

# AIM2CERV Phase III in Cervical Cancer

Axalimogene Filolisbac (AXAL)

**ADVAXIS**  
IMMUNOTHERAPIES™

## High-risk, locally advanced cervical cancer

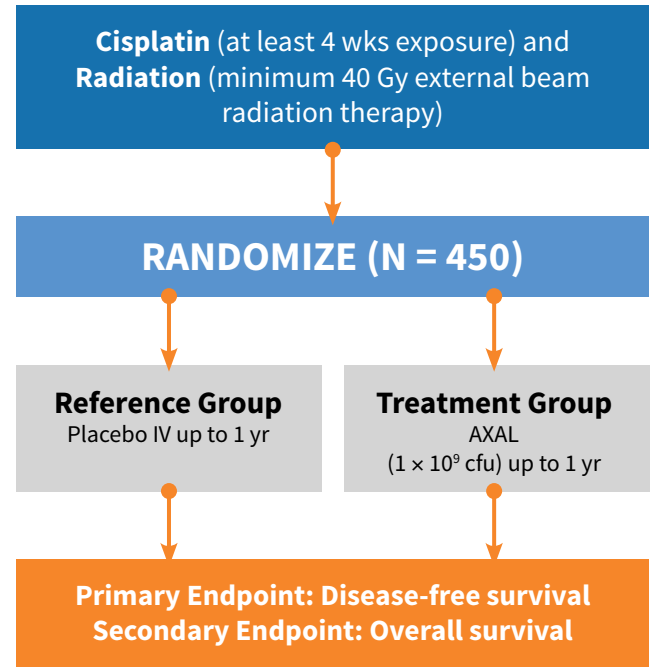
- FIGO stage I-II with positive pelvic nodes
- FIGO stage III-IV
- Any FIGO stage with para-aortic nodes

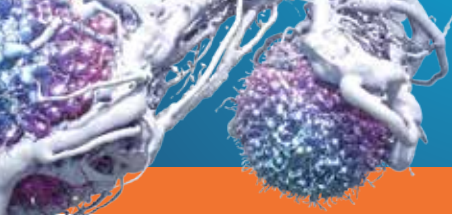
## Total sites: 150 sites in 20 countries

GOG is supporting AIM2CERV by acting as a Site Management Organization

## Trial timeline (predicted)

- First patient enrollment: 3Q16
- Last patient enrollment: 2Q18
- Final data readout: 3Q19





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<b>TRIAL PHASE</b>	Phase III
<b>STUDY CENTERS</b>	Multicenter, global in 20 countries; 150 sites
<b>TRIAL BLINDING</b>	Double-blinded, placebo-controlled
<b>NUMBER OF TRIAL PATIENTS</b>	Approximately 450
<b>ESTIMATED DURATION</b>	Approximately 21 months for recruitment <ul style="list-style-type: none"><li>• 1 year of treatment</li><li>• 3-5 years follow up</li></ul>
<b>RANDOMIZATION RATIO</b>	1:2 Arm A to Arm B
<b>METHODOLOGY</b>	This is a double-blind, placebo-controlled randomized study of AXAL administered in the adjuvant setting after completion of cisplatin-based CCRT in patients with locally advanced cervical cancer at higher risk for recurrence, progression, or death

<b>OBJECTIVES</b>	<ul style="list-style-type: none"><li>• Primary: Disease-free survival (DFS)</li><li>• Secondary: Safety, tolerability, and overall survival</li></ul>
<b>STATISTICAL CONSIDERATIONS</b>	<ul style="list-style-type: none"><li>• 184 events provide 85% power for detecting a treatment hazard ratio of 0.620</li><li>• DFS will be defined as the time from randomization until death, progression, or first documented relapse, categorized as either locoregional (primary site or regional nodes) failure or distant metastasis</li><li>• An interim analysis will be performed when there is at least one-half the number of DFS events required for full maturity of the study</li><li>• Logrank test of the null hypothesis <math>H_0: E</math>, DFS will be calculated and futility will be assessed</li></ul>
<b>COUNTRIES</b>	Argentina, Brazil, Canada, Chile, Hong Kong, Ireland, Korea, Malaysia, Mexico, Netherlands, Poland, Romania, Russia, Serbia, Spain, Taiwan, UK, Ukraine, US