Advaxis Provides Update on Clinical Pipeline

November 2, 2018

- *ts Phase 3 AIM2CERV Study*
- *Anticipates Data on ADXS-PSA, ADXS-NEO and ADXS-HOT (NSCLC) in 2019*
- *Conference Call Today at 11:00 a.m. Eastern Time*

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 it will be continuing its ongoing Phase 3, randomized, double-blinded, placebo-controlled, pivotal study of axalimogene filolisbac (AXAL) in high-risk, locally advanced cervical cancer (AIM2CERV).

The current trial design has a planned sample size of 450 subjects to maintain adequate statistical power over a broader range of survival outcomes, as well as a pre-planned interim analysis (IA) of safety and efficacy. However, the Company is evaluating the possibility of accelerating the IA timeline and establishing a more stringent futility boundary. The Company anticipates that over the next couple of months it will finalize the redesign of the trial and review it with the U.S. Food and Drug Administration (FDA). During this time, the study is continuing to enroll patients under its current design, which is being conducted under a Special Protocol Assessment with the FDA.

"We believe this approach affords the best opportunity to demonstrate the therapeutic potential of drug candidates generated from our unique and proprietary Lm platform."

“Based on discussions over the past several months with a number of experts in the field regarding our AIM2CERV trial, we have become increasingly optimistic about the prospects of this study. We believe that continuing to invest in this study, along with certain other product candidates, provides us with a diversified portfolio across drug constructs, cancer types and stages of development,” said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. “We believe this approach affords the best opportunity to demonstrate the therapeutic potential of drug candidates generated from our unique and proprietary *Lm* platform.” He concluded, “The redesign of AIM2CERV with an earlier interim analysis would allow us to alter course or, if necessary, stop the study, depending on the results. If the FDA accepts our proposed revisions, we anticipate having a recommendation based on the interim analysis from the data monitoring committee as early as the fourth quarter of 2020.”

In addition to continuing its AIM2CERV trial for AXAL, the Company plans to initiate an investigator-sponsored trial with a major research center in head and neck cancer in early 2019. The Company is also continuing to follow subjects in its Phase 1/2 study of ADXS-PSA in combination with KEYTRUDA® in metastatic castration-resistant prostate cancer. Intriguing early data from 37 patients in this study presented at the American Society of Clinical Oncology (ASCO) earlier this year showed an improvement in survival in subjects with PSA declines from baseline of 50% or greater (~19% of all treated subjects). The Company expects to provide an update on survival rates along with correlative biomarker work in the first quarter of 2019.

To maximize the efficient use of clinical funding resources, the Company will not continue enrollment in its Phase 1/2 study of AXAL in combination with durvalumab for the treatment of patients with advanced, recurrent or refractory cervical cancer and HPV-associated head and neck cancer, and will not initiate its ADVANCE study for the treatment of women with persistent, recurrent or metastatic (squamous or non-squamous cell) carcinoma of the cervix.

The Company’s Phase 1 dose-escalation study of ADXS-NEO expressing personalized tumor antigens in subjects with various solid tumors, in collaboration with Amgen, is continuing to enroll subjects and Advaxis anticipates providing safety, tolerability and immune correlative data from the first two cohorts in the first half of 2019.

The Company also continues to progress its ADXS-HOT 503 drug candidate, expressing public (shared) tumor antigens both as monotherapy and in combination with KEYTRUDA® for the treatment of non-small cell lung cancer (NSCLC). The Company plans to have the first subject enrolled in this Phase 1/2 study by the end of 2018 with an anticipated readout of safety, tolerability and immune correlative data from the first cohort in the first half of 2019. The Company’s clinical testing of ADXS-HOT in prostate cancer and bladder cancer will continue as the next areas of focus. Initiation of clinical trials in each of these cancers will be delayed until early 2020 to ensure adequate funding for the Company’s other programs.

In support of these programs, Advaxis anticipates its annual cash usage to be approximately $45 million, which was reduced from an annual cash usage of approximately $80 million earlier this year.

The Company will be holding a conference call today, November 2, 2018, at 11:00 a.m. Eastern time to provide an update on its clinical programs.

Conference Call & Webcast Information
DOMESTIC DIAL-IN: (844) 348-6133
INTERNATIONAL DIAL-IN: (631) 485-4564
CONFERENCE ID: 1538717
WEBCAST: ir.advaxis.com/events-presentations

For those unable to participate in the live conference call or webcast, a digital recording will be available beginning today two hours after the close of the conference call. To access the recording, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the operator with the

conference ID: 1538717. In addition, an audio webcast will be archived on the Company's website for a period of time at www.advaxis.com.

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 four franchises in various stages of clinical and preclinical development: 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 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; 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, the 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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