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Elizabeth K. Lee
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RINATABART SESUTECAN (RINA-S®) FOR PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER: FIRST EFFICACY AND SAFETY RESULTS FROM THE PHASE 2 COHORT OF THE RAINFOL™-01 STUDY

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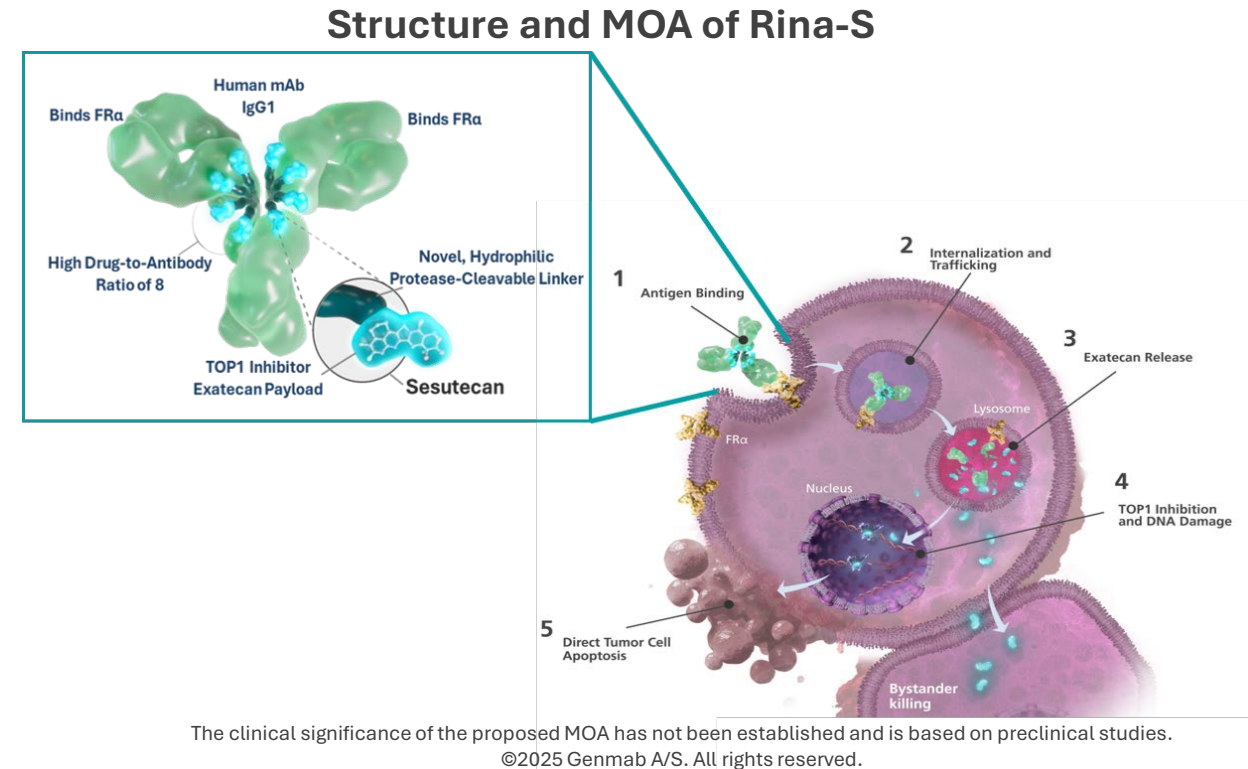
Disclosures

	No, nothing to disclose
x	Yes, please specify:

Company Name	Honoraria/ Expenses	Consulting/ Advisory Board	Funded Research	Royalties/ Patent	Stock Options	Ownership/ Equity Position	Employee	Other (please specify)
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GlaxoSmithKline	x	x	x					
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PROC Background and Rina-S[®] Introduction

- Patients who develop PROC have a median overall survival of 12-18 months^{1,2}
- Unmet need remains for more convenient and efficacious therapies with manageable safety profiles
- FR α is frequently expressed in OC, with positivity rates up to 100%³
- Rina-S is an investigational FR α -directed ADC with a TOP1 inhibitor payload (DAR: 8) and a hydrophilic protease-cleavable linker^{4,5}
- Rina-S 120 mg/m² was selected as the RP2D in OC based on the totality of evidence from dose optimization⁶



Here, we report single-arm phase 2 results from RAINFOL[™]-01 (NCT05579366) evaluating Rina-S 120 mg/m² Q3W monotherapy in patients with PROC

ADC, antibody-drug conjugate; DAR, drug-to-antibody ratio; FR α , folate receptor alpha; MOA, mechanism of action; OC, ovarian cancer; PROC, platinum-resistant ovarian cancer; Q3W, every 3 weeks; RP2D, recommended phase 2 dose; TOP1, topoisomerase I.

1. Colombo N, et al. *Lancet*. 2026;407:1525-37. 2. Lorusso D, et al. *Lancet*. 2026;407:1513-24. 3. Cherlariu-Raicu A, et al. *Int J Gynecol Cancer*. 2023;33:420-429. 4. Call JA, et al. *J Immunother Cancer*. 2023;11(suppl 1):A803. 5. Call JA, et al. *J Clin Oncol* 41, TPS3157-TPS3157(2023). 6. Lee EK, et al. *Gynecol Oncol*. 2025;200:36-37.

RAINFOL™-01 Study Design:

Phase 2 Single-Arm Evaluation of Rina-S Monotherapy in PROC

Key Eligibility Criteria

- High-grade serous OC, primary peritoneal cancer, or fallopian tube cancer
- Received 1 to 3 prior lines of therapy
 - 1 to 4 lines of prior therapy were allowed if MIRV was used as the last line of therapy for patients with FRα ≥75% PS2+
- Received prior bevacizumab
- Received prior PARP inhibitor as maintenance treatment, if eligible
- Primary platinum refractory disease was excluded
- Prior therapy with a TOP1 inhibitor-based ADC was excluded
- Enrollment was not restricted by FRα expression level

N=109 Patients With PROC

Rina-S 120 mg/m² Q3W

Treatment continues until disease progression or unacceptable toxicity

Enrollment occurred in the US between June 2024 and September 2025

Primary Endpoint:

- ORR per RECIST v1.1

Key Secondary Endpoints:

- DOR
- PFS
- OS
- Safety

ADC, antibody-drug conjugate; DCO: data cutoff; DOR, duration of objective response; FRα, folate receptor alpha; MIRV, mirvetuximab soravtansine-gynx; OC, ovarian cancer; ORR, objective response rate; OS, overall survival; PARP, poly ADP-ribose polymerase; PFS, progression-free survival; PROC, platinum-resistant ovarian cancer; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; TOP1, topoisomerase I.

DCO: July 9, 2026.

Baseline Demographics and Clinical Characteristics

Characteristic	N=109
Median age (range), years	65.0 (33-86)
≥65 years, n (%)	55 (50.5)
ECOG PS, n (%)	
0	63 (57.8)
1	46 (42.2)
Historical FRα status (PS2+), ^a n (%)	
<75%	76 (69.7)
≥75%	33 (30.3)

- Half of patients received 3-4 pLOT overall
- In the PROC setting, 62% of patients had ≥1 pLOT
- One-third of patients had received prior MIRV

Characteristic	N=109
Prior lines of therapy, median (range)	3 (1-4)
Prior lines of therapy, n (%)	
1	7 (6.4)
2	44 (40.4)
3-4 ^b	58 (53.2)
Prior lines of therapy in PROC setting, n (%)	
0	42 (38.5)
1	50 (45.9)
2-3	17 (15.6)
Prior systemic therapy, n (%)	
Taxane ^c	109 (100)
Bevacizumab	109 (100)
PLD/doxorubicin	75 (68.8)
PARP inhibitor	54 (49.5)
MIRV ^d	36 (33.0)

^aFRα status based on an FDA-approved test (Ventana FOLR1 RxDx Assay). FRα expression <75% or ≥75% of viable tumor cells with moderate (PS2+) or strong (PS3+) membrane staining. ^bEleven (10.1%) patients received 4 prior lines of therapy. ^cNine patients received taxanes in the PROC setting. ^dOne patient with FRα ≥75% did not receive prior MIRV due to documented medical exception of ocular toxicity, and 4 patients with FRα <75% received prior MIRV. Of the 36 patients who received prior MIRV, 29 (81%) received it as 3rd or 4th line of therapy. ECOG PS, Eastern Cooperative Oncology Group performance status; FRα, folate receptor alpha; MIRV, mirvetuximab soravtansine-gynx; PARP, poly ADP-ribose polymerase; PLD, pegylated liposomal doxorubicin; pLOT, prior line of therapy; PROC, platinum-resistant ovarian cancer.

Treatment Exposure and Study Follow-Up

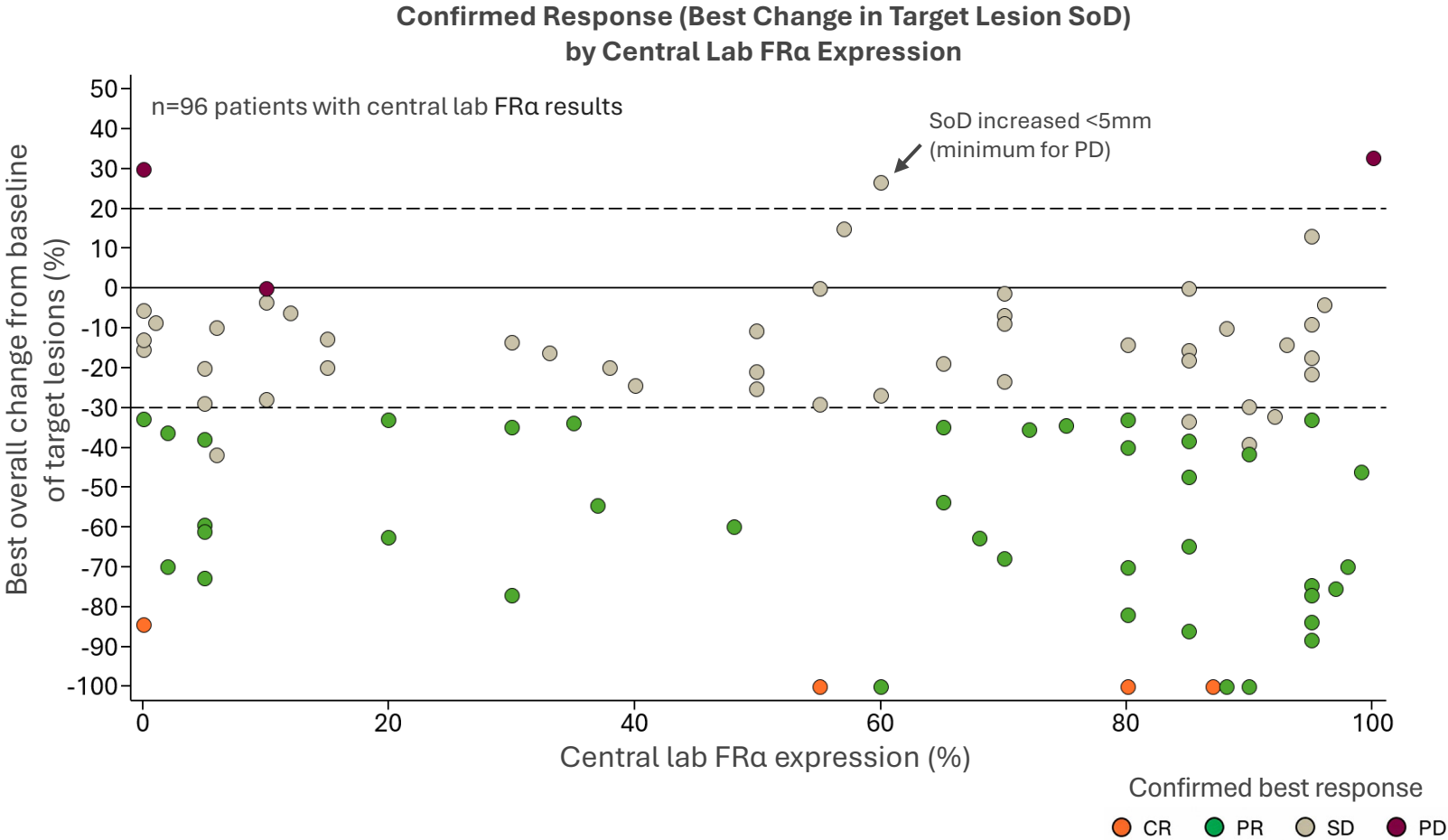
Treatment Exposure and Study Follow-up		N=109
Median number of cycles (range)		12.0 (1-36+)
Median duration of treatment (range), months		7.6 (0-24.1+)
Median relative dose intensity, %		94
Median follow-up on study (95% CI), months		13.6 (11.76-15.31)

- Patients were treated with Rina-S for a median of 12 cycles and median relative dose intensity was 94%
- Patients were followed on study for a median of >1 year

Antitumor Activity Including by FRa Expression

N=109	
Confirmed ORR per INV, % (95% CI)	45.9 (36.3-55.7)
CR, n (%)	5 (4.6)
PR, n (%)	45 (41.3)
SD, n (%)	53 (48.6)
PD, n (%)	5 (4.6)
NE, n (%)	1 (0.9)
DCR, % (95% CI)	94.5 (88.4-98.0)

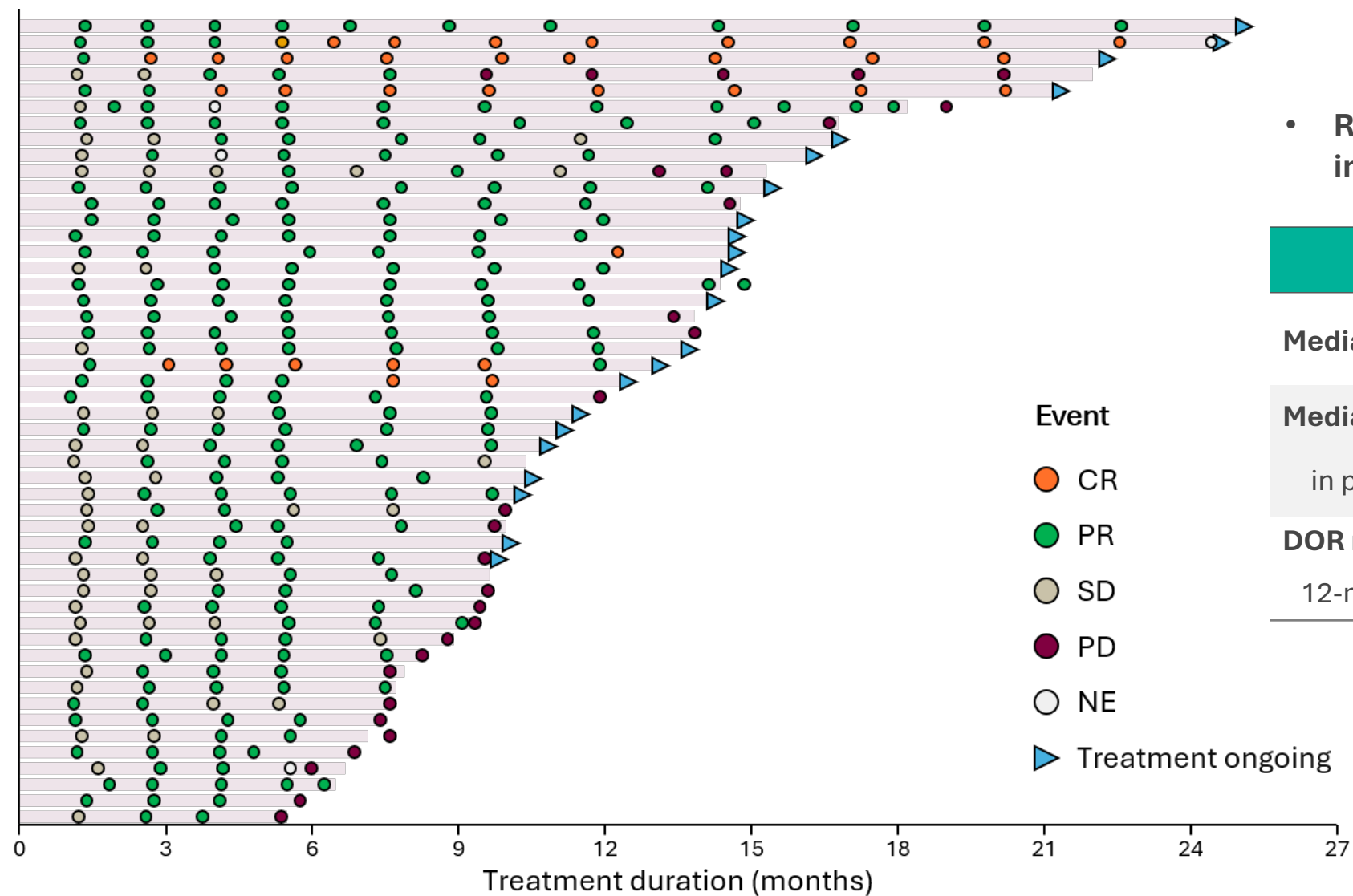
Post DCO: One additional confirmed PR resulting in an updated confirmed ORR of 46.8%



- **ORR in patients with 1-2 and 3-4 pLOT: 45.1% and 46.6%, respectively**
- **ORR of 51.4% in patients who were MIRV-naïve^a and 34.4% in patients with prior MIRV^b**
- **Responses were observed across FRa expression levels, including in patients with undetectable FRa expression**

^aIn 72 patients who were MIRV-ineligible with FRa <75% PS2+. ^bIn the 32 patients who were eligible to receive MIRV with FRa ≥75%. CR, complete response; DCR, disease control rate; DCO, data cutoff; FRa, folate receptor alpha; INV, investigator; NE, not evaluable; ORR, objective response rate; PD, progressive disease; pLOT, prior lines of therapy; PR, partial response; SD, stable disease; SoD, sum of diameters.

Response Over Time

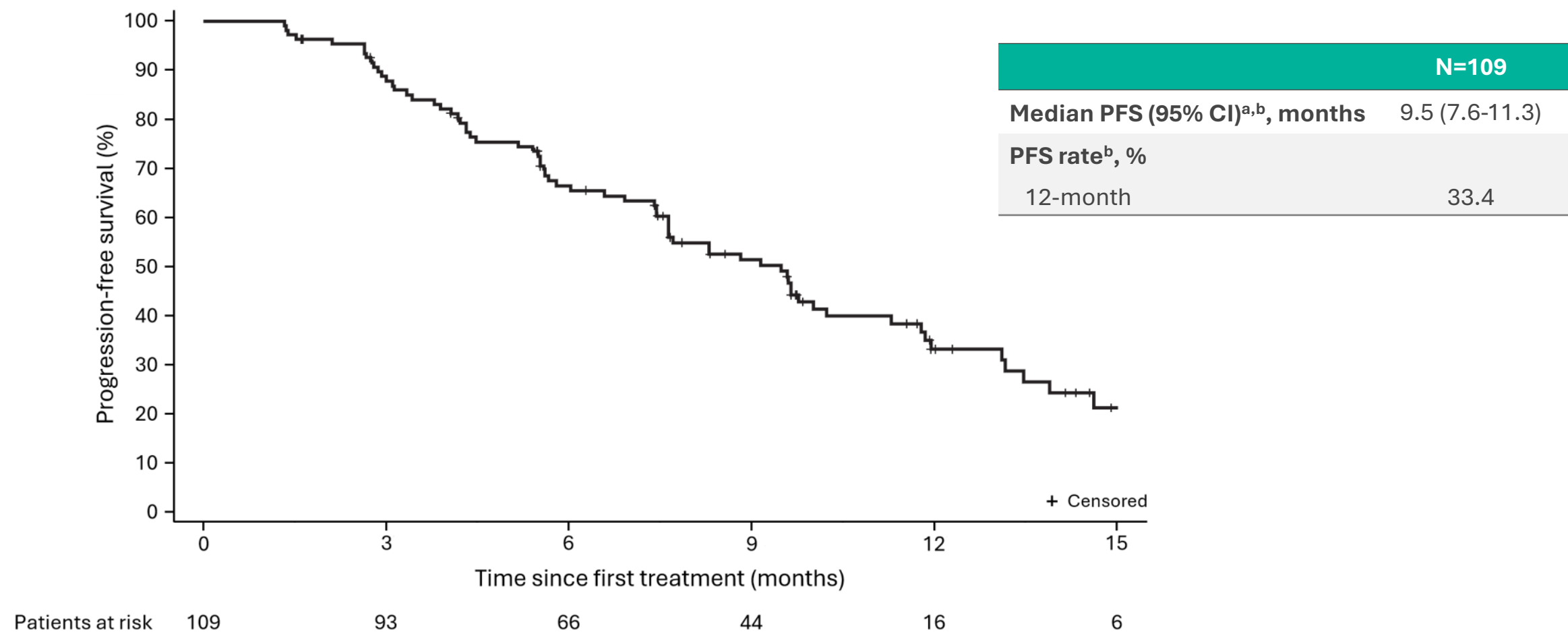


- Responses with Rina-S were durable including in patients with prior MIRV

N=50	
Median time to response, months	1.9 (8.4 weeks)
Median DOR (95% CI) ^{a,b} , months	12.1 (6.5-15.4)
in patients with prior MIRV ^c	13.1 (4.4-NR)
DOR rate ^b , %	
12-month	51.9

^aMedian follow-up for responders: 10.5 months (95% CI, 9.0-18.9). ^bEstimated based on the Kaplan-Meier method. ^cIn the 11 patients who had a response with Rina-S that previously received MIRV. CR, complete response; DCO, data cutoff; DOR, duration of response; MIRV, mirvetuximab soravtansine-gynx; NE, not evaluable; NR, not reached; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease.

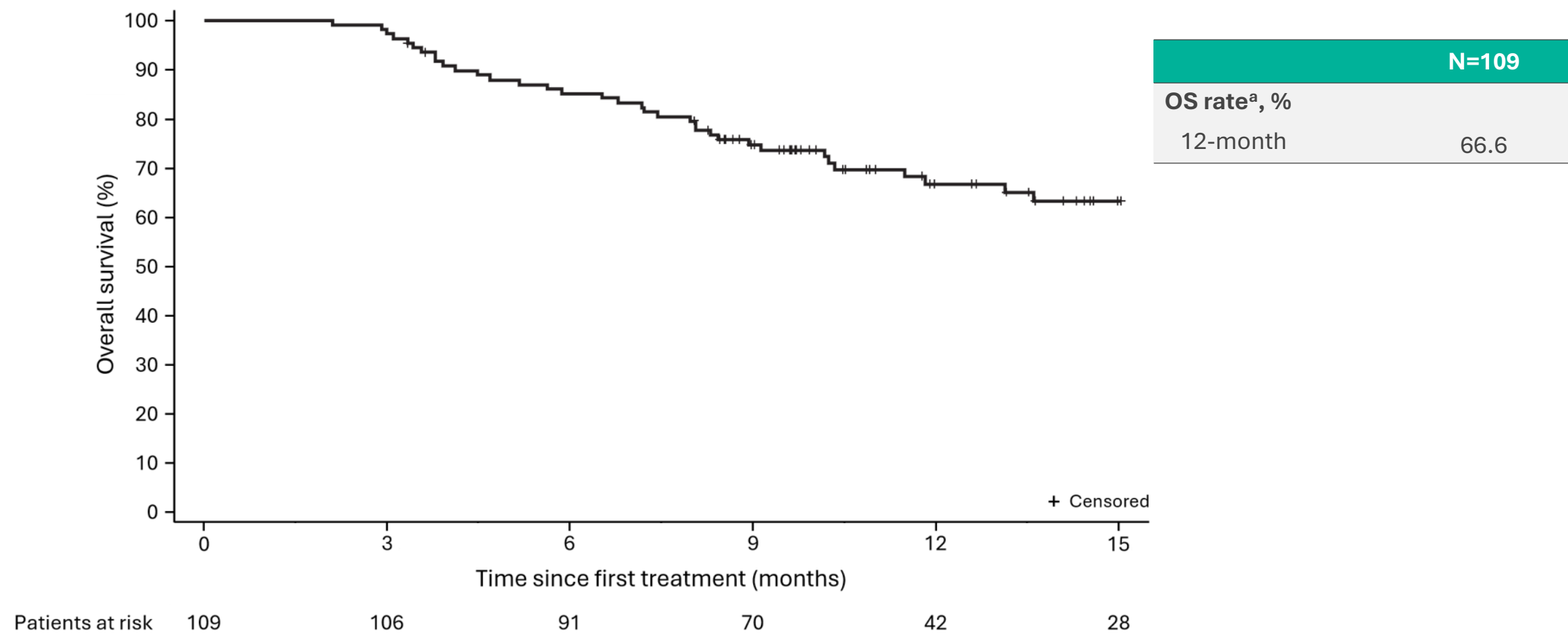
Progression-Free Survival



- **Durable responses translated to a meaningful PFS**

^aMedian follow-up for PFS: 11.9 months (95% CI, 9.8-14.3). ^bEstimated based on the Kaplan-Meier method.
PFS, progression-free survival.

Overall Survival

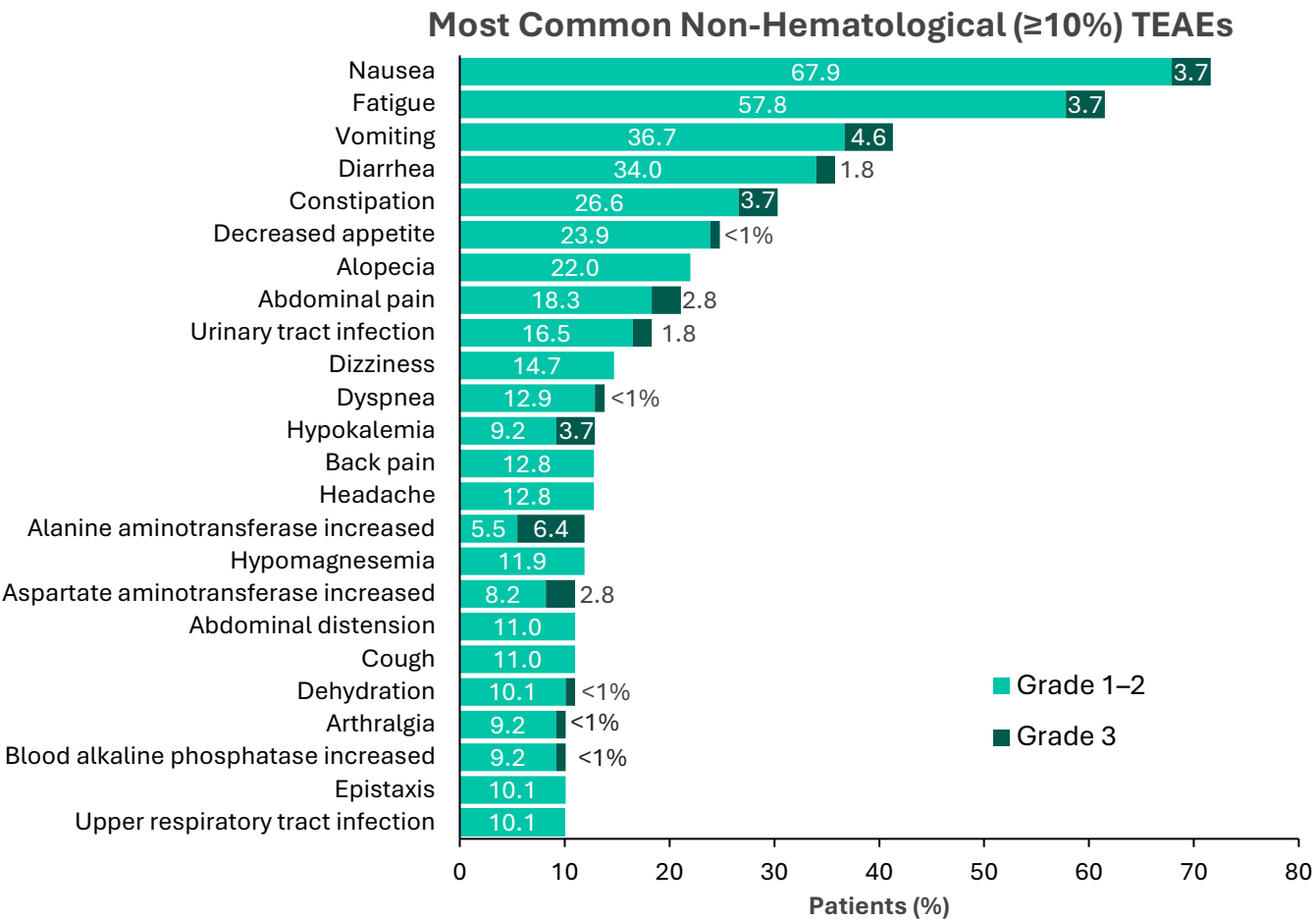


- Encouraging preliminary overall survival

^aEstimated based on the Kaplan-Meier method.
OS, overall survival.

Safety Overview & Non-Hematological Adverse Events

TEAE, n (%)	N=109
Any grade	109 (100)
Related	104 (95.4)
Grade 3-4	72 (66.1)
Related	50 (45.9)
Grade 5	0
Treatment-emergent SAE	34 (31.2)
Related	17 (15.6)
TEAE leading to	
Dose reduction	40 (36.7)
Treatment discontinuation	6 (5.5)
Related ^a	2 (1.8)



- No fatal TEAEs
- Low rates of discontinuation due to TEAE
- Non-hematological TEAEs were mainly low-grade GI events
- No safety signals of ocular events, peripheral neuropathy, ILD, or stomatitis were observed

^aIncludes pneumonitis (grade 2, n=1) and anemia (grade 3, n=1).
GI, gastrointestinal; ILD, interstitial lung disease; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

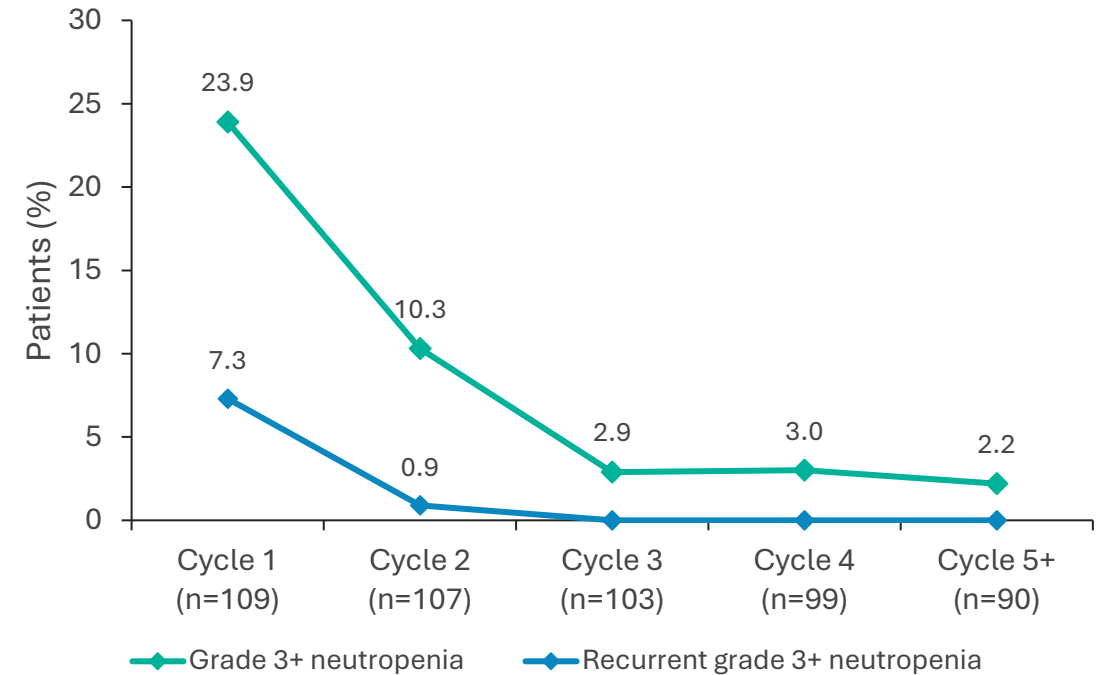
Hematological Adverse Events

Most common hematological TEAEs ^a , n (%)	All grades	Grade 3	Grade 4
Anemia	63 (57.8)	33 (30.3)	0 (0)
Neutropenia ^b	56 (51.4)	19 (17.4)	18 (16.5)
Thrombocytopenia ^b	38 (34.9)	7 (6.4)	19 (17.4)

- **Hematologic TEAEs included grade 3 anemia and grade 3-4 neutropenia^c and thrombocytopenia (no clinically significant bleeding)**

^aMonitoring for cytopenias occurred weekly for the first 2 cycles. ^bConsolidated terms: neutropenia includes neutropenia and neutrophil count decreased; thrombocytopenia includes thrombocytopenia and decreased platelet count. ^cFebrile neutropenia occurred in 7 (6.4%) patients. G-CSF, granulocyte-colony stimulating factor; TEAE, treatment-emergent adverse event.

Percentage of Patients With Grade 3+ Neutropenia^b by Cycle



- **Grade 3+ neutropenia was generally manageable with routine supportive care**
- **G-CSF was used as primary prophylaxis in 55% of patients**

Conclusions

- **Rina-S 120 mg/m² Q3W led to substantial and durable antitumor activity which translated into meaningful PFS in an unselected broad population of patients with PROC**
 - Robust responses were observed across pLOT, in patients with and without prior MIRV and regardless of FRα expression
 - mDOR of 12.1 months
 - mPFS of 9.5 months
- **Rina-S had a tolerable safety profile with manageable TEAEs**
 - Low rates of treatment discontinuation due to TEAEs (5.5%; <2% related)
 - Non-hematological TEAEs were mainly low-grade gastrointestinal events
 - Grade 3-4 hematological TEAEs were generally manageable with routine supportive care
- **Rina-S 120 mg/m² is being evaluated in phase 3 trials for patients with ovarian cancer**
 - RAINFOL™-02 (NCT06619236; ENGOT-OV86; GOG-3107): Rina-S versus IC chemotherapy for PROC
 - RAINFOL™-04 (NCT07225270; ENGOT-OV96; GOG-3134): Rina-S + SOC versus SOC as maintenance for 2L PSOC
 - RAINFOL™-07 (NCT07564141; ENGOT-OV103; GOG-3143): Rina-S +/- BEV versus IC platinum +/- BEV for 2L PSOC
 - RAINFOL™-10 (ENGOT-OV111; GOG-3153): Rina-S + SOC versus SOC as maintenance in 1L OC

Acknowledgments

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