

# Discussion on Advaxis' ADXS-NEO, ADXS-HOT Programs Held During the International Congress on Immunotherapies in Cancer

Presentation detailed Advaxis' bacterial vector system, new preclinical program in hotspots

PRINCETON, N.J., Dec. 12, 2016 (GLOBE NEWSWIRE) -- <u>Advaxis</u>, <u>Inc.</u> (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, announced that the company's proprietary bacterial vector system, its *Lm* Technology<sup>™</sup>, was the focal point of a luncheon during the <u>1<sup>st</sup> Annual International Congress on Immunotherapies in Cancer: Focus on Practice-Changing Application</u> on Dec. 10, 2016.

Advaxis Chief Scientific Officer Robert Petit, PhD, joined congress co-chairs Antoni Ribas, MD, PhD, Director of the Tumor Immunology Program, Jonsson Comprehensive Cancer Center and Naiyer Rizvi, MD, Director of Thoracic Oncology, to discuss *Lm* Technology and highlight the two newest applications of Advaxis' *Listeria monocytogenes* bacterial vector system, ADXS-NEO and ADXS-HOT.

"Advaxis' bioengineered attenuated strain of *listeria* has demonstrated significant therapeutic potential in its ability to stimulate T-cell responses against tumors cells and reduce the tumor cell's own defense systems," said Ribas. "This platform has broad clinical potential in multiple cancer types."

Dr. Petit provided information on the preclinical ADXS-HOT program, which will utilize the company's *Lm* Technology to develop constructs that will target tumor driver genes that carry mutations occurring in hotspots. These hotspots, often called public mutations, are commonly observed in multiple patients' tumors and found in multiple tumor types. With ADXS-HOT, Advaxis will be developing a library of off-the-shelf agents that can be administered to patients with cancer who test positive for biomarkers that detect common genetic mutations. These constructs will be available for immediate use, thereby reducing the turnaround time between a patient's biopsy and the start of treatment. The company will initially focus on constructs targeting several of the most critical mutations in tumor driver genes associated with many cancers and plans to file an IND for ADXS-HOT in the second half of 2017.

"We know from the analysis of tens of thousands of tumor specimens that some of these hotspots are present and shared by multiple patients across most tumor types. The ADXS-HOT program gives us an opportunity to provide a mutation targeted, off-the-shelf

approach against these mutations that could represent a significant therapeutic option for multiple cancer patient populations, and may avoid some of the immune tolerance that impedes non-mutated tumor targets," Petit said.

Earlier this year, Advaxis announced a global collaboration with Amgen to develop its MINE™ (My Immunotherapy Neo-Epitopes) program and ADXS-NEO, which is designed to activate a patient's immune system to respond against the unique mutations, or neoepitopes, contained in each individual patient's tumor by using parallel DNA sequencing. Unlike ADXS-HOT for public hotspots, ADXS-NEO is directed at patient-specific mutations. The company recently joined the Parker Institute for Immunotherapy and the Cancer Research Institute, along with other industry and academia leaders, to further the research of neoepitope-based immunotherapies.

### 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<sup>TM</sup>. 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 Special Protocol Assessment 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 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 necepitopes, contained in and identified from each individual patient's tumor, with plans to enter the clinic in 2017.

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

# **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 <a href="http://www.sec.gov">http://www.sec.gov</a>, 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.

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Source: Advaxis