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# Interactive ADC Discussion

## *All Faculty*

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# New Advancements in Ovarian Cancer, Understanding Treatment Opportunities

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The Ohio State University, Columbus, OH

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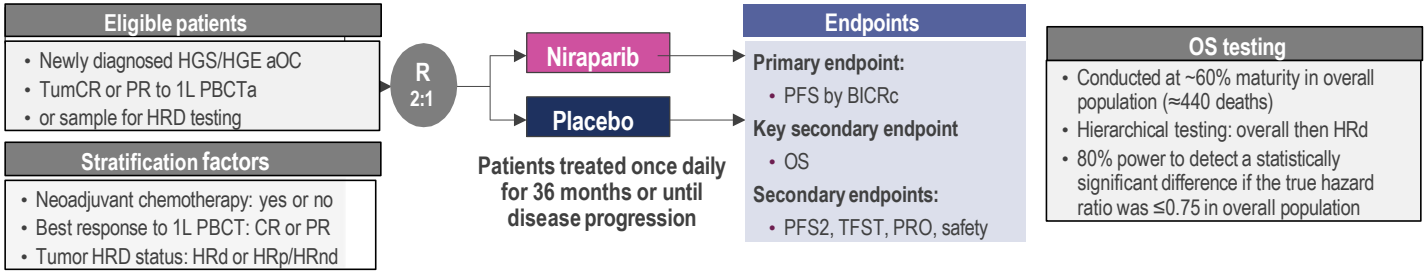
# PRIMA/ENGOT-OV26/GOG-3012 Trial of Niraparib 1L Maintenance

***Phase 3 PRIMA trial enrolled patients with newly diagnosed aOC at a high risk for disease recurrence***




**Disease stage**

**35.1%** stage IV disease at diagnosis

**Initial treatment**

**66.7%** received neoadjuvant chemotherapy

**30.6%** achieved partial response to 1L PBCT

**Residual disease**

**>99%** stage III disease at diagnosis with residual disease after primary debulking surgery

**47.5%** postoperative visible residual disease or no debulking surgery

**Tumor HRD/*BRCA* status**

**50.9%** HRd

**30.4%** HRd/*BRCA*m

**34.0%** HRp

NCT02655016

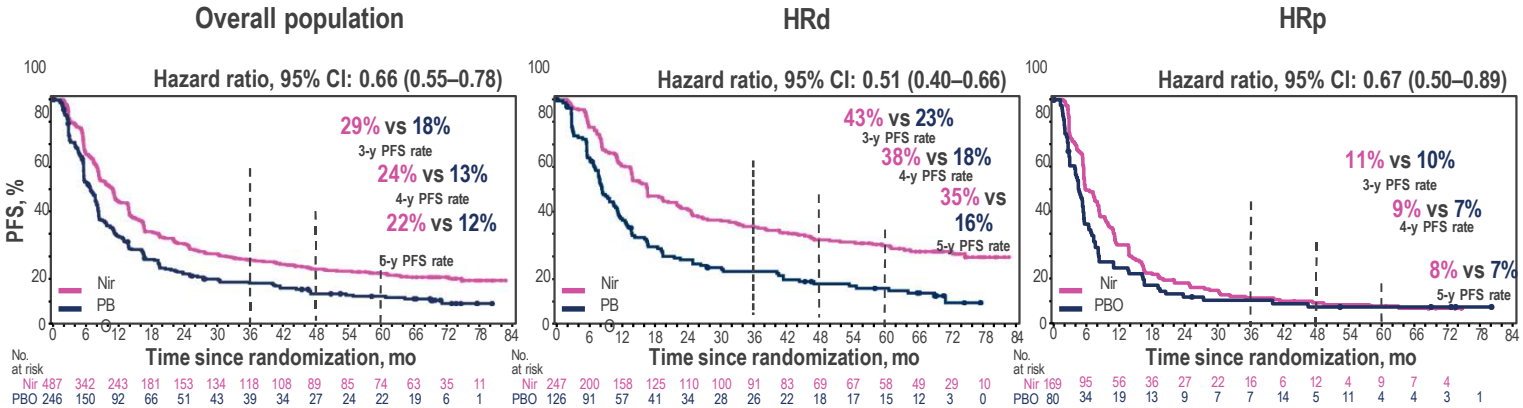


González-Martín A, et al. Presented at European Society for Medical Oncology (ESMO) Annual Meeting; 13-17 September 2024; Barcelona, Spain.

# PRIMA/ENGOT-OV26/GOG-3012 Trial of Niraparib 1L Maintenance *cont.*

***Updated long-term PFS (ad hoc, Investigator-assessed)[a,b]***

Niraparib PFS benefit sustained with additional follow-up in the overall and HRd populations




- Data cutoff date, 8 April 2024; median follow-up, 6.2 years
- Among patients alive at 5 years in the HRd population, patients who received niraparib were twice as likely to be progression free (35%) than patients who received placebo (16%)
- Delaying progression is critical to maintain health-related quality of life[1]

**NCT02655016**

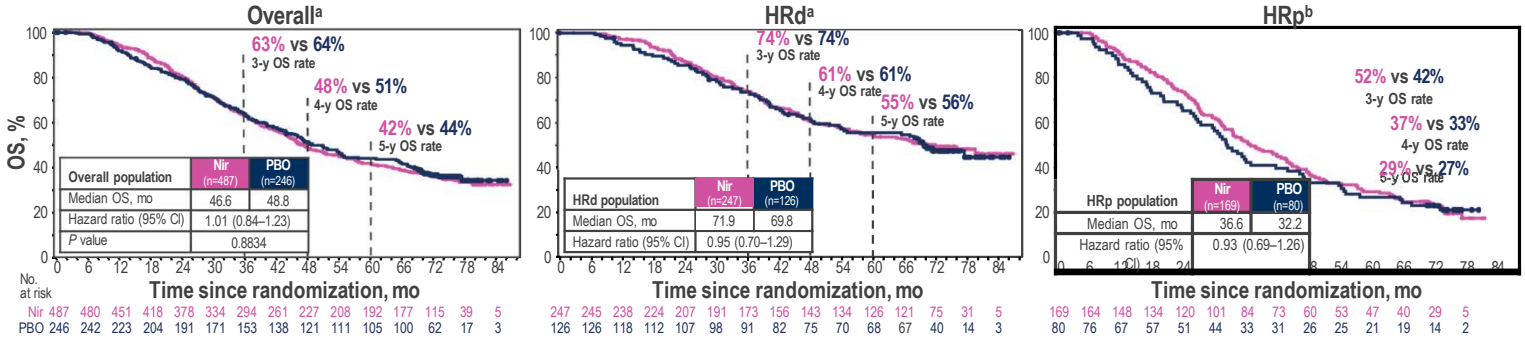
aAt study start, patients were monitored for disease progression (CT/MRI) every 12 weeks (3 cycles); in August 2019, the protocol was amended to monitor patients who stayed on study treatment for more than 2 years for disease progression every 24 weeks (6 cycles).
bPFS hazard ratios and associated 95% CI calculated using stratified Cox proportional hazards model. For all analyses, stratification factors were those used in randomization. CT, computed tomography; HRd, homologous recombination deficient; HRp, homologous recombination proficient; MRI, magnetic resonance imaging; Nir, niraparib; PBO, placebo; PFS, progression-free survival.

1. Chase DM, et al. *Gynecol Oncol*. 2022;166(3):494–502.
2. González-Martín A, et al. Presented at European Society for Medical Oncology (ESMO) Annual Meeting; 13-17 September 2024; Barcelona, Spain.

# PRIMA/ENGOT-OV26/GOG-3012 Trial of Niraparib 1L Maintenance *cont.*

***Final OS (62.5% maturity in overall population)***

No difference in OS between niraparib and placebo arms in the overall, HRd, and HRp populations




- OS results for all prespecified biomarker-defined subgroups consistent with overall population[c]
- Assessment of long-term efficacy outcomes in high-risk aOC may be complicated by multiple factors[1]
  - Patient population[2–4]
  - Extended postprogression survival[1,5]
  - Subsequent therapy[1,5]

**NCT02655016**

aHazard ratios and 95% CIs for overall and HRd populations calculated using stratified Cox proportional hazards model with randomization stratification factors. bHazard ratio and 95% CI for HRp population calculated using unstratified Cox proportional hazards model. cOS results for the HRnd population (unstratified): hazard ratio (95% CI), 1.39 (0.88–2.19). aOC, advanced ovarian cancer; HRd, homologous recombination deficient; HRnd, homologous recombination status not determined; HRp, homologous recombination proficient; OS, overall survival; Nir, niraparib; PBO, placebo.

1. Matulonis UA, et al. *Cancer*. 2015;121(11):1737–1746.; 2. Siegel RL, et al. *CA Cancer J Clin*. 2024;74(1):12–49.; 3. Elattar A, et al. *Cochrane Database Syst Rev*. 2011;201(8):CD007565.; 4. Sun C, et al. *PLoS One*. 2014;9(5):e95285.; 5. Delgado A, et al. *Am J Cancer Res*. 2021;11(4):1121–1131.; 6. González-Martín A, et al. Presented at European Society for Medical Oncology (ESMO) Annual Meeting; 13-17 September 2024; Barcelona, Spain.

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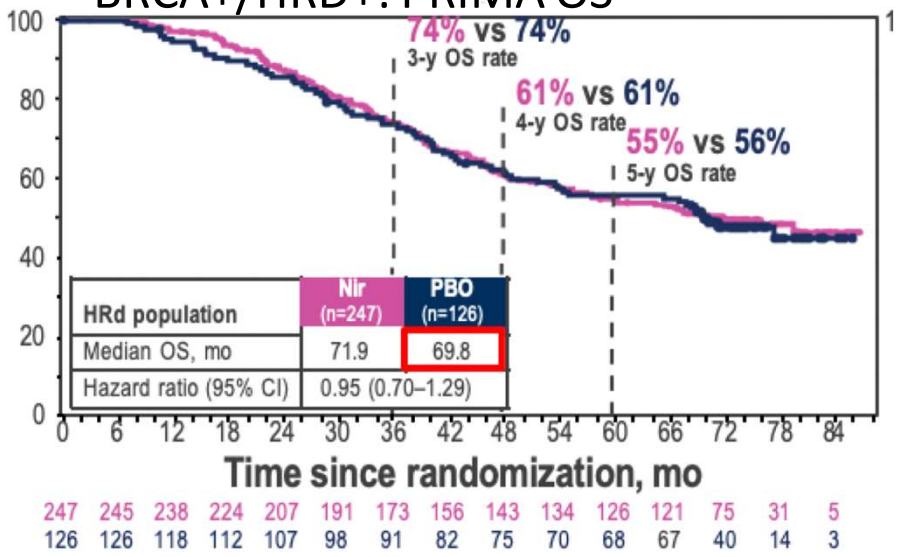
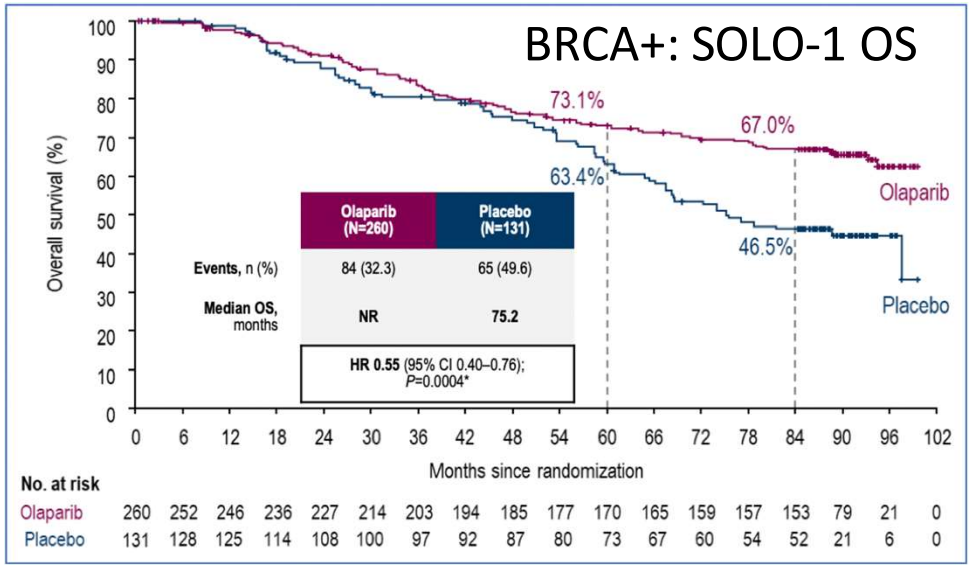
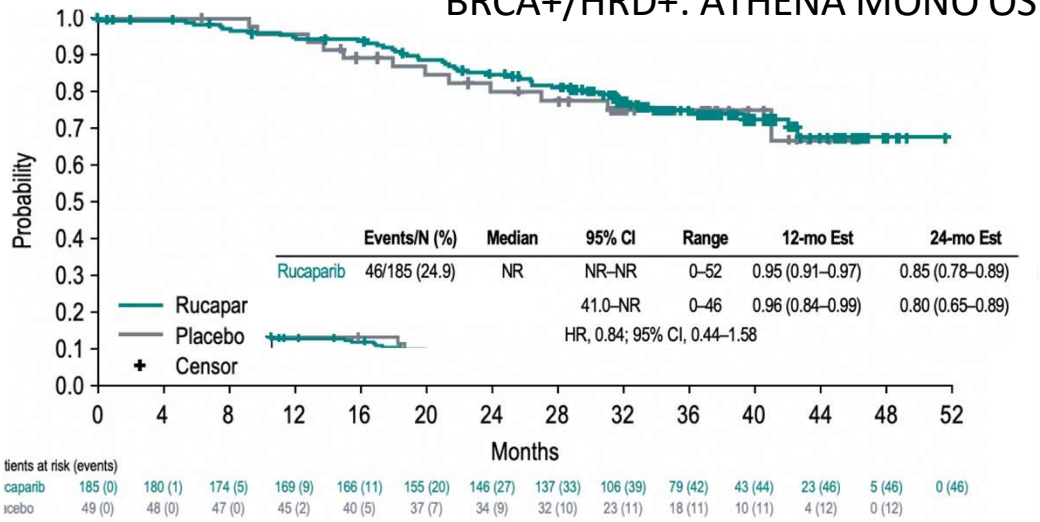
## BRCA+/HRD+: PRIMA OS



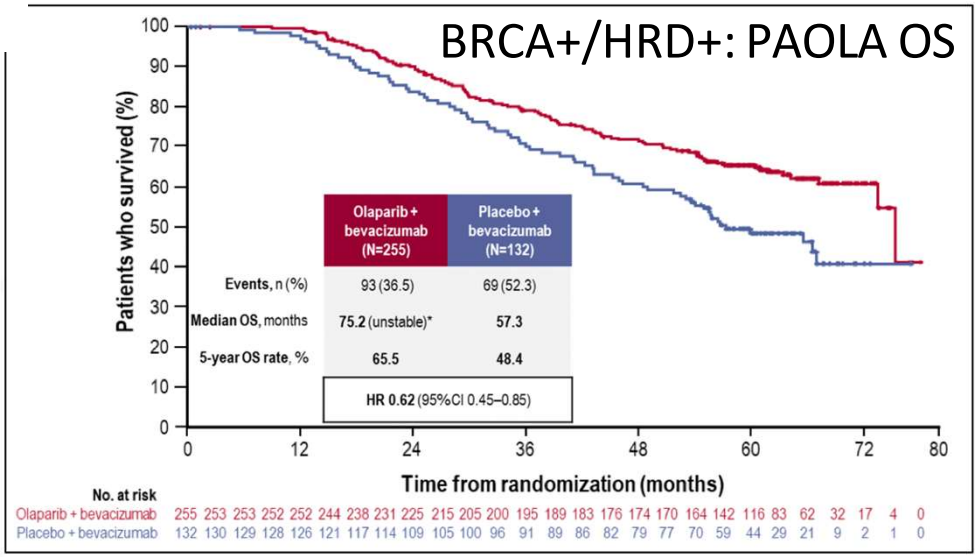

## BRCA+: SOLO-1 OS




## BRCA+/HRD+: ATHENA MONO OS

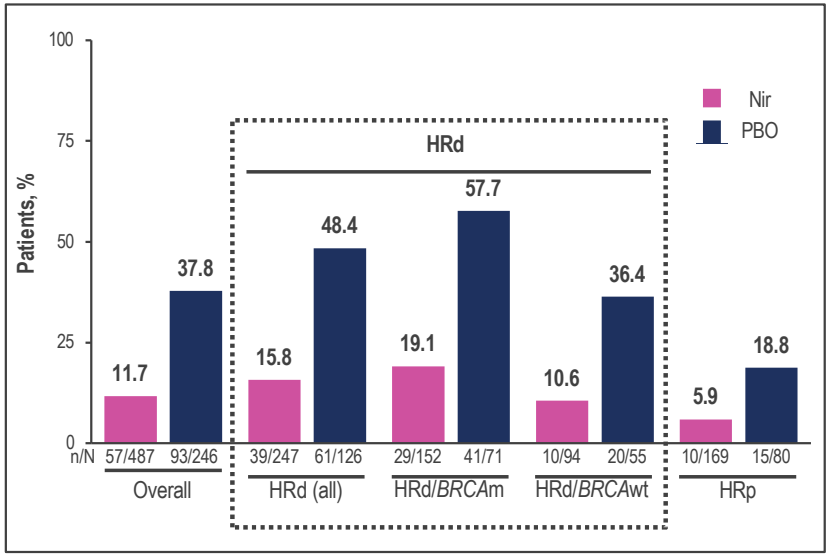



## BRCA+/HRD+: PAOLA OS



# PRIMA/ENGOT-OV26/GOG-3012 Trial of Niraparib 1L Maintenance *cont.*

## *3-fold Higher Subsequent PARPi Use In Placebo Arm Than Niraparib Arm Across Populations*




**Subsequent PARP inhibitor use:**

- Most predominant in HRd population, with highest use in HRd/*BRCA*m population
- Most patients initiated in the 2L setting

| Any subsequent PARP inhibitor by treatment line, %[a] | Overall | | HRd | |
|---|---|---|---|---|
| | Nir (n=487) | PBO (n=246) | Nir (n=247) | PBO (n=126) |
| Any treatment line | 11.7 | 37.8 | 15.8 | 48.4 |
| 2L | 8.2 | 30.5 | 13.0 | 37.3 |
| 3L+ | 3.5 | 7.3 | 2.8 | 11.1 |

[a]Percentages calculated out of the total number of patients in each population, not the number of patients who experienced disease progression. 2L, second-line; 3L+, third-line and beyond; *BRCA*m, *BRCA*-mutated; *BRCA*wt, *BRCA* wild-type; HRd, homologous recombination deficient; HRp, homologous recombination proficient; Nir, niraparib; PARP, poly(ADP-ribose) polymerase; PBO, placebo.

NCT02655016



González-Martín A, et al. Presented at European Society for Medical Oncology (ESMO) Annual Meeting; 13-17 September 2024; Barcelona, Spain.

# Subsequent PARPi?

| Trial | Placebo | PARPi |
|---|---|---|
| **SOLO1/GOG-3004** | 44.3 | 14.6 |
| **PAOLA** | 45.7 | 19.6 |
| **PRIMA/GOG-3012** | 37.8<br>BRCA+: 57.7 | 11.7<br>BRCA+: 19.1 |
| **ATHENA/GOG-3020** | Not reported | Not reported |



*Slide Courtesy Philipp Harter*

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# Up Front Therapy in Ovarian Cancer

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# ATHENA/GOG-3020 Study Schema

## Key Patient Eligibility

- Newly diagnosed, stage III–IV, advanced, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer
- Completed frontline platinum-doublet chemotherapy and surgery
  - Achieved investigator-assessed CR or PR
  - Received cytoreductive surgery (primary or interval; complete resection permitted)
- ECOG PS 0 or 1
- No prior frontline maintenance treatment for ovarian cancer

## Randomization 4:4:1:1

**Arm A (n≈400)**
**rucaparib 600 mg BID PO + nivolumab 480 mg IV**

**Arm B (n≈400)**
**rucaparib 600 mg BID PO + placebo IV**

Arm C (n≈100)
placebo PO + nivolumab 480 mg IV

Arm D (n≈100)
placebo PO + placebo IV

**Randomization Stratification Factors**

- Tumor HRD test status[a]
- Disease status post-chemotherapy
- Timing of surgery

Treatment for 24 months,[b] with a 4-week lead-in of rucaparib; study drugs could be discontinued independently

## Study Analyses

**ATHENA-COMBO**

**Arm A (n≈400)**
rucaparib 600 mg BID PO + nivolumab 480 mg IV

**Arm B (n≈400)**
rucaparib 600 mg BID PO + placebo IV

**ATHENA-MONO**

**Arm B (n≈400)**
rucaparib 600 mg BID PO + placebo IV

**Arm D (n≈100)**
placebo PO + placebo IV

**Primary endpoint: Investigator-assessed PFS in the ITT population**

NCT03522246

NCT03522246. [a]Centrally assessed, determined by FoundationOne CDx next-generation sequencing assay (BRCA mutation, BRCA wild-type/LOH high [LOH ≥16%], BRCA wild-type/LOH low [LOH <16%], BRCA wild-type/LOH indeterminate). [b]Treatment for 24 months or until radiographic progression, unacceptable toxicity, or other reason for discontinuation. IV placebo was intended to commence on Day 1 of Cycle 2 and treatment cap defined as 24 months after the start of IV placebo; 28-day cycles.
BID, twice daily; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; HRD, homologous recombination deficiency; ITT, intent-to-treat; IV, intravenous; LOH, loss of heterozygosity; PFS, progression-free survival; PO, by mouth; PR, partial response.
Monk B, et al. Presented at European Society for Medical Oncology (ESMO) Annual Meeting; 13-17 September 2024; Barcelona, Spain.

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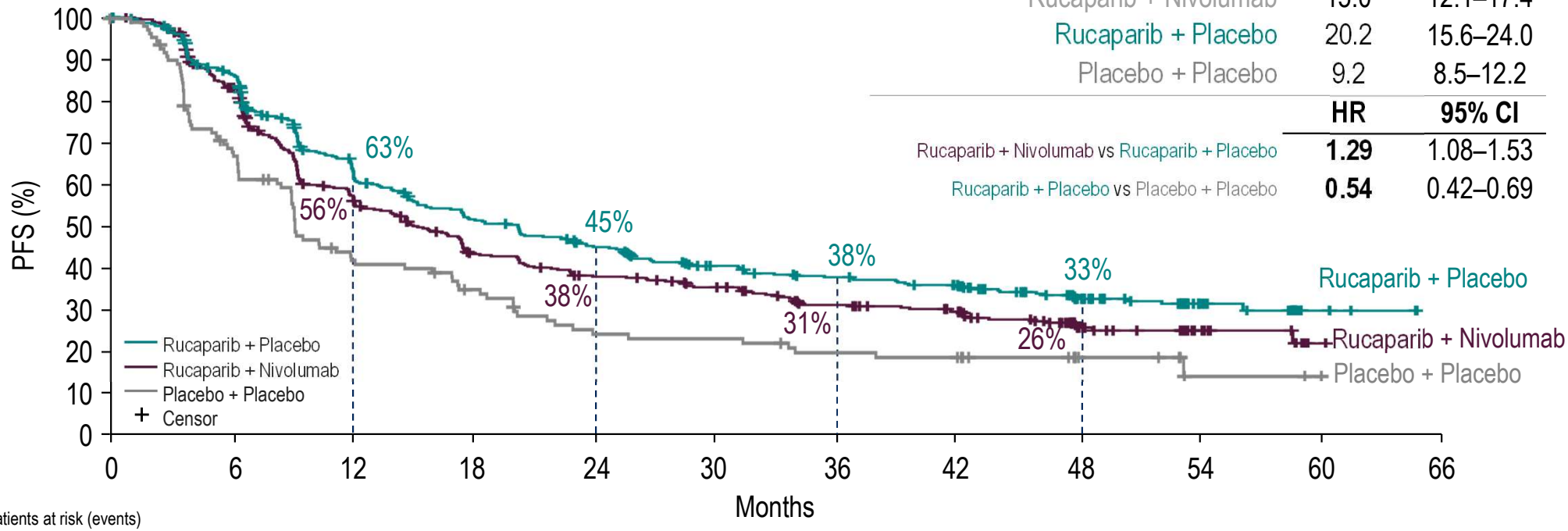
# ATHENA-Combo: Investigator Assessed PFS *(ITT)*

| | Median | 95% CI |
|---|---|---|
| Rucaparib + Nivolumab | 15.0 | 12.1–17.4 |
| Rucaparib + Placebo | 20.2 | 15.6–24.0 |
| Placebo + Placebo | 9.2 | 8.5–12.2 |
| | **HR** | **95% CI** |
| Rucaparib + Nivolumab vs Rucaparib + Placebo | **1.29** | 1.08–1.53 |
| Rucaparib + Placebo vs Placebo + Placebo | **0.54** | 0.42–0.69 |




Patients at risk (events)

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ruca+Nivo | 436 (0) | 333 (69) | 218 (174) | 159 (224) | 136 (244) | 122 (253) | 98 (267) | 87 (272) | 44 (280) | 14 (282) | 1 (283) | 0 (283) |
| Ruca+Plac | 427 (0) | 352 (57) | 246 (149) | 197 (193) | 166 (218) | 136 (234) | 123 (243) | 113 (249) | 68 (258) | 24 (260) | 4 (261) | 0 (261) |
| Plac+Plac | 111 (0) | 73 (34) | 43 (61) | 33 (69) | 23 (78) | 21 (80) | 17 (83) | 16 (84) | 8 (84) | 2 (85) | 1 (85) | 0 (85) |

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Data cutoff date: May 17, 2024.
CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; Nivo, nivolumab; PFS, progression-free survival; Plac, placebo; Ruca, rucaparib.
Monk B, et al. Presented at European Society for Medical Oncology (ESMO) Annual Meeting; 13-17 September 2024; Barcelona, Spain.

NCT03522246

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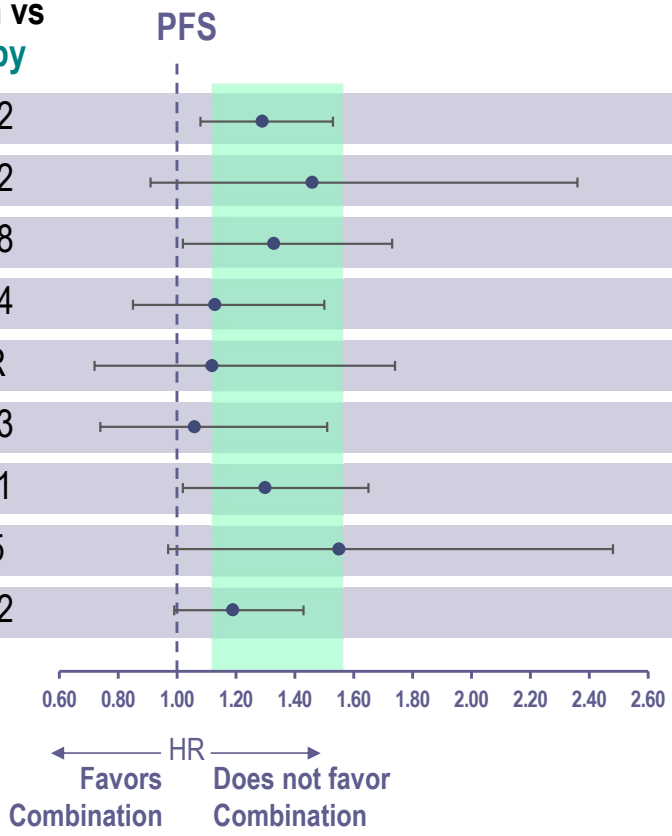
# ATHENA-Combo: Investigator Assessed PFS *(Exploratory Subgroups)*

| Population | Rucaparib + Nivolumab (n) | Rucaparib + Placebo (n) | Median, months Combination vs Monotherapy | HR (95% CI) |
|---|---|---|---|---|
| ITT | 436 | 427 | 15.0 vs 20.2 | 1.3 (1.1–1.5) |
| PD-L1 ≥5% | 69 | 72 | 22.8 vs 52.2 | 1.5 (0.9–2.4) |
| PD-L1 ≥1% | 199 | 197 | 18.3 vs 25.8 | 1.3 (1.0–1.7) |
| HRD | 193 | 185 | 28.9 vs 31.4 | 1.1 (0.9–1.5) |
| **BRCA mutation** | 94 | 91 | 48.0 vs NR | 1.1 (0.7–1.7) |
| **BRCA wild-type/LOH$^{high}$** | 99 | 94 | 17.3 vs 22.3 | 1.1 (0.7–1.5) |
| **BRCA wild-type/LOH$^{low}$** | 188 | 189 | 11.0 vs 12.1 | 1.3 (1.0–1.7) |
| **BRCA wild-type/LOH$^{indeterminate}$** | 55 | 53 | 9.2 vs 17.5 | 1.6 (1.0–2.5) |
| No BRCA mutation | 357 | 336 | 12.1 vs 15.2 | 1.2 (1.0–1.4) |




Data cutoff: May 17, 2024.
Populations in bold are stratification factors.
BRCA wild-type/LOH high (LOH cutoff, ≥16%), BRCA wild-type/LOH low (LOH cutoff, <16%).
BRCA, BRCA1 or BRCA2; CI, confidence interval; HR, hazard ratio; HRD, homologous recombination deficiency; ITT, intent-to-treat; LOH, loss of heterozygosity; NR, not reached; PD-L1, programmed death-ligand 1; PFS, progression-free survival.
Monk B, et al. Presented at European Society for Medical Oncology (ESMO) Annual Meeting; 13-17 September 2024; Barcelona, Spain.

NCT03522246

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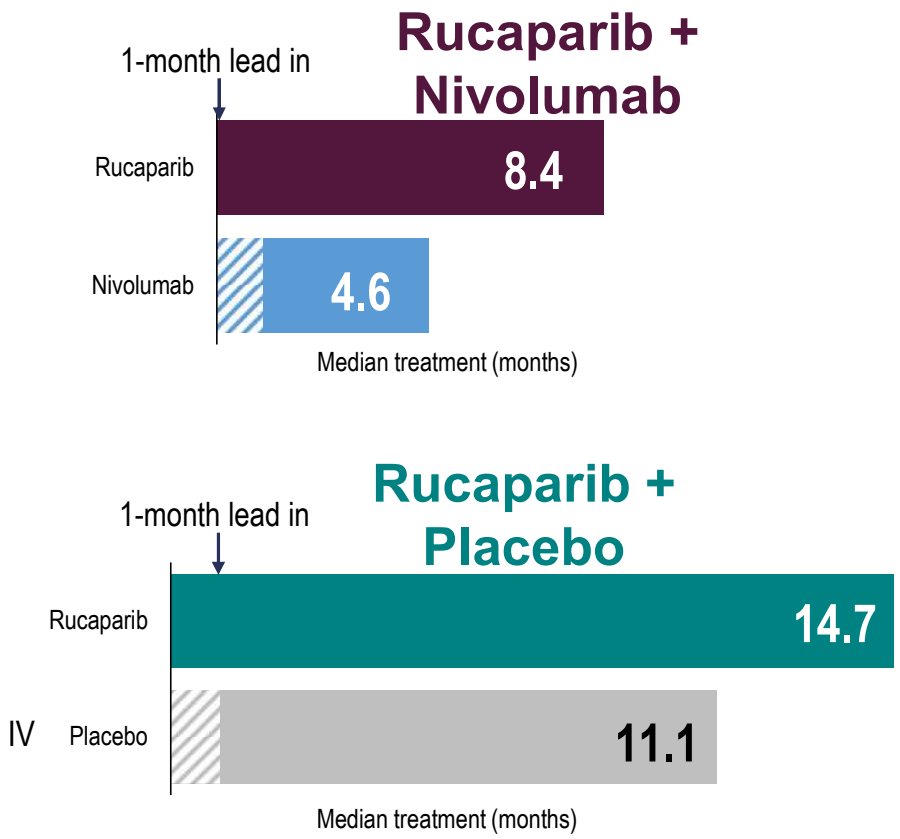
# ATHENA-Combo: Treatment Exposure in Efficacy (ITT)




- Patients in the **rucaparib + placebo** arm had 43% longer exposure to rucaparib than those in the rucaparib + nivolumab arm

- Median relative dose intensity of rucaparib:
  - **Rucaparib + nivolumab = 0.84**
  - **Rucaparib + placebo = 0.89**

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Relative dose intensity = last dose − first dose.
ITT, intent-to-treat; IV, intravenous.
Monk B, et al. Presented at European Society for Medical Oncology (ESMO) Annual Meeting; 13-17 September 2024; Barcelona, Spain.

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# Right When You Thought IO Was Done in 1L OC…

**FIRST Study Design**

20 December 2024

Issued: London, UK

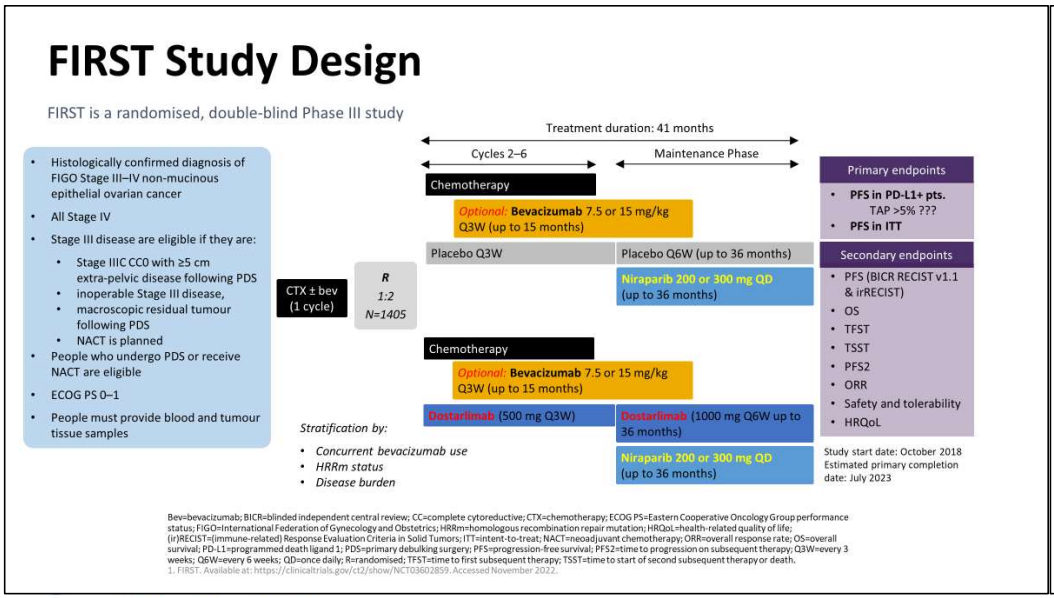
For media and investors only

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

**KEYLYNK-001 Study Design | non-BRCAm**

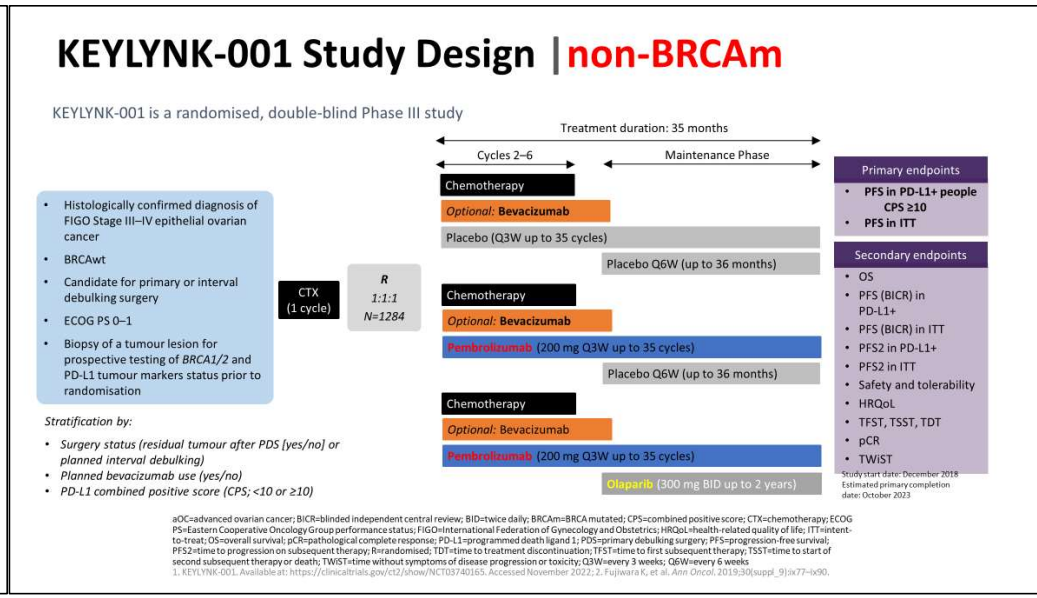
Merck Announces Phase 3 KEYLYNK-001 Trial Met Primary Endpoint of Progression-Free Survival (PFS) in Patients With Advanced Epithelial Ovarian Cancer

December 9, 2024 6:45 am ET




Bev=bevacizumab; BICR=blinded independent central review; CC=complete cytoreductive; CTX=chemotherapy; ECOG PS=Eastern Cooperative Oncology Group performance status; FIGO=International Federation of Gynecology and Obstetrics; HRRm=homologous recombination repair mutation; HRQoL=health-related quality of life; (ir)RECIST=(immune-related) Response Evaluation Criteria in Solid Tumors; ITT=intent-to-treat; NACT=neoadjuvant chemotherapy; ORR=overall response rate; OS=overall survival; PD-L1=programmed death ligand 1; PDS=primary debulking surgery; PFS=progression-free survival; PFS2=time to progression on subsequent therapy; Q3W=every 3 weeks; Q6W=every 6 weeks; QD=once daily; R=randomised; TFST=time to first subsequent therapy; TSST=time to start of second subsequent therapy or death.

1. FIRST. Available at: https://clinicaltrials.gov/ct2/show/NCT03602859. Accessed November 2022.




aOC=advanced ovarian cancer; BICR=blinded independent central review; BID=twice daily; BRCAm=BRCA mutated; CPS=combined positive score; CTX=chemotherapy; ECOG PS=Eastern Cooperative Oncology Group performance status; FIGO=International Federation of Gynecology and Obstetrics; HRQoL=health-related quality of life; ITT=intent-to-treat; OS=overall survival; pCR=pathological complete response; PD-L1=programmed death ligand 1; PDS=primary debulking surgery; PFS=progression-free survival; PFS2=time to progression on subsequent therapy; R=randomised; TDT=time to treatment discontinuation; TFST=time to first subsequent therapy; TSST=time to start of second subsequent therapy or death; TWiST=time without symptoms of disease progression or toxicity; Q3W=every 3 weeks; Q6W=every 6 weeks

1. KEYLYNK-001. Available at: https://clinicaltrials.gov/ct2/show/NCT03740165. Accessed November 2022; 2. Fujiwara K, et al. *Ann Oncol*. 2019;30(suppl_9):ix77–ix90.

# PICCOLO (NCT05041257) – Study Design[1-3]

**A single-arm, open-label, phase 2 trial of MIRV in patients with ≥3L platinum-sensitive ovarian cancer with FRα-high expression**

## PICCOLO Patient Population (N=79)

**Enrollment and Key Eligibility**

- Platinum-sensitive disease (defined as radiographic progression >6 months from last dose of most recent platinum therapy)
- FRα detected by IHC with PS2+ intensity among ≥75% of viable tumor cells[a]
- At least 2 prior platinum-containing regimens[b]
- Prior PARPi required if *BRCA*+
- Prior BEV not required
- Appropriate for single-agent therapy

## Treatment Regimen

**MIRV**
(6 mg/kg AIBW Q3W)

## Primary Endpoint

ORR by INV

## Key Secondary Endpoint

DOR by INV

## Other Secondary Endpoints

- Safety and tolerability
- CA-125 response (GCIG criteria)
- PFS
- OS
- Sensitivity analyses[c]

[a]FRα expression measured by the VENTANA FOLR1 (FOLR1-2.1 RxDx) Assay. [b]1 prior line if documented platinum allergy. [c]ORR, DOR, and PFS by BICR will be summarized as sensitivity analyses.

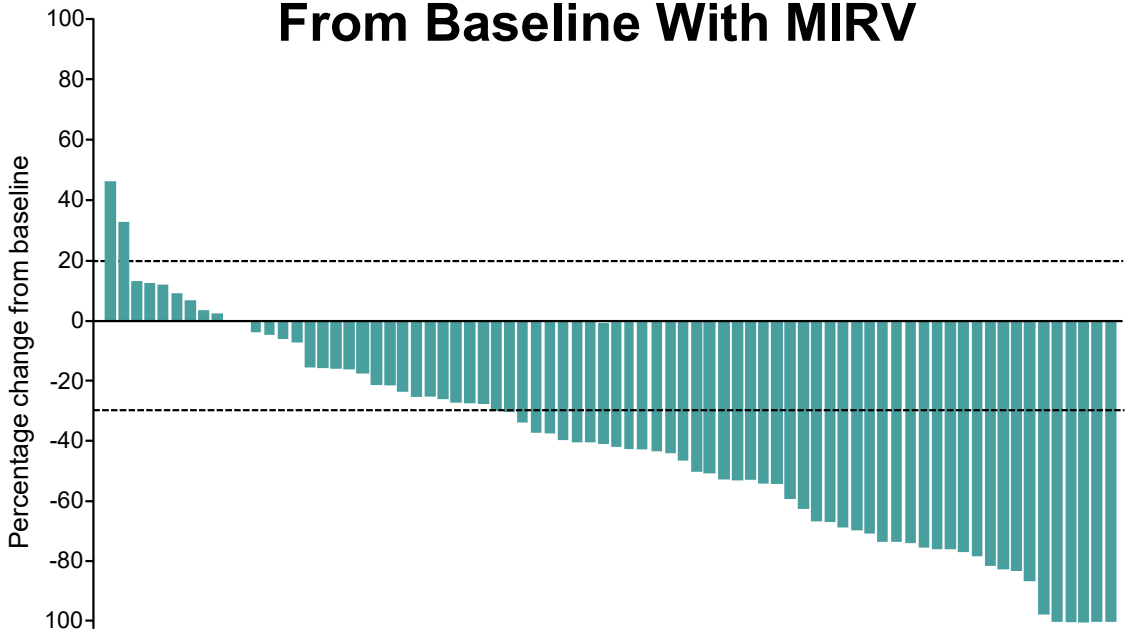
3L, third-line; AIBW, adjusted ideal body weight; BEV, bevacizumab; BICR, blinded independent central review; *BRCA*, BReast CAncer gene; CA-125, cancer antigen 125; DOR, duration of response; FRα, folate receptor alpha; GCIG, Gynecological Cancer InterGroup; IHC, immunohistochemistry; INV, investigator; MIRV, mirvetuximab soravtansine-gynx; ORR, objective response rate; OS, overall survival; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitor; PFS, progression-free survival; PS2+, positive staining intensity ≥2; Q3W, every 3 weeks.

1. ClinicalTrials.gov identifier: NCT05041257. Updated April 22, 2024. Accessed July 29, 2024.; 2. Alvarez Secord A, et al. Poster presented at: International Gynecologic Cancer Society (IGCS) Annual Global Meeting; 29 September-1 October 2022; New York City, NY USA [Abstract 1556]. 3. Alvarez Secord A, et al. Poster presented at: Society of Gynecologic Oncology's (SGO) Annual Meeting on Women's Cancer; 18-21 March,2022; Phoenix, AZ USA. [Abstract 300].

# Investigator Assessed Efficacy Measures

NCT05041257

## Maximum Tumor Percentage Change From Baseline With MIRV




**Median time to response was 1.58 months**
**Median number of treatment cycles was 9 (range, 1 to 27)**

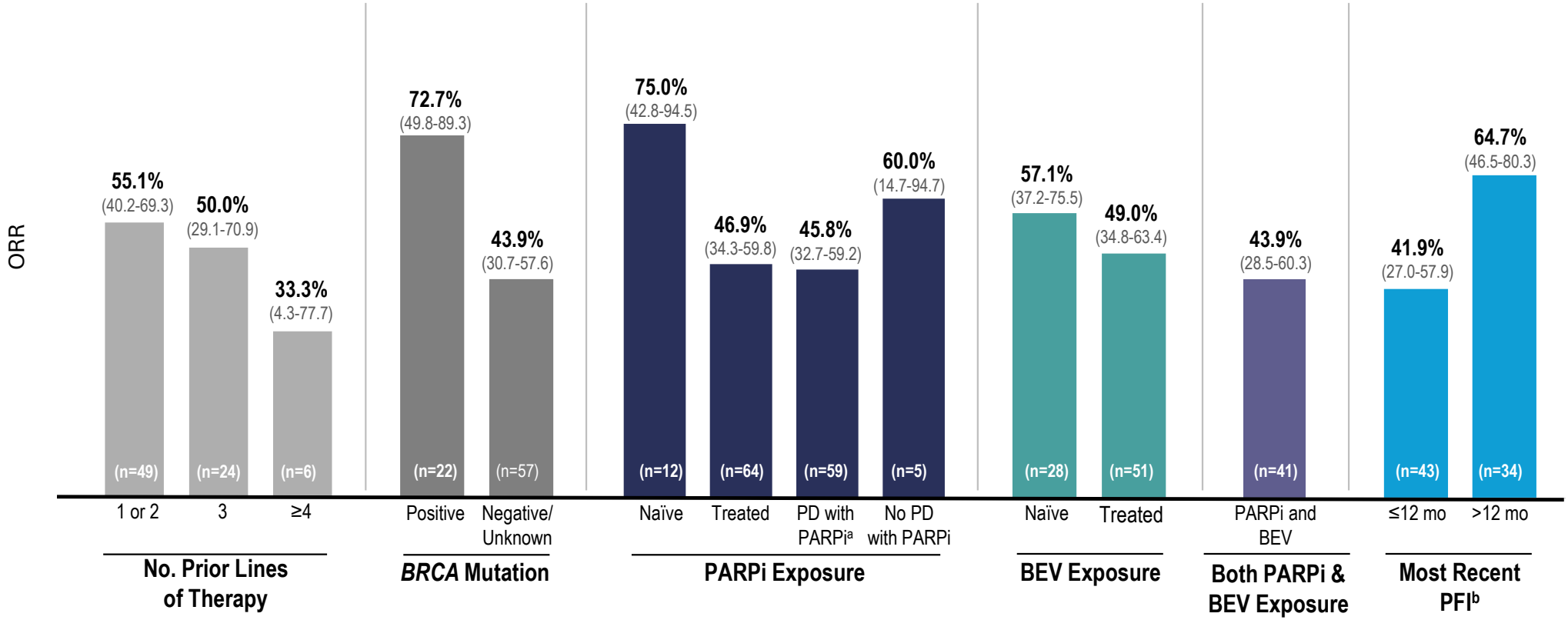
| Primary Endpoint | N=79 |
|---|---|
| **ORR, n (%)**<br>95% CI | 41 (51.9)<br>40.4-63.3 |
| **Best overall response, n (%)** | |
| CR | 6 (7.6) |
| PR | 35 (44.3) |
| SD | 29 (36.7) |
| PD | 7 (8.9) |
| Not evaluable | 2 (2.5) |

| Secondary Endpoints | |
|---|---|
| **Median DOR[a]** | n=41 |
| Months (95% CI) | 8.25 (5.55-10.78) |
| **Median PFS** | N=79 |
| Months (95% CI) | 6.93 (5.85-9.59) |
| **CA-125 response[b]** | n=47 |
| n (%) | 35 (74.5) |
| 95% CI | 59.7-86.1 |

Data cutoff: January 17, 2024.
aCalculated among participants who had a complete or partial response. bAnalysis performed on the CA-125–evaluable population.
CA-125, cancer antigen 125; CI, confidence interval; CR, complete response; DOR, duration of response; MIRV, mirvetuximab soravtansine-gynx; ORR, objective response rate; PFS, progression-free survival; PD, progressive disease; PR, partial response; SD, stable disease.
1. ClinicalTrials.gov identifier: NCT05041257. Updated April 22, 2024. Accessed July 29, 2024.; 2. Alvarez Secord A, et al. Poster presented at: International Gynecologic Cancer Society (IGCS) Annual Global Meeting; 29 September-1 October 2022; New York City, NY USA [Abstract 1556]. 3. Alvarez Secord A, et al. Poster presented at: Society of Gynecologic Oncology's (SGO) Annual Meeting on Women's Cancer; 18-21 March,2022; Phoenix, AZ USA. [Abstract 300].

# ORR by Subgroups

## Total Population ORR: 51.9% (95% CI, 40.4-63.3)




NCT05041257

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Data cutoff: January 17, 2024. ORR presented with 95% CI.
[a]If the participant had progression of disease within 30 days after the last dosing of a PARPi or progression was listed as the reason for treatment discontinuation of a PARPi, the participant was defined as having progressive disease on prior PARPi and was included in this category. [b]Platinum-free interval is defined as time from last dose of the latest line platinum therapy to the date of disease progression and/or relapse following that line of therapy (time rounded to whole number).
BEV, bevacizumab; BRCA, Breast Cancer gene; CI, confidence interval; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitor; PD, progressive disease; PFI, platinum-free interval; ORR, objective response rate.

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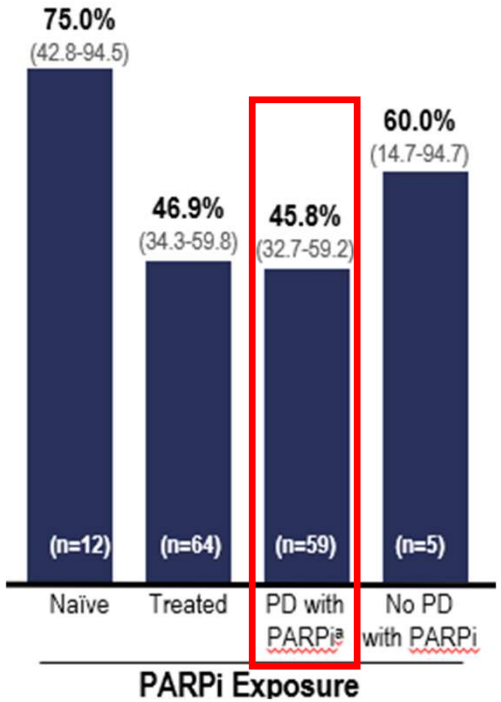
# ORR by Subgroups *cont.*

**Total Population ORR: 51.9% (95% CI, 40.4-63.3)**




| Exposure to PARPis | Median DOR months (95% CI) |
|---|---|
| Naïve | 8.8 (3.5-NR) |
| Treated | 8.3 (5.5-10.8) |
| PD with PARPi[a] | 7.3 (5.0-10.8) |
| No PD with PARPi | 8.4 (7.0-NR) |

NCT05041257

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Data cutoff: January 17, 2024. ORR presented with 95% CI.
a. If the participant had progression of disease within 30 days after the last dosing of a PARPi or progression was listed as the reason for treatment discontinuation of a PARPi, the participant was defined as having progressive disease on prior PARPi and was included in this category.; b. Platinum-free interval is defined as time from last dose of the latest line platinum therapy to the date of disease progression and/or relapse following that line of therapy (time rounded to whole number).
CI, confidence interval; DOR, duration of response; PARPi, poly (adenosine diphosphate [ADP]-ribose) polymerase inhibitor; PD, progressive disease; ORR, objective response rate.

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# GOG Partners Phase III Portfolio: Front Line, PSOC, LGSOC

| | Trial | Phase | Regimen | Prior total Therapies | End point | Tumor testing/ Prevalence |
|---|---|---|---|---|---|---|
| Front-Line | GOG-3068 (HOTT) | 3 | HIPEC vs no HIPEC followed by Niraparib maintenance | 0 | PFS | HRD |
| | GOG-3102 | 3 | TBD | 0 | | |
| | GOG 3112 | 3 | TBD | 0 | | |
| PSOC | GOG-3078 (GLORIOSA) | 3 | Bevacizumab +/- mirvetuximab as maintenance following bev-containing plat therapy | 1 | PFS | Frα |
| | GOG-3103 | 3 | TBD | 1 | | |
| | GOG-3106 | 3 | TBD | 1 | | |
| LGSOC | GOG-3097 (RAMP 301) | 3 | VS-6766 + FAKi in recurrent LGSC vs SOC | Unlimited | PFS | KRAS |

# CHIPOR trial (NCT01376752): Multicenter Randomized Phase III Trial

Median laparotomy
Complete resection

- First relapse of epithelial ovarian cancer
- PFI ≥6 months
- Response to 6 cycles of platinum-based chemotherapy
- Complete surgery achievable

N=415

SURGERY

**Randomization during surgery**

**CC0/1**

R 1:1

**HIPEC**
(cisplatin 75 mg/m$^2$ 41ºC for 60 min)
**n=207**

**No HIPEC**
**n=208**

**SOC maintenance therapy**

**Stratification:**
- **Center**
- **Residual disease (none vs <0.25 cm)**
- **PFI (6–12 vs >12–18 vs >18 months)**
- **Planned PARP inhibitor (yes vs no)[a]**

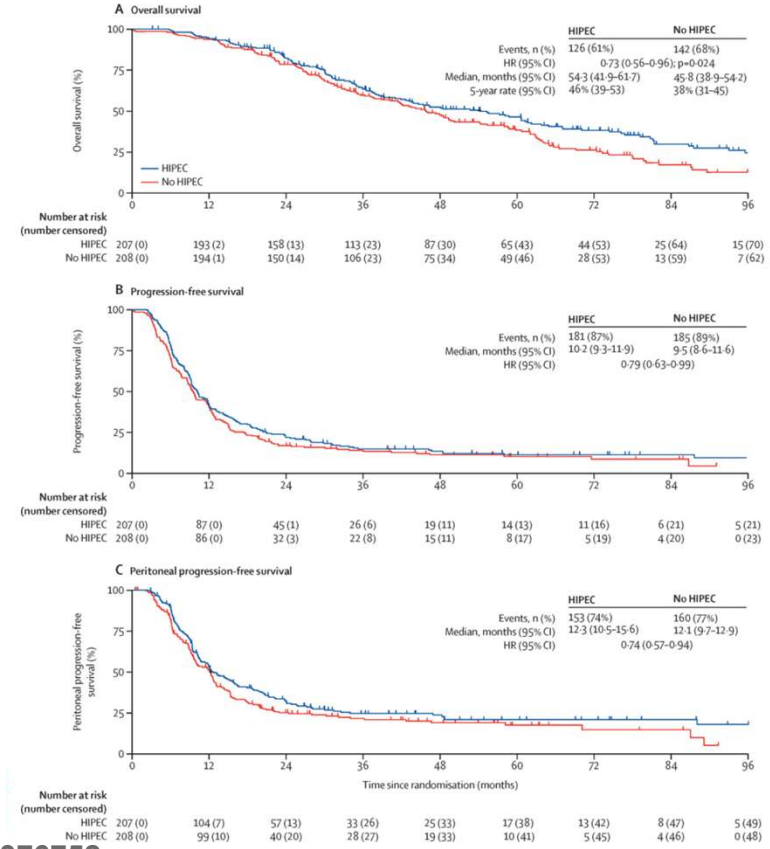
GOG Highlight Reel

a.Added October 8, 2020.
CC0 = no macroscopic residual; CC1 = residual <0.25 cm; PFI = platinum-free interval; SOC = standard of care.
Classe J-M, et al. *HIPEC in platinum-sensitive relapsed epithelial ovarian cancer: The CHIPOR randomized phase III trial.*
Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; 2-6 June 2023; Chicago, IL USA.

GOG FOUNDATION

# Hyperthermic intraperitoneal chemotherapy for recurrent ovarian cancer (CHIPOR): a randomised, open-label, phase 3 trial

Jean-Marc Classe, Pierre Meeus, Delphine Hudry, Romuald Wernert, François Quenet, Frédéric Marchal, Gilles Houvenaeghel, Anne-Sophie Bats, Fabrice Lecuru, Gwenaël Ferron, Cécile Brigand, Dominique Berton, Laurence Gladieff, Florence Joly, Isabelle Ray-Coquard, Sylvaine Durand-Fontanier, Gabriel Liberale, Marc Pocard, Constantin Georgeac, Sébastien Gouy, Jean-Marc Guilloit, Frédéric Guyon, Cristina Costan, Jean-Marc Rousselet, Lara de Guerké, Naoual Bakrin, Emilie Brument, Elodie Martin, Bernard Asselain, Loic Campion, Olivier Glehen for the UNICANCER/CHIPOR Investigators*




NCT01376752

The Lancet Oncology

Volume 25, Issue 12, December 2024, Pages 1551-1562

| | Number of events/ number of patients | | Stratified HR (95% CI) |
|---|---|---|---|
| | HIPEC | No HIPEC | |
| **Age** | | | |
| ≥65 years | 52/88 | 45/73 | 0·65 (0·36–1·18) |
| <65 years | 74/119 | 97/135 | 0·85 (0·60–1·21) |
| **Histology** | | | |
| High-grade serous | 91/151 | 107/159 | 0·77 (0·56–1·05) |
| Other | 34/55 | 33/46 | 0·56 (0·23–1·37) |
| **Median PCI** | | | |
| >5 | 58/84 | 70/87 | 0·38 (0·22–0·66) |
| ≤5 | 55/103 | 65/100 | 0·95 (0·61–1·46) |
| **Completeness of cytoreduction score** | | | |
| CC1 | 20/27 | 24/28 | 0·07 (0·01–0·44) |
| CC0 | 106/180 | 118/180 | 0·84 (0·64–1·12) |
| **Platinum-free interval** | | | |
| 6–12 months | 40/53 | 41/54 | 0·63 (0·38–1·04) |
| 12–18 months | 34/55 | 33/51 | 0·94 (0·56–1·60) |
| >18 months | 52/99 | 68/103 | 0·70 (0·47–1·05) |
| ***BRCA* status** | | | |
| Mutated | 26/50 | 29/53 | 1·36 (0·59–3·14) |
| Not mutated | 74/125 | 85/124 | 0·71 (0·48–1·03) |
| **All patients** | **126/207** | **142/208** | **0·73 (0·56–0·96)** |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# 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

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NCT05659381

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Transforming the standard of care

# Active Trials in Ovarian Cancer

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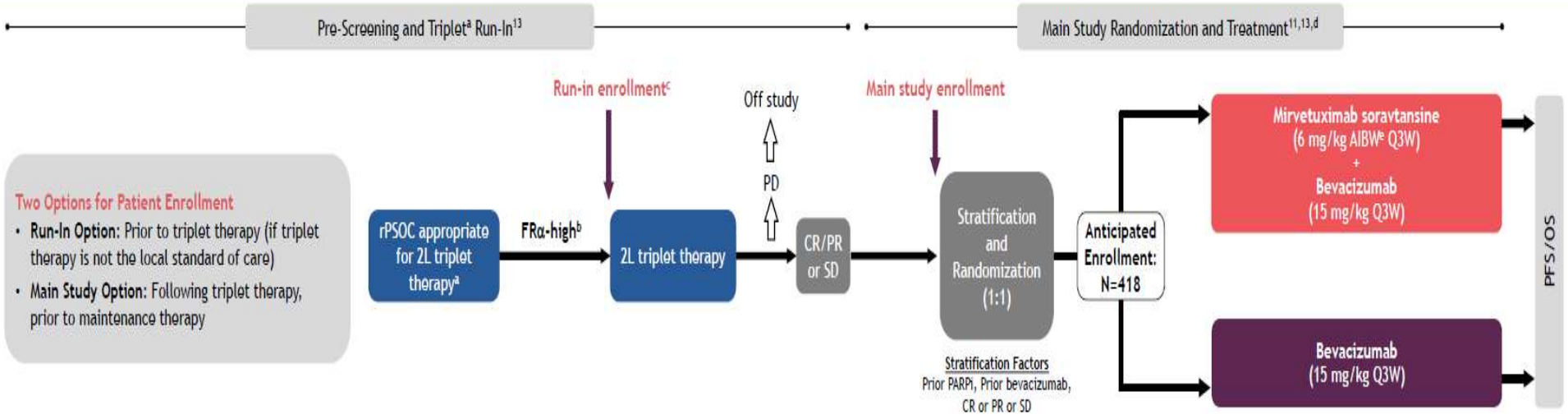
# GOG-3078 | ENGOT-ov76 | IMGN853-0421 |GLORIOSA




[a]Triplet treatment consists of platinum+chemotherapy+bevacizumab for planned 6 cycles (minimum 4 and maximum 8 cycles), including at least 3 cycles of bevacizumab. [b]Pre-screening consent must be obtained for tissue testing for FRα expression by Ventana FOLR1 Assay. [c]FRα-high patients who desire to be treated and followed while on their run-in triplet therapy must sign a run-in consent as part of the main consent form if they meet eligibility criteria as assessed by the investigator. [d]Maintenance treatment must begin ≤12 weeks from last dose of triplet therapy and within 30 days of randomization. Treatment continues until PD, unacceptable toxicity, withdrawal of consent, death, or sponsor study termination. [e]AIBW, also known as AdjBW, is calculated as IBW (kg) + 0.4 (actual weight – IBW). IBW for females is calculated as 0.9*height (cm) – 92.

**Key Eligibility Criteria:**

- Platinum-sensitive HGS ovarian cancer
  - 1 prior platinum treatment
  - Prior PARPi required if BRCA+
  - CR, PR, or SD after treatment with platinum-based doublet + bevacizumab required



NCT05445778

# GOG Partners Phase 2/3 Portfolio: PROC

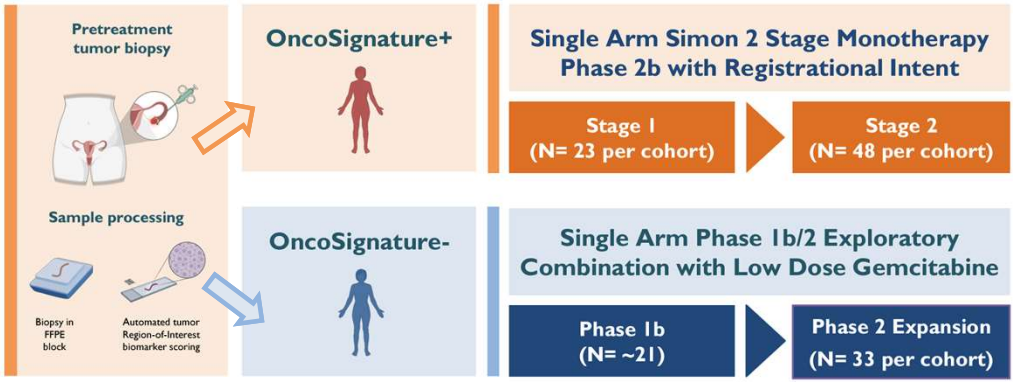
## *(Ongoing, & completed but not yet reported)*

| | Trial | Phase | Regimen | Prior total lines | Prior total lines for PROC | Tumor Testing/ Prevalence |
|---|---|---|---|---|---|---|
| Taxanes | GOG-3073 (ROSELLA) | 3 | Nab Paclitaxel+/- relacorliant **Completed** | 3 | <3 | No |
| ADCs | GOG-3086 (REFRaME-01) | 2/3 | Luveltamab tazevibulin (luvelta) versus SOC | 1-3 | ND | Frα |
| | GOG-3096 (REJOICE) | 2/3 | Raludotatug Deruxtecan (R-DXd) versus SOC | 1-3 | ND | Yes |
| | GOG-3107 (RAINFOL) | 3 | (Rina-S) versus SOC | 1-5 | ND | Yes |
| IO therapy | GOG-3063 (ARTISTRY 7) | 3 | Nemvaleukin + pembrolizumab vs Pen<br>Nemvaleukin vs Investigator Choice cl **Completed** | Unlimited (prior bev requ) | <6 | No |
| | GOG-3076 (OnPrime) | 3 | Olvi-Vec followed by platinum doublet + bev vs. IC chemo | ≥3 | ND | No |
| | GOG-3081 (PRESERVE-004) | 2 | ONC-392 (CTL A4) + Pembro in PROC **Completed** | 1-3 | ND | No |
| | GOG-3084 (SURPASS-3) | 2 | RPh2 of MAGE directed SPEAR T cell +/- Nivo **Closed** | 1-4 | ND | Yes |
| Targeting DDR/PARPi resistance | GOG-3066 (DENALI) | 2 | Durvalumab/Olaparib/Cediranib vs Olaparib/Cediranib vs Durvalumab/cediranib vs Investigator Choice chemotherapy | 5 (prior bev req) | | No |
| | GOG-3067 (MAMMOTH) | 2 | Olaparib + copanlisib vs Investigator Choice chemotherapy (PARPi resistant) **Closed** | Unlimited (prior bev requ) | ≤2 | No |
| | GOG-3072 (ZN-c3-002) | 2 | ZN-c3 (wee-1) as monotx and in combo | | | +/- |
| | GOG-3082 (ACR-368-201) | 1b/2 | ACR-368 (CHK1/2) + gemcitabine in PROC | 1-4 | ND | Yes |

# Acrivon Therapeutics: ACR-368-201 |GOG-3082

***A Phase 2 basket study of ACR-368 as monotherapy and a Phase 1B/2 study in combination with low dose gemcitabine***

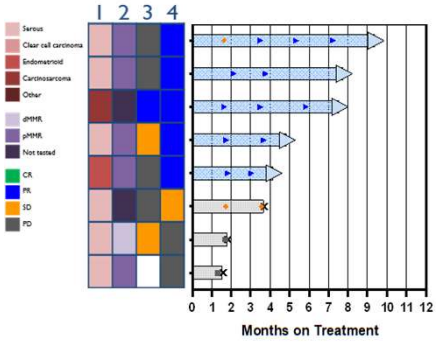
PI: Jung-Min Lee, MD



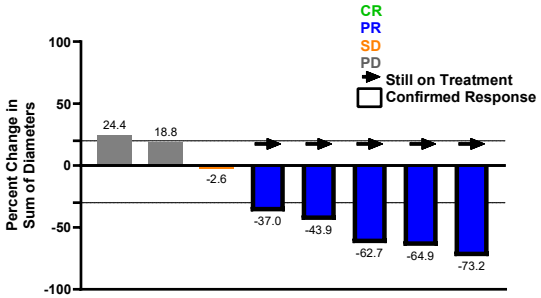

**Confirmed ORR 62.5%** reported in prospective monotherapy cohort of **OncoSignature+ EC patients** who were efficacy-evaluable *(data cut July 25, 2024).*

| Overall Response | BM+ | BM- |
|---|---|---|
| | N = 8 | N = 15 |
| | N (%) | N (%) |
| CR | 0 (0) | 1 (7) |
| cPR | 5 (63) | 0 (0) |
| uPR | 0 (0) | 1 (7) |
| SD | 1 (13) | 6 (40) |
| PD | 2 (25) | 7 (47) |
| cORR (95% CI) | 62.5% (30.4, 86.5) | 6.7% (0.84, 31.8) |
| OncoSignature BM+ vs BM- Segregation P = 0.009 | | |

mDoR not yet reached
(~6 months at time of data cut)




Data current as of 25July2024, includes all BM+ subjects enrolled after OncoSignature threshold lock.
1 – Histology; 2 – MMR; 3 – BOR on most recent prior line; 4 – BOR on ACR-368

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