November 11, 2016

Advaxis to Present Phase 1 Combination Data and New Preclinical Data Using AXAL at Upcoming Society for Immunotherapy of Cancer (SITC) 2016 Annual Meeting

- *Phase 1 AXAL and durvalumab combination trial shows safety and tolerability in cervical and HPV+ head and neck cancer*
- *Preclinical data demonstrate synergistic antitumor effects of AXAL combined with a CD137 agonistic antibody, or with an anti- CTLA-4 antibody*

PRINCETON, N.J., Nov. 11, 2016 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, announced new data highlighting the potential therapeutic benefit of Advaxis' lead immunotherapy candidate, axalimogene filolisbac (AXAL), both as a monotherapy and in combination with antibody-based immunotherapies in multiple patient populations with HPV+ cancers. These data will be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting & Associated Programs this week in National Harbor, MD.

- **A Phase 1/2 study of durvalumab alone or in combination with AXAL in recurrent/persistent or metastatic cervical or human papillomavirus (HPV)+ squamous cell cancer of the head and neck (HNSCC): Preliminary Phase 1 results** (SITC 2016 abstract no. 215354)

This Phase 1 (Part A; 3+3) dose-escalation study was designed to assess the overall safety and select the recommended phase 2 dose (RP2D) of AXAL in combination with durvalumab in patients with recurrent/metastatic cervical or HPV+ HNSCC cancer. Patients received AXAL (1×10^9 colony-forming units [CFU]) every four weeks and durvalumab (3 mg/kg or 10 mg/kg) every two weeks.

Preliminary results from Part A dose escalation showed that there were no dose limiting toxicities observed, and the safety profile was consistent with previous findings for both AXAL and durvalumab. The recommended phase 2 dose was established as 1×10^9 CFU for AXAL and 10 mg/kg for durvalumab. One patient with cervical cancer achieved a complete response, which remains ongoing after 12 months of follow-up, and one patient, also with cervical cancer, achieved a partial response with subsequent disease progression. In addition, two patients with HNSCC achieved stable disease. Treatment related adverse events (TRAE) were reported in 91 percent of patients; the majority were either grade 1 or grade 2 events such as chills, fever, nausea and hypotension. Grade 3

TRAEs occurred in three patients, and one patient experienced a grade 4 event.

“When treating or evaluating investigational therapies for these kinds of metastatic, recurrent tumors, it is rare for an immunotherapy to result in a complete response,” said Brian Slomovitz, MD, principal investigator and Director of the Division of Gynecologic Oncology in the Department of Obstetrics and Gynecology at the University of Miami Miller School of Medicine. “These early data show encouraging anti-tumor activity of the combination of AXAL and durvalumab and the regimen was generally well tolerated, which supports continued study of this combination regimen.”

- **Combination of Listeria-based human papillomavirus (HPV)-E7 cancer vaccine (AXAL) with CD137 agonistic antibody provides an effective immunotherapy for HPV+ tumors in a mouse model** (SITC 2016 abstract no. 215321)

A preclinical study evaluated the ability of AXAL to control tumor growth, prolong survival and reprogram the tumor microenvironment in combination with agonistic antibodies of T cell co-stimulatory receptors or with antagonistic antibodies of immune checkpoint inhibitors in an HPV+ tumor model. Of the monoclonal antibodies (mAbs) tested, anti-CD137 mAb and anti-CTLA-4 mAb were the most effective at synergizing with AXAL to eradicate established HPV+ tumors and to provide long-term survival (>8 weeks). Complete tumor regression was observed in 28 percent of the AXAL + anti-CD137 mAb treatment group and in 33 percent of the AXAL + anti-CTLA-4 mAb treatment group.

The study demonstrated a reprogramming of the tumor microenvironment in favor of antitumor immunity in both of the combination treatment groups. Importantly, there were increased percentages of tumor antigen-specific T cells and mature dendritic cells as well as decreased percentages of regulatory T cells and immunosuppressive macrophages compared to the single-agent treatments. Together, these data show that AXAL in combination with a CD137 agonistic antibody or with a CTLA-4 antagonistic antibody synergize to enhance antitumor immunity.

- **AIM2CERV: a randomized phase 3 study of adjuvant AXAL immunotherapy following chemoradiation in patients who have high-risk locally advanced cervical cancer (HRLACC)** (SITC 2016 abstract no. 214095)

Advaxis’ Phase 3 AIM2CERV trial is a double-blind, placebo-controlled, multinational, multicenter, randomized study (NCT02853604). AIM2CERV is designed to demonstrate the efficacy and safety of AXAL as an adjuvant treatment in patients with stage I-IVA high risk, locally-advanced cervical cancer who have received cisplatin-based concurrent chemoradiation therapy (CCRT). Following CCRT, patients will receive AXAL for up to one year. A disease-free survival analysis will be conducted following at least 184 events. The study will enroll approximately 450 patients at 150 sites. Several trial sites are currently open and actively screening patients. In July, Advaxis received a Special Protocol Assessment for the AIM2CERV trial, as well as Fast Track designation for AXAL as an adjuvant therapy for HRLACC patients. For more information on Advaxis clinical trials, visit www.clinicaltrials.gov.

The presentation slides and audio are now available atwww.advaxis.com.

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 FDA has granted AXAL orphan drug designation for each of these three clinical settings, as well as Fast Track designation for adjuvant therapy for HRLACC patients and a Special Protocol Assessment for the Phase 3 AIM2CERV trial in HRLACC patients. 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. In addition, Advaxis and Amgen are developing ADXS-NEO, a preclinical 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 enter the clinic in 2017.

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

Advaxis Forward-Looking Statement

This press release contains forward-looking statements, including, but not limited to: statements regarding the completion and timing of the offering of shares. 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, as well as the risks identified or incorporated by reference in the registration statement and the prospectus supplement relating to the offering. 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.

CONTACTS:

Company:

Advaxis, Inc.
Greg Mayes, Executive Vice President and CBO
mayes@advaxis.com
609.250.7515

Media Contact:

JPA Health Communications
David Connolly
dconnolly@jpa.com
617.945.9316

Source: Advaxis