



Advaxis Announces Initiation of Phase 1 Clinical Trial of ADXS-504 for the Treatment of Early Prostate Cancer

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Study in biochemically recurrent prostate cancer expands off-the-shelf ADXS-HOT program to second indication

MONMOUTH JUNCTION, N.J., July 15, 2021 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products, today announced the initiation of its Phase 1 clinical study evaluating ADXS-504 in patients with biochemically recurrent prostate cancer. The study, being conducted at Columbia University Irving Medical Center, is the first clinical evaluation of ADXS-504, Advaxis' off-the-shelf neoantigen immunotherapy drug candidate for early prostate cancer. Mark Stein, M.D., associate professor of medicine in the Division of Hematology/Oncology at Columbia University Vagelos College of Physicians and Surgeons, is the study's principal investigator.

"Evaluating ADXS-504 in patients with biochemically recurrent prostate cancer is the first step in testing whether *Lm*-based immunotherapies may have a role in the adjuvant setting in cancer patients who have undergone radical therapy and who have no detectable primary tumor or metastatic disease at enrollment," said Dr. Andres Gutierrez, Chief Medical Officer of Advaxis. "This Phase 1 study will evaluate the safety, tolerability, immunogenicity and clinical activity of ADXS-504 in men who have undergone radical prostatectomy or radiotherapy and whose prostate specific antigen (PSA) levels in the blood are rising, which we believe are ideal patients to evaluate with this approach. Moreover, we believe our multi-neoantigen vector has the potential to drive T cell responses against both hormone-sensitive and hormone-resistant cancer cells, which could result in disease control and may delay the start of androgen blockade therapy and its associated long-term complications. This study will also examine our lowest dose of an *Lm*-based immunotherapy to date, which could enhance the risk/benefit ratio that we have previously observed in our ADXS-HOT program."

Kenneth A. Berlin, President and Chief Executive Officer of Advaxis stated, "We are pleased to be launching the first clinical evaluation of ADXS-504, expanding the reach of our off-the-shelf neoantigen immunotherapy program to a second potential indication. Our strong foundation of clinical data generated across both prostate cancer and non-small cell lung cancer suggest *Lm*-based immunotherapy may bring meaningful clinical benefit to patients and we look forward to continued momentum across the ADXS-HOT program."

The Phase 1 open-label dose escalation study will evaluate the safety and tolerability of two dose levels (1e7 and 1e8 CFU) of ADXS-504 monotherapy, administered via infusion every four weeks for six total doses in 9-18 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 study will also evaluate preliminary clinical and immune responses following treatment with ADXS-504 monotherapy.

ADXS-504 is a novel *Lm*-based immunotherapy, bioengineered to elicit T cell responses against 24 tumor antigens that include 14 peptide antigens derived from frequently occurring and commonly shared 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 to which patients may generate a broad set of effector T cells for 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.

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. 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. Such risks include, but are not limited to: the success and timing of the Company's clinical trials, including patient accrual; the Company's ability to develop and commercialize its products; the Company's ability to identify license and collaboration partners and to maintain existing relationships; the Company's available cash and its ability to obtain additional funding; and any outcomes from the Company's review of strategic transactions. 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 January 22, 2021, as amended, and its periodic reports on Form 10-Q and Form 8-K. 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 whether as a result of new information, future events or otherwise, except as otherwise required by law.

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