Advaxis Announces FDA Allowance of IND Application for ADXS-HOT Drug Candidate for Non-Small Cell Lung Cancer

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Selects Bladder Cancer as Third ADXS-HOT Drug Candidate to Take into the Clinic after Non-Small Cell Lung and Prostate Cancers

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Advances Goal to Have Five Neoantigen-Based Drug Candidates in Clinical Evaluation by 4Q 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) has allowed the Company's IND application for its ADXS-HOT drug candidate for non-small cell lung cancer (NSCLC). Advaxis anticipates that because of this timely allowance, the first patient in the Phase 1/2 trial for this NSCLC drug candidate will be dosed by the end of 2018.

ADXS-HOT is a cancer-type specific immunotherapy approach that leverages the Company's proprietary *Lm* technology platform to target hotspot mutations that commonly occur in specific cancer types as well as other proprietary tumor-associated antigens. To date, more than 10 drug candidates have been designed for different tumor types in the ADXS-HOT program.

"This is an exciting time for Advaxis as we prepare to initiate the first clinical trial with a drug candidate from our ADXS-HOT program. This drug candidate, ADXS-503, has been designed for the treatment of patients with NSCLC," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "With our increased strategic focus on neoantigen-based therapeutics, including the personalized, patient-specific approach of our ADXS-NEO program, already in a clinical trial, we anticipate having five neoantigen-based drug candidates in clinical evaluation by the end of 2019. Our next two ADXS-HOT drug candidates will focus on prostate and bladder cancers. These two tumor types, along with NSCLC, were prioritized based on our evaluation of a number of factors relating to each, including the unmet medical need, time and investment required to demonstrate meaningful clinical activity and immunological sensitivity," concluded Mr. Berlin.

The Company plans to initiate a Phase 1/2 clinical trial that will seek to establish the safety, tolerability and effectiveness of ADXS-503 administered alone and in combination with a checkpoint inhibitor in approximately 50 patients with metastatic NSCLC in different lines of therapy, at up to 20 centers across the U.S.

"I am pleased we can move forward to advance our first trial with ADXS-503, the first drug candidate in our ADXS-HOT program. This is an important clinical milestone as we seek to demonstrate proof-of-concept for ADXS-HOT immunotherapy in NSCLC, where there remains significant unmet need despite the introduction of checkpoint inhibitors and targeted therapies," said Andres Gutierrez, M.D., Ph.D., Chief Medical Officer and Executive Vice President of Advaxis. "Earlier drug candidates from our *Lm* platform expressing a single antigen have shown a favorable safety profile and preliminary clinical activity in more than 500 subjects treated to date across different tumor types. This clinical experience with prior *Lm* drug candidates, combined with our ability to leverage the large capacity of our *Lm* vector to express multiple neoantigens and other tumor-associated antigens, provides the foundation for our belief that ADXS-HOT drug candidates such as ADXS-503 for NSCLC can provide a new standard for off-the-shelf neoantigen vaccines."

Advaxis affirms plans to submit a total of four INDs for drug candidates from its ADXS-HOT program by the fourth quarter of 2019. Beyond NSCLC, prostate cancer and bladder cancer, the fourth ADXS-HOT drug candidate will be selected from breast, colorectal, ovarian or head and neck cancers.

About ADXS-HOT

ADXS-HOT is a program that leverages the Company's proprietary *Lm* technology to target hotspot mutations that commonly occur in specific cancer types. ADXS-HOT drug candidates are designed to target acquired shared or "public" mutations in tumor driver genes along with other cancer-testes and oncofetal tumor-associated antigens that also commonly occur in specific cancer types. Although ADXS-HOT drug candidates have not yet been tested in patients, they are an off-the-shelf treatment approach been designed to potentially treat all patients with a specific cancer type, without the need for pretreatment biomarker testing, biopsy, DNA sequencing or diagnostic testing.

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 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 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 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 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 of our product candidates to successfully perform in clinical trials; our ability to execute clinical trials; our ability to maintain collaborations; our ability to initiate pilot studies and clinical trials, enroll our trials, obtain and maintain approval of our product candidates; 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
Miriam Weber Miller, 212-838-3777
mmiller@lhai.com
or
Advaxis, Inc.
Ranya Dajani, 609-250-7559
dajani@advaxis.com