RaPiDS (GOG-3028): Randomized Phase II study of balstilimab alone or in combination with zalifrelimab in cervical cancer

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Primary objective

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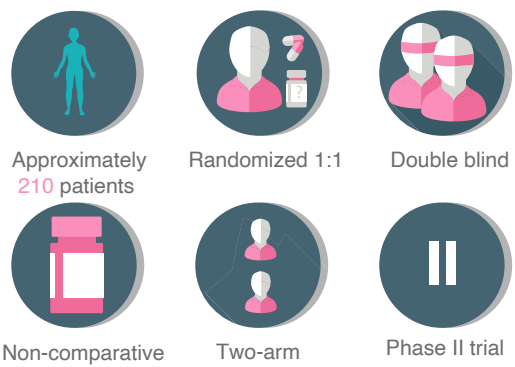
To evaluate ORR, per RECIST v1.1 and assessed by IRRC, for balstilimab plus placebo (monotherapy) and in combination with zalifrelimab

Secondary key objectives

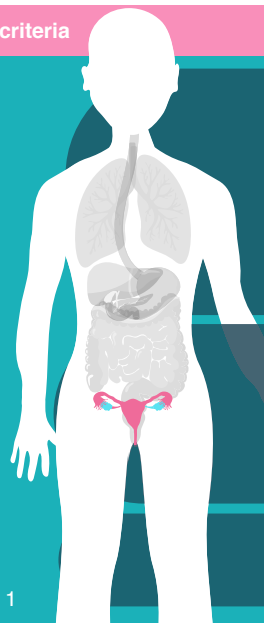
- To confirm the safety and tolerability of balstilimab as monotherapy and in combination with zalifrelimab
- To determine PFS, assessed by IRRC and investigators, for balstilimab monotherapy and in combination with zalifrelimab
- To assess DOR, per RECIST v1.1 and assessed by IRRC, for balstilimab monotherapy and in combination with zalifrelimab
- To evaluate OS for balstilimab monotherapy and in combination with zalifrelimab

Study design and treatment



- In Arm 1, placebo will be administered with balstilimab at corresponding time points to zalifrelimab dosing in Arm 2.
- The blinded portion of the study applies to whether zalifrelimab or placebo is administered; balstilimab dosing is not blinded.
- Each treatment cycle is 6 weeks.

Key eligibility criteria



≥18
Age ≥18 years

RECIST v1.1
Measurable disease per RECIST v1.1

ECOG PS 0 or 1
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Histologically or cytologically confirmed diagnosis of recurrent/metastatic squamous cell carcinoma, adenosquamous carcinoma, or adenocarcinoma of the cervix.

Patients must have relapsed after a first-line, platinum-based treatment regimen for metastatic, persistent, and/or unresectable disease.

No prior therapy with a checkpoint inhibitor.

Adult patients with recurrent/persistent/metastatic cervical cancer

One prior platinum-based regimen for advanced disease

Target enrollment n = 210

R 1:1

Balstilimab 300 mg Q3W + placebo

Balstilimab 300 mg Q3W + Zalifrelimab 1mg/kg Q6W

Treatment is permitted for up to 24 months, or until disease progression, development of unacceptable toxicity, or investigator/patient decision to withdraw

- Non-comparative trial design
- No patient stratification

Outcome measures/end points

Primary end point:
ORR for each treatment arm

Key secondary end points:
DOR, DCR, PFS, OS, safety and tolerability for each treatment arm

Exploratory end points:
Association of tumor PD-L1 expression with response; Association of TMB with response

Glossary

DCR: Disease control rate; DOR: Duration of response; IRRC: Independent Radiology Review Committee; IV: Intravenously; ECOG PS: Eastern Cooperative Oncology Group performance status; ORR: Objective response rate; OS: Overall survival; PFS: Progression-free survival; PD-L1: Programmed death ligand 1; Q3W: Once every three weeks; Q6W: Once every 6 weeks; RECIST: Response Evaluation Criteria in Solid Tumors; TMB: Tumor mutational burden