
SGO
ANNUAL MEETING
ON WOMEN'S CANCER
ADVANCING SCIENCE
EMPOWERING TEAMS
EMBRACING CHANGE
SAN JUAN, PR | APRIL 10-13, 2026 | WWW.SGO.ORG

SGO
ANNUAL MEETING ON WOMEN'S CANCER
SAN JUAN, PR
APRIL 10-13, 2026

NRG-GY033: A Phase II Study of Androgen Receptor Inhibition by Darolutamide in combination with Leuprolide Acetate and Exemestane in Recurrent Adult-type Ovarian Granulosa Cell Tumor

Elizabeth E Hopp,[1] Danielle Enserro,[2] Susana Campos,[3] Viola Chitiyo,[4] Gloria Huang,[5] Heather Lankes,[2] Erin K. Crane,[6] Anna Hoekstra,[7] Jean Siedel,[8] Debra L. Richardson,[9] Carol Aghajanian,[4] Janet S. Rader[1]

[1]Medical College of Wisconsin, Milwaukee, WI; [2]NRG Oncology, Philadelphia, PA;[3]Dana Farber Cancer Institute, Boston, MA; [4]Memorial Sloan Kettering Cancer Center, New York, NY; [5]Yale Cancer Center, New Haven, CT; [6]Carolinas Medical Center/Levine Cancer Institute, Charlotte, NC; [7]CRC West Michigan, Kalamazoo, MI; [8]University of Michigan, Ann Arbor, MI; [9]University of Oklahoma, Oklahoma City, OK

Unlabeled/Investigational Uses

SGO ANNUAL MEETING ON WOMEN'S CANCER
SAN JUAN, PR
APRIL 10-13, 2026

I will be discussing unlabeled or investigational uses of the following pharmaceutical product: Darolutamide. This pharmaceutical product is being discussed in the context of the presented clinical trial.

Financial Disclosures

SGO
ANNUAL MEETING ON WOMEN'S CANCER
SAN JUAN, PR
APRIL 10-13, 2026

I have the following financial relationships with ACCME defined ineligible companies to report over the past 24 months:

Advisory Board: Corcept Therapeutics

Adult-type Ovarian Granulosa Cell Tumor (AGCT)

- Rare tumor characterized by hormonal excess, a nearly universal missense point mutation *FOXL2* gene and long latency periods
- Majority of AGCT are Stage I at diagnosis with high survival rates
- Approximately 1/3 of patients will recur and 50-80% of patients will die from disease

AGCT Immunohistochemistry

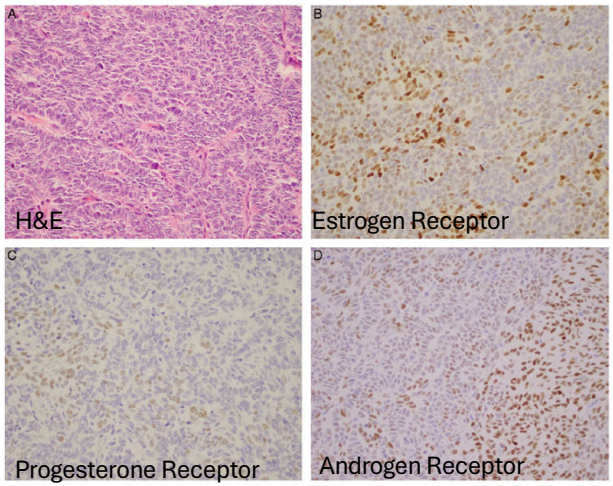


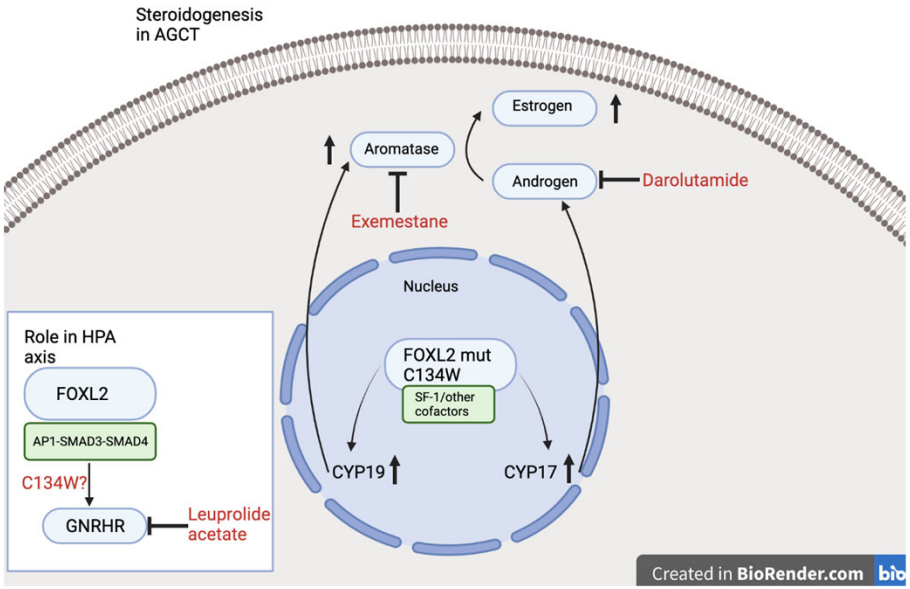
FIG. 1. Representative AGCT histology (A), ER IHC (B), PR IHC (C), and AR IHC (D).

Unmet need lies in the treatment of recurrent/metastatic AGCT

Moh M, Hopp E et al, *Int J Gynecol Pathol,* 2024

Research Objective

- To determine efficacy and safety of a novel treatment regimen combining darolutamide (second-generation androgen receptor pathway inhibitor), exemestane (aromatase inhibitor), and leuprolide acetate (gonadotropin-releasing hormone receptor agonist) in recurrent AGCT
- Response rate of 28.6% (2/7 patients) demonstrated in institutional recurrent AGCT cohort using the combination therapy, which included heavily pre-treated patients who had all progressed on a previous aromatase inhibitor



Summey RM, Hopp E, et al. *Gynecol Oncol Rep,* 2022

Study Schema

SGO ANNUAL MEETING ON WOMEN'S CANCER
SAN JUAN, PR
APRIL 10-13, 2026

Accrual Open: 01/22/2024

Accrual Closed: 04/25/2024

Patients with recurrent AGCT

↓

≥1 prior treatment regimen
Progression on a prior aromatase inhibitor
Measurable disease by RECIST 1.1 criteria

↓

Darolutamide 600 mg PO twice daily + exemestane 25 mg PO once daily+leuprolide acetate 7.5 mg IM every 4 weeks

↓

Study treatment continued until disease progression or unacceptable toxicity

Statistical Plan: Simon's Optimal two-stage design

One-sided α=0.095 and 90% power when the true response rate is 40%

Stage I: N=17 patients → if 4 or more responses, Stage 2: N=20 patients for total N=37

Study Objectives

SGO ANNUAL MEETING ON WOMEN'S CANCER
SAN JUAN, PR
APRIL 10-13, 2026

Primary Objective:

- To determine the **objective response rate (ORR)** of darolutamide, leuprolide acetate, and exemestane in recurrent AGCT

Secondary Objectives:

- To determine **duration of response**, **progression-free survival (PFS)**, and **overall survival (OS)** of darolutamide, leuprolide acetate, and exemestane in AGCT
- To elucidate the **toxicities** of darolutamide, leuprolide acetate, and exemestane using CTCAE v5

Baseline Characteristics

SGO ANNUAL MEETING ON WOMEN'S CANCER
SAN JUAN, PR
APRIL 10-13, 2026

Characteristic		N=17
Age, median (range)		58 (30-87)
Race	White Black/African-American Asian Not Specified	12 (70.6%) 3 (17.6%) 1 (5.9%) 1 (5.9%)
FIGO Stage at Initial Diagnosis	IA IC1 IC2 IIA IIB IIIB IIIC IVA IVB Not Reported	2 (11.8%) 4 (23.5%) 2 (11.8%) 1 (5.9%) 1 (5.9%) 1 (5.9%) 2 (11.8%) 1 (5.9%) 2 (11.8%) 1 (5.9%)
Prior Hormone Therapy	Yes	17 (100%)
Prior Immunotherapy	Yes No	11 (64.7%) 6 (35.3%)

Data cutoff 02/10/2026

Objective Response Rate and Duration of Response

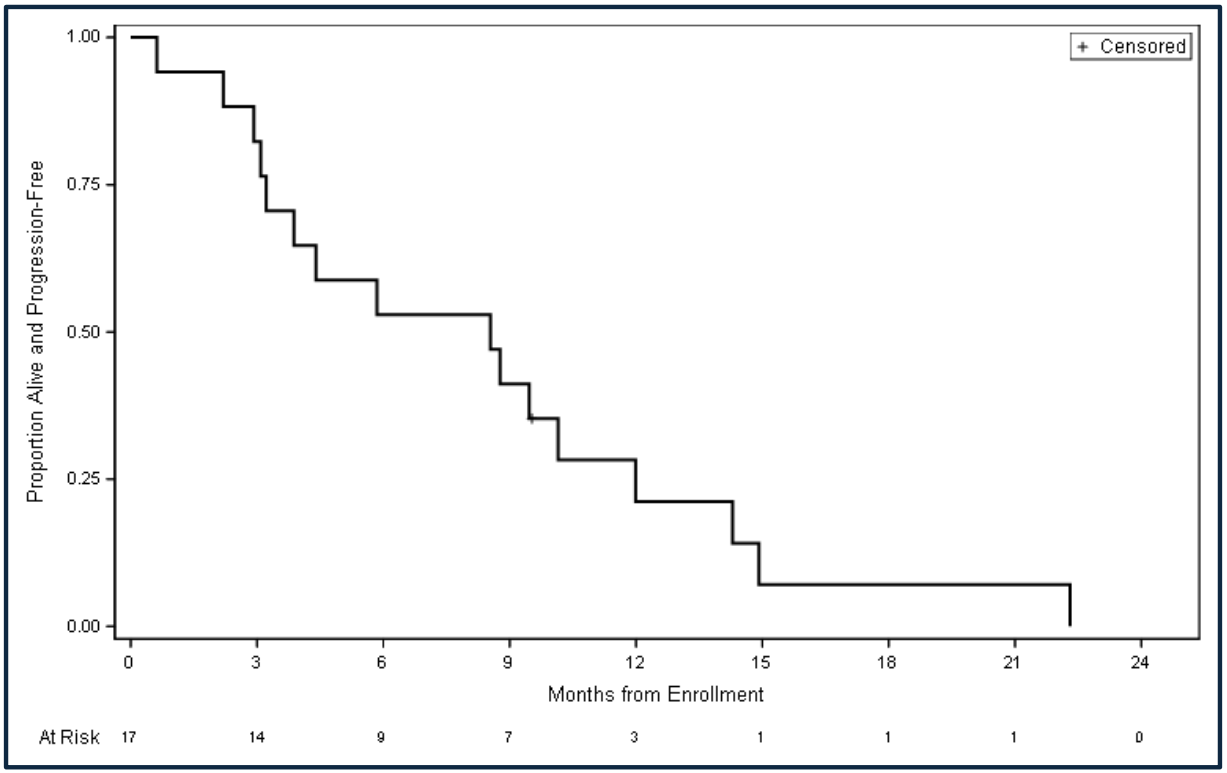
Best Confirmed Response	Darolutamide +Exemestane +Leuprolide Acetate N (%)
Complete Response (CR)	0 (0.00)
Partial Response (PR)	1 (6.25) [Duration of Response=8.8 months]
Stable Disease (SD)	10 (62.50) [Median Duration of Stable Disease=8.3 months; min 4.1 months, max 21.9 months]
Progressive Disease (PD)	5 (31.25)
Total *	16 (100.00)

*One patient excluded due to not initiating leuprolide acetate

- Trial closed prematurely as it did not meet the prespecified ORR to progress to second stage

Data cutoff 02/10/2026

Progression-Free Survival

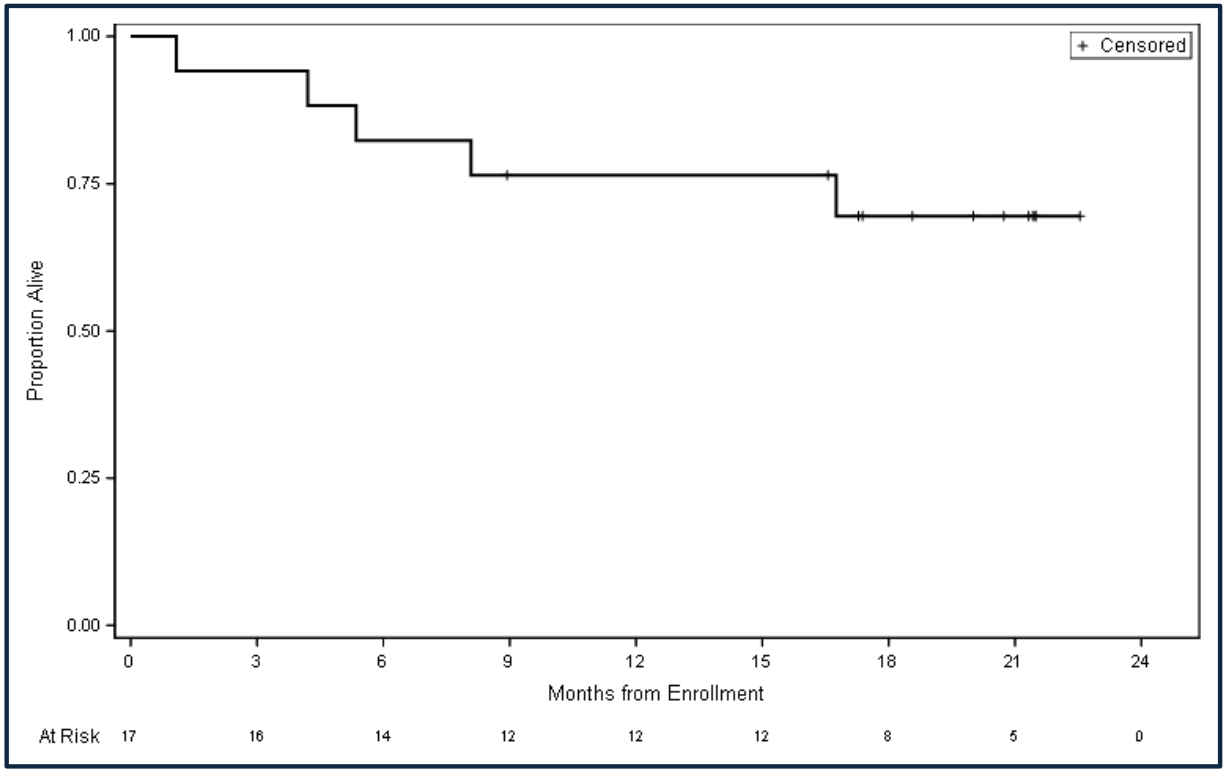


Median PFS=8.5 months

Median follow-up time=20.7 months

Data cutoff 02/10/2026

Overall Survival

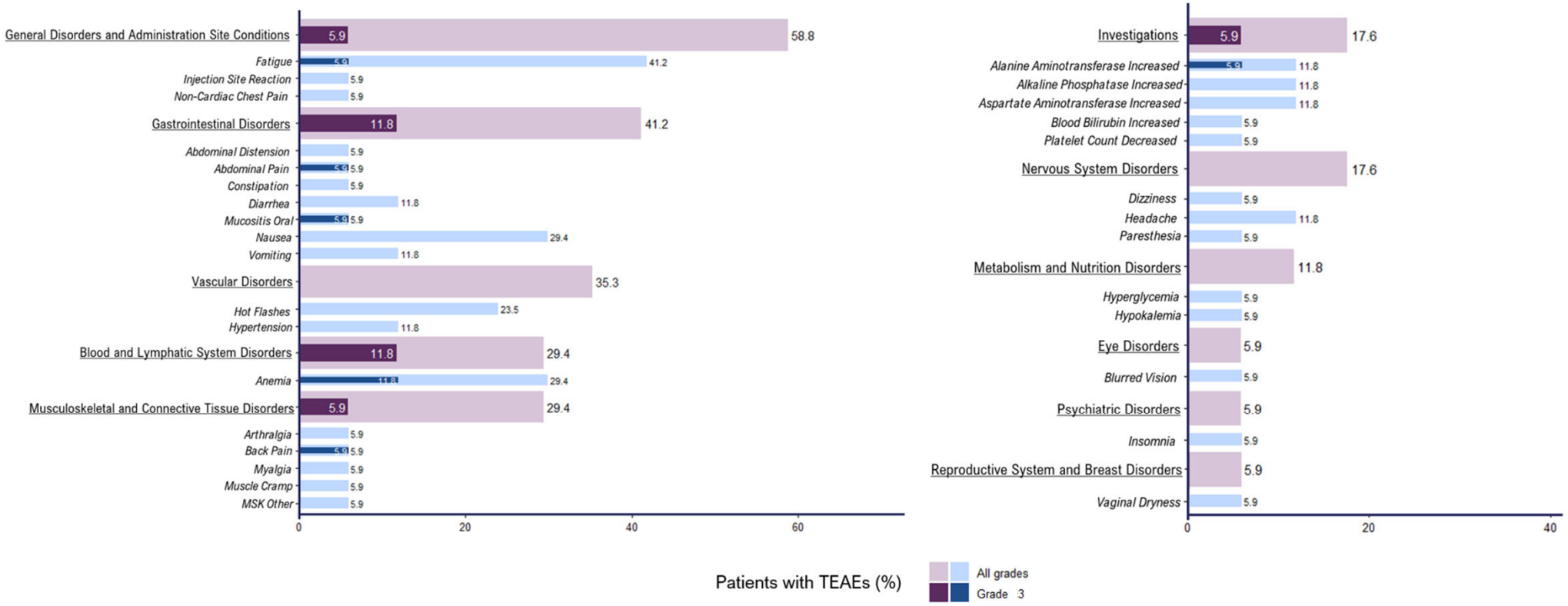


Median OS not reached

Median follow-up time=20.7 months

Data cutoff 02/10/2026

Adverse Events



Data cutoff 02/10/2026

Conclusions

- Though the trial did not meet its primary endpoint, there was one partial response to the treatment regimen and the majority of patients had durable, stable disease
- Clinically meaningful PFS of 8.5 months was demonstrated
- Tolerable safety profile noted
- Consideration of this treatment regimen is warranted as a potential therapeutic option in recurrent AGCT

Acknowledgements

- All of the patients on this trial and their families
- All of the clinical investigators and research teams