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The FRα Frontier

New Pathways in Platinum-Resistant Ovarian Cancer



This activity is supported by an educational grant from Genmab.



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Disclosures

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All identified conflicts of interest have been mitigated.

LEARNING OBJECTIVES

1. Select an antibody-drug conjugate (ADC) therapy for patients with platinum-resistant ovarian cancer (PROC) based on folate receptor alpha (FRα) expression
2. Evaluate current clinical evidence supporting FRα-targeted therapy in the management of PROC
3. Apply current treatment sequencing principles to optimize therapeutic decision-making for patients with PROC
4. Apply a standardized monitoring and escalation protocol to manage FRα-targeted ADC toxicity in patients with PROC

Part 1

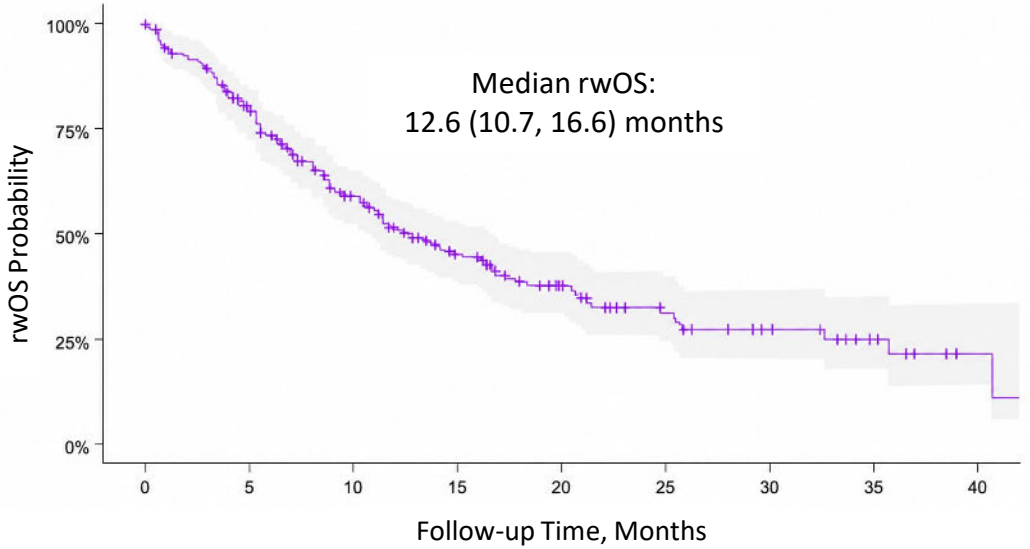
Folate receptor α in PROC: What does it tell you?

Unmet Clinical Need in PROC

~80% of ovarian cancers become platinum-resistant at some point in the disease course

- Real-world study of 230 women with PROC
- ~74% treated in a community setting

Outcome Parameter	Broad Cohort (n = 230)
rwTTD, median (95% CI), months	3.3 (2.9, 3.7)
rwTTNT, median (95% CI), months	5.6 (4.9, 6.9)
rwOS , median (95% CI), months	12.6 (10.7, 16.6)

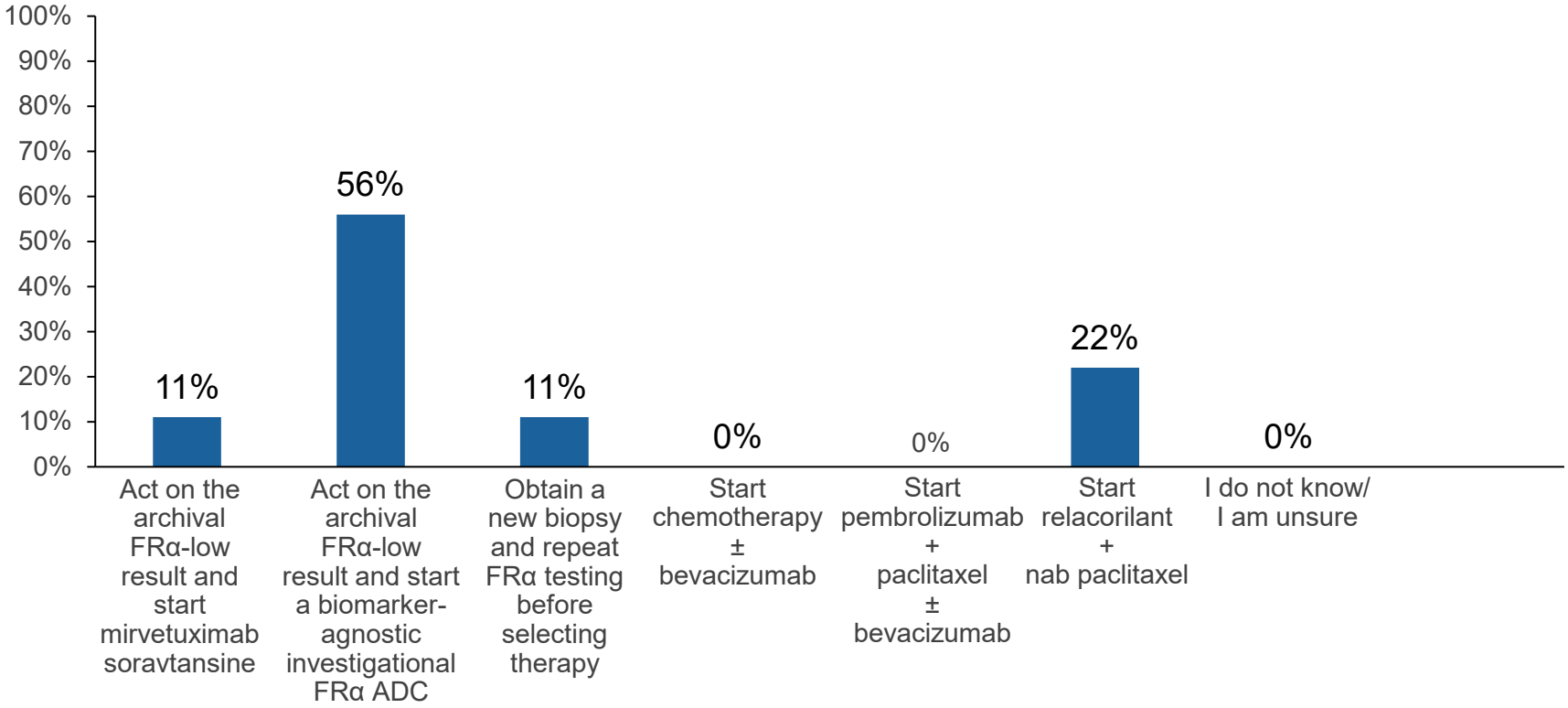


CI = confidence interval; rwOS = real-world overall survival; rwTTD = real-world time to treatment discontinuation; rwTTNT = real-world time to next treatment.

A 64-year-old with high-grade serous ovarian cancer (HGSOC) progresses 4 months after her second platinum regimen. Her only FRα result is PS2+ 30% from her primary debulking 3 years ago and PD-L1 CPS = 0. Assuming equal access to all options, what would you most likely do next?

A. Act on the archival FRα-low result and start mirvetuximab soravtansine
B. Act on the archival FRα-low result and start a biomarker-agnostic investigational FRα ADC
C. Obtain a new biopsy and repeat FRα testing before selecting therapy
D. Start chemotherapy ± bevacizumab
E. Start pembrolizumab + paclitaxel ± bevacizumab
F. Start relacorilant + nab paclitaxel
G. I do not know/I am unsure

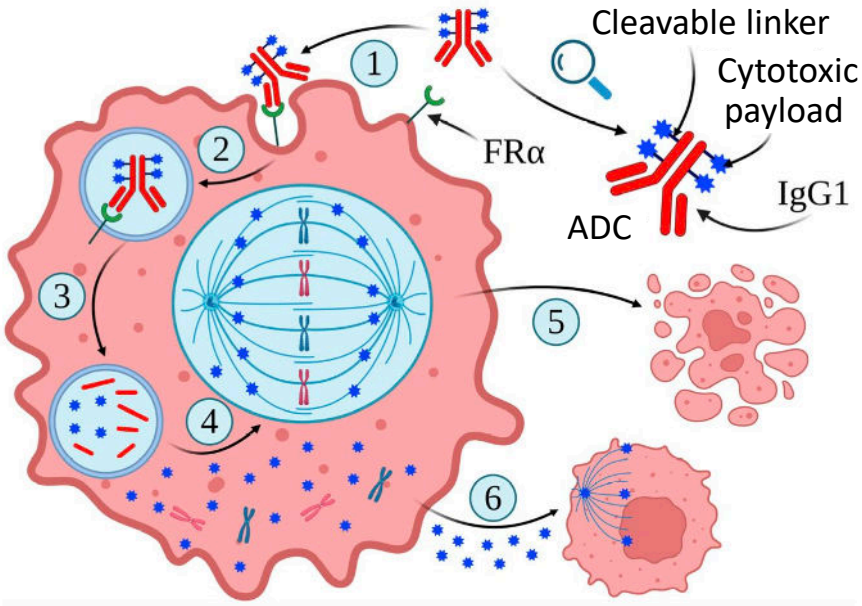
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Results recorded on October 2, 2026.

Rationale for Targeting FRα in Ovarian Cancer (OC)

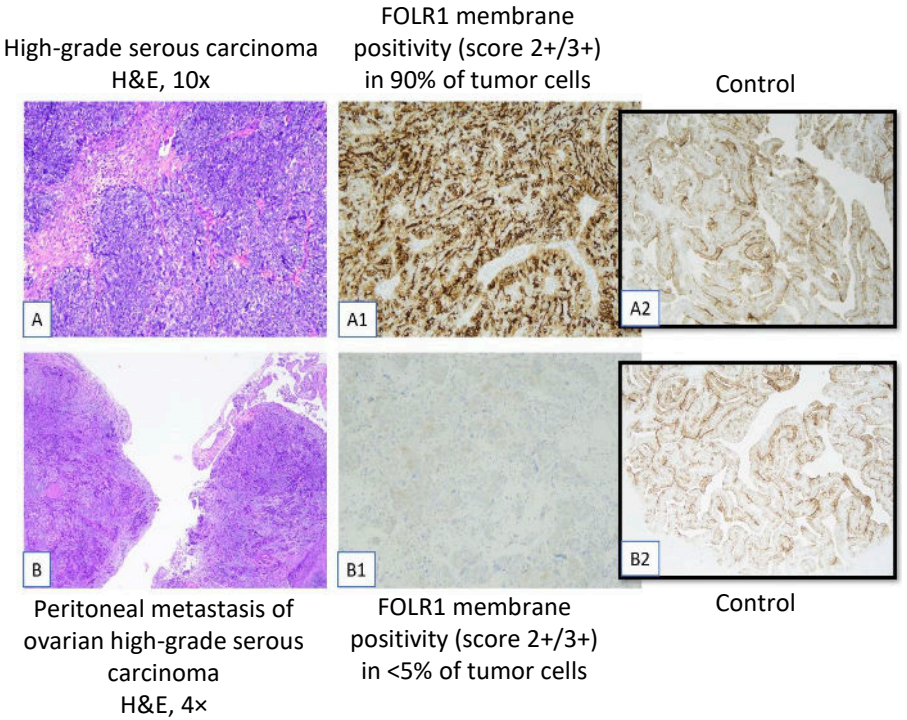
- FRα is expressed in most OCs, with high expression in ~35%-40%
- Expression on normal tissue is limited
- FRα efficiently internalizes bound antibody via receptor-mediated endocytosis, enabling intracellular delivery of cytotoxic payloads



Bukowski K, et al. *Int J Mol Sci*. 2024;25(22):11927. Bax HJ, et al. *Br J Cancer*. 2023;128(2):342-353.

FRα Testing in OC

- FRα-high with approved FRα ADC is defined as ≥75% of viable tumor cells with ≥2+ membrane staining intensity (PS2+ scoring)
  - This threshold is specific to mirvetuximab soravtansine
- Scoring is semi-quantitative and pathologist-dependent



H&E = hematoxylin and eosin.

Approved and Investigational FRα-Targeted ADCs in OC

ADC	Linker	Payload	DAR	Current Status
Mirvetuximab soravtansine	Cleavable disulfide bond	DM4 maytansine (microtubule inhibitor)	~3.3-4	FDA-approved for FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, after 1-3 prior therapies
Sofetabart mipitecan*	Protease-cleavable	Exatecan (TOPO1 inhibitor)	~8	FDA breakthrough therapy designation
Rinatabart sesutecan*	Protease-cleavable	Exatecan (TOPO1 inhibitor)	~8	FDA fast track designation
Torvutatug samrotecan*	Protease-cleavable	Campothecin derivative (TOPO1 inhibitor)	~8	Investigational
Farletuzumab ecteribulin*	Protease-cleavable	Eribulin (microtubule inhibitor)	~4	Investigational

*These agents are not FDA-approved for the management of ovarian cancer.
DAR = drug-to-antibody ratio; TOPO1 = topoisomerase 1.

Moore KN, et al. *Nat Rev Clin Oncol*. 2026;23(9):672-693. Yonemori K, et al. *Int J Gynaecol Obstet*. 2026;173(3):1334-1342.

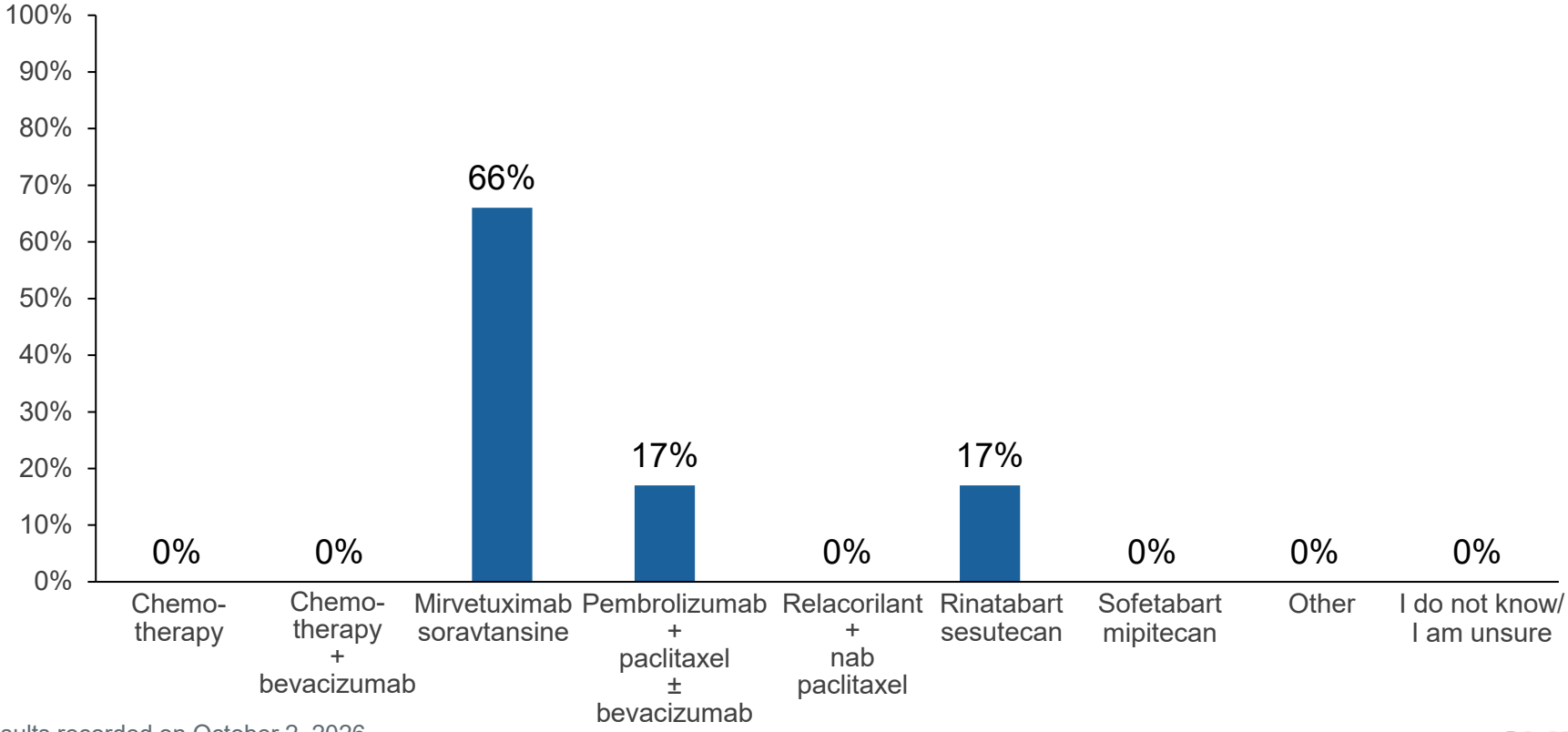
Part 2

Current state of ADCs for PROC

A 58-year-old with FRα-high HGSOC received first-line carboplatin/paclitaxel with bevacizumab followed by niraparib maintenance, followed by carboplatin/pegylated liposomal doxorubicin at platinum-sensitive relapse with progression 3 months after her last dose. Assuming equal access to all options, which systemic therapy would you most likely recommend next?

A. Chemotherapy
B. Chemotherapy + bevacizumab
C. Mirvetuximab soravtansine
D. Pembrolizumab + paclitaxel ± bevacizumab
E. Relacorilant + nab paclitaxel
F. Rinatabart sesutecan
G. Sofetabart mipitecan
H. Other
I. I do not know/I am unsure

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Results recorded on October 2, 2026.

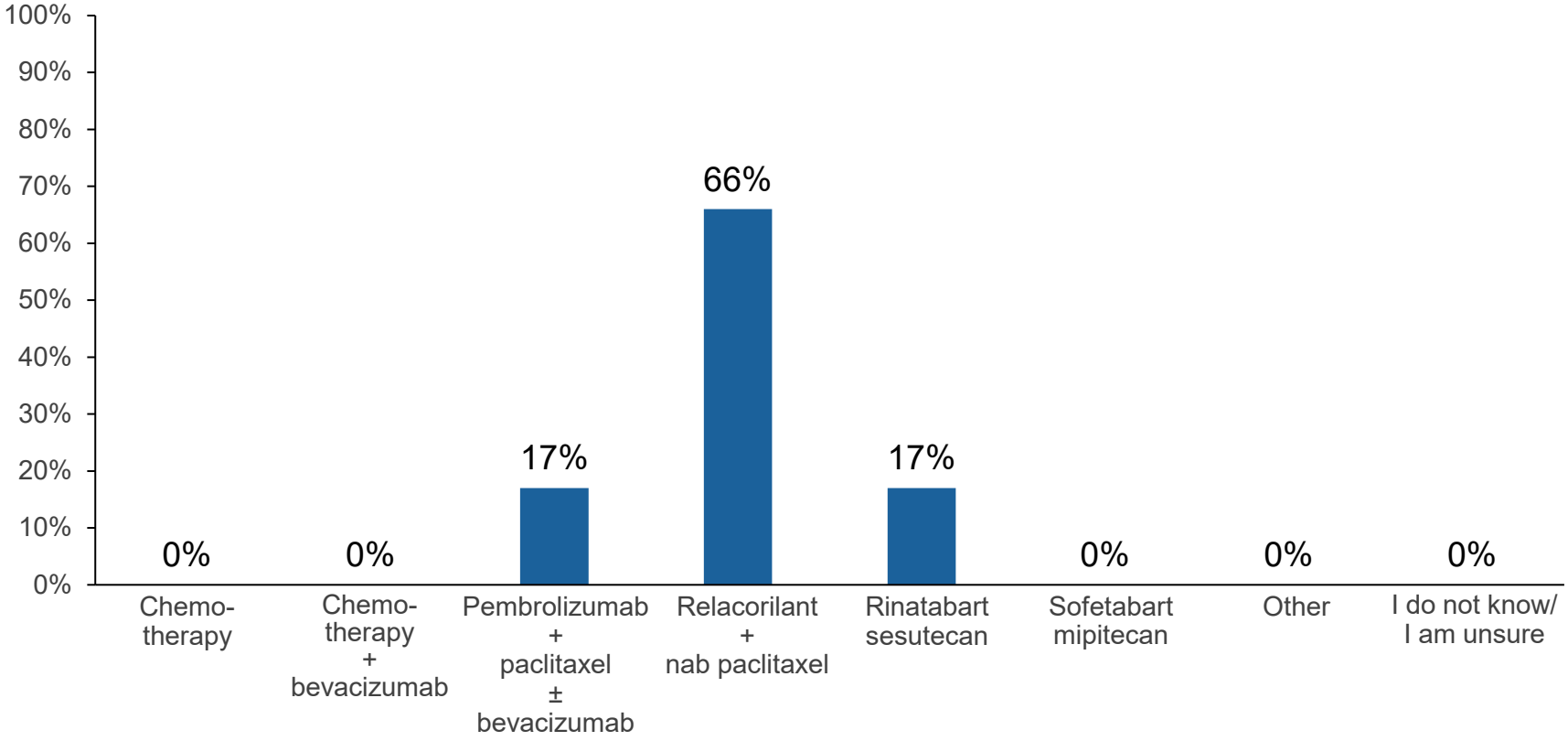
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A. Chemotherapy
B. Chemotherapy + bevacizumab
C. Mirvetuximab soravtansine
D. Pembrolizumab + paclitaxel ± bevacizumab
E. Relacorilant + nab paclitaxel
F. Rinatabart sesutecan
G. Sofetabart mipitecan
H. Other
I. I do not know/I am unsure

An individual with FRα-high PROC has a partial response to mirvetuximab lasting 8 months before experiencing disease progression. Assuming equal access to all options, what would you most likely pursue next?

A. Chemotherapy
B. Chemotherapy + bevacizumab
C. Pembrolizumab + paclitaxel ± bevacizumab
D. Relacorilant + nab paclitaxel
E. Rinatabart sesutecan
F. Sofetabart mipitecan
G. Other
H. I do not know/I am unsure

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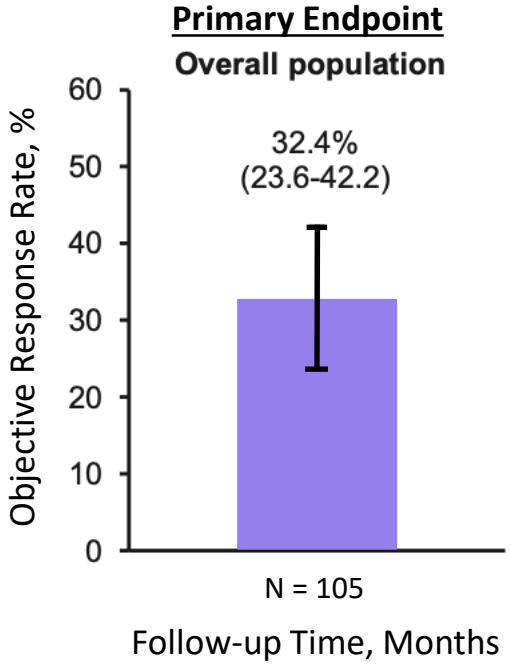


Results recorded on October 2, 2026.

SORAYA: Phase 2 Single-Arm Study of Mirvetuximab Soravtansine in FRα-High PROC

- 105 patients with FRα-high PROC received mirvetuximab soravtansine

Outcome	Mirvetuximab soravtansine
Median DOR, mo	6.9 (5.6–9.7)
Median OS, mo	15.0 (11.5–18.7)
CR rate	5% (5/104)



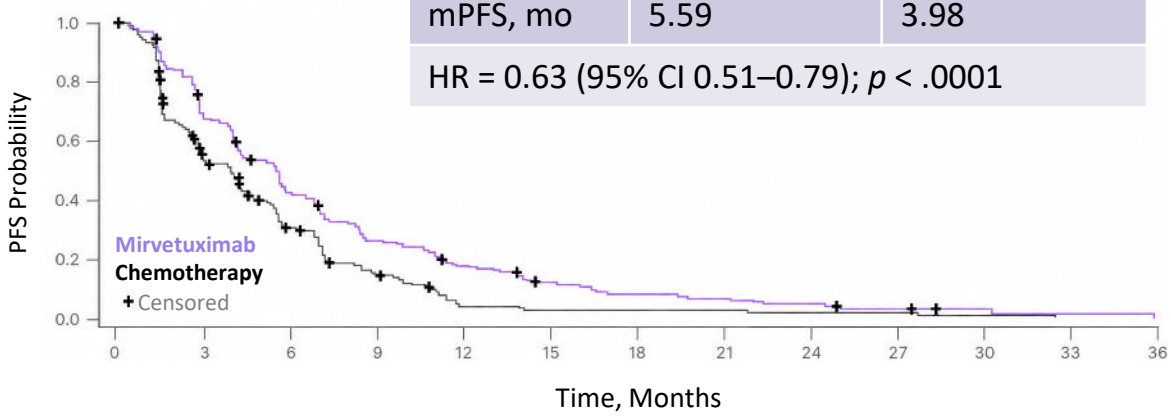
CR = complete response; DOR = duration of response; OS = overall survival.

MIRASOL: Phase 3 Study of Mirvetuximab Soravtansine in FRα-High PROC

- 453 participants with previously treated (1-3 lines of therapy) platinum-resistant HGSOC and high FRα expression were randomized 1:1 to mirvetuximab (n = 227) or chemotherapy (n = 226)
- Median OS was 16.85 months vs. 13.34 months
  - HR 0.68 (95% CI 0.54–0.84); *p* = .0004)

Primary Endpoint

Outcome	Mirvetuximab	Chemotherapy
mPFS, mo	5.59	3.98
HR = 0.63 (95% CI 0.51–0.79); *p* < .0001		



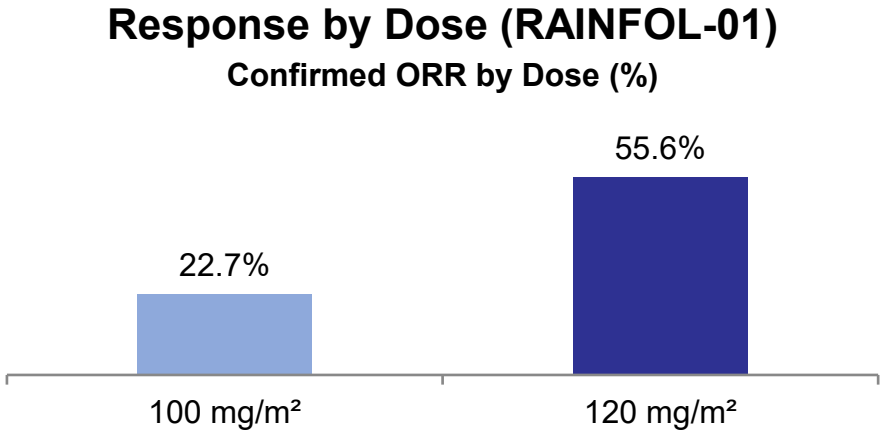
Both NCCN (v4.2026) and ESMO (2026) now endorse mirvetuximab soravtansine as standard of care for FRα-high PROC with NCCN as a Category 1 preferred single agent (≥75% FRα expression) and ESMO with a I, A recommendation

ESMO = European Society for Medical Oncology; HR = hazard ratio; mPFS = median progression-free survival; NCCN = National Comprehensive Cancer Network.

Gardner Coffman L, et al. *Ann Oncol.* 2024;35(suppl 2):S566.

RAINFOL-01: Phase 1/2 Study of Rinatabart Sesutecan in PROC

- Heavily pretreated patients with advanced ovarian cancer (epithelial ovarian, primary peritoneal, or fallopian tube) received single-agent Rina-S* every 3 weeks in dose-expansion cohorts
- Confirmed responses occurred regardless of FRα expression level
- 120 mg/m² selected as the recommended phase 3 dose; median DOR not reached



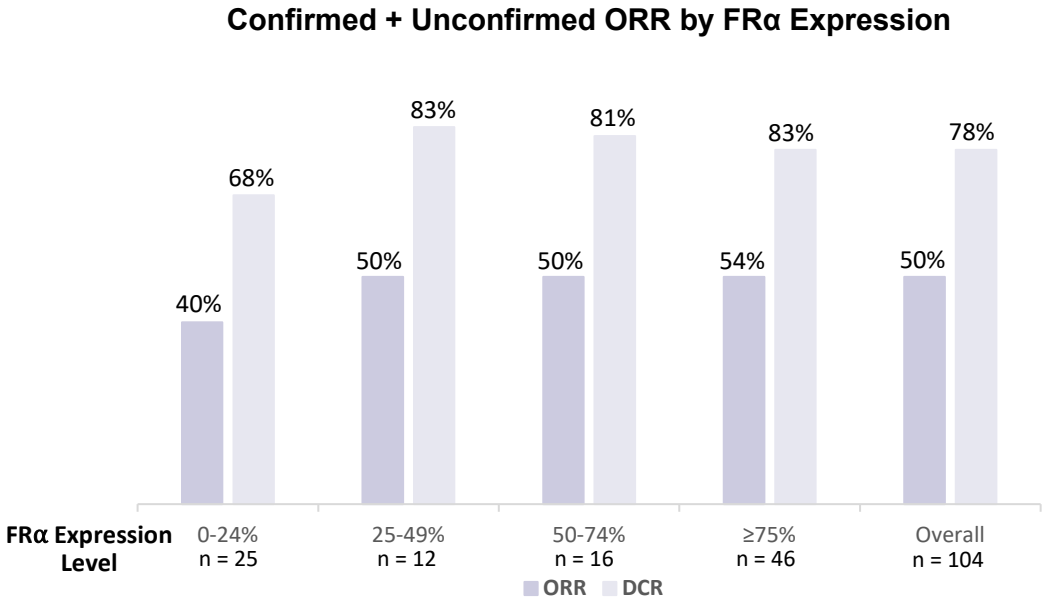
Outcome	100 mg/m² (n = 22)	120 mg/m² (n = 18)
Confirmed ORR	22.7%	55.6%
DCR	86.4%	88.9%
Median DOR	—	Not reached

120 mg/m² = recommended phase 3 dose; active regardless of FRα expression

*Rinatabart sesutecan is not FDA-approved for the management of ovarian cancer.
ORR = overall response rate; Rina-S = rinatabart sesutecan.

Sofetabart Mipitecan*: First-in-Human Phase 1 Study in Platinum-Resistant HGSOC

- 105 heavily pretreated patients (median 5 prior regimens; 96% platinum-resistant; 92% serous; 17% prior mirvetuximab) received sofetabart mipitecan IV Q3W at dose levels of 2-6 mg/kg
- Objective responses occurred across all FRα expression levels, including FRα-low/negative tumors, and regardless of prior mirvetuximab



ORR includes unconfirmed responses; phase 1, doses pooled (2-6 mg/kg); excludes 5 pending FRα (ORR 60%)

*Sofetabart mipitecan is not FDA-approved for the management of ovarian cancer.
IV = intravenous.

Ray-Coquard I, et al. *Ann Oncol.* 2025;36(suppl 2):S671-S672. Pothuri B, et al. *Gynecol Oncol*. 2026;208(Suppl):S34-S35.

Select Ongoing Phase 3 Trials of FRα-Directed ADCs in OC

Trial	Population	Arms	Primary Endpoint	Estimated Primary Completion
GLORIOSA NCT05445778	Recurrent PSOC and no disease progression after second-line platinum chemotherapy + bevacizumab	*Mirvetuximab soravtansine + bevacizumab vs bevacizumab	PFS	Enrollment complete
RAINFOL-02 NCT06619236	PROC	*Rinatabart sesutecan vs. investigator's choice of chemotherapy	PFS	2027
RAINFOL-04 NCT07225270	Recurrent PSOC after second-line platinum doublet chemotherapy regardless of FRα expression	*Rinatabart sesutecan + bevacizumab or observation vs. bevacizumab or observation	PFS	2028
RAINFOL-07 NCT07564141	Second-line treatment in recurrent PSOC	*Rinatabart sesutecan ± bevacizumab vs. chemotherapy ± bevacizumab	PFS	2029
FRAmework-01 NCT07213804	Part A: PROC Parts B &C: PSOC	Part A: Sofetabart mipitecan* vs. chemotherapy or mirvetuximab soravtansine	PFS	2028
TREVI-OC-01 NCT07218809	High-grade PROC with high or low FRα	FRα-high: Torvutatug samrotecan* vs. mirvetuximab FRα-low: Torvutatug samrotecan* vs. chemotherapy*	PFS	2028
TREVI-OC-03 NCT07816666	Maintenance treatment in relapsed PSOC	Torvutatug samrotecan ± bevacizumab* vs. bevacizumab or observation	PFS	2028

*These regimens are not FDA-approved for the management of ovarian cancer.
PSOC = platinum-sensitive ovarian cancer.

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O'Malley DM, et al. Future Oncol. 2024;20(32):2423-2436. Alvarez Secord A, et al. *Int J Gynecol Cancer.* 2025;35(11 suppl 1):102614. Ray-Coquard IL, et al. *J Clin Oncol.* 2026;44(16 suppl):TPS5644. ClinicalTrials.gov. NCT07218809. https://clinicaltrials.gov/study/NCT07218809. Van Gorp T, et al. *J Clin Oncol.* 2026;44(16 suppl):TPS5641.

Part 3

Integrating FRα-directed ADCs into PROC care

Where Do FRα-Directed ADCs Fit?

PROC — progression after 1-3 prior lines

Assess FRα expression by PS2+ IHC
***Retest at progression if prior FRα was negative**

FRα-high (≥75%, ≥2+)

Mirvetuximab soravtansine
Approved standard of care ● NCCN Category 1
Only approved FRα-directed ADC

FRα-low / negative

No approved FRα-directed ADC
Biomarker-agnostic TOPO1 ADCs in phase 3 trials (rinatabart sesutecan, sofetabart mipitecan, torvutatug samrotecan) ● chemotherapy ± bevacizumab ● clinical trial

Across both paths:

- Weigh prior therapy (PARP inhibitor, bevacizumab) and platinum-free interval
- After prior mirvetuximab, evidence suggests emerging TOPO1-payload ADCs retain activity
- Sequence to limit overlapping toxicities

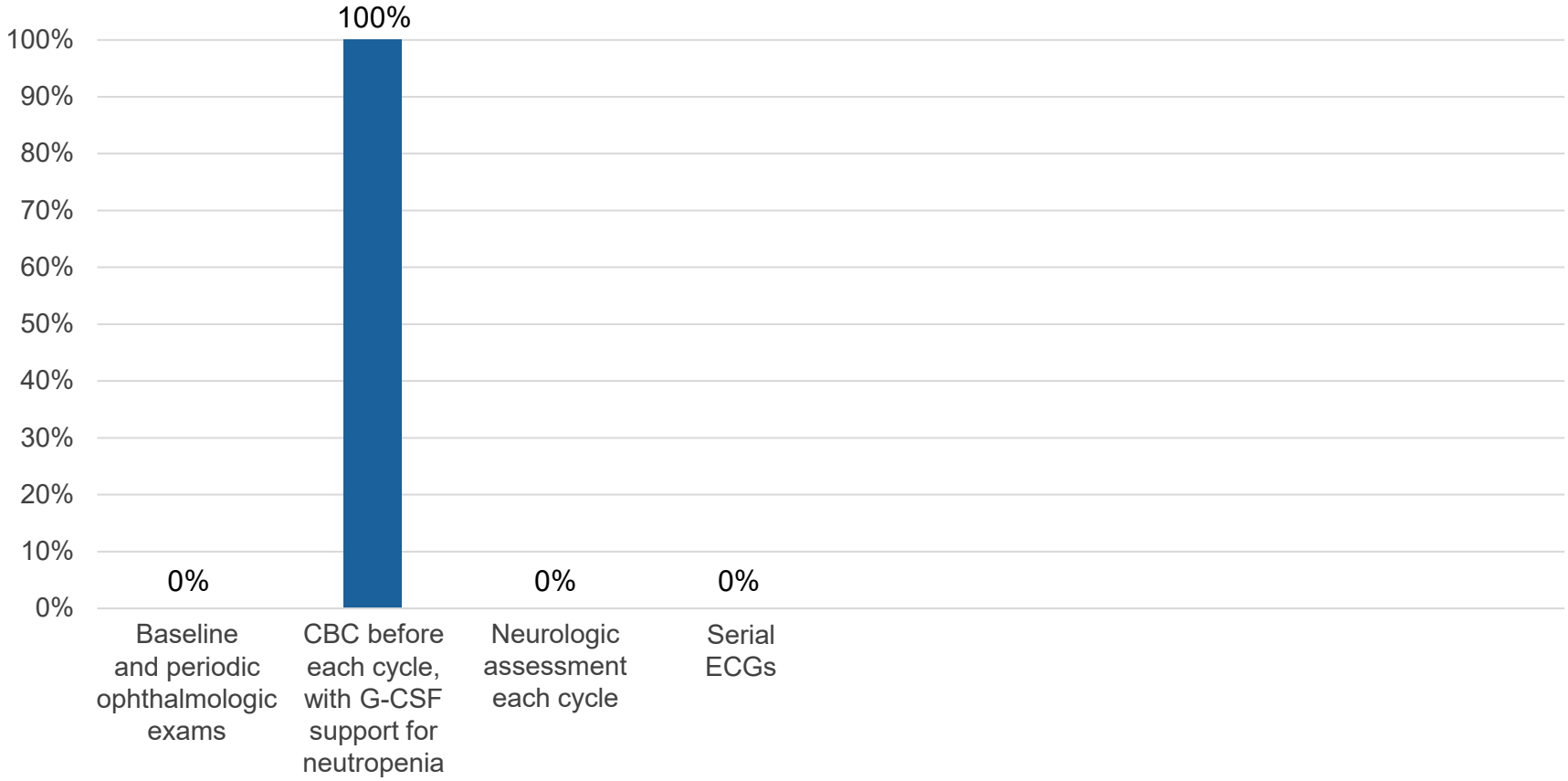
*Reflects faculty perspectives on testing; NCCN guidelines recommend tumor biomarker testing to of most recently available tumor tissue to identify potential benefit from targeted therapy prior to initiation of therapy for persistent/recurrent disease if not previously performed.
IHC = immunohistochemistry; PARP = poly (ADP-ribose) polymerase; PS2+ = positive staining 2+.

NCCN Guidelines . Ovarian Cancer v4.2026. https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf
González-Martín A, et al. *ESMO Open*. 2026;11(2):106032. Moore KN, et al. *Nat Rev Clin Oncol*. 2026;23(9):672-693.

A patient with PROC is beginning treatment with Rina-S. Based on available safety data, which monitoring plan should be prioritized?

A. Baseline and periodic ophthalmologic exams
B. Complete blood count (CBC) before each cycle, with granulocyte colony-stimulating factor (G-CSF) support for neutropenia
C. Neurologic assessment each cycle
D. Serial electrocardiograms (ECGs)

A patient with PROC is beginning treatment with Rina-S. Based on available safety data, which monitoring plan should be prioritized?



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Adverse Event Profiles of FRα-Directed ADCs

Adverse Event Any-Grade (Grade 3-4)	Mirvetuximab Soravtansine *DM4 Payload ● MIRASOL, Phase 3, n = 218*	Rina-S* *Exatecan/TOPO1 ● RAINFOL-01, 120 mg/m²*	Sofetabart Mipitecan* *TOPO1 Payload ● Phase 1a, n = 104*
Diarrhea	29% (1%)	35% (0%)	33% (1%)
Nausea	27% (2%)	60% (0%)	64% (3%)
Fatigue	30% (2%)	45% (0%)	53% (2%)
Alopecia	1% (0%)	25% (0%)	10% (NR)
Neutropenia	11%/ (<1%)	25% (45%)	34% (24%)
Anemia	10% (<1%)	35% (40%)	39% (25%)
Thrombocytopenia	8% (<1%)	20% (25%)	NR
Peripheral neuropathy	22% (1%)	NR	3% (NR)
Interstitial lung disease	NR	NR	8% (2%)
Ocular toxicity	56% (20%)	NR	NR
Grade ≥3 neutropenia	1%	45%	24%

*These agents are not FDA-approved for the management of ovarian cancer.
NR = not reported.

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Moore KN, et al. *Nat Rev Clin Oncol*. 2026;23(9):672-693. Moore KN, et al. *N Engl J Med*. 2023;389(23):2162-2174. Lee EK, et al. Society of Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer; 2025. Abstract No. 809034. Pothuri B, et al. *Gynecol Oncol*. 2026;208(Suppl):S34-S35.

Considerations for Monitoring and Management of FRα ADC Toxicity

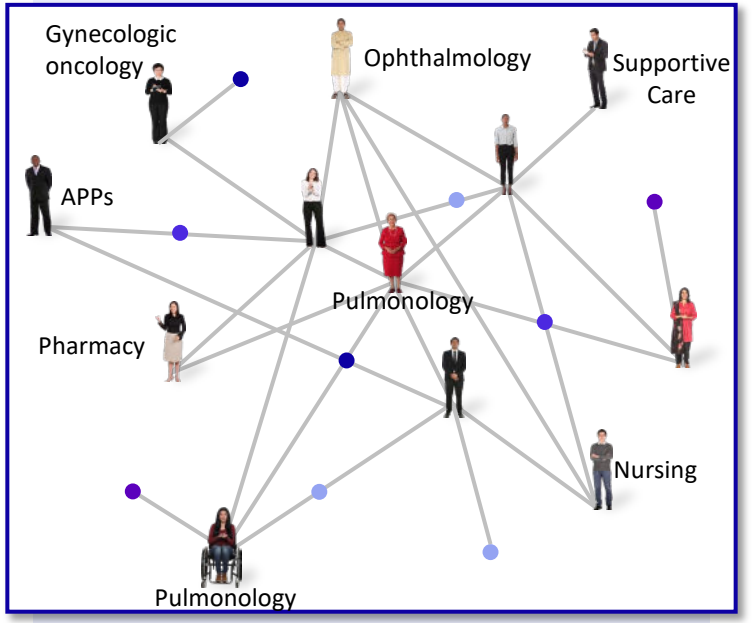
Toxicity	Monitoring	Management Considerations
Ocular	Baseline eye exam (BCVA, slit-lamp); repeat every other cycle for first 8 cycles, then as indicated; lubricating ± corticosteroid drops; avoid contact lenses	Manage with dose modification—interruption, reduction, or discontinuation—based on severity and per prescribing information; coordinate with ophthalmology
Interstitial lung disease / pneumonitis	Monitor pulmonary symptoms; imaging if suspected	Interrupt therapy and consider corticosteroids for symptomatic events; discontinuation may be warranted for severe or persistent cases per prescribing information
Hematologic	CBC before each cycle	Manage with dose delay or reduction and supportive care, including growth-factor support where appropriate, per prescribing information and institutional protocols
Gastrointestinal (nausea, vomiting, diarrhea)	Assess at each visit	Supportive care with antiemetics and antidiarrheals as needed; consider dose modification for persistent symptoms
Peripheral neuropathy	Neurologic assessment each cycle	Dose modification based on severity; consider discontinuation for severe or persistent symptoms per prescribing information

BCVA = best-corrected visual acuity.

Hendershot A, et al. *Gynecol Oncol Rep*. 2023;47:101155. Mirvetuximab soravtansine [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761310Origs005lbl.pdf.

Team-Based Approach for the Management of FRα-Directed ADC Toxicity

- Each discipline brings a distinct lens— gynecologic oncology, advanced practice providers (APPs), nursing, pharmacy, palliative/supportive care, and consulting specialties
  - The team is strongest when these perspectives inform one another
- Understanding one another's roles clarifies accountability
- Sharing real-world practices across the team sharpens early detection, patient education, and prompt symptom reporting across care settings
- Collaborative dose-modification decisions sustain treatment continuity while minimizing severe toxicity



Goals for Increased Interprofessional Communication and Collaboration



Establishment of clear communication channels



Commitment to evidence-based practices



Respect for other HCPs' unique knowledge and contribution

Evans S, et al. *J Interprof Care*. 2025 Feb 6. [Epub ahead of print]. Bowman KS, et al. *Behav Anal Pract*. 2021;14(4):1191-1208. Price JR, et al. *Sch Psychol*. 2024;39(4):419-432.

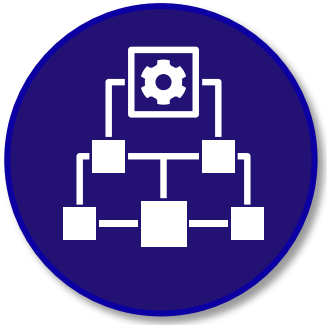
Goals for Increased Interprofessional Communication and Collaboration



Assess collaboration competency and willingness to accept feedback from other HCPs



Patient and care partner values, preferences, and needs are considered by all HCPs



Use frameworks for structured communication

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Put information into action!

Takeaways from this program can be implemented into your practice to improve patient care.

- Within 6 months: Increase the proportion of eligible patients with PROC who have FRα expression assessed by a validated IHC assay by 20%
- Within 6 months: Increase the proportion of patients with confirmed FRα-high PROC who are appropriately offered or initiated on an FRα-directed ADC by 20%
- Within 6 months: Increase the proportion of patients initiating an FRα-directed ADC who receive guideline-concordant baseline and ongoing toxicity monitoring by 20%
- Within 6 months: Increase the proportion of emergent toxicities mitigated by proactive supportive care and protocol-based dose modification by 15%, reducing avoidable treatment discontinuations

Additional Resources

Visit www.ceconcepts.com
for clinical information and
certified educational activities

cec ONCOLOGY

The FRα Frontier

New Pathways in Platinum-Resistant Ovarian Cancer



This activity is supported by an educational grant from Genmab.