

GOG-0265 Open-Label Phase II 2-Stage Study

Axalimogene Filolisbac (AXAL) in Recurrent Cervical Cancer

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Persistent or recurrent squamous or nonsquamous cell carcinoma, adenosquamous carcinoma, or adenocarcinoma of the cervix

- Documented disease progression via pathology report
- Measurable disease with at least 1 “target” lesion

Simon 2-stage trial design (currently in Stage 2)

Study sponsored by Advaxis and CTEP/NCI and coordinated by the Gynecologic Oncology Group in collaboration with the National Cancer Institute

Trial timeline (projected)

- Stage 2 trial enrollment to commence 3Q16

In collaboration with



<https://clinicaltrials.gov/ct2/show/record/NCT01266460>

For more information, contact Allison Gladden, Director, Clinical Operations:

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305 College Road East

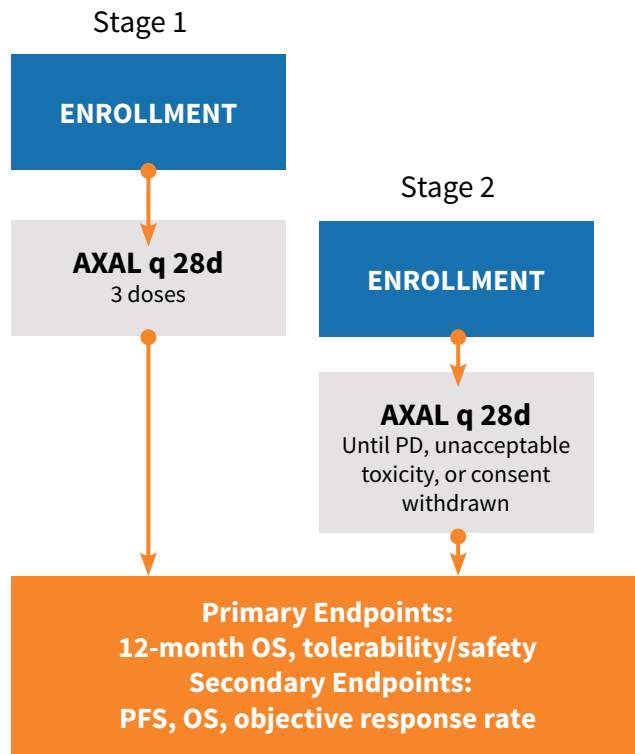
Princeton, NJ 08540

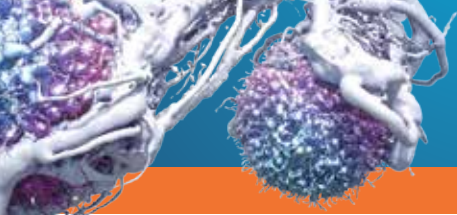
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TRIAL PHASE	Phase II 2-stage
STUDY CENTERS	Multicenter in US
TRIAL BLINDING	Open-label, single-arm
NUMBER OF TRIAL PATIENTS	Approximately 60 patients with persistent or recurrent cervical cancer (per protocol amendment)
ESTIMATED DURATION	Approximately 12 months for recruitment <ul style="list-style-type: none">• Treatment to be repeated until disease progression or unacceptable toxicity• Up to 5 years follow up

METHODOLOGY	This is a multicenter US open-label study of AXAL in patients with persistent or recurrent squamous or nonsquamous cell carcinoma, adenosquamous carcinoma, or adenocarcinoma of the cervix with documented disease progression (disease not amenable to curative therapy)
OBJECTIVES	<ul style="list-style-type: none">• Primary: AEs; number of patients with dose-limiting toxicities; 12-month OS• Secondary: Distribution of OS and PFS; objective response rate
STATISTICAL CONSIDERATIONS	<ul style="list-style-type: none">• Sample size calculation is based on the expected null proportion of patients surviving 12 months across historical trials = 20%• 90% power to detect a 15% increase in 12-month survival (20% to 35%) at a one-sided significance level of 0.10• Trial has proceeded to Stage 2 of enrollment based on conditional power at the end of Stage 1 >20%

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