FDA Lifts Partial Clinical Hold on Phase 3 AIM2CERV Study of Axalimogene Filolisbac

May 15, 2019

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 or Agency) has lifted the partial clinical hold on AIM2CERV, the company's Phase 3 clinical trial of axalimogene filolisbac (AXAL) for the treatment of patients with high-risk locally advanced cervical cancer. In its letter, the FDA acknowledged that the company satisfactorily addressed all hold questions.

As announced on January 23, 2019, the FDA placed a partial clinical hold on this study relating to the Agency's requests for additional information pertaining to certain AXAL chemistry, manufacturing and controls (CMC) matters. The Agency did not cite any safety issues related to the trial and all enrolled patients continued to receive treatment, per the trial protocol. However, no new patients were permitted to enroll in AIM2CERV during this partial hold.

"The Advaxis team worked diligently to provide a comprehensive response back to the FDA's requests for additional CMC information, and through constructive dialogue, we successfully resolved the partial clinical hold"

"The Advaxis team worked diligently to provide a comprehensive response back to the FDA's requests for additional CMC information, and through constructive dialogue, we successfully resolved the partial clinical hold," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "Our AXAL product has demonstrated a manageable safety profile in the over 400 patients we have dosed to date, and we look forward to working with our clinical research organization to reopen enrollment at AIM2CERV sites. We remain focused on our mission of developing innovative therapies to address unmet needs and improving the lives of people with cancer."

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 T cells to eliminate tumors. Advaxis has four programs in various stages of clinical development: ADXS-HPV for cervical cancer; ADXS-NEO, a personalized neoantigen-directed therapy for multiple cancers; ADXS-503 for non-small cell lung cancer, from its ADXS-HOT off-the-shelf neoantigen-directed program; and ADXS-PSA for prostate cancer.

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

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: the success and timing of our clinical trials, including subject accrual; our ability to avoid any clinical holds; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our ability to obtain the appropriate labeling of our products under any regulatory approval; our plans to develop and commercialize our products; the successful development and implementation of our sales and marketing campaigns; the size and growth of the potential markets for our product candidates and our ability to serve those markets; our ability to successfully compete in the potential markets for our product candidates, if commercialized; regulatory developments in the United States and other countries; the rate and degree of market acceptance of any of our product candidates; new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements; market conditions in the pharmaceutical and biotechnology sectors; our available cash, including to support current and planned clinical activities; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our ability to obtain additional funding; our ability to obtain and maintain intellectual property protection for our product candidates; the success and timing of our preclinical studies including IND-enabling studies; the timing of our IND submissions; our ability to get FDA approval for study amendments; the timing of data read-outs; the ability of our product candidates to successfully perform in clinical trials; our ability to initiate,

enroll, and execute pilots and clinical trials; our ability to maintain collaborations; our ability to manufacture and the performance of third-party manufacturers; the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; our ability to successfully implement our strategy; and, other risk factors identified from time to time in our reports filed with the SEC. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

CONTACT:

Investors:
LHA Investor Relations
Yvonne Briggs, (310) 691-7100
ybriggs@lhai.com