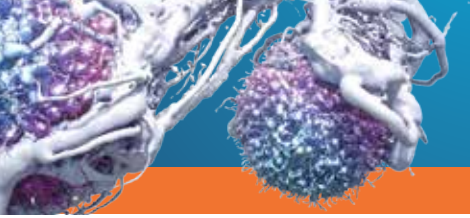


Phase I/II Study in Recurrent/Persistent Metastatic Cervical or HPV+ Head & Neck Cancer

Axalimogene Filolisbac (AXAL)

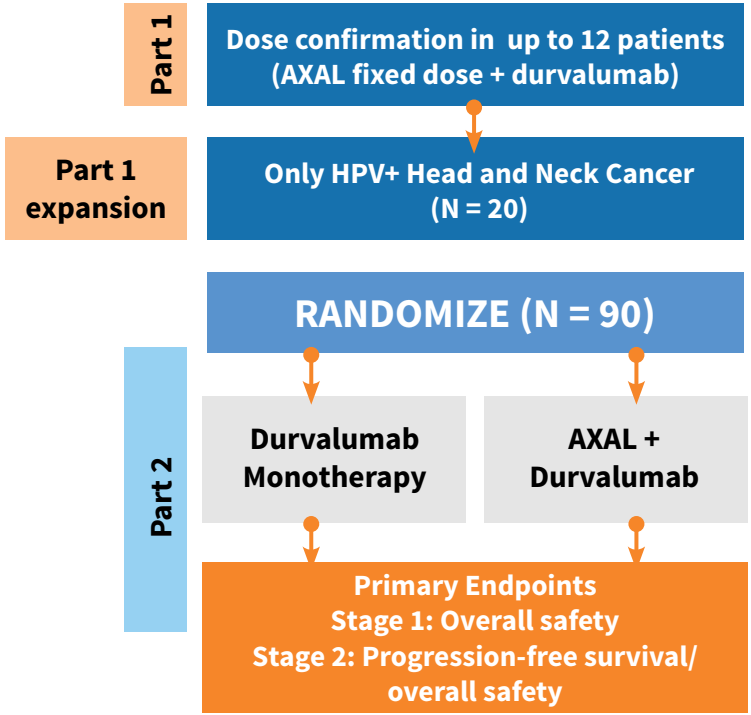
ADVAXIS IMMUNOTHERAPIES™

Patient characteristics

- Diagnosis of cervical cancer or HPV+ squamous cell carcinoma of the head/neck with measurable and/or evaluable disease by RECIST 1.1
- Have ECOG performance status of 0 or 1
- No diagnosis of immunodeficiency

Trial timeline (projected)

- Part 1 first patient cohort enrollment complete: 1Q16
- Part 1 second patient cohort enrollment complete: 2Q16
- Part 1 expansion initiated: 3Q16
- Part 2 first patient enrolled: 3Q16
- Study completion: 2018

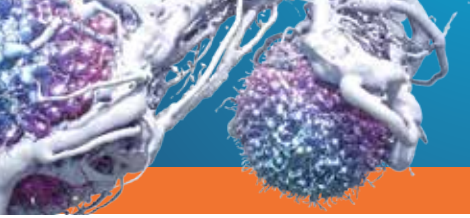


In collaboration with MedImmune

https://clinicaltrials.gov/ct2/show/NCT02386501

For more information, contact Janet Flisak, Senior Director, Clinical Operations: flisak@advaxis.com Phone: 609-250-7505

 305 College Road East Princeton, NJ 08540 Phone: 609-452-9813 Fax: 609-452-9818



Phase I/II Study in Recurrent/Persistent Metastatic Cervical or HPV+ Head & Neck Cancer

Axalimogene Filolisbac (AXAL)

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TRIAL PHASE	Phase I/II
STUDY CENTERS	Multicenter, US only
TRIAL BLINDING	Open-label, unblinded
NUMBER OF TRIAL PATIENTS	Approximately 122 • 6-12 in Part 1 (dose-finding) • 20 in Part 1 expansion (H&N only) • 90 in Part 2, phase II (cervical only)
ESTIMATED DURATION	Approximately 6 years • Includes active study treatment (~12 months) • Includes 3–year *Lm* surveillance period
RANDOMIZATION RATIO	• No randomization in Part 1 and Part 1 expansion • Part 2: 1:1 randomization to durvalumab or AXAL + durvalumab
METHODOLOGY	• Part 1, phase I dose escalation of combination AXAL + durvalumab (3+3 design to determine recommended dose in Part 2, phase II) • Once 28-day DLT period is completed, the Part 1 expansion, and Part 2 randomized portion of the study will commence
OBJECTIVES	• Part 1: Safety and tolerability to select recommended phase II dose • Part 1 expansion: Preliminary signs of efficacy by RECIST 1.1 and irRECIST, duration of response, and PFS • Part 2: Tumor response and PFS by RECIST 1.1 and irRECIST of durvalumab alone compared with combination of AXAL + durvalumab
STATISTICAL CONSIDERATIONS	• Summarized by treatment arm and disease type. Statistical testing for treatment comparisons will be performed as a reference • Overall RR will be tested by Fisher's exact test • Two-sided 90% and 95% CIs for difference in RR as well as CIs for each are individually constructed

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