Advaxis Lead Immunotherapy Candidate Continues to Build Recognition Among Industry Leaders

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Axalimogene Filolisbac Phase 2 Data and Investigational Mechanism of Action Featured by Oncology Researchers

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products based on its proprietary Lm-based antigen delivery system, today announced presentation of clinical data and a publication reviewing the mechanism of action via two prestigious oncology forums for its lead immunotherapy candidate, axalimogene filolisbac.

The European Society for Medical Oncology (ESMO) [3] has accepted an abstract for a poster presentation at its 2017 Congress, featuring data from Advaxis' Phase 2 FAWCETT study in patients with advanced anal cancer. This poster, entitled “Phase 2 study of ADXS11-001 immunotherapy in patients with persistent/recurrent surgically unresectable locoregional, or metastatic squamous cell anal cancer,” will feature Stage 1 data from the trial, which shows promising activity with axalimogene filolisbac in patients with late-stage anal cancer. It will be presented by Principal Investigator Cathy Eng, MD, FACP, Professor and Associate Medical Director, colorectal cancer, Division of Cancer Medicine at the University of Texas MD Anderson Cancer Center. Considered the most influential meeting for oncology professionals in Europe, the ESMO annual conference will take place in Madrid, September 8-12 this year.

The peer-reviewed journal Gynecologic Oncology Research and Practice (GORP) published a review article, entitled “Mechanistic insights into ADXS11-001 human papillomavirus-associated cancer immunotherapy,” (DOI: 10.1186/s40661-017-0046-9), illustrating the mechanism of action of axalimogene filolisbac and the scientific validity of using Listeria monocytogenes (Lm) as an immunotherapeutic bacterial vector. Brett A. Miles, MD, of the Division of Head and Neck Cancer Surgery, Department of Otolaryngology at the Icahn School of Medicine at Mount Sinai; Bradley J. Monk, MD, Professor, Gynecologic Oncology; University of Arizona and Creighton University; and Howard P. Safran, MD, of the Brown University Oncology Group, cowrote the article. According to Dr. Miles, the lead author, axalimogene filolisbac has shown a consistent safety profile and promising signs of anti-tumor activity in multiple clinical investigations, paving the way for registrational quality phase 3 trials. In addition, a second article titled, “Therapeutic options for treatment of HPV-associated cancers – novel immunologic vaccines: ADXS11-001,” has also been accepted for publication in GORP. It will showcase the potential for widespread application of axalimogene filolisbac across various types of HPV-associated cancers, placing it among the promising immunotherapeutic tools currently in clinical development.

“We are pleased to have our lead immunotherapy candidate receive recognition from the oncology community through these important scientific platforms,” says Anthony Lombardo, interim chief executive officer. “Advaxis is committed to pursuing the clinical potential of axalimogene filolisbac in HPV-associated cancers, to bring new treatment options to patients, and potentially extend lives.”

To learn more about Advaxis and its immunotherapy clinical programs, visit www.advaxis.com/clinical-trials [4].

About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a late-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary Lm Technology”. 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 immunotherapies axalimogene filolisbac and ADXS-DUAL target HPV-associated cancers and are in clinical trials for invasive and metastatic cervical cancer, head and neck cancer and 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 enter the clinic in 2017.

To learn more about Advaxis, visit www.advaxis.com [5] and connect on Twitter [6], LinkedIn [7], Facebook [8], and YouTube [9].

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 immunotherapies, axalimogene filolisbac and ADXS-DUAL. These forward-looking statements are subject to a number of risks including the risk factors set forth in Form 10-K for the fiscal year ended October 31, 2016, which is available at http://www.sec.gov [10].

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.

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