August 11, 2016

Advaxis Announces that Phase 2 Head and Neck Cancer Study with AXAL Advances to Second Stage

AXAL meets stage 1 primary objective, demonstrates increased systemic HPV-reactive T-cell responses

PRINCETON, N.J., Aug. 11, 2016 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, today announced that its Phase 2 “window of opportunity” clinical study of its lead immunotherapy candidate, axalimogene filolisbac (AXAL), in patients with late-stage HPV-associated oropharyngeal cancer (HPVOPC) met its stage 1 primary objective and is advancing into the second stage of the clinical study.

This is an investigator-initiated prospective clinical study of patients with stage I-IV HPVOPC who are to undergo ablative trans-oral robotic surgery (TORS) as a preoperative treatment. The clinical study leverages the five- to six-week period between diagnosis and TORS, making it possible to analyze and compare the tumor microenvironment as well as peripheral blood samples collected before and after AXAL treatments.

The clinical study is designed to show that AXAL is highly immunogenic and worth further investigation if the overall rate of vaccine-induced T-cell responses is 75 percent or more. By looking at both IFN-γ and TNFα expressing T cells in the peripheral blood, it was found that systemic HPV-reactive T-cell responses were increased in enough patients treated with AXAL to meet the stage 1 immune response target. This evidence of systemic response is consistent with a recent abstract presented at the American Association for Cancer Research (AACR) describing increased cytotoxic T-cell infiltration into the tumor microenvironment in HPVOPC patients treated with AXAL.

“The assessment of the TNFα and IFN-γ response based on data from eight of the anticipated nine patients to be enrolled in stage 1 confirmed that the clinical study has already met the target for the overall rate of vaccine-induced T-cell response, paving the way for us to progress to stage 2,” said the study’s lead investigator Andrew G. Sikora, MD, PhD, of the Bobby R. Alford Department of Otolaryngology-Head and Neck Surgery at Baylor College of Medicine. “Together with our prior published data showing increased intratumoral T-cell infiltration in a significant number of AXAL treated patients, these data provide the confidence needed to move forward with the definitive evaluation of its immunogenicity.”

Stage 2 of the clinical study will enroll up to 13 patients with late-stage HPVOPC. This stage of the clinical study will be conducted at the Icahn School of Medicine at Mount Sinai and a second investigative site anticipated to be the Baylor College of Medicine. The

study received a three-year $1.1 million grant from the U.S. Food and Drug Administration's Office of Orphan Products Development, which funds research for the development of products for rare diseases.

HPV-Associated Head and Neck Cancers

More than 90 percent of head and neck squamous cell oropharyngeal cancers originate from the mucosal linings of the oral cavity, pharynx or larynx. Currently, 60 to 80 percent of these cancers are caused by HPV. Head and neck cancers are treated by surgical removal of the cancer and lymph nodes, often followed by radiation and chemotherapy based on the extent of the disease. While patients may achieve good long-term survival, standard treatments can change their physical appearance and are associated with significant short and long-term toxicities which may interfere with salivary gland function, taste, smell, and the ability to swallow.

The incidence of HPV-associated head and neck cancers has been increasing at an epidemic rate, while head and neck cancers from other causes have been decreasing. According to the World Health Organization, approximately 15 to 20 percent of the 400,000 new cases of head and neck cancer are HPV-related. In the US, there are about 12,000 new cases of HPV-associated head and neck cancer per year and it affects men about 3 times more frequently than women. HPV-associated head and neck cancer is growing fastest in developed countries like the U.S.

About Axalimogene Filolisbac

AXAL 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. AXAL has Orphan Drug Designation in the U.S. for the treatment of these three indications. In a completed randomized Phase 2 study in recurrent/refractory cervical cancer, AXAL 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.

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 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, AXAL, targets human papillomavirus (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 U.S. Food and Drug Administration (FDA) has granted AXAL orphan drug designation for each of these three clinical settings, as well as a Special Protocol Assessment for the Phase 3 AIM2CERV trial in patients with high risk, locally advanced cervical cancer. AXAL has also

been classified as an advanced therapy medicinal product for the treatment of cervical cancer by the European Medicines Agency's Committee for Advanced Therapies. 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+.

Advaxis Forward-Looking Statement

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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