Advaxis Announces Enrollment of the First Patient in its Phase 1/2 Trial for ADXS-HOT in the Treatment of Non-Small Cell Lung Cancer

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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, announced it has initiated its Phase 1/2 clinical trial to evaluate ADXS-503, part of the Company's ADXS-HOT program, in the treatment of non-small cell lung cancer (NSCLC) and has enrolled the first patient in the trial. ADXS-HOT is a cancer-type specific immunotherapy program which leverages Advaxis' 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 under the ADXS-HOT program.

"The ADXS-HOT program supports our goal of leveraging the significant experience we have gained from our proprietary platform in order to advance programs in the fight against cancer for patients in need of new therapeutic options and we look forward to studying these constructs in the clinic."

"Coming on the heels of the presentation of data from our immunotherapy platform at the I/O 360 conference last week, we are excited to announce the enrollment of the first ADXS-HOT patient in our Phase 1/2 trial evaluating ADXS-503 for the treatment of NSCLC. The data presented at I/O 360 suggest that our neoantigen-directed constructs from both our ADXS-NEO and ADXS-HOT programs have the potential to demonstrate best-in-class CD+8 T cell response for neoantigen therapies," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. He continued, "We believe our ADXS-HOT drug constructs have significant advantages compared to certain other neoantigen-focused therapies in development as our ADXS-HOT drug constructs are off-the-shelf and immediately available to administer to the patient and have a favorable cost to manufacture." He concluded, "The ADXS-HOT program supports our goal of leveraging the significant experience we have gained from our proprietary platform in order to advance programs in the fight against cancer for patients in need of new therapeutic options and we look forward to studying these constructs in the clinic."

The Phase 1/2 clinical trial for ADXS-503 will seek to establish the recommended dose, safety, tolerability and clinical activity of ADXS-503 administered alone (initially) and in combination with a checkpoint inhibitor in approximately 50 patients with NSCLC in different lines of therapy, at up to 20 centers across the U.S. Advaxis anticipates initial data from the first cohort of ADXS-503 in the first half of 2019.

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 proprietary cancer-testes and oncofetal tumor-associated antigens that also commonly occur in specific cancer types. ADXS-HOT drug candidates are an off-the-shelf treatment, designed to potentially treat all patients with a specific cancer type, without the need for pretreatment biomarker testing, DNA sequencing or diagnostic testing.

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 programs 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 resolve FDA's partial clinical hold, 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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