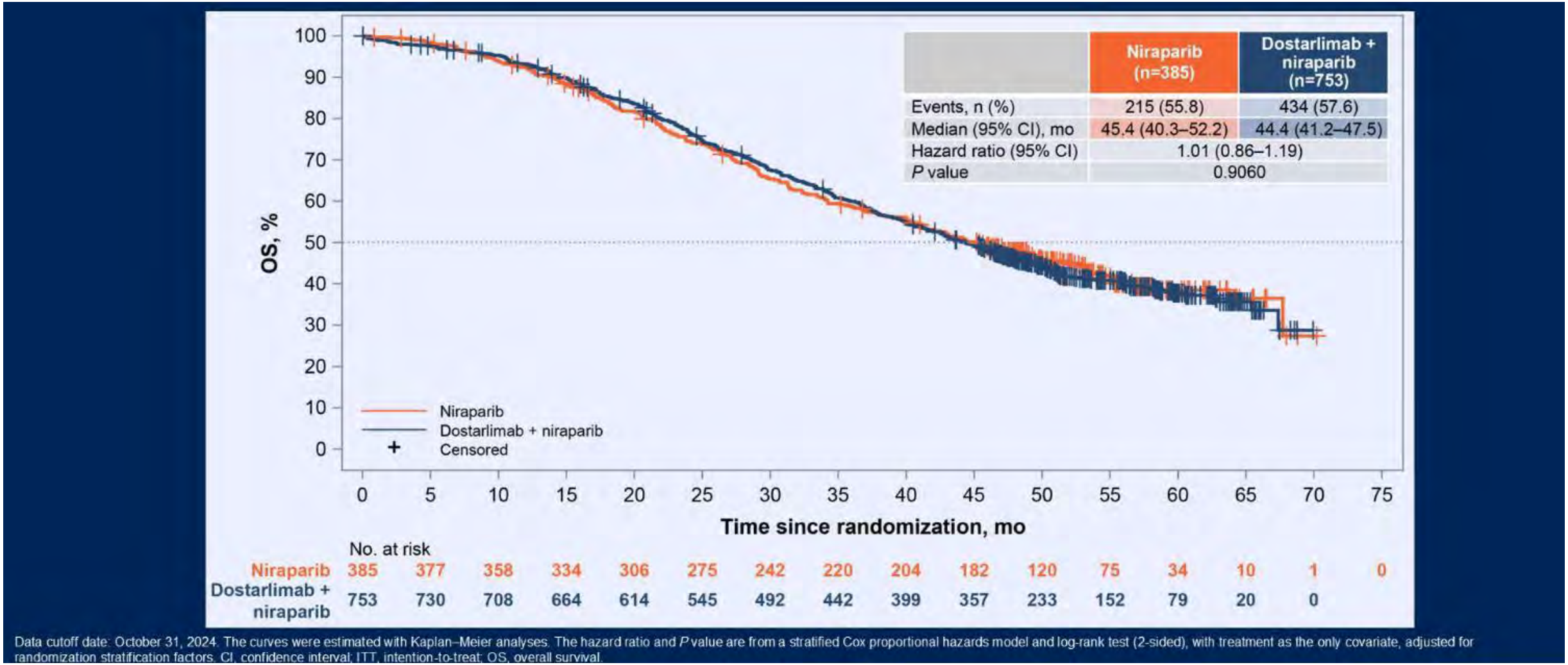


	Niraparib (n=385)	Dostarlimab + niraparib (n=753)
Events, n (%)	260 (67.5)	443 (58.8)
Median (95% CI), mo	19.2 (16.6–21.0)	20.6 (19.2–22.8)
Hazard ratio (95% CI)	0.85 (0.73–0.99)	
P value	0.0351	

Data cutoff date: October 31, 2024. Curves estimated with Kaplan–Meier analyses. Hazard ratio and *P* value are from a stratified Cox proportional hazards model and log-rank test (2-sided), with treatment as only covariate, adjusted for randomization stratification factors. Reasons for nonadministrative censoring included no baseline/postbaseline tumor assessments, early study discontinuation without event, initiation of subsequent anticancer therapy before or without event, or 2 consecutive missed tumor assessments before event. The main contributor to nonadministrative censoring was initiation of subsequent anticancer therapy before or without event. CI, confidence interval; ITT, intention-to-treat; PFS, progression-free survival; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1.

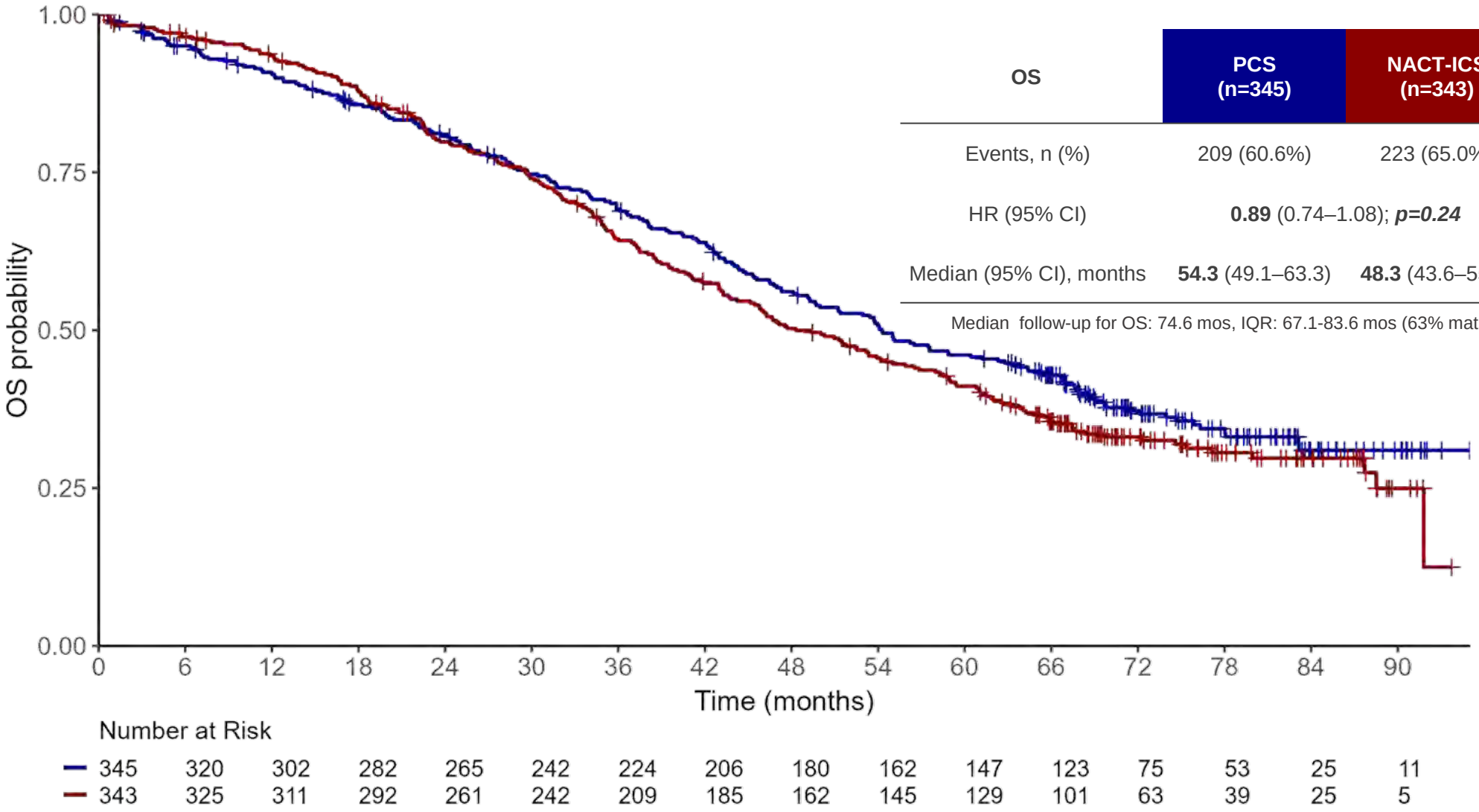
OS in the ITT Population

OS had reached 57% maturity.



Data cutoff date: October 31, 2024. The curves were estimated with Kaplan–Meier analyses. The hazard ratio and *P* value are from a stratified Cox proportional hazards model and log-rank test (2-sided), with treatment as the only covariate, adjusted for randomization stratification factors. CI, confidence interval; ITT, intention-to-treat; OS, overall survival.

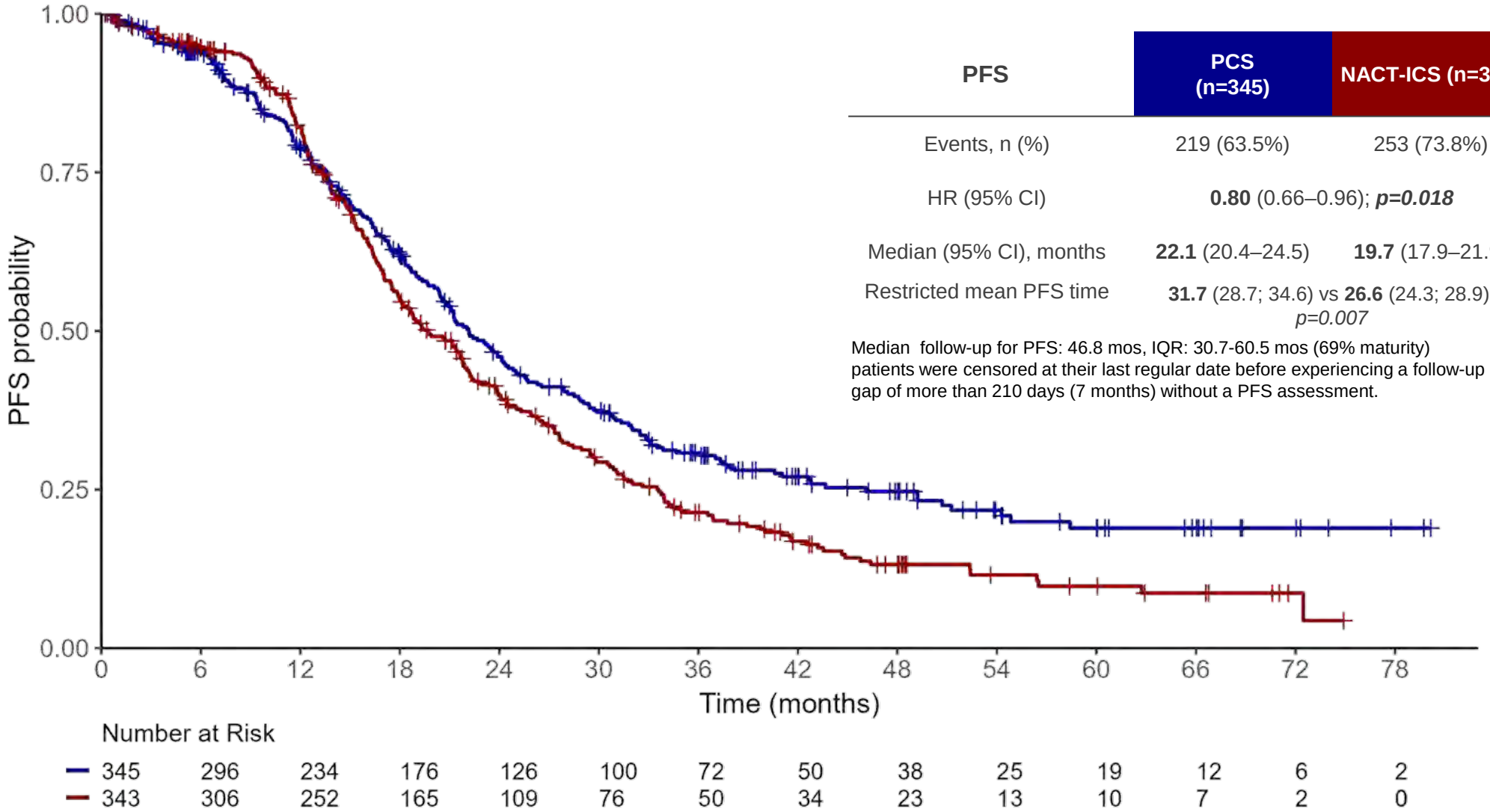
TRUST Results: Overall Survival (ITT)



OS	PCS (n=345)	NACT-ICS (n=343)
Events, n (%)	209 (60.6%)	223 (65.0%)
HR (95% CI)	**0.89** (0.74–1.08); ***p=0.24***	
Median (95% CI), months	**54.3** (49.1–63.3)	**48.3** (43.6–55.9)

Median follow-up for OS: 74.6 mos, IQR: 67.1-83.6 mos (63% maturity)

TRUST Results: Progression-free Survival (ITT)

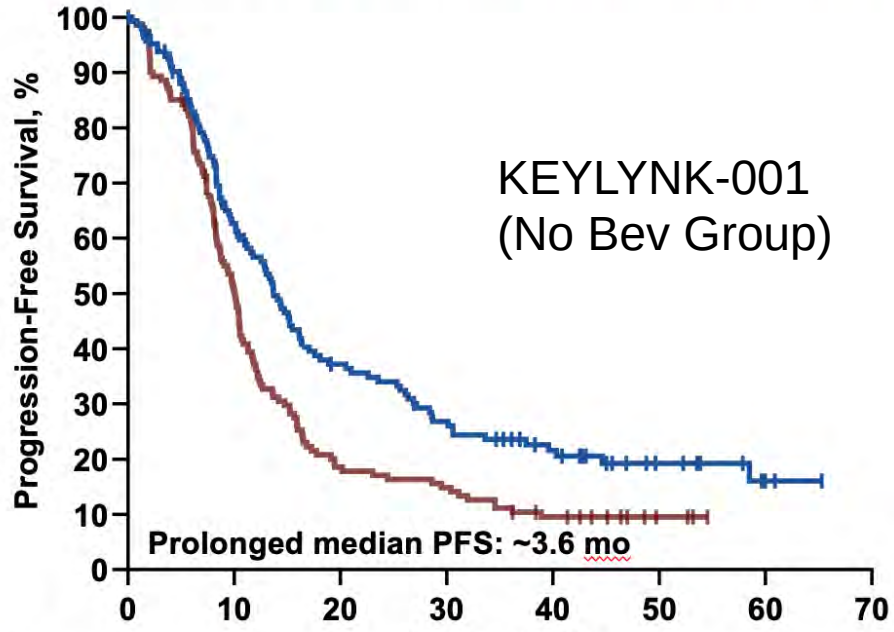


PFS	PCS (n=345)	NACT-ICS (n=343)
Events, n (%)	219 (63.5%)	253 (73.8%)
HR (95% CI)	**0.80** (0.66–0.96); ***p=0.018***	
Median (95% CI), months	**22.1** (20.4–24.5)	**19.7** (17.9–21.9)
Restricted mean PFS time	**31.7** (28.7; 34.6) vs **26.6** (24.3; 28.9); *p=0.007*	

Median follow-up for PFS: 46.8 mos, IQR: 30.7-60.5 mos (69% maturity)
patients were censored at their last regular date before experiencing a follow-up gap of more than 210 days (7 months) without a PFS assessment.

HRD- Subgroups

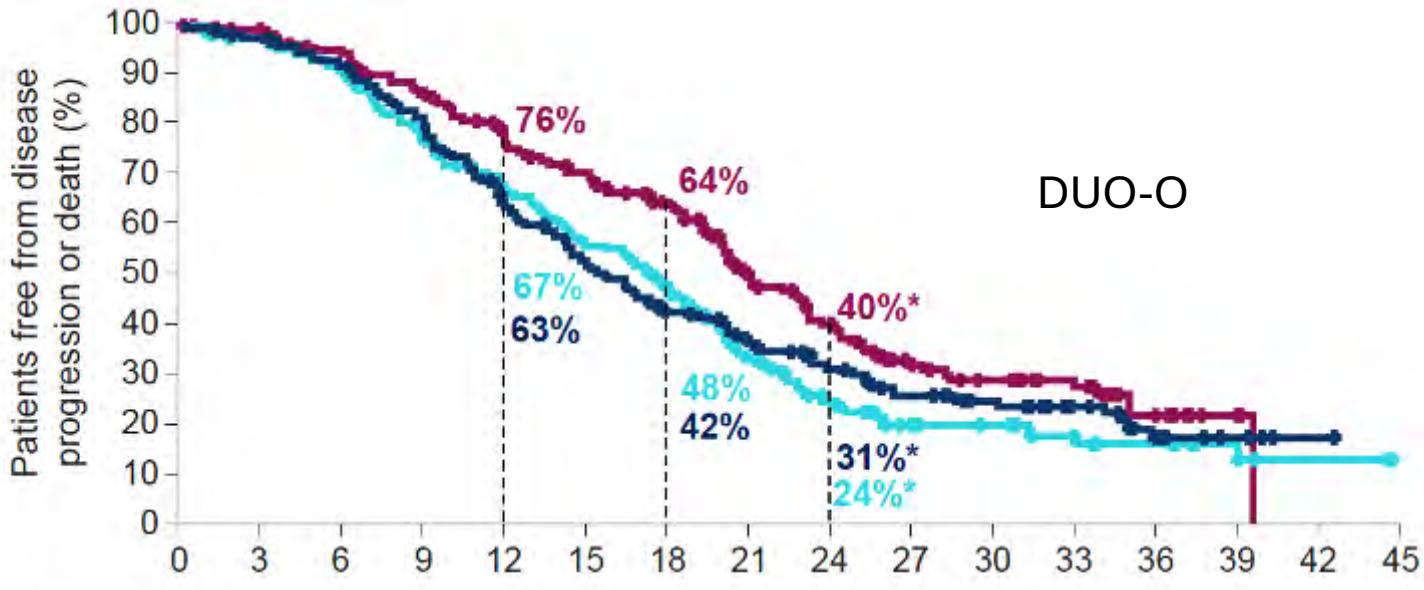
ITT Population	Median, months	Events	HR (95% CI)
P–O Group	13.7	71.1%	0.66 (0.51–0.85)
C Group	10.1	86.0%	



KEYLYNK-001
(No Bev Group)

No. at risk								
P–O Group	149	83	47	33	21	10	2	0
C Group	143	68	25	20	11	3	0	0

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



DUO-O

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

Key Issues for Development & Discussion

- How do we identify and adapt treatment to tumor modification?
- What are the most informative endpoints?
  - PFS, OS, second PFS, PFS2, Landmark risk?
  - Hierarchical designs?
  - Biomarker expression efficacy and safety differentiators?

TRUST Study Design

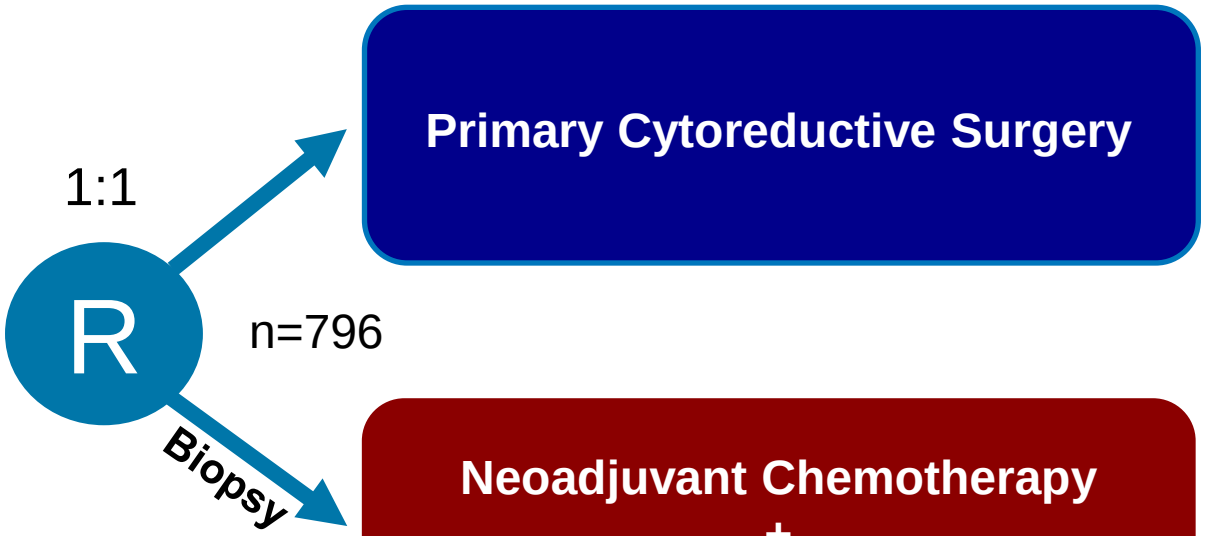
Main Inclusion Criteria

- Epithelial ovarian, fallopian tube or peritoneal cancer
  - FIGO stage IIIB/C, IVA/B
  - Considered resectable
- Fit enough to tolerate radical surgery

Stratification factors

- Center
- Age-ECOG-combination ECOG0 and age ≤65y vs. ECOG>0 or age >65y

Qualification process for participating centers to ensure surgical quality



Recommended systemic treatment:

- Carboplatin AUC5, Paclitaxel 175mg/m^2 q3w
- Bevacizumab 15mg/kg q3w as indicated
- PARPi as indicated
- Study participation or any other treatment as long as applicable for both study arms

Primary endpoint

- Overall survival

Key secondary endpoints

- Progression-free survival
- Complete resection rate
- Surgical procedures
- Surgical morbidity
- Quality of life

Predefined exploratory and translational endpoints

TRUST Results: Surgical Morbidity

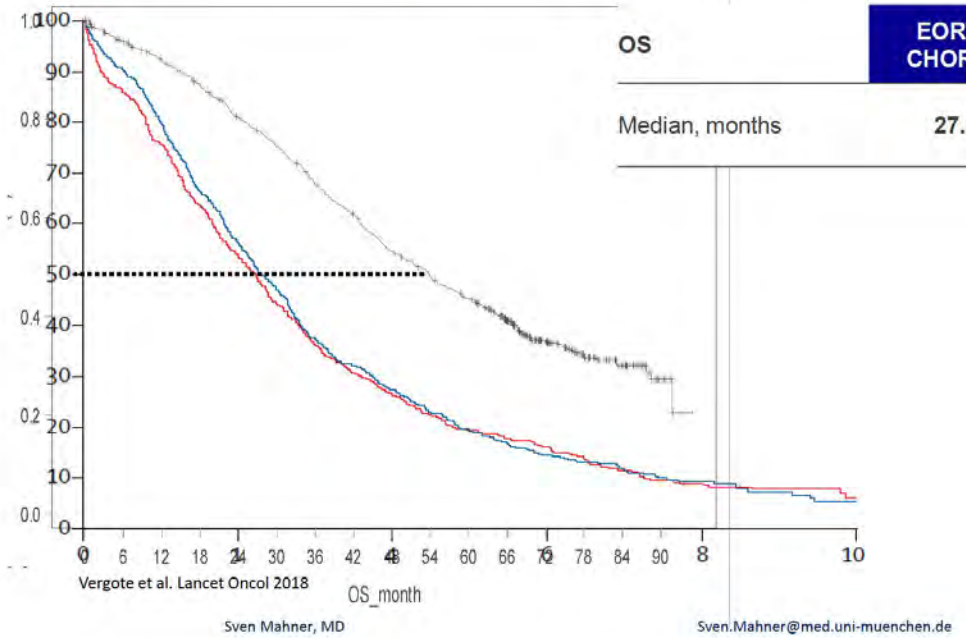
Complication, n* (%)	PCS (n=331)	NACT-ICS (n=328)
Any complication	60 (**18%**)	39 (**12%**)
>10 packed red blood cells within 24h	0	0
30-day post-op mortality	3 (**0.9%**)	2 (**0.6%**)
Re-laparotomy	21 (**6.3%**)	12 (**3.7%**)
Wound breakdown	11 (**3.3%**)	11 (**3.4%**)
Deep venous thrombosis	3 (**0.9%**)	1 (**0.3%**)
Pulmonary embolism	5 (**1.5%**)	3 (**0.9%**)
Sepsis	6 (**1.8%**)	4 (**1.2%**)
Anastomotic leak / fistula	11 (**3.3%**)	7 (**2.1%**)
Intraabdominal abscess	2 (**0.6%**)	1 (**0.3%**)
Nerve damage	1 (**0.3%**)	3 (**0.9%**)
Liver/renal failure	6 (**1.8%**)	2 (**0.6%**)
Serious cardiovascular event	8 (**2.4%**)	1 (**0.3%**)
Readmittance b/o any other complication	11 (**3.3%**)	5 (**1.5%**)

*. patients with documented cytoreductive surgery; analyzed as treated; complications that occurred within 28 days of debulking surgery

TRUST and EORTC/CHORUS comparison

		TRUST	EORTC	CHORUS
No of pts		**688 pts**	670 pts	550 pts
Median age		**64y**	62y	65y
FIGO Stage IV	PCS	**32%**	23%	25%
	ICS	**30%**	24%	25%
Duration of surgery	PCS	**331 min**	180 min	120 min
	ICS	**284 min**	165 min	120 min
Complete gross resection	PCS	**70%**	19%	17%
	ICS	**84%**	51%	39%
PFS	PCS	**22.2 months**	12 months	10.7 months
	ICS	**19.7 months**	12 months	12 months
OS	PCS	**54.3 months**	29 months	22.6 months
	ICS	**48.3 months**	30 months	24.1 months

TRUST: pooled survival compared to EORTC and CHORUS



GOG-3068/HOTT

Intraperitoneal Chemotherapy (HIPEC) Cisplatin Versus No HIPEC At Interval Cytoreductive Surgery (iCRS) Followed By Niraparib Maintenance In Patients With Newly Diagnosed Stages III and IV Ovarian, Peritoneal, and Fallopian Tube Cancer (Hyperthermic Ovarian Treatment Trial)

PI: Leslie Randall, MD | Co-PI: Oliver Zivonavic | DEI Chair: Adulrahman Sinno, MD

Registration and HRD testing during NACT Q21 days for 3-4 cycles

↓

Optimal (R0/R1) iCRS
Intraoperative Randomization (1:1)
Stratified by 1/R0 v R1 2/FIGO III v IV 3/HRD+ v HRD-

↓

HIPEC:
Cisplatin 100 mg/m^2 IP x 90 min @ 42°C with sodium thiosulfate renal protection

NO HIPEC

↓

- Resume chemotherapy for 6 total cycles
- Mandatory niraparib maintenance
- Individualized starting dose to 36 months, disease progression, or unacceptable toxicity

Key Eligibility:

- Stage III or IVA/IVB serous or endometrioid epithelial ovarian, fallopian tube or primary peritoneal carcinoma
- CR, PR or SD to NACT and deemed resectable of extra-abdominal disease on pre-operative imaging
- Cytoreductive surgery (iCRS) candidate and must have no gross residual disease or no disease >1 cm following iCRS prior to randomization
- Any BRCA/HRD status with results prior to randomization
- ECOG PS 0-1

GOG Highlight Reel

NCT05659381

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Key Issues for Development & Discussion

- What is the best strategy to build a clinical trial portfolio?
  - Phase Ib/II and phase III strategy
  - Multiple phase III's in the same setting
  - Strategic planning based on targeted opening/closing targets

GOG FOUNDATION®
Transforming the standard of care

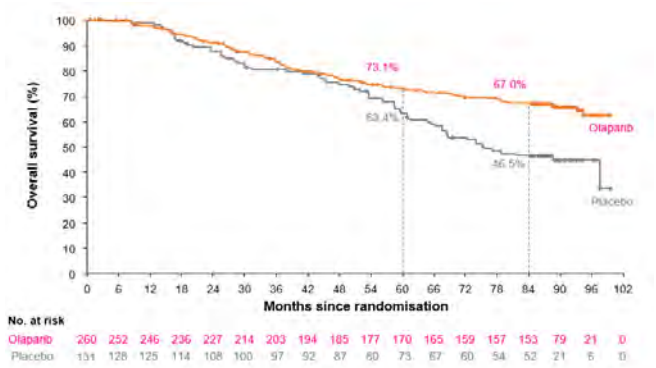
Innovations in Treatment for Ovarian Cancer

Kathleen Moore, MD
University of Oklahoma
Stephenson Cancer Center
Oklahoma City, Oklahoma

GOG Highlight Reel

After decades of marginal gains, novel therapies are improving OS

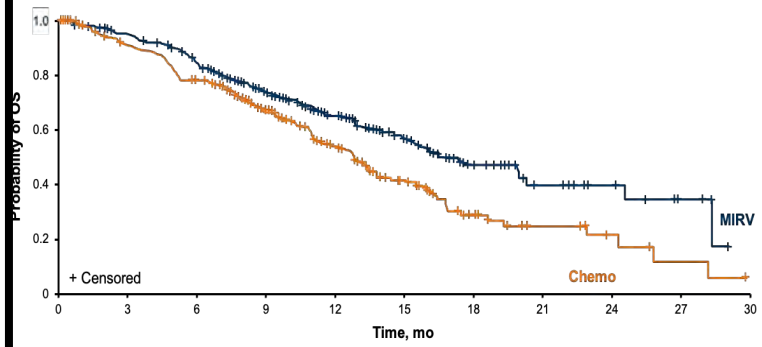
PARPI (SOLO-1 OS)



	Olaparib (N=260)	Placebo (N=131)
Events, n (%)	84 (32.3)	65 (49.6)
Median OS, months	**NR**	**75.2**
HR: 0.55 (95% CI: 0.40–0.76) *P*=0.0004[a]		

Disilvestro et al. J Clin Oncol 2023

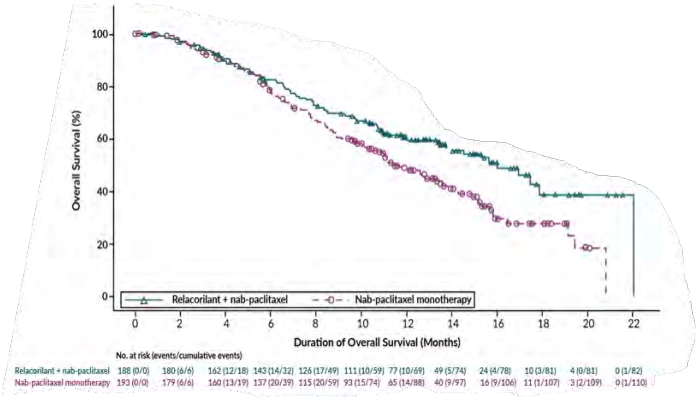
ADCs (MIRASOL OS)



	MIRV (n = 227)	IC Chemo (n = 226)
mOS (95% CI)	16.46 (14.46-24.57)	12.75 (10.91-14.36)
Events, n (%)	90 (39.6)	114 (50.4)
HR (95% CI)	**0.67 (0.50-0.89)**	
P	**.0046**	

Moore et al. NEJM 2023

Metabolic (ROSELLA OS)



Relacorilant + nab-paclitaxel vs nab-paclitaxel had improved PFS (HR: 0.70; p-value: 0.008) and at interim evaluation of OS had a significant improvement in OS, with a HR: 0.69; p-value: 0.012.

Olawaiye et al. ASCO 2025

We are heading into an era where EOC can no longer be characterized by one biomarker

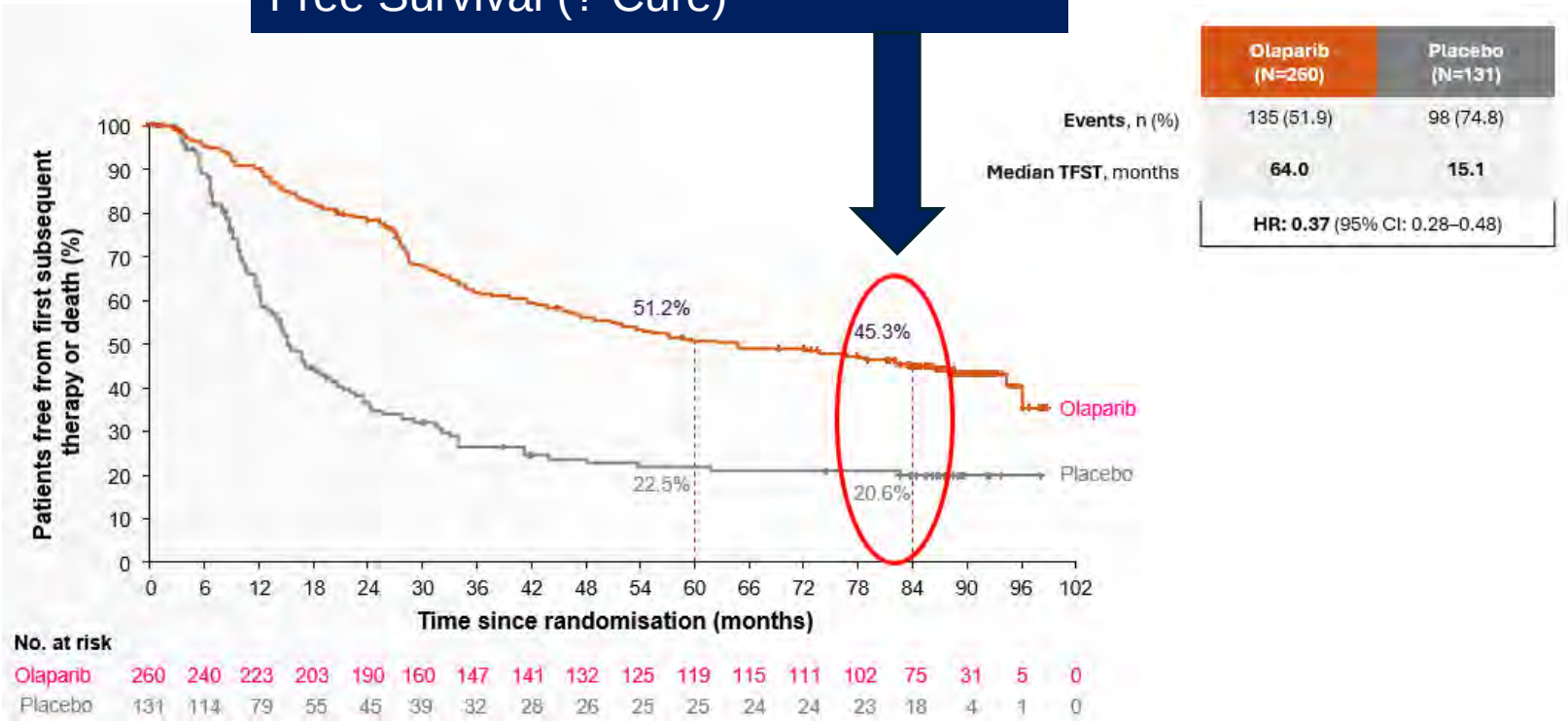
While we want to think all tumors with BRCA mutations will have outstanding outcomes…….

BRCA mutated: Everyone does well right?

Case: AB
46 year old diagnosed with Stage IV HGS. *gBRCA1*, FRα neg (15%)

NACT→iCRS→ Adj T/C for a total of 6 cycles followed by maintenance Olaparib.

Time to first subsequent therapy in SOLO-1 = Long Term, Recurrence Free Survival (? Cure)



	Olaparib (N=260)	Placebo (N=131)
Events, n (%)	135 (51.9)	98 (74.8)
Median TFST, months	64.0	15.1
HR: 0.37 (95% CI: 0.28–0.48)		

Paul DiSilvestro, MD et al. J Clin Oncol 2022; 41:609-617.

The truth is, more of these tumors recur and recur earlier than we would like to accept…..

BRCA mutated: Everyone does well right?

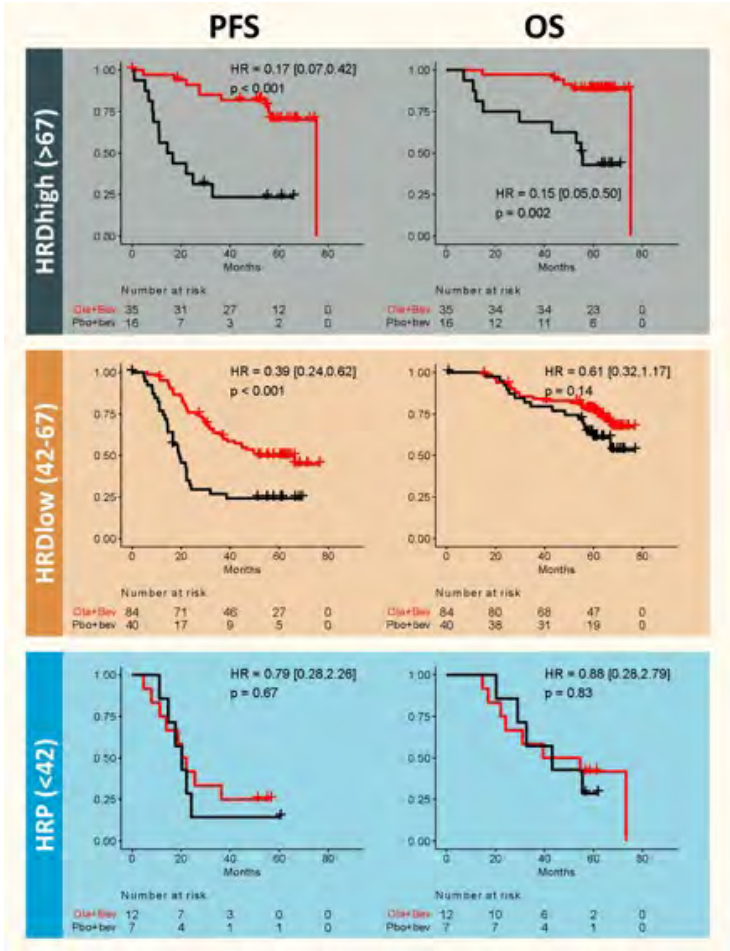
Case: AB
46 year old diagnosed with Stage IV HGS. *gBRCA1*, FRα neg (15%)

NACT→iCRS→ Adj T/C for a total of 6 cycles followed by maintenance Olaparib.
Recurrence 8 months later

PSOC: Treated with PLD/Carbo/bevacizumab x 4 with PD

< 12 months since dx now with widespread PROC

Could this early recurrence for a BRCAmut tumor have been predicted?



BRCAmut HRD high (GIS > 67) 26.3% of *BRCA mut* on PAOLA-1.
This is where we see cures

Sandoval JL et al. ASCO 2025 Abstract 5576

The truth is, more of these tumors recur and recur earlier than we would like to accept…..

BRCA mutated: Everyone does well right?

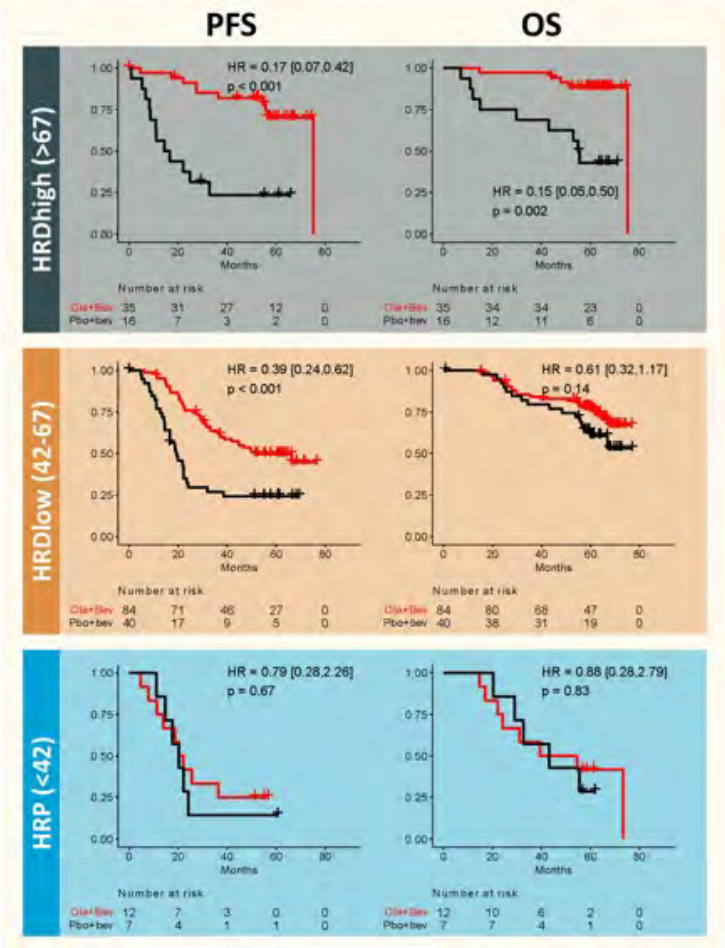
Case: AB
46 year old diagnosed with Stage IV HGS. *gBRCA1*, FRα neg (15%)

NACT→iCRS→ Adj T/C for a total of 6 cycles followed by maintenance Olaparib.
Recurrence 8 months later

PSOC: Treated with PLD/Carbo/bevacizumab x 4 with PD

< 12 months since dx now with widespread PROC

Could this early recurrence for a BRCAmut tumor have been predicted?



BRCAmut HRD low (GIS 42-67) 64% of *BRCA mut* on PAOLA-1. **PFS still looks really good. OS may be lost**

Sandoval JL et al. ASCO 2025 Abstract 5576

The truth is, more of these tumors recur and recur earlier than we would like to accept…..

BRCA mutated: Everyone does well right?

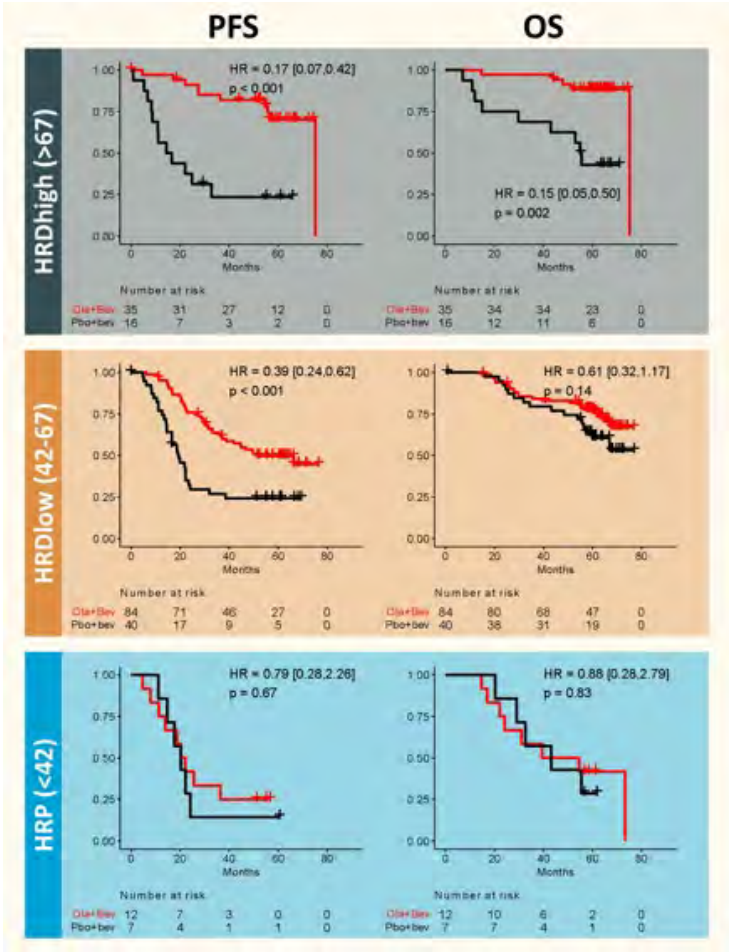
Case: AB
46 year old diagnosed with Stage IV HGS. *gBRCA1*, FRα neg (15%)

NACT→iCRS→ Adj T/C for a total of 6 cycles followed by maintenance Olaparib.
Recurrence 8 months later

PSOC: Treated with PLD/Carbo/bevacizumab x 4 with PD

< 12 months since dx now with widespread PROC

Could this early recurrence for a BRCAmut tumor have been predicted?



BRCAmut HRD very low (GIS <42) 10% of *BRCA mut* on PAOLA-1. **PFS here no better than bev. Does this group need something else?**

Sandoval JL et al. ASCO 2025 Abstract 5576

HRD Tumors: Progression on Frontline PARPi – impact on OS?

BRCAwt/HRD: Patients with these tumors should do well?

Case: CD
70 year old diagnosed with Stage IIIC HGS. HRD, FRα high

NACT→iCRS→ Adj T/Cx 8 followed by maintenance bevacizumab + olaparib.
Recurrence 20 months later

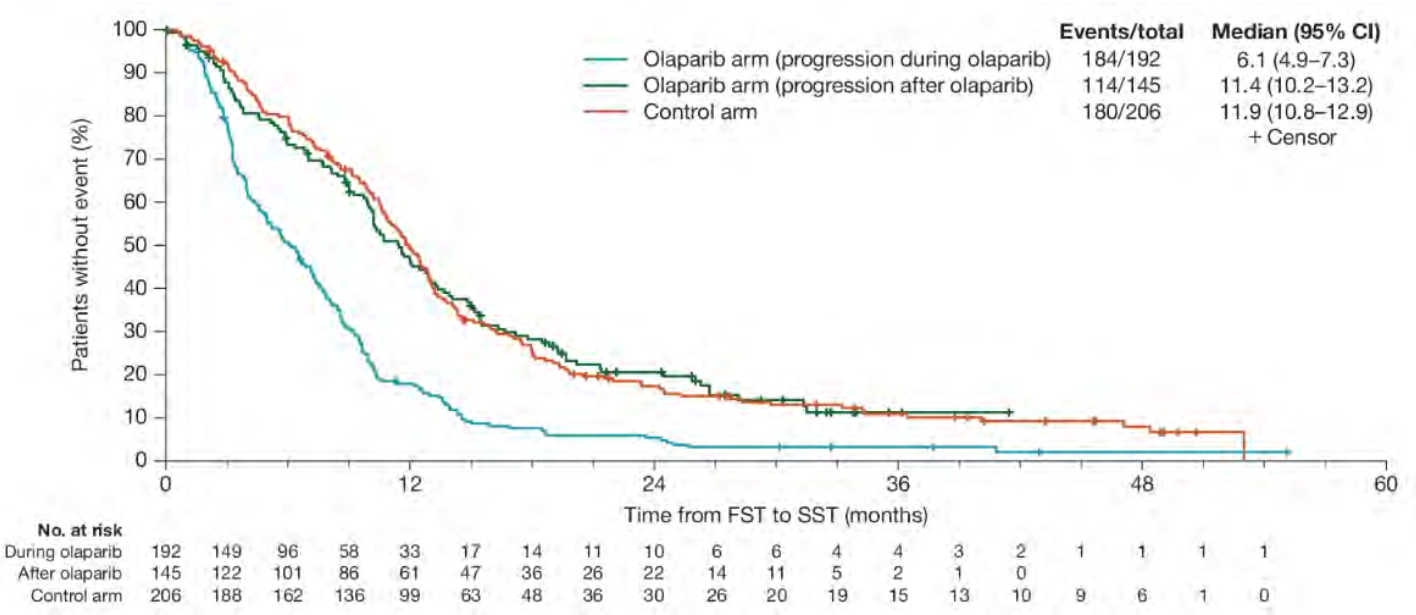
PSOC: Treated with
PLD/Carbo/Bevacizumab x 4 with PD

PROC: Gem/CDDP x 3 with PD
MIRV/bev x 2 PD
wPaclitaxel x 3 PD

Death 3.5 years post dx

PAOLA-1: Post hoc analysis of 2nd PFS for tumors that progressed on PARPi (blue) vs. progressed after PARPi discontinuation (dark green) vs no PARPi (orange)

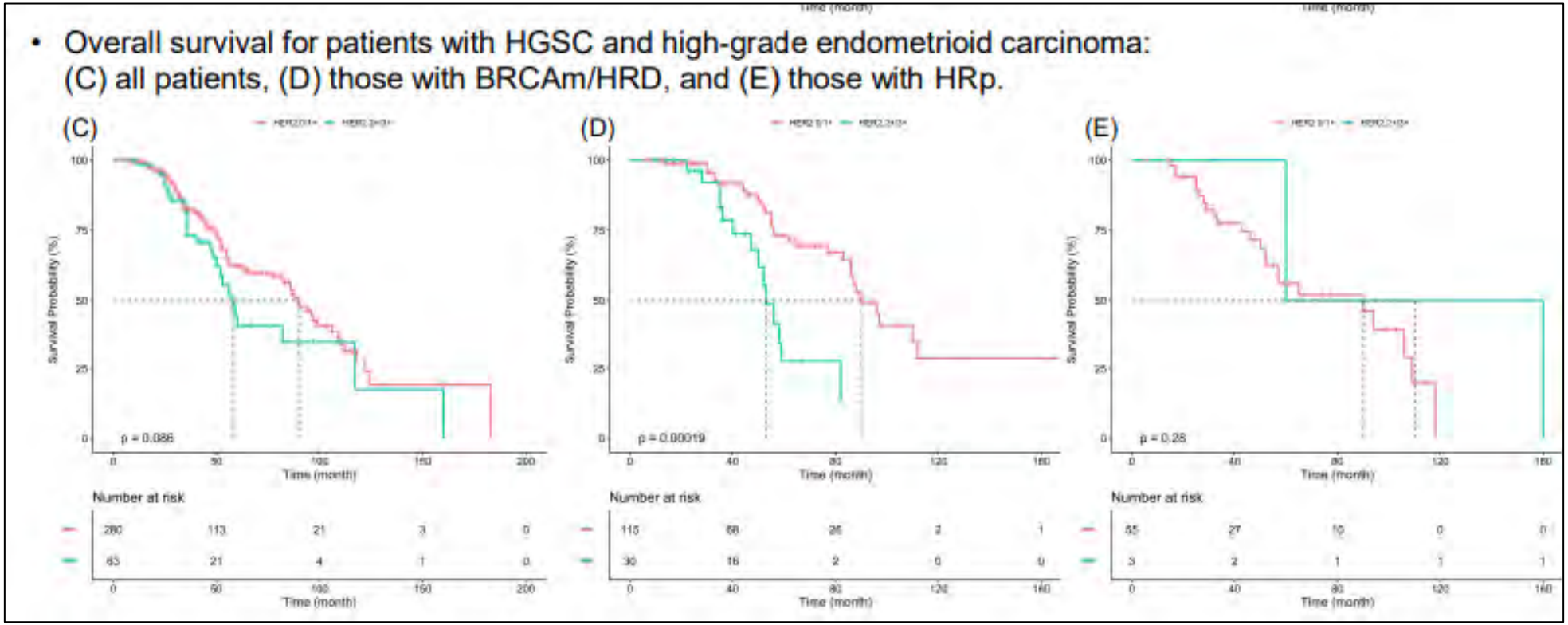
Does progression on PARPI just = early recurrence and **biologically aggressive disease** or is the **PARPi inducing resistance?**



Harter et al. ASCO 2023 Abstract 5550

Biomarkers in Frontline therapy will evolve to BRCA (y/n) , HRD (? GIS level) and tumor associated antigens like HER2

- Overall survival for patients with HGSC and high-grade endometrioid carcinoma: (C) all patients, (D) those with BRCAm/HRD, and (E) those with HRp.



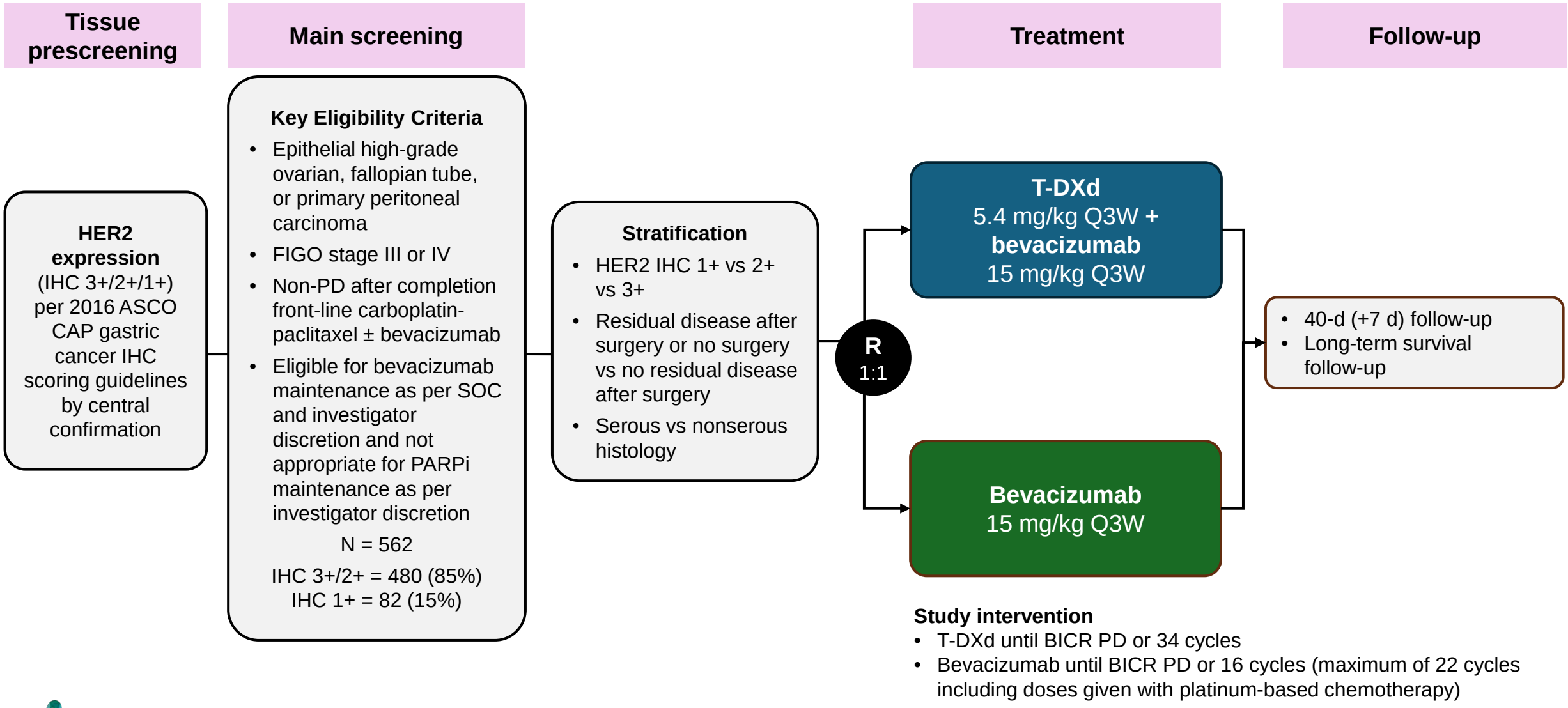
BRCAm/HRD: HER 2 2+ or 3+ appears negatively prognostic.

a) Is this “fixable” with PARPI or
b) This is a group that does poorly with PARPi and should be included in HER2 ADC studies?

@DrKatyMoore

Lee D et al. ESMO 2024 765P

This may open new opportunities for patients:
Phase 3 DESTINY-Ovarian01: T-DXd + Bevacizumab as 1L maintenance therapy in HER2-Expressing Ovarian Cancer[1]

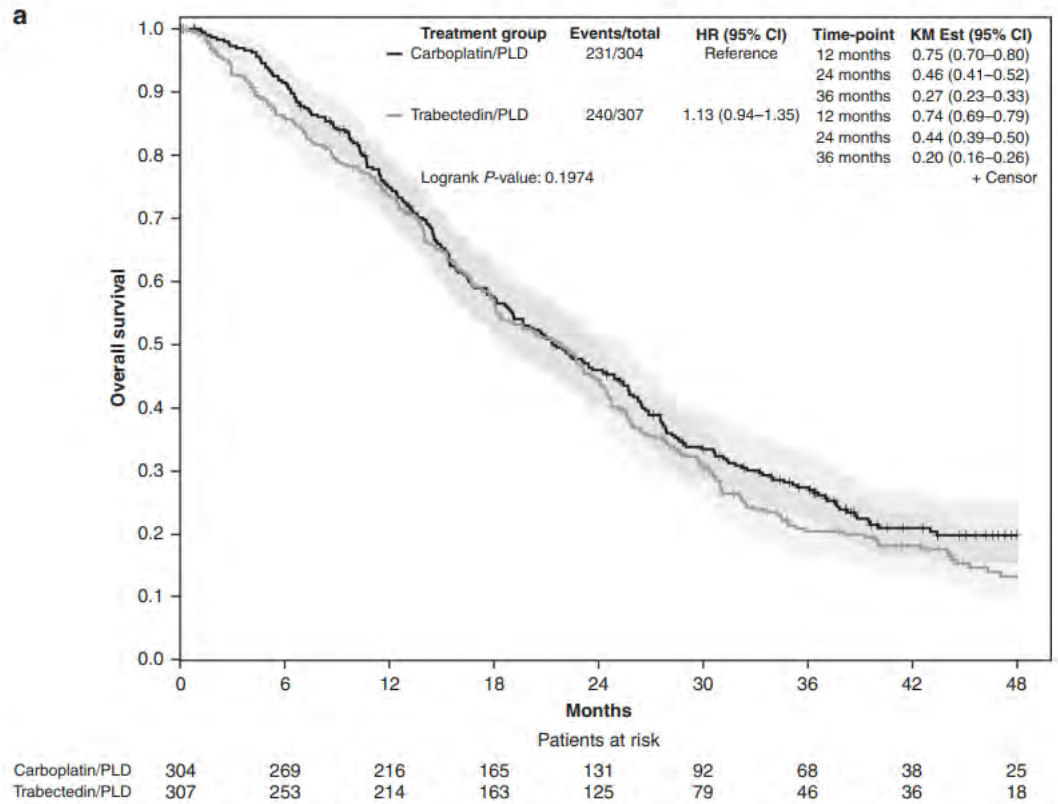


Study intervention
- T-DXd until BICR PD or 34 cycles
- Bevacizumab until BICR PD or 16 cycles (maximum of 22 cycles including doses given with platinum-based chemotherapy)

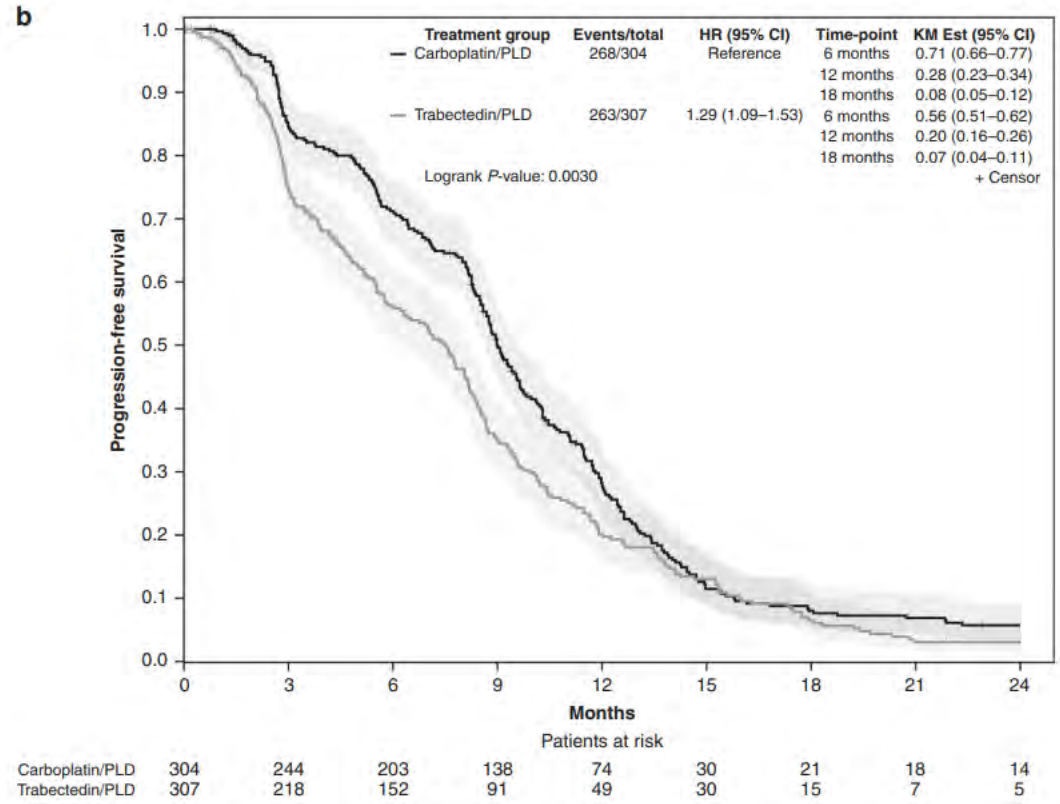
1. https://clinicaltrials.gov/study/NCT06819007; [ENGOT-ov89/GOG 3112].

The definition of “platinum sensitive” as defined by PFI > 6 months has been challenged for years
INOVATYON/ENGOT-ov5 was an idea ahead of its’ time….

OS



PFS

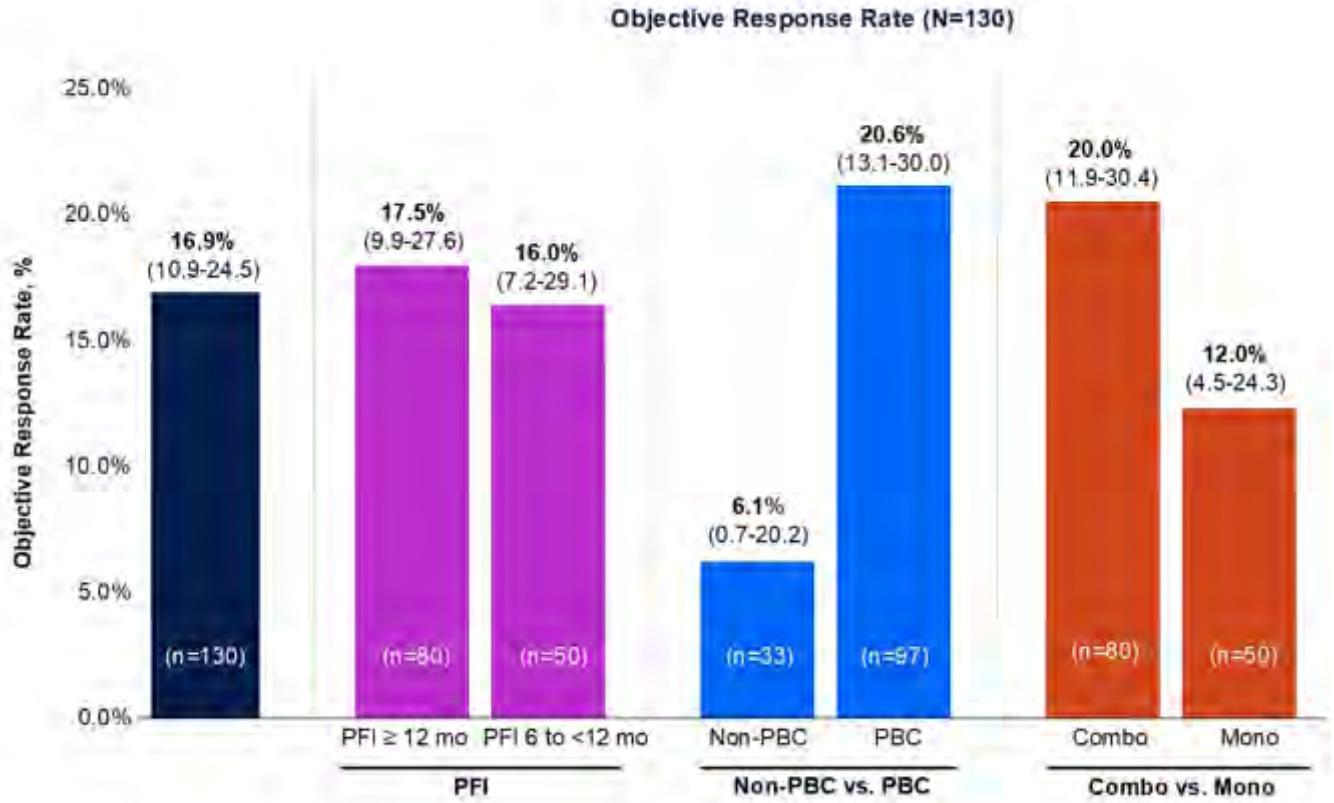


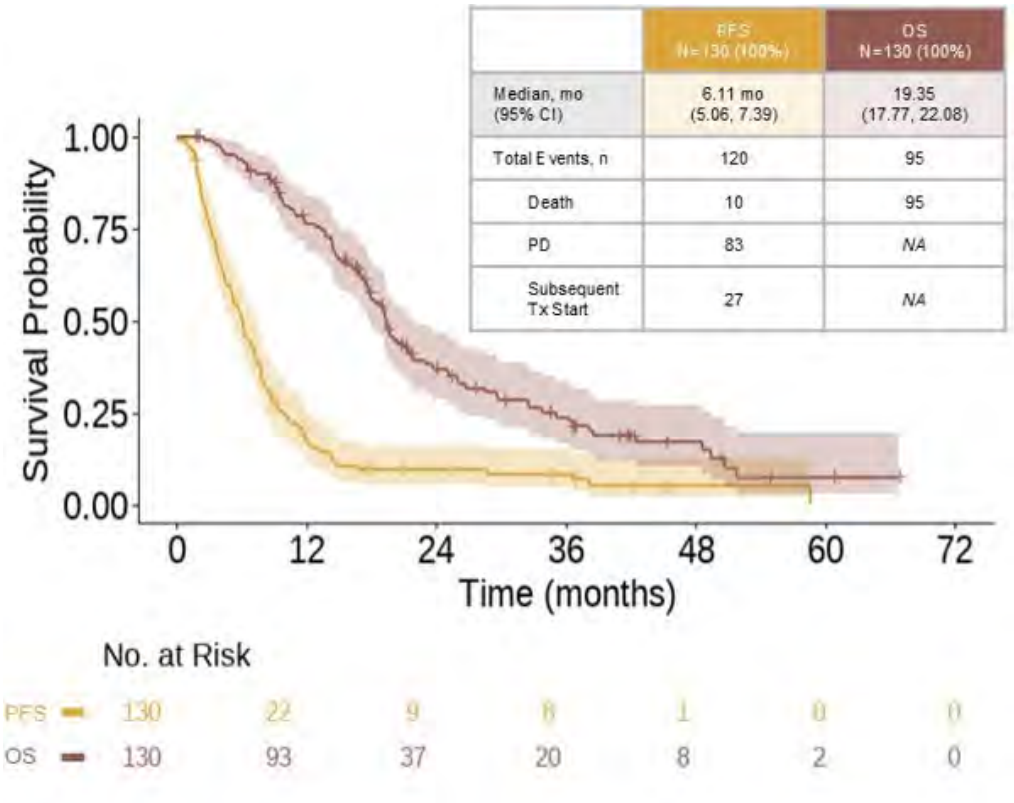
1. Would Inovatyon (or MITO 8) been positive if they had used a more active “non platinum”?
2. What is the “high risk” group who should not get a platinum?

Colombo N et al. British Journal of Cancer 2023

@DrKatyMoore

If progression on PARPi is the new “high risk” marker for poor anticipated response to platinum, what do we know about expectations for platinum in this setting?





	PFS N=130 (100%)	OS N=130 (100%)
Median, mo (95% CI)	6.11 mo (5.06, 7.39)	19.35 (17.77, 22.08)
Total Events, n	120	95
Death	10	95
PD	83	*NA*
Subsequent Tx Start	27	*NA*

ORR is 20% at highest and mPFI is around 6-7 months

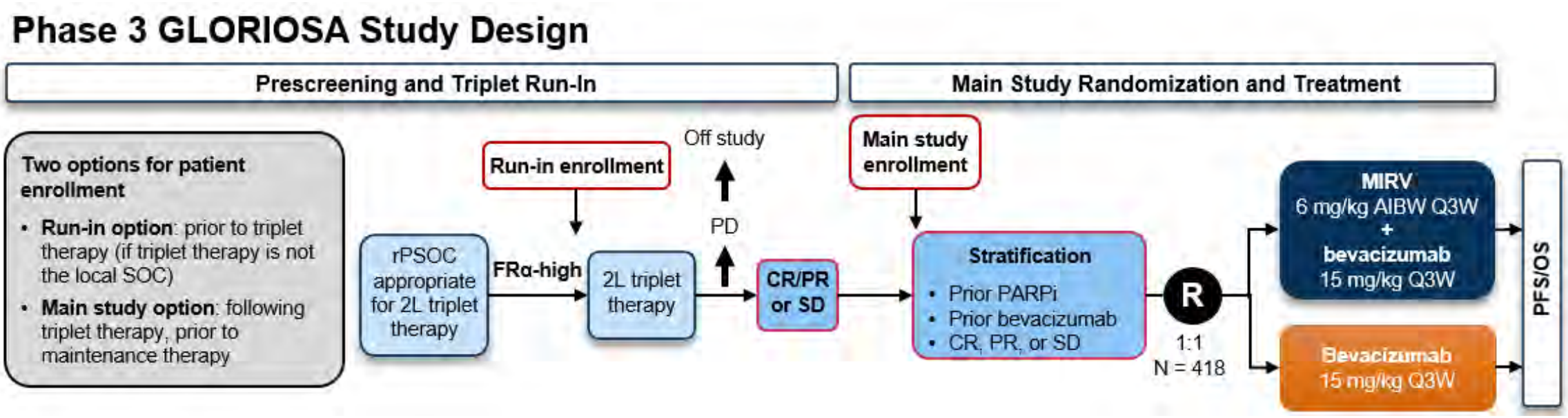
Coleman et al. ASCO 2025

Data for ADCs in PSOC is starting to emerge….. Will they be better than platinum even in high risk tumors?

	Sacituzumab tirumotecan 5mg/kg D1, D15 N=5 (PSOC)	Datopotamab deruxtecan N=9 (PSOC)	Mirvetuximab soravtansine N=79 (PICCOLO)	Raludotatug deruxtecan N=18	Coleman et al. PSOC post PARPi PD Platinum
Payload	Belotecan derivative Topoisomerase I	Topoisomerase 1-deruxtecan	DM4	Topoisomerase 1 – deruxtecan	Platinum
DAR	7.4	4	4	8	NA
Linker	Sulfonyl pyrimidine CL2A-carbonate linker	Cleavable tetrapeptide based linker	Cleavable linker	Tetrapeptide-based cleavable linker	NA
Trial	NCT06049212	NCT05489211	NCT05041257	NCT04707248	ASCO 2025
ORR	60% (PSOC N=5)	66.7% (PSOC N=9)	51.9% (95%CI 40.4-63.3) 45.8% (95% CI 32.7-59.2)	72.2% (9% CI 46.5-90.3) ITT 58.3% (95% CI 27.7-84.8) Post Pi	20.6%
DOR	ND	ND	8.25 (95% CI 5.55-10.78) ITT 7.33 (95% CI 5.03-10.78) Post Pi	5.7 (4.2-NE) ITT 5.1 (2.8- NE) Post Pi	NR
mPFS	ND	ND	6.93 (95% CI 5.85-9.59) ITT 6.18 (95% CI 5.55-8.41) post Pi	8.1 (4.1-NE) ITT 7.1 (2.8-NE) Post Pi	7.39 (combo data)

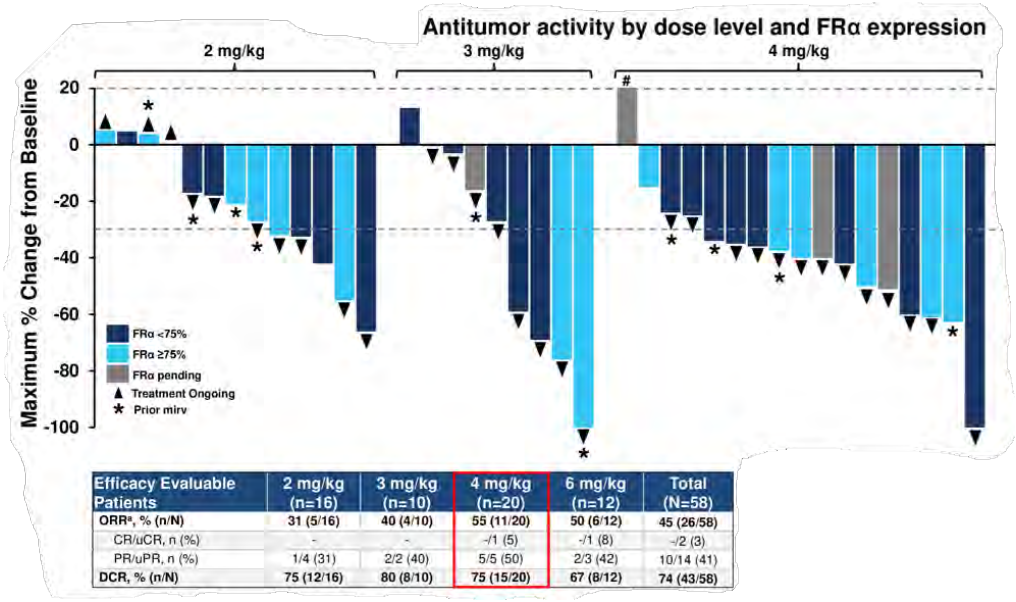
Wang et al. ESMO 2024, Oaknin A et al. ESMO 2024, Alvarez Secord ESMO Gyne 2025, Moore ESMO Gyne 2025

Or for those tumors deemed not high risk for platinum failure do we use ADCs as maintenance? GLORIOSA



New ADCS from ASCO 2025

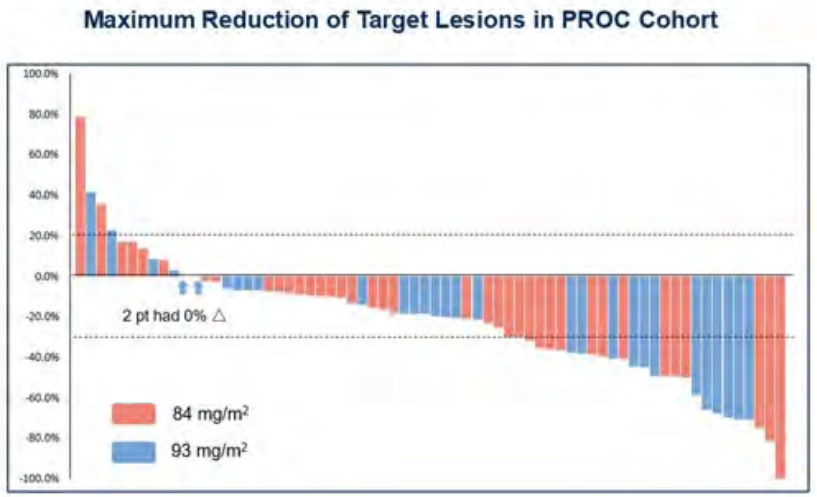
LY4170156 FRα ADC with exatecan payload and DAR of 8



Efficacy Evaluable Patients	2 mg/kg (n=16)	3 mg/kg (n=10)	4 mg/kg (n=20)	6 mg/kg (n=12)	Total (N=58)
ORR[a], % (n/N)	31 (5/16)	40 (4/10)	55 (11/20)	50 (6/12)	45 (26/58)
CR/uCR, n (%)	-	-	-/1 (5)	-/1 (8)	-/2 (3)
PR/uPR, n (%)	1/4 (31)	2/2 (40)	5/5 (50)	2/3 (42)	10/14 (41)
DCR, % (n/N)	75 (12/16)	80 (8/10)	75 (15/20)	67 (8/12)	74 (43/58)

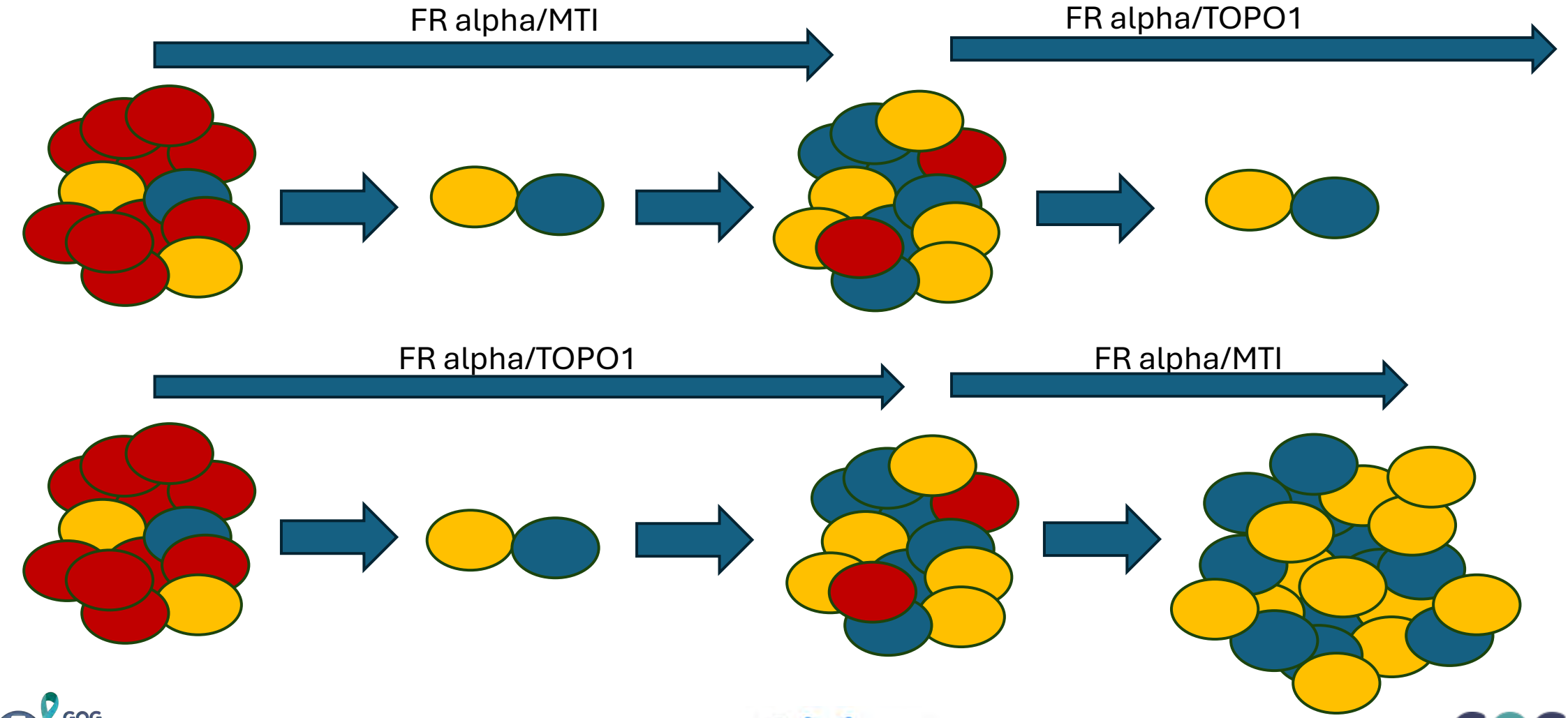
Ray Coquard I et al. ASCO 2025 Abstract 3023; Jia H et al. ASCO 2025 Abstract 5550

BAT8006 FRα ADC with exatecan payload and DAR of 8

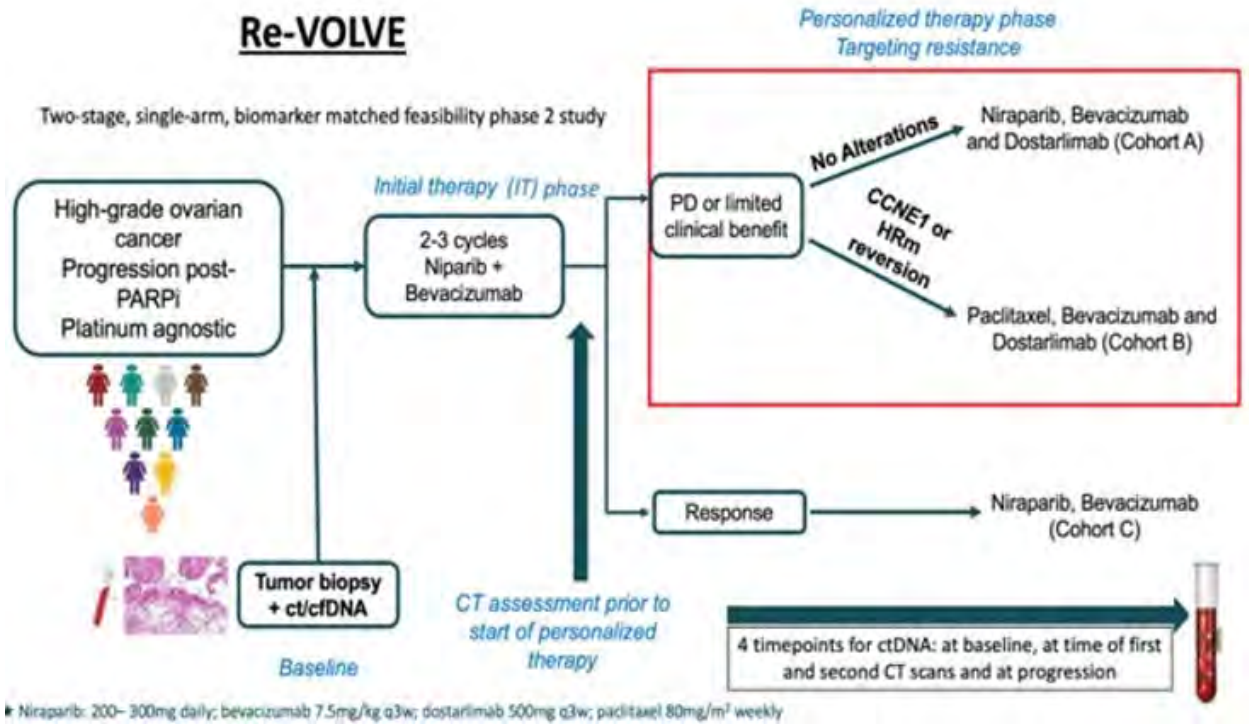


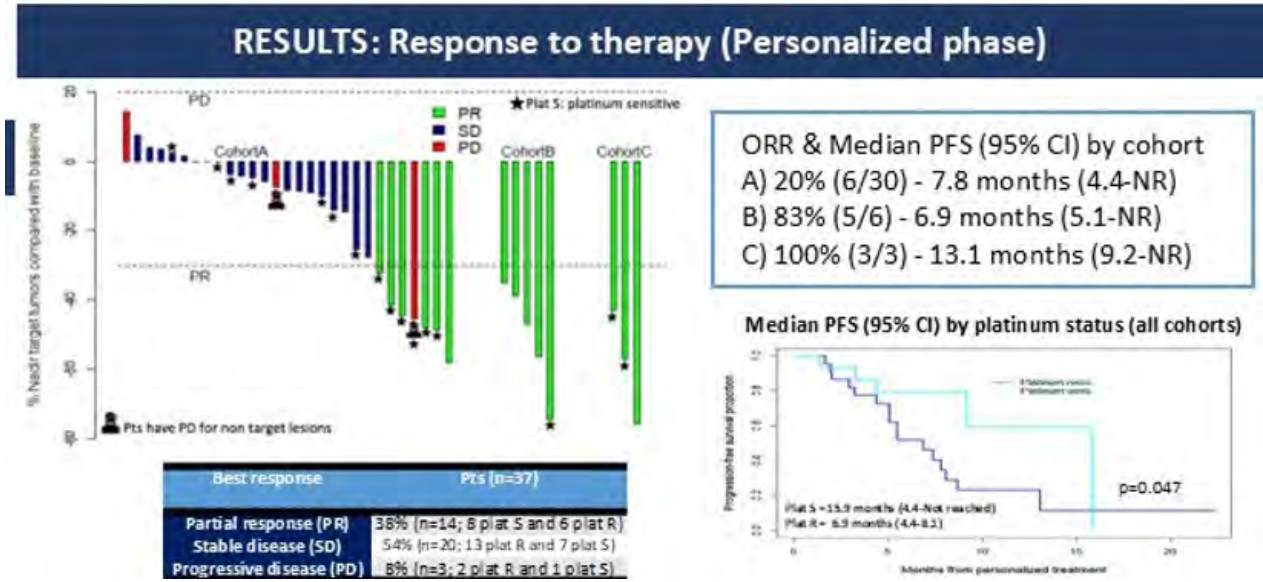
	84mg/m2 (n=38)	93mg/m2 (n=31)
ORR, n(%)	14 (36.8%)	13 (41.9%)
CR, n(%)	1 (2.6%)	1 (3.2%)
PR, n(%)	13 (34.2%)	12 (38.7%)

Sequencing may become important: Will we use two folate targeting ADCs in the future?



Beyond ADCs – what are options for post PARPi PSOC? Molecularly selected therapy- Re-Volve



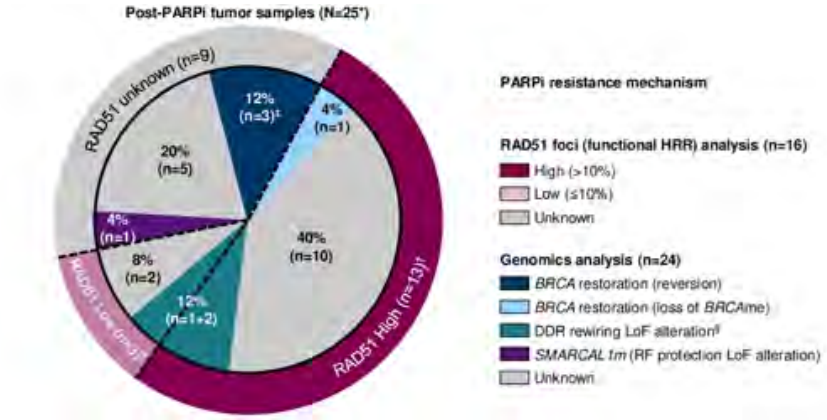


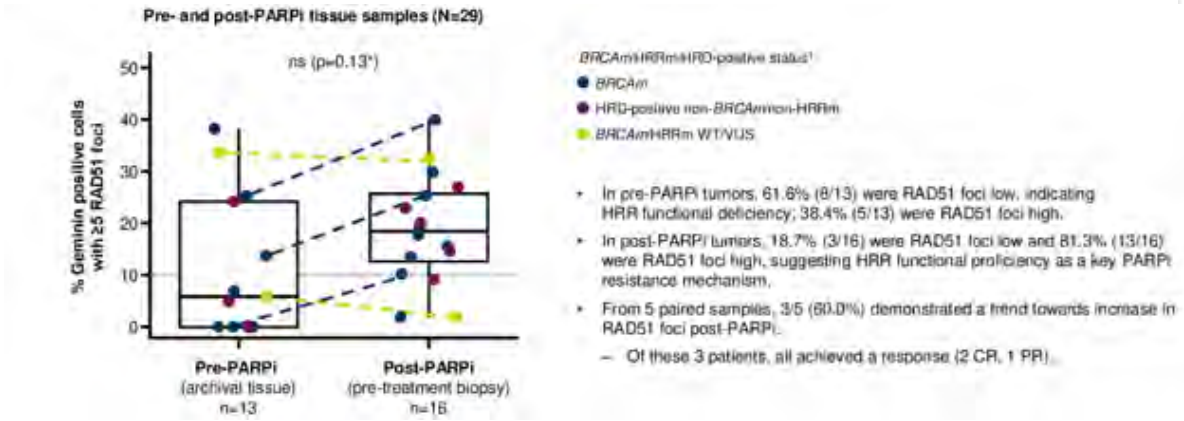
Only 3 patients with PARPi PD responded to Nira/bev

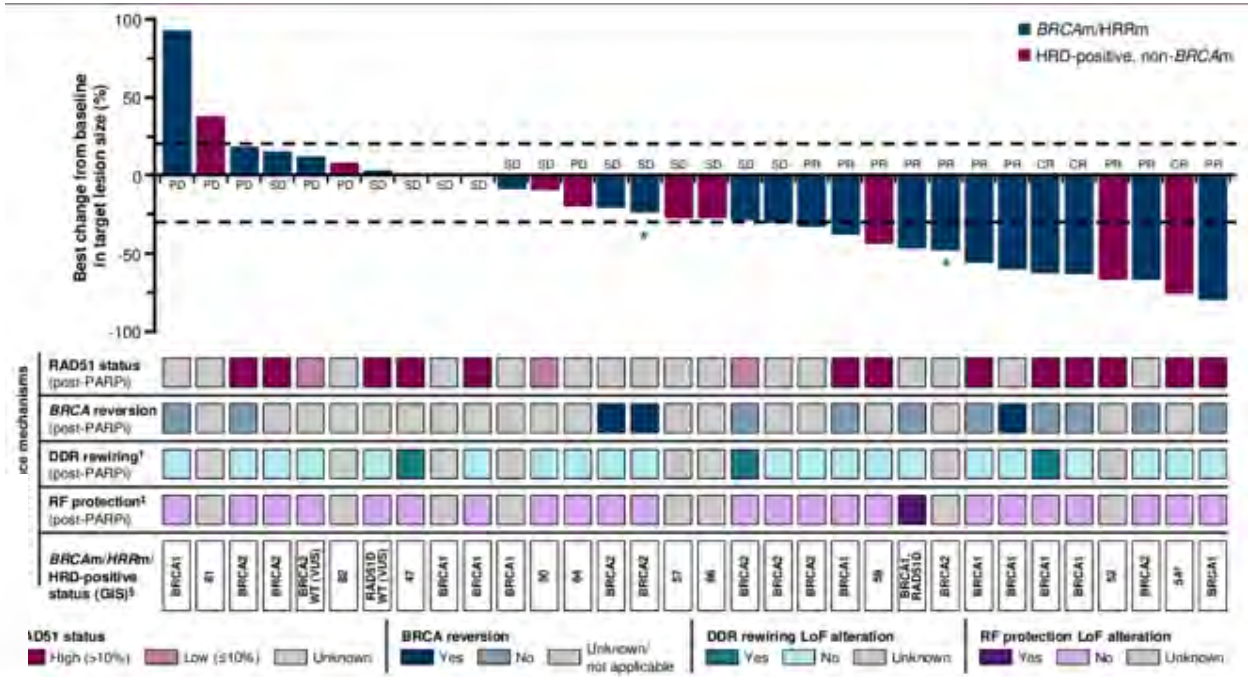
Individualization of therapy based on initial response and molecular profile may aid in outcomes

Pino et al. ASCO 2025 Abs 5561

Beyond ADCs – what are options for post PARPi PSOC? Ceralasertib + Olaparib







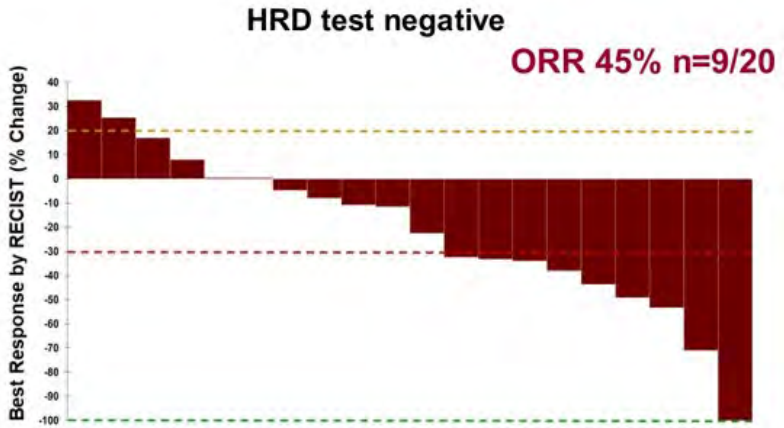
Pre treatment biopsies

ORR in the ITT was **40%**
Higher responses were seen in BRCA/HRR as compared to HRD/HRR neg (45 vs 30%)
81% of pts with pre-tx biopsy had HRR proficiency as judged by RAD51 foci high and yet still responded to the combination

Roux et al. ASCO 2025 Abs 5542

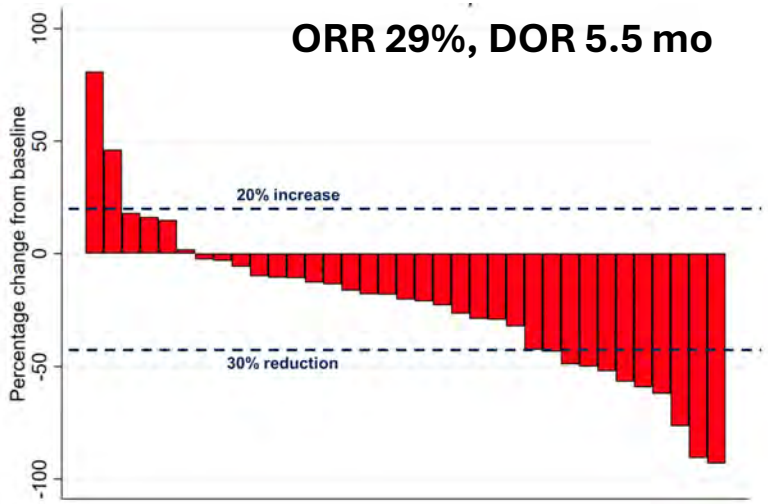
Increased understanding of cell cycle machinery and targeting may move novel agents into registration trials….

CAPRI Cohort A: PSOC, no prior PARPi, HRD test neg
Ceralasertib + Olaparib

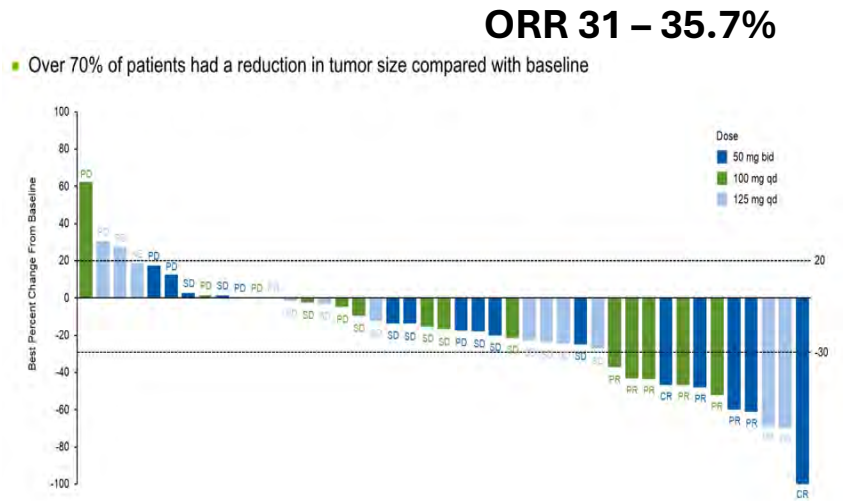


Benchmark for HRD test neg, PARPi naïve is **ORR 10%** with olaparib alone

EFFORT:
Progression on a PARPI
Adavosertib + Olaparib



INCB123667:
CCNE1 amp/CyclinD1 OE
CDK2 inhibitor



Simpkins et al. ASCO 2024; Westin ASCO 2021, Lorusso K et al ASCO 2025

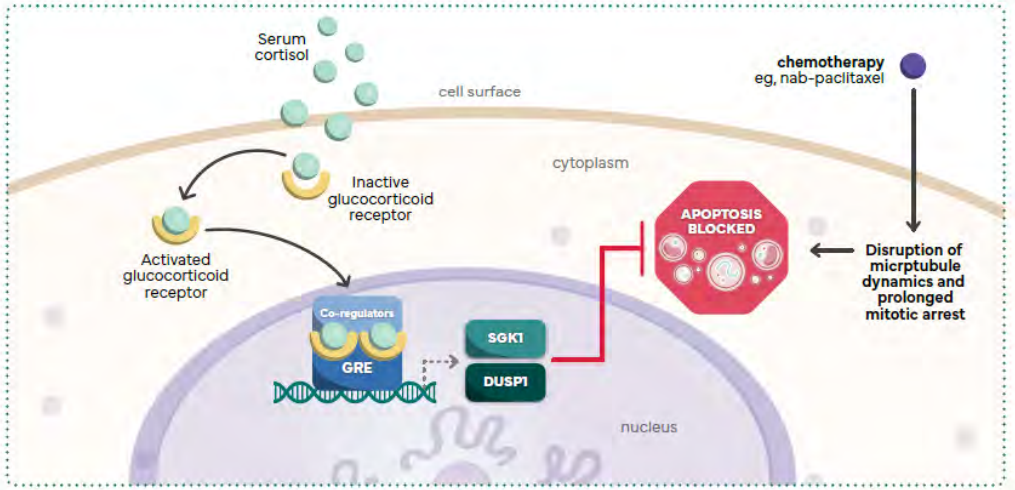
For PROC: AURELIA suggested that a taxane combination might be better

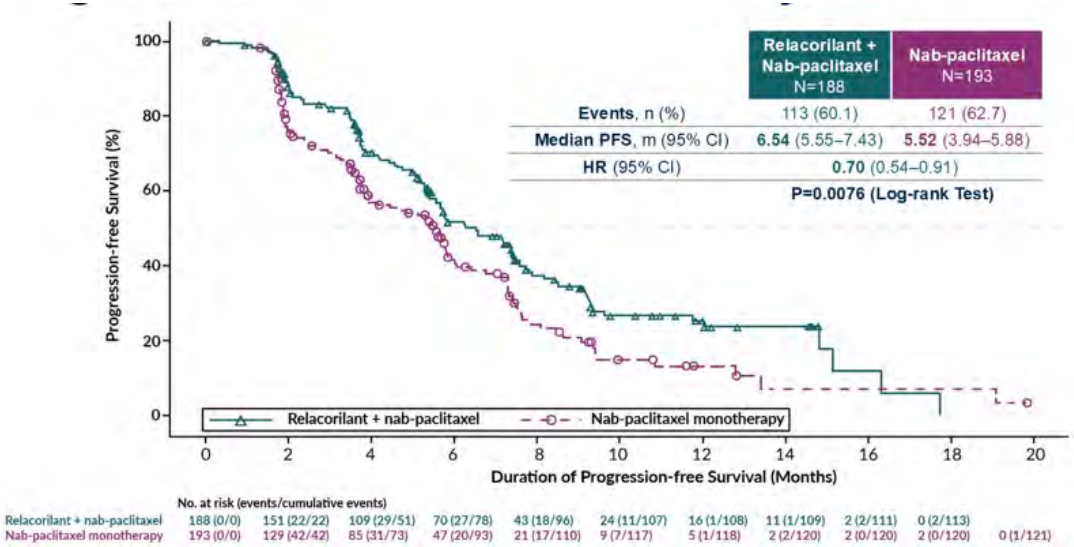
Study	Study population	Chemotherapy arm	ORR, %	mPFS, mo mOS, mo
OVAL (n=409)	≤5 priors, PROC, excluded refractory (70% prior bev)	Weekly paclitaxel +/- ofranergene obadenovec	28.9%/ 29.6%	5.29/5.36 13.37/13.14
AXLerate (n=360)	PROC 1–4 priors, PROC (51% prior bev)	Weekly paclitaxel +/- batiraxcept	25.2%/ 26.2%	5.13/5.49 14.29/14.39
INNOVATE-3 (n=558)	PROC ≤5 priors (65.9% prior bev)	Weekly paclitaxel +/- TTF	30.3/ 31.6%	4.1/ 4.7 12.2/11.9
PROFECTA-II (n=150)	PROC ≤ 5 priors (81% prior bev)	Weekly paclitaxel +/- afuresertib	25%/ 18%	4.3/4.1 11.2/13.1
AURELIA (n=115)	PROC ≤2 priors; 25% platinum refractory (8% prior bev)	Weekly paclitaxel +/- bev	30.2%/53.3%	10.4/3.9 22.4/13.2

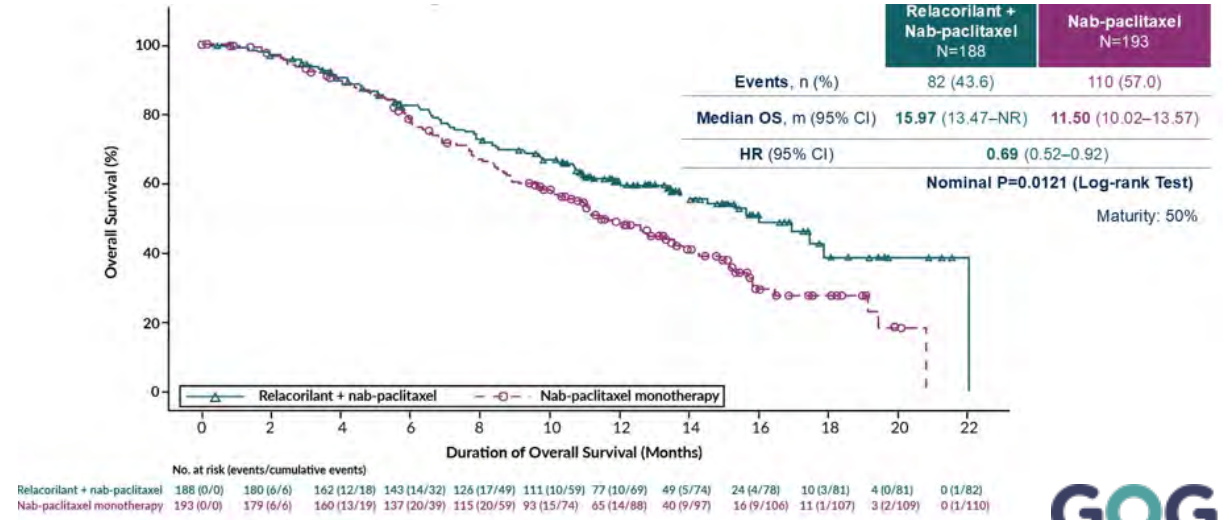
Arend RC et al. J Clin Oncol. 2024 42(2):170; Fuh KC et al. J Clin Oncol 42, 2024(suppl 17; abstr LBA 5515); Vergote I et al. European Journal of Cancer, 2025; Herzog T et al. SGO 2025; Poveda et al. Annals of Oncology 2012

Relicorilant + nab-Paclitaxel

Enhanced understanding of chemotherapy resistance: Relacorilant







Glucocorticoid receptor (GR) activation by cortisol leads to expression of anti-apoptotic genes *SGK1* and *DUSP1* suggesting a role for GR blockade

Olawaiye et al. Lancet 2025

Transforming Traditional Chemotherapy

Combinations are evolving ……B96 is yet to be presented… How do we select??

Study	Study population	Chemotherapy arm	ORR, %	mPFS, mo mOS, mo
OVAL (n=409)	≤5 priors, PROC, excluded refractory (70% prior bev)	Weekly paclitaxel +/- ofranergene obadenovec	28.9%/ 29.6%	5.29/5.36 13.37/13.14
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AURELIA (n=115)	PROC ≤2 priors; 25% platinum refractory (8% prior bev)	Weekly paclitaxel +/- bev	30.2%/53.3%	10.4/3.9 22.4/13.2
ROSELLA (n=381)	PROC ≤3 priors, 7% platinum refractory (100% prior bev)	Weekly nab-paclitaxel +/- relacorilant	36.9%/ 30.1%	6.54/5.52 15.97/11.5 (int)
AXLerate (n=61)	PROC 1–4 priors, PROC (51% prior bev) just AXL high	Weekly paclitaxel +/- batiraxcept	NR	5.78/3.71 17.8/8.11

Arend RC et al. J Clin Oncol. 2024 42(2):170; Fuh KC et al. J Clin Oncol 42, 2024(suppl 17; abstr LBA 5515); Vergote I et al. European Journal of Cancer, 2025; Herzog T et al. SGO 2025; Poveda et al. Annals of Oncology 2012, Olawaiye A et al. Lancet 2025

Progress in Rare Tumors
ASCO and ESMO Gyne 2025

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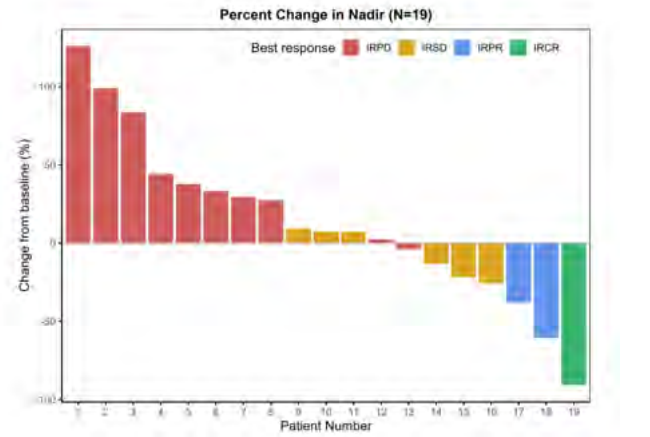
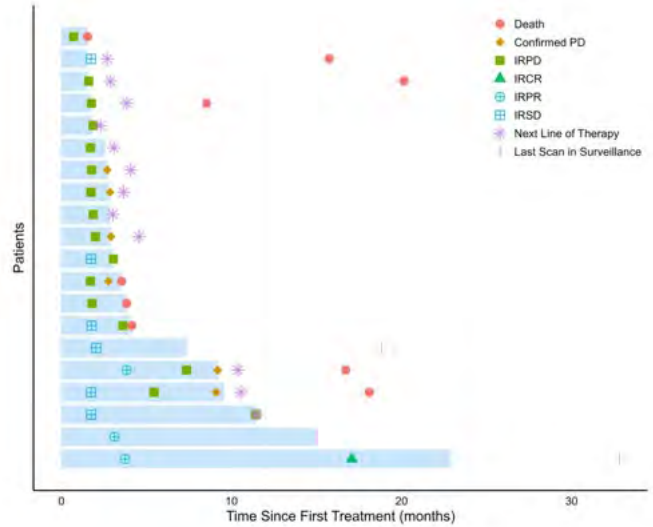
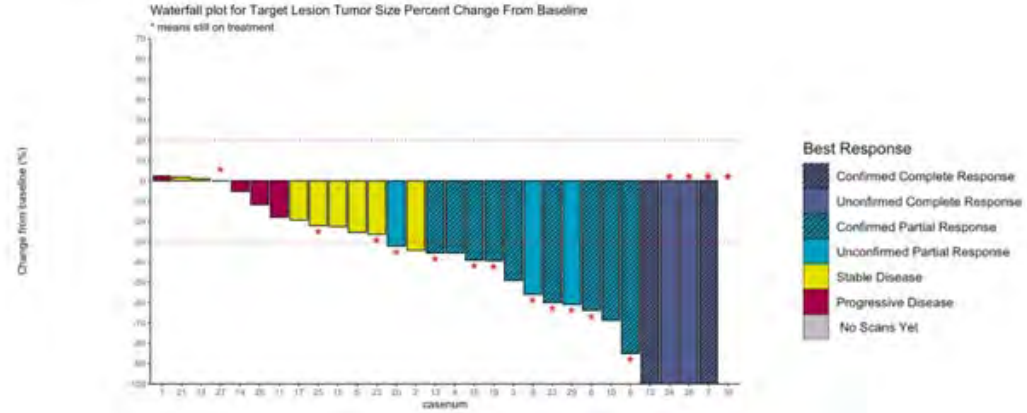
Ovarian Clear Cell Carcinoma

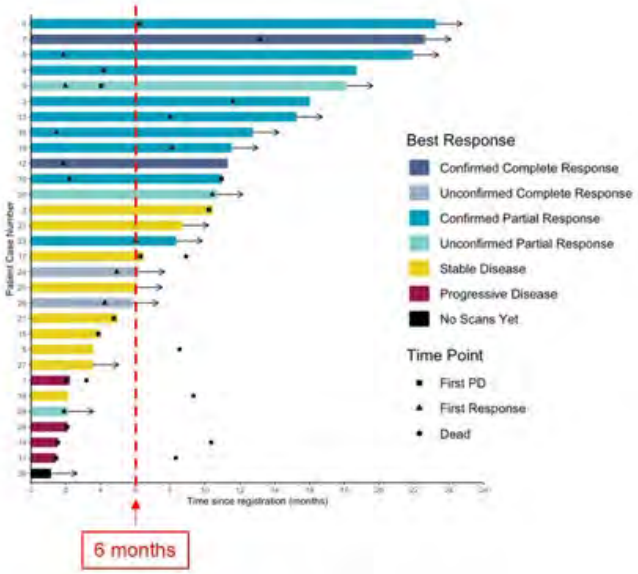
Etigilimab + Nivolumab in OCCC
ORR 15%/CBR 30%





Pembrolizumab + Lenvatinib in OCCC
ORR 36.7%





@DrKatyMoore

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Son et al. ASCO 2025, Lee et al. ASCO 2025

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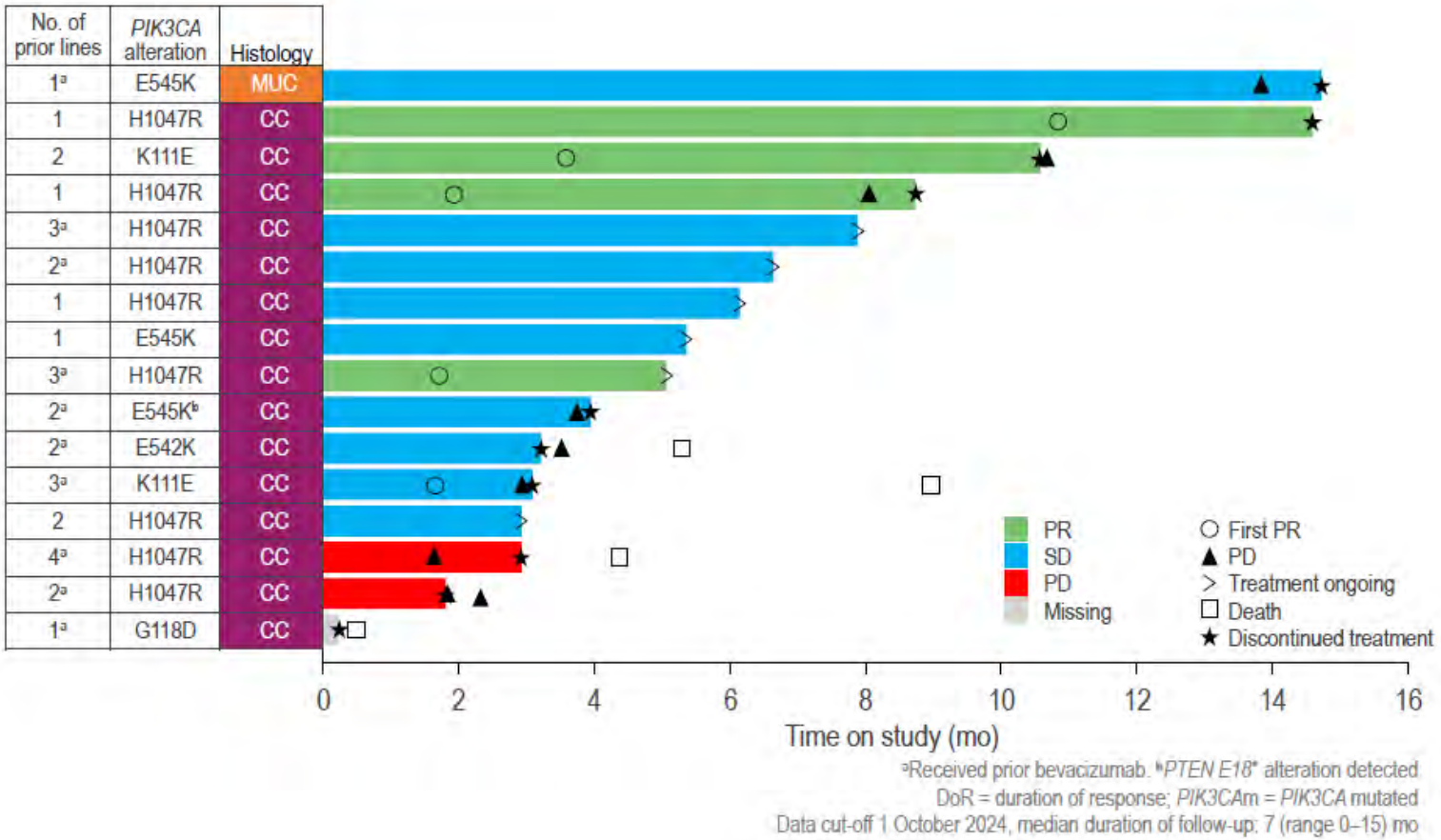
Ovarian Clear Cell Carcinoma: Inavolisib + palbociclib in PIK3CAm (BOUQUET Trial)

- 94% CC, 75% 1–2 prior lines, 63% prior bevacizumab
- Median treatment duration: 5.2 mo inavolisib, 5.1 mo palbociclib
  - 6 patients still on treatment

Endpoint (95% CI)	n=16
cORR	25% (7–52)
Median DoR, mo	6.6 (6.1–NE)
DCR	63% (35–85)
Median PFS, mo	8.0 (3.5–NE)
6-mo PFS rate	63% (39–86)



[a]Received prior bevacizumab. [b]*PTEN E18** alteration detected
DoR = duration of response; *PIK3CAm* = *PIK3CA* mutated
Data cut-off 1 October 2024, median duration of follow-up: 7 (range 0–15) mo

Ray-Coquard et al. ESMO Gyne 2025

LGSOC: Avutometinib + Defactinib
RAMP 201

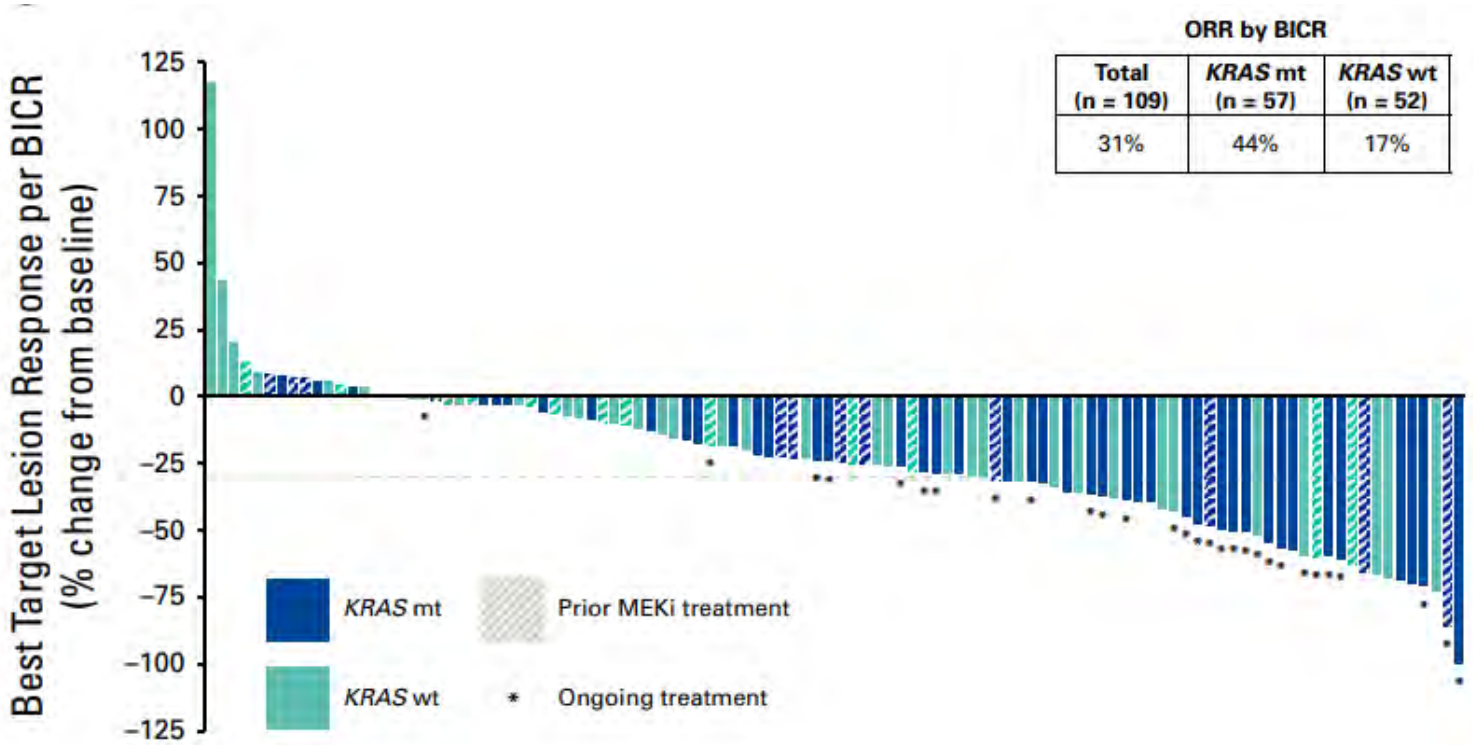
News | Article | May 8, 2025

FDA Approves Avutometinib Plus Defactinib for KRAS-Mutated Recurrent Low-Grade Serous Ovarian Cancer

Author(s): Kristi Rosa

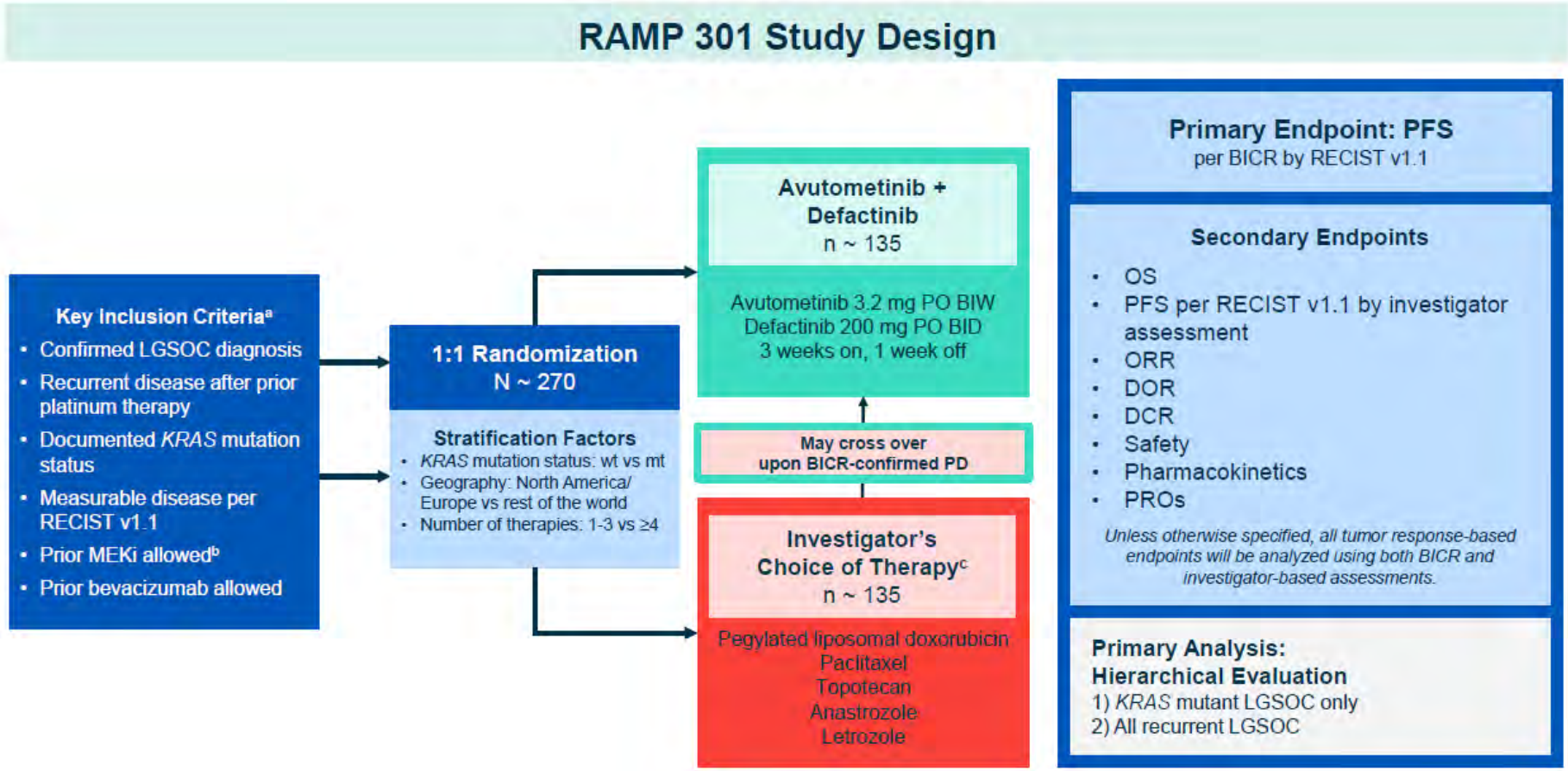
ORR by BICR

Total (n = 109)	*KRAS* mt (n = 57)	*KRAS* wt (n = 52)
31%	44%	17%



Banerjee SN et al. J Clin Oncol July 2025

LGSOC: Avutometinib + Defactinib
RAMP 301



Grisham R et al. SGO 2025 TIPs

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Panel Discussion and Audience Q&A

GOG Highlight Reel

Final Comments, Future Perspectives and Announcement of the Winter 2026 GOG Highlight Reel

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Participants who complete the educational activity, pre- and post-test, and evaluation will receive a certificate of credit.

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