# Advaxis Granted U.S. Patent Relating to Axalimogene Filolisbac

March 25, 2019

*Currently in a Phase 3 Pivotal Study for High-Risk Locally Advanced Cervical Cancer*

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. **(NASDAQ: ADXS)** (the Company), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, announces that the U.S. Patent and Trademark Office has granted patent number 10,189,885 titled "*Non-Hemolytic LLO Fusion Proteins and Methods of Utilizing Same.*" This composition-of-matter patent extends protection for axalimogene filolisbac (AXAL) through March 2028.

**"Non-Hemolytic LLO Fusion Proteins and Methods of Utilizing Same."**

"We are pleased to receive another patent to further expand our robust intellectual property portfolio of more than 400 issued or pending patents worldwide," said Robert G. Petit, Ph.D., Chief Scientific Officer of Advaxis. "The issuance of this patent provides additional intellectual property protection for AXAL, which has demonstrated clinical activity across multiple tumor types."

**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. The U.S. Food and Drug Administration (FDA or Agency) has granted AXAL Fast Track designation for adjuvant therapy for high-risk locally advanced cervical cancer, and a Special Protocol Assessment (SPA) for the Phase 3 AIM2CERV trial evaluating its potential to delay or prevent the recurrence of locally advanced cervical cancer. The FDA has also granted AXAL orphan drug designation in three clinical indications.

Advaxis is in discussions with FDA regarding the partial clinical hold on its Phase 3 AIM2CERV trial and is working to address the questions raised by the Agency surrounding prior AXAL chemistry, manufacturing and controls matters. The FDA did not cite any safety issues related to the trial and all currently enrolled patients are continuing to receive treatment, although no new patients are being enrolled. Advaxis is also in dialogue with FDA to request an amendment to the SPA to include an earlier interim analysis for efficacy.

**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 (AXAL) 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 and to resolve FDA's partial clinical hold; 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; 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.

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