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

January 7, 2020

ADXS-504 is the Company's second drug product candidate from the HOT program to receive IND clearance from FDA

PRINCETON, N.J., Jan. 07, 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 the Investigational New Drug (IND) application for the initiation of a Phase 1 clinical study of ADXS-504, the Company's ADXS-HOT candidate for prostate cancer. ADXS-HOT is the Company's off-the-shelf neoantigen clinical program targeting hotspot mutations that currently includes over ten cancer-type specific drug constructs in various stages of development.

"With encouraging proof-of-concept data within our neoantigen program, we believe the ADXS-HOT program has potential to provide off-the-shelf, neoantigen targeted immunotherapies to a broad patient population," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "We are proud of the progress we have made to date with our HOT program, which includes advancing the clinical development of ADXS-503, our candidate for non-small cell lung cancer, while also seeking to launch our next clinical program, ADXS-504, in prostate cancer. We look forward to presenting immunogenicity and safety data from the first cohort from our lung program later this quarter."

About Advaxis, Inc.
Advaxis, Inc. is a clinical-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 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 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.

Contact:
Tim McCarthy, LifeSci Advisors, LLC
212.915.2564
tim@lifesciadvisors.com

Source: Advaxis, Inc.