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Dosing Begins in High Dose Expansion Cohort in Phase 2 Study of Axalimogene Filolisbac in Patients With Recurrent Cervical Cancer

Expansion Phase of Study Follows Successful Completion of 2 Prior Escalating Dose Levels

PRINCETON, N.J., March 07, 2016 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, today announced dose administration for the first patient in the expansion phase of an ongoing Phase 2 clinical trial of its lead *Lm* immunotherapy candidate, axalimogene filolisbac (AXAL), in patients with persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC).

The interventional, open-label, non-randomized dose-escalation study is designed to evaluate the safety, efficacy and immunological effect of AXAL administered at doses up to 1 x 10^{10} colony forming units (CFU) in repeat cycles of treatment in approximately 25 women with cervical cancer whose disease recurred after receiving one prior cytotoxic treatment regimen. The study is being led by principal investigator Sharad Ghamande, M.D., Director of Gynecology Oncology at GRU Cancer Center, Augusta University in Augusta, Ga.

Launch of the expansion phase follows a poster presentation of preliminary data at the Society for Immunotherapy of Cancer 2015 Annual Meeting, where data from 9 patients showed that AXAL could be safely administered with prophylactic antibiotics up to 1 x10^{10} CFU, a tenfold increase from prior dosing regimens at 1 x 10^{9}. Adverse events at this high dose were consistent with previous experience with predominately grade 1 or grade 2, transient events that self-resolved or were resolved with anti-inflammatory agents (NSAIDS) and antiemetics. The high dose expansion phase will include 15 patients.

“The launch of the expansion phase of this clinical study is an important next step in AXAL's development program. This study will further explore what our research has shown to date - that a higher dose drives an increase in protein expression in the cytosol and results in greater generation of T cells to the HPV target,” said Daniel J. O’Connor, President and Chief Executive Officer of Advaxis. “AXAL holds the potential to fill an unmet treatment gap for women with recurrent cervical cancer.”

About Cervical Cancer

Cervical cancer is the fourth most common cancer in women worldwide. In the United States, nearly 13,000 new cases are diagnosed and approximately 4,100 deaths are reported because of cervical cancer. According to the WHO/ICO Information Centre on HPV and Cervical Cancer, about 3.9 percent of women in the U.S. are estimated to harbor high-risk cervical HPV infection at a given time, and 71.7 percent of invasive cervical cancers are attributed to high-risk HPV strains.

About Axalimogene Filolisbac

Axalimogene filolisbac (ADXS-HPV) is Advaxis' lead *Lm* Technology™ immunotherapy candidate for the treatment of HPV-associated cancers and is in clinical trials for three potential indications: invasive cervical cancer, head and neck cancer, and anal cancer. In a completed randomized Phase 2 study in recurrent/refractory cervical cancer, axalimogene filolisbac showed apparent prolonged survival, objective tumor responses, and a manageable safety profile alone or in combination with chemotherapy, supporting further development of the company's *Lm* Technology™. Axalimogene filolisbac has Orphan Drug Designation in the U.S. for the treatment of invasive cervical cancer, head and neck, and anal cancer.

About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a clinical-stage 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 a cancer antigen 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 human papillomavirus (HPV)-associated cancers and is in clinical trials for three potential indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The U.S. Food and Drug Administration (FDA) has granted axalimogene filolisbac orphan drug designation for each of these three clinical settings. Advaxis has two additional immunotherapy products: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, in human clinical development.

For additional information on Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook, YouTube and Google+.

Forward-Looking Statements

This media statement 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 immunotherapies. 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, 2015, which is available at http://www.sec.gov. Advaxis undertakes no obligation to publicly release the result of any revision to these forward-looking statements, which may be made to reflect the events or

circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

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