Phase III Study of Sacituzumab Govitecan vs Treatment of Physician's Choice in Participants with Endometrial Cancer After Platinum-Based Chemotherapy and Immunotherapy

ASCENT-GYN-01

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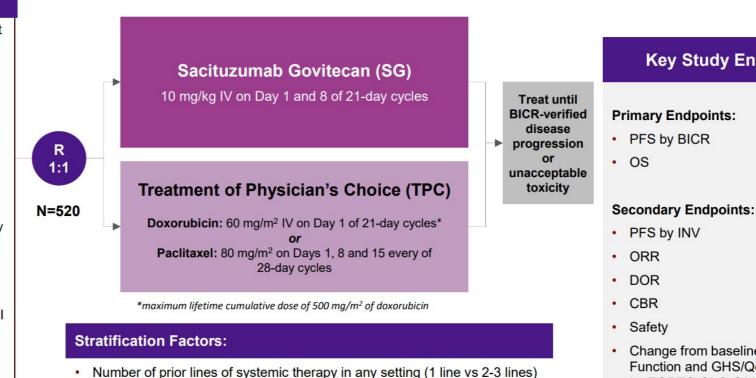
ASCENT-GYN-01/GOG-3104/ENGOT-en26: A Randomized, Open-label, Phase 3 Study of SG vs TPC in Participants with Endometrial Cancer Who Have Received Prior Platinum-based Chemotherapy and Anti-PD-1/PD-L1 Immunotherapy

Key Eligibility

- Documented evidence of recurrent/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-PD1/PD-L1 therapy, either in combination or separately

For participants who are ineligible for anti-PD-1/PD-L1 therapy due to medical comorbidities, or if anti-PD-1/PD-L1 agents are not available as standard-of-care therapy in any line of treatment according to local standards, prior treatment with an anti-PD-1/PD-L1 agent is not required.

- Radiologically evaluable disease (either measurable or nonmeasurable) by CT or MRI per RECIST v1.1 criteria by investigator assessment
- ECOG PS 0-1
- No prior treatment with a TROP-2 directed ADC or a topoisomerase I inhibitor
- Availability of adequate tumor tissue from archival or fresh biopsy



Enrollment of participants who have not received prior anti-PD-1/PD-L1

Key Study Endpoints

Change from baseline in Physical Function and GHS/QoL as assessed

by EORTC-QLQ-C30 at week 13

ORR

DOR

CBR

Safety

18 BICR = blinded independent central review; CBR = clinical benefit rate; DOR = duration of response; ECOG PS = Eastern Cooperative Oncology Group performance score; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer quality of life Questionnaire-Core 30 Version 3.0; GHS/QoL = Global Health Status/quality of life; INV = investigator; IV = intravenous; N = number of participants; OS = overall survival; ORR = objective response rate; PD-1 = programmed cell death protein 1; PD-L1 = programmed cell death ligand 1; PFS = progression-free survival; R = randomization; RECIST v1.1 = Response Evaluation Criteria in Solid Tumors Version 1.1; ROW = rest of world; SG = sacituzumab govitecan; TPC = treatment of physician's choice.

Prior anti-PD-1/PD-L1 therapy (yes vs no)

therapy will be capped at approximately 10%

Geographic region (North America/Europe vs Asia/RoW)

Key Inclusion Criteria – Patient Population





Documented evidence of recurrent/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.

- Neoadjuvant and/or adjuvant therapy is considered 1 prior line of systemic therapy.
- Prior monoclonal antibodies or targeted therapies, including but not limited to bevacizumab, poly (adenosine diphosphate-ribose) polymerase inhibitors, trastuzumab, will count as a line of treatment if given as a single agent with the intent of controlling disease. If these agents are given in combination with chemotherapy and continued as maintenance monotherapy, they will not be counted as a separate line of treatment.
- There is no restriction regarding prior hormonal or hormonal-based therapy. Hormonal or hormonal-based therapy does not count as a line of therapy.
- For participants who are ineligible for anti-PD-1/PD-L1 therapy due to medical comorbidities, or if anti-PD-1/PD-L1 agents are not available as standard-of-care therapy in any line of treatment according to local standards, prior treatment with an anti-PD-1/PD-L1 agent is not required.

Eligible for treatment with either doxorubicin or paclitaxel as determined by the investigator

Radiologically evaluable disease (either measurable or nonmeasurable) by CT or MRI per RECIST v1.1 criteria by investigator assessment

• If a participant has disease based on pleural effusion or ascites alone (with no other radiologically evaluable lesions), this must be cytologically confirmed.

Documented disease progression by CT or MRI during or after the most recent therapy per RECIST v1.1 criteria by investigator assessment.

ECOG performance status score of 0 or 1

Life expectancy of >= 3 months

Key Exclusion Criteria



Uterine leiomyosarcoma and endometrial stromal sarcomas

Participants who are candidates for curative-intent therapy at the time of study enrollment

Patients eligible for rechallenge with platinum-based chemotherapy as determined by the investigator

Received any prior treatment with a Trop-2 directed ADC

Received any prior treatment (including an ADC) containing a chemotherapeutic agent targeting topoisomerase I

Have had a prior anticancer biologic agent within 4 weeks prior to the first dose of study drug or have had prior chemotherapy, target small molecule therapy, or radiation therapy within 2 weeks prior to the first dose of study drug

Use of other investigational drug (drugs not marketed for any indication) within 28 days or 5 half-lives (whichever is longer) of first dose of study drug