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EMA Certification Paves the Way for the MAA Submission for Axalimogene Filolisbac in Metastatic Cervical Cancer

PRINCETON, N.J., March 23, 2017 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a biotechnology company developing cancer immunotherapies, today announced the European Medicines Agency (EMA) issued an advanced therapy medicinal product certificate for manufacturing quality and non-clinical data. The certification procedure involved a thorough scientific evaluation over several months of the quality (CMC) data and non-clinical data by the EMA's Committee for Advanced Therapies (CAT). After a positive opinion from CAT, EMA issued a certificate confirming that the CMC and non-clinical data comply with the standards that apply for evaluating the Marketing Authorization Application (MAA) of axalimogene filolisbac for the treatment of metastatic cervical cancer. Advaxis is now positioned to file the complete MAA in the second half of 2017.

"EMA's issuance of this certification is a major milestone for Advaxis," said Daniel J. O'Connor, President and CEO. "With a significant portion of the MAA now reviewed and certified, we are preparing to file the complete MAA as we work to bring this innovative immunotherapy to patients with metastatic cervical cancer who have limited treatment options."

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.

CONTACTS:

Company:

Advaxis, Inc.
Ranya Dajani, Vice President, Business Development
dajani@advaxis.com
609.250.7559

Media Contact:

JPA Health Communications
David Connolly
dconnolly@jpa.com
617.945.9316

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