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Advaxis Provides Phase 1 Data of Higher Dose Axalimogene Filolisbac

PRINCETON, N.J., March 27, 2017 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a biotechnology company developing cancer immunotherapies, today published online a poster previously presented at the National Cancer Research Institute (NCRI) Cancer Conference in Liverpool that showed axalimogene filolisbac achieved durable response in a patient with persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC).

Nine patients who had documented disease progression after they had received curative treatments of chemotherapy and/or radiation with or without bevacizumab were enrolled in this phase 1, open-label, dose-determining study. Axalimogene filolisbac was well-tolerated across two dose levels. The study also established a recommended phase 2 dose of 1×10^{10} CFU and demonstrated antitumor activity at that dose. Axalimogene filolisbac was safely administered at 5 and 10 times the dose levels previously studied, without any significant toxicity. One patient experienced an ongoing and durable partial response. This patient was recently featured in the Augusta Chronicle, as she is being treated at the Georgia Cancer Center at Augusta University. Read the full Augusta Chronicle article here.

“The best overall tumor response in eight of the nine enrolled patients is encouraging in evaluating the potential of axalimogene filolisbac,” said Sharad Ghamande, principal investigator and Professor and Director of Gynecologic Oncology at the Georgia Cancer Center at Augusta University. “We were pleased to see a sustained and durable partial response in one patient, which is very rare for this kind of tumor that is unresponsive to chemotherapy, and survival in these patients is often less than 10 months. In addition, we could safely administer the drug at 5 and 10 times the dose levels previously studied, without any significant toxicity.”

There was only one instance of dose-limiting toxicity, with that patient experiencing a grade 3 treatment related adverse event (TRAE) of hypotension at a dose of 5×10^{9} CFU. Across all doses, eight of nine patients experienced a grade 1-2 TRAE, including chills, nausea and hypotension.

The poster on the phase 1 data, “High-dose treatment with ADXS11-001, a *Listeria monocytogenes*-listeriolysin O (*Lm*-LLO) immunotherapy, in women with cervical cancer: a phase I, dose-escalation study” (no. 58) is available at www.advaxis.com. The company is preparing to initiate a phase 3 trial in PRmCC later this year.

About Axalimogene Filolisbac

Axalimogene filolisbac is a targeted *Listeria monocytogenes (Lm)*-based immunotherapy

that attacks HPV-associated cancers by altering a live strain of *Lm* bacteria to generate cancer-fighting T cells against cancer antigens while neutralizing the tumor's natural protections that guard the tumor microenvironment from immunologic attack. In a phase 2 trial evaluating axalimogene filolisbac for the treatment of persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC), the drug candidate showed a 12-month overall survival rate of 38 percent observed in 50 patients in the trial. This is a 52 percent improvement over the 12-month overall survival rate that was expected in the trial's patient population based on prognostic factors.

Axalimogene filolisbac has received Fast Track designation for adjuvant therapy for high-risk locally advanced cervical cancer (HRLACC) and a Special Protocol Assessment for the Phase 3 AIM2CERV trial in HRLACC patients. The immunotherapy has also received orphan drug designation in three clinical indications.

About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a biotechnology company developing multiple cancer immunotherapies based on its proprietary *Lm* Technology™. The *Lm* Technology, using bioengineered live attenuated *Listeria monocytogenes* (*Lm*) bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancer fighting T cells directed against cancer antigens and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis' lead *Lm* Technology immunotherapy, axalimogene filolisbac, targets HPV-associated cancers and is in clinical trials for three potential indications: Phase 3 in invasive cervical cancer, Phase 2 in head and neck cancer, and Phase 2 in anal cancer. The FDA has granted axalimogene filolisbac orphan drug designation for each of these three clinical settings, as well as Fast Track designation for adjuvant therapy for HRLACC patients and a SPA for the Phase 3 AIM2CERV trial in HRLACC patients. Axalimogene filolisbac has also been classified as an advanced therapy medicinal product for the treatment of cervical cancer by the EMA's CAT. Advaxis has two additional immunotherapy products: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, in human clinical development. In addition, Advaxis and Amgen are developing ADXS-NEO, an investigational cancer immunotherapy treatment designed to activate a patient's immune system to respond against the unique mutations, or neoepitopes, contained in and identified from each individual patient's tumor, with plans to commence a Phase 1 clinical trial in 2017.

To learn more about Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook, and YouTube.

Advaxis Forward-Looking Statement

This press release contains forward-looking statements, including, but not limited to, statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies, and the safety and efficacy of Advaxis' proprietary immunotherapy, axalimogene filolisbac. These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in Advaxis' SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2016, which is available at http://www.sec.gov.

Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law.

You are cautioned not to place undue reliance on any forward-looking statements.

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