Advaxis Announces FDA Lifts Clinical Hold on Phase 1/2 Combination Study of Axalimogene Filolisbac with Durvalumab

July 13, 2018

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Company's Investigational New Drug (IND) application for its Phase 1/2 study of axalimogene filolisbac (AXAL) in combination with durvalumab for the treatment of patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer.

The clinical hold for this study was issued on March 9, 2018 following submission by the Company of a safety report to the FDA regarding a patient death that occurred on February 27, 2018, post-dosing, involving acute respiratory failure after nine months of combination therapy. New guidelines for the early detection and treatment of such rare events were agreed to with the FDA and will be implemented for this combination study. Enrollment and dosing in all other Advaxis and durvalumab clinical programs were not affected by the clinical hold.

"We are pleased to have resolved this issue with the FDA and will implement these guidelines across Advaxis' portfolio as needed, to ensure patient safety. We remain confident in the safety of axalimogene filolisbac based on our experience in treating approximately 400 patients and more than 1200 doses across multiple trials in HPV-associated cancers," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis.

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% in 50 patients. This is a 52% 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.

Advaxis, Inc. is a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-based antigen delivery products. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes* (*Lm*) bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy and are designed to access and direct antigen presenting cells to stimulate anti-tumor T cell immunity, activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the tumor microenvironment to enable the T cells to eliminate tumors. Advaxis has product candidates in various stages of clinical and preclinical development in the following areas: HPV-associated cancers, neoantigen therapy, hotspot/cancer antigens and prostate cancer.

To learn more about Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook.

Advaxis Forward-Looking Statement

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include:

our ability to develop and commercialize the next generation of cancer immunotherapies; the safety and efficacy of our proprietary immunotherapies; the success and timing of our clinical trials, including patient accrual; our ability to release the clinical hold and reduce the impact to our trials; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our plans to develop and commercialize our products; our ability to successfully compete in the potential markets for our product candidates, if commercialized; our ability to obtain additional funding; the success and timing of our preclinical studies including IND enabling studies; and our ability to successfully implement our strategy. These forward-looking statements are subject to a number of risks including the forward-looking statements and risk factors set forth from time to time in Advaxis' SEC filings including, but not limited to, our report on Form 10-K for the fiscal year ended October 31, 2017, and on Form 10-Q for the quarter ended January 31, 2018, which are available at www.sec.gov.

Any forward-looking statements set forth in this press release 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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