ADXS11-001 IMMUNOTHERAPY: 12 MONTH SURVIVAL AND SAFETY DATA FROM A PHASE 2 STUDY IN RECURRENT CERVICAL CANCER

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ABSTRACT

Lm-LLO-E7-015 is a live attenuated vaccine strain engineered by Advaxis, Inc. for the treatment of HPV-associated cancer.

- ADXS11-001 is a genetically engineered, live attenuated Listeria monocytogenes (Lm) expressing LLO
- Expresses LLO, a bacterial virulence factor which inhibits the cell-mediated immune system, and E7, a TAA
- Lm-LLO-E7-015 is sponsored by Advaxis, Inc., Princeton, NJ

Recruitment: Phase 3 Trial to Assess the Safety and Efficacy of ADXS11-001 in patients with high risk cervical cancer

- N = 110
- Median age: 56
- All patients received ADXS11-001 with cisplatin chemotherapy
- Safety and efficacy data for ADXS11-001 alone

Methods

- Patients randomized to either 1 cycle (3 doses) of ADXS11-001 at 1x10⁹ cfu or 4 doses of ADXS11-001 as an IV infusion (1x10⁹ cfu), followed by antibiotic beginning 3 days post-dosing, followed 4 weeks later with 5 weekly IV administrations of ADXS11-001 + cisplatin
- Patients received ADXS11-001 as an IV infusion (1x10⁹ cfu), followed by antibiotic beginning 3 days post-dosing, followed 4 weeks later with 5 weekly IV administrations of ADXS11-001 + cisplatin

Overall Survival

- Overall survival observed with ADXS11-001 is consistent with an active agent in recurrent cervical cancer.
- Final 12 month overall survival of 36% with a (current) 18 month survival of 22% is notable in this disease setting.

Tumor responses were observed in all strains of high-risk HPV detected including HPV 16, 18, 31, 33 and 45

Using RECIST criteria 20 patients had a best overall response of progressive disease, 12 patients had objective responses (6CR/6PR), and 33 patients had stable disease ≥ 3 months.

Stable disease >3 months was 31% for aggressive disease and 26% for non-aggressive disease.

15-fold increase is observed in the level of cytokines (IL-6, IL-8, IL-10 and TNF-β) during the first few hours of the Lm-LLO-E7-015 administration.

The Kaplan Meier curve on the left represents overall survival for all patients that completed at least 12 months of follow-up.