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Advaxis Announces FDA Acceptance of IND for Groundbreaking Personalized Neoepitope Immunotherapy, ADXS-NEO

PRINCETON, N.J., March 06, 2017 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has indicated the Investigational New Drug (IND) application for ADXS-NEO, a personalized neoantigen-targeted approach to cancer immunotherapy that is being developed in collaboration with Amgen, can proceed.

This ground-breaking IND paves the way for bringing a new precision immunotherapy for the treatment of cancers into the clinic this year. ADXS-NEO employs Advaxis' proprietary *Listeria monocytogenes (Lm)*-based antigen delivery technology, its *Lm* Technology™, to target multiple patient-specific neoantigens in each individual patient's tumor that are not present in normal cells. ADXS-NEO is designed to stimulate both the innate and adaptive arms of the immune system.

Advaxis bioengineers ADXS-NEO constructs by programming its *Lm*-based antigen delivery technology to present the unique protein fragments or neoantigens associated with mutations found in a patient's own cancer cells. These cancer-specific mutations are identified by comparing the DNA sequences of cancer cells with normal cells. ADXS-NEO works by presenting a large payload of neoantigens directly into dendritic cells within the patient's immune system to generate new cancer-fighting white blood cells. These T cells hunt down cancer cells bearing these neoantigens while at the same time broadly stimulating the immune system and reducing the ability of the cancer to resist.

ADXS-NEO constructs can present multiple neoantigens that can be targeted by a patient's immune system simultaneously. Tumors may accumulate up to 100 or more mutations that can generate neoantigens, and each patient has a set of mutations that are unique to his or her own tumors. ADXS-NEO is designed to hit multiple targets at once to improve the likelihood of a benefit.

ADXS-NEO will be manufactured in Advaxis' newly constructed facility in Princeton, N.J., utilizing a process that minimizes the time required to develop the patient-specific immunotherapy. A single manufacturing run can provide sufficient product to treat each patient repeatedly for more than one year.

"The IND acceptance is a landmark step towards escaping the one-size-fits-all approach to cancer treatments by building innovative, patient-specific immunotherapies. This highly personalized approach has the potential to transform the treatment of care across multiple types of cancers," said Robert Petit, Ph.D., Chief Scientific Officer of Advaxis. "This

enables us to employ *Lm* Technology to focus the attention of a patient's immune system against the very mutations within their cancer that turned their cells malignant in the first place."

ADXS-NEO is under development through a collaboration between Amgen and Advaxis, bringing together Amgen's expertise in immuno-oncology development and commercialization and Advaxis' proprietary *Lm*-based antigen delivery technology and it's My Immunotherapy Neo-Epitopes or MINE™ platform. Advaxis plans to initiate a phase 1 trial evaluating ADXS-NEO in multiple tumor types later this year.

"Over the past several years, the field of cancer immunotherapy has brought promising new treatments with meaningful benefits to cancer patients. Amgen remains committed to a multi-modality approach in immunotherapy, and our collaboration with Advaxis adds to the toolkit of cancer-fighting options available for patients," said David M. Reese, Senior Vice President, Translational Sciences at Amgen. "We look forward to our continued work with Advaxis to explore the potential of ADXS-NEO in the clinic and across multiple tumor types."

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 *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 high risk locally advanced cervical cancer (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, 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.

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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