Advaxis Announces FDA Clearance of New IND for ADXS-504 for Treatment of Prostate Cancer

September 24, 2020

Strategic transition to Investigator sponsored IND from previously announced Advaxis sponsored IND

Initiation of investigator sponsored Phase 1 study of ADXS-504 in prostate cancer on-track for Q4 2020

PRINCETON, N.J., Sept. 24, 2020 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products, today announced the U.S. Food and Drug Administration (FDA) has cleared a new Investigational New Drug (IND) application for the initiation of an Investigator Sponsored Phase 1 clinical study of ADXS-504, the Company's off-the-shelf neoantigen ADXS-HOT candidate for prostate cancer. This new IND is in addition to the Advaxis sponsored IND, previously announced in January 2020. Advaxis intends to first advance the clinical evaluation of ADXS-504 through an Investigator Sponsored Phase 1 study in prostate cancer patients with biochemical recurrence which remains on-track for initiation in the fourth quarter this year.

"We are excited to announce the transition of our ADXS-504 HOT prostate program to an investigator sponsored study at this time," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "By partnering with a prestigious academic medical center, we would be gaining access to world-class expertise and a high volume of patients that together, may expedite both enrollment and eventual study results. This strategic decision also conserves resources which can be leveraged to support our encouraging and expanding HOT program in NSCLC. Our data generated to date with ADXS-503 in NSCLC leave us increasingly confident that our off-the-shelf neoantigen program can provide well-tolerated treatments with robust innate and adaptive immune responses and potential clinical activity. We look forward to the initiation of this Phase 1 study with ADXS-504 monotherapy in patients with prostate cancer before year end."

About Advaxis, Inc.
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.

To learn more about Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook and YouTube.

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 December 20, 2019 and Form 10-K/A on February 28, 2020, and its 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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