Preliminary Data from Phase 1 Study Evaluating ADXS-NEO Suggest Rapid Immunogenicity and Clinical Activity

March 29, 2019

Data to be Presented at AACR Annual Meeting

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PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. **(NASDAQ: ADXS)**, a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, announces the presentation of ADXS-NEO data in a poster discussion entitled "*Safety and Immunogenicity of a Personalized Neoantigen-Listeria Vaccine in Cancer Patients"* at the American Association for Cancer Research (AACR) Annual Meeting underway in Atlanta. The discussion will be held on Sunday, March 31, 2019 from 1:00-5:00 p.m. ET and will be led by J. Randolph Hecht, M.D., Professor of Clinical Medicine, David Geffen School of Medicine at UCLA and Director of the UCLA Gastrointestinal Oncology Program.

ADXS-NEO is a live, attenuated *Listeria monocytogenes (Lm) immunotherapy,* using personalized antigen delivery based on whole-exome sequencing of a patient's tumor to identify personal neoantigens. The ongoing Phase 1 trial is designed to evaluate the safety, tolerability and preliminary clinical immunological activity of ADXS-NEO alone (Part A) and in combination with anti-PD-1 antibody therapy (Part B) in subjects with certain types of advanced or metastatic solid tumors. Part C of the trial will be an expansion of the combination therapy arm and will be initiated based on emerging data from the first two parts of the trial.

Preliminary findings from the ADXS-NEO Phase 1 study include the following:

- Substantial anti-tumor immunity, including T cell responses to neoantigens and antigen spreading, was observed within one week of first dose at both dose levels
- Dosing of ADXS-NEO at $1x10^8$ colony forming units (CFU) has been well-tolerated in two patients
- ADXS-NEO dosed at $1x10^9$ CFU was beyond the maximum tolerated dose (MTD)
    - Reversible Grade 3 hypoxia (n=2) and Grade 3 hypotension (n=1) were dose-limiting toxicities (DLTs)
- Manufacturing of ADXS-NEO, comprised of 40 personal neoantigens, was successfully completed within seven to eight weeks for each subject

"Advaxis' ADXS-NEO is a novel, personalized vaccine encoding mutations specific to an individual patient's tumor designed to induce anti-cancer immunity. Four patients have been evaluated across two dose levels thus far in this ongoing clinical trial. While dose level 1 ($1x10^9$ CFU) was determined to be above the MTD, dose level -1a ($1x10^8$ CFU) has been safe and well tolerated in two patients treated to date, with primarily Grade 1 and Grade 2 chills, fever and tachycardia. Substantial immunological activity was observed across both dose levels, including rapid neoantigen-specific CD8+ T cell generation, which is essential for potential clinical benefit. We look forward to the planned combination therapy arm with checkpoint inhibitors," said Dr. Hecht.

"The patients being evaluated for safety and tolerability in Part A all have late-stage disease and have been treated with numerous prior therapies. As a result, we did not expect to observe significant clinical activity in this cohort," said Andres Gutierrez, M.D. Ph.D., Chief Medical Officer of Advaxis. "Nevertheless, we have seen some encouraging clinical signals to date, including one patient at dose level 1 with non-small cell lung cancer who achieved stable disease after only two doses of ADXS-NEO, which is consistent with rapid immune activation." He concluded, "This is the first presentation of clinical data from our ADXS-NEO program at a major medical conference. We are continuing to enroll subjects and gather additional clinical and immune correlative data, and plan to share updated data from this study throughout this year."

The full abstract is available at www.advaxis.com and the poster will be available on the Company's website on Sunday, March 31, 2019 at 1:00 p.m. ET.

About ADXS-NEO

ADXS-NEO is an investigational personalized *Lm*-based immunotherapy designed to generate immune response against mutation-derived tumor-specific neoantigens identified through DNA sequencing of a patient's own tumor. The program focuses on creating a customized treatment for each patient targeting multiple neoantigens found in a biopsy of the patient's tumor.

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 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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