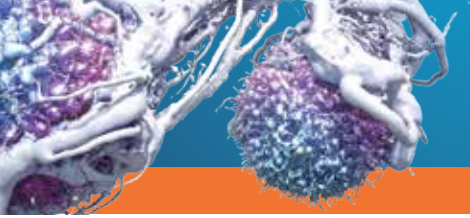

Phase II FAWCETT Study in Anal Cancer

Axalimogene Filolisbac (AXAL)

ADVAXIS IMMUNOTHERAPIES™

Two-part study of AXAL monotherapy

- Primary and secondary endpoints: Overall response rate (ORR) by RECIST (primary) and irRECIST (secondary); 6-month PFS
- Other endpoints: Safety and tolerabilty, duration of response, PFS, and overall survival
- Proceed to stage 2 if stage 1 response rate ≥10% or if 6-month PFS ≥20%
- *Note: Stage 2 may include checkpoint inhibitor combination*

Patient characteristics

- Persistent/recurrent, locoregional, or metastatic squamous cell cancer of the anorectal canal
- Stage 1 enrollment: 31 patients
- Stage 2 enrollment: 24 additional patients

Trial timeline (projected)

- First patient enrollment: 3Q16
- Study completion: 2021

Treatment naive in metastatic setting or progressed after platinum-based therapy

↓

AXAL Monotherapy
Every 3 weeks for up to 2 years

↓

Key Endpoints:
Overall Response Rate
6-Month PFS

↓

Interim Analysis and Stage 2 Enrollment
Additional 24 patients if ≥10% RR or ≥25% 6-month PFS

https://clinicaltrials.gov/ct2/show/NCT02399813

For more information, contact Allison Gladden, Director, Clinical Operations: gladden@advaxis.com Phone: 609-250-7523

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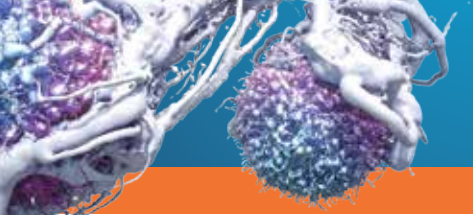

Phase II FAWCETT Study in Anal Cancer

Axalimogene Filolisbac (AXAL)

ADVAXIS IMMUNOTHERAPIES™

TRIAL PHASE	Phase II
STUDY CENTERS	Multicenter US
TRIAL BLINDING	Open-label 2-stage study; stage 1 will be AXAL (ADXS11-001) monotherapy; stage 2 will be randomized, possibly in combination with a PD-1 checkpoint inhibitor
NUMBER OF TRIAL PATIENTS	Approximately 55
ESTIMATED DURATION	Up to 2 years of treatment and 5 years of total follow-up
RANDOMIZATION RATIO	1:1 planned for stage 2

METHODOLOGY	• Stage 1 will be a single-arm study of AXAL monotherapy • Stage 2 will be a randomized study of an AXAL-based regimen vs a comparator arm in patients with relapsed or recurrent HPV+ anal cancer (potential checkpoint inhibitor combination)
OBJECTIVES	• Primary: ORR by RECIST • Others: ORR by irRECIST; 6-month PFS, safety and tolerability, duration of response, PFS, and overall survival
STATISTICAL CONSIDERATIONS	PFS 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

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