Advaxis Announces Dosing of First Patient with ADXS-NEO, an Investigational Customized Immunotherapy Approach Targeting Personal Neoantigens

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-ADXS-NEO is being evaluated in a Phase 1 clinical trial in various cancers

-First patient dosed is being treated for NSCLC

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, announced it has commenced a Phase 1 trial with the dosing of the first patient with ADXS-NEO, an investigational personalized immunotherapy approach targeting personal neoantigens found by sequencing a patient's own cancer cells. ADXS-NEO is being evaluated in an open-label, dose-escalation, multicenter Phase 1 clinical trial in the United States. The study is open to patients with metastatic non-small cell lung cancer (NSCLC), metastatic microsatellite stable colon cancer and metastatic squamous head and neck cancer. The first patient dosed is being treated for non-small cell lung cancer. ADXS-NEO is being developed in collaboration with Amgen. Advaxis is leading clinical development through proof-of-concept.

"We are extremely pleased to advance ADXS-NEO into the clinic. This program brings our clinically-validated Lm Technology to the cutting-edge area of neoantigen immuno-oncology"

Pre-clinical findings for ADXS-NEO were presented at the 2018 American Association for Cancer Research (AACR) Annual Meeting. The company presented data in mouse models showing that ADXS-NEO generates T cell responses against neoantigen peptides that control tumor growth, even when they were identified as "non-immunogenic" using a conventional peptide-adjuvant immunization. Additionally, data were presented highlighting the capacity of the Advaxis *Lm* vector and its ability to target frameshift mutations of greater than 90 amino acids, and to generate T cells to multiple neoantigens per frameshift in tumor mouse models.

"We are extremely pleased to advance ADXS-NEO into the clinic. This program brings our clinically-validated *Lm* Technology to the cutting-edge area of neoantigen immuno-oncology," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "We are committed to realizing the potential of ADXS-NEO to mobilize patients' immune systems against mutations that accumulate within and contribute to the development of their cancer, and to bring the potential benefits of our technology to more patients and their families."

Enrolled patients will undergo a biopsy, and Advaxis will then manufacture an investigational personalized treatment for each patient based on an analysis of their tumor neoantigen mutations, which will be ready to dose within 8 weeks of the initial biopsy. More information about the trial is available at www.clinicaltrials.gov.

About ADXS-NEO

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

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, 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: 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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