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

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Evaluation completed of first dose level in investigator-sponsored study in biochemically recurrent prostate cancer

Enrollment initiated for second dose level

MONMOUTH JUNCTION, N.J., June 29, 2022 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq: 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, are the study's principal and senior investigators, respectively.

The Phase 1 open-label dose escalation study completed evaluation of the safety and tolerability of the first dose level (DL-1 1e7 CFU) and has initiated enrollment of the second dose level cohort (DL-2 1e8 CFU). In this cohort, ADXS-504 will be 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.

The preliminary clinical assessment of patients at the first dose level has shown that ADXS-504 monotherapy is safe and well tolerated. Clinical and immunogenicity data, including PSA values, for patients in both cohorts will be presented at a future medical conference.

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 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.

Dr. Runcie remarked, "Thus far, patients have only experienced mild and short-lived flu-like symptoms after the infusion of ADXS-504 at the first dose level. We look forward to collecting data at the second dose level to gain further insight into the safety and efficacy of this novel therapy."

Kenneth A. Berlin, President and Chief Executive Officer of Advaxis, said, "We are encouraged by the recent data regarding the safety profile of this new Advaxis' HOT construct at the first dose level. As ADXS-504 is now being administered to healthier patients with longer life expectancies than to those evaluated in other *Lm* immunotherapy programs, it is important to have a relatively clean safety profile in this setting," he added. "Safety is an essential component of the regimen in this healthier population, which will now move on to dose level 2 at 1e8 CFU, a level that has also proven to be a relatively safe in our other *Lm* HOT-program," he concluded.

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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