Advaxis Updates on the Phase 1 Clinical Trial of ADXS-504 for the Treatment of Early Prostate Cancer

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Dose escalation has been completed and enrollment at second dose level will be expanded at Columbia University

ADXS-504 has been well tolerated with no serious adverse events reported
Four out of six patients treated are still on study and PSA values are being followed up

MONMOUTH JUNCTION, N.J., Jan. 12, 2023 (GLOBE NEWSWIRE) -- Advaxis, Inc. (OTCQX: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products, today announced an update on the Phase 1 clinical study evaluating ADXS-504, the company's off-the-shelf neoantigen drug candidate, in patients with biochemically recurrent (early) prostate cancer that is being conducted at Columbia University Irving Medical Center. Karie Runcie, MD, assistant professor of medicine, and Mark N. Stein, MD, associate professor of medicine, in the division of hematology/oncology at Columbia University Vagelos College of Physicians and Surgeons and members of the Herbert Irving Comprehensive Cancer Center, are the study's principal and senior investigators, respectively.

The study design of this phase 1 open-label dose escalation study for patients in both dose cohorts was presented at the 2022 ASCO Annual Meeting by Dr. Runcie (**Abstract #:** TPS5115). The clinical assessment of three patients at the first dose level (1e7 CFU) and three at the second dose level (1e8 CFU) has shown that ADXS-504 monotherapy is safe and well-tolerated.

In this study, ADXS-504 is being administered via infusion every four weeks for a total of six doses, followed by four additional maintenance doses every twelve weeks, in patients with biochemically recurrent prostate cancer, i.e., those with elevation of prostate-specific antigen (PSA) in the blood after radical prostatectomy or radical radiotherapy (external beam or brachytherapy) and who are not currently receiving androgen ablation therapy. Patients have experienced mild and short-lived flu-like symptoms after the infusion of ADXS-504 at both the first and second dose levels.

The trial is currently expanding enrollment at the second dose level by up to six additional patients for a total of nine patients. The study investigators will evaluate the immunogenicity data after all of the patients at the higher dose level have completed the study treatment.

ADXS-504 is a novel *Lm*-based immunotherapy, bioengineered to elicit T cell responses against 24 tumor antigens, including 14 peptide antigens derived from hotspot mutations in patients with prostate cancer and 10 peptide antigens derived from sequence-optimized tumor-associated antigens (TAAs) that are differentially expressed or overexpressed in prostate cancer. ADXS-504 is designed to express multiple tumor antigen targets, potentially leading to generation of a broad set of effector T cells and NK cells that may enhance tumor control. Similar to Advaxis's other *Lm*-based immunotherapies, ADXS-504 is expected to induce an innate immune response followed by the adaptive response and modification of the immunosuppressive tumor microenvironment (TME) by reducing regulatory T cells (Tregs) and myeloid-derived suppressor cell (MDSC) frequencies in the TME.

"We have completed evaluation of the dose-limiting-toxicity period for three patients at the second dose level for this Phase 1 trial of ADXS-504. At both the first and at this higher dose level, patients have experienced mild and short-lived flu-like symptoms after the infusion of ADXS-504," said Dr. Runcie. "The safety of ADX-504 and encouraging early data led to our decision to increase enrollment at the second dose level to better characterize its clinical activity."

Kenneth A. Berlin, President and Chief Executive Officer of Advaxis, commented, "We are excited that our collaborators at Columbia have elected to expand the enrollment of this Phase 1 trial in ADXS-504. We are also encouraged by the safety data and we are actively collecting long-term PSA results from all the patients in this trial. We look forward to analyzing the composite data to gain further insight into the safety and efficacy of this novel therapy."

About Advaxis

Advaxis, Inc. is a clinical-stage biotechnology company focused on the 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.

Forward-Looking Statements
This press release contains forward-looking statements that are made pursuant to the safe harbor provisions within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are any statements that express the current beliefs and expectations of management, including but not limited to statements related to the expected clinical development of the Company's drug product candidates. These and other risks are discussed in the Company's filings with the SEC, including, without limitation, its Annual Report on Form 10-K, filed on filed on January 22, 2022, and its subsequent periodic reports on Form 10-Q and Form 8-K. Any statements contained herein that do not describe historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. The Company cautions readers not to place undue reliance on any forward-looking statements, which speak only as of the date they were made. The Company undertakes no obligation to update or revise forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

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