Advaxis Announces Positive Clinical Data in Ongoing Phase 1/2 ADXS-503 Trial in NSCLC at the IASLC 2020 Targeted Therapies of Lung Cancer Meeting

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ADXS-503 safe and tolerable with potential signs of clinical activity in 4 of 7 evaluable patients achieving stable disease in the refractory setting

Patient who previously progressed on pembrolizumab showed stable disease with a 25% reduction in a site lesion in combination arm

PRINCETON, N.J., Feb. 20, 2020 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announced results from the monotherapy and combination arms of the Company's ongoing Phase 1/2 study investigating ADXS-503 in patients with non-small cell lung cancer (NSCLC) at the IASLC 2020 Targeted Therapies of Lung Cancer Meeting in Santa Monica, California. The trial is evaluating ADXS-503, part of the Company's ADXS-HOT cancer-type specific immunotherapy program which leverages Advaxis' proprietary *Lm* technology platform to target hotspot mutations that commonly occur in specific cancer types as well as other proprietary, tumor-associated antigens, alone and in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy.

Key findings presented by Jennifer Carlisle, M.D., Assistant Professor Department of Hematology and Medical Oncology, Winship Cancer Institute of Emory University
and study investigator, titled, "A Phase 1/2 Study of ADXS-503 Alone and in Combination with Pembrolizumab in Subjects with Metastatic Squamous or Non-Squamous Non-Small Cell Lung Cancer" include:

- Nine patients have been dosed to date; seven in the monotherapy arm and two in the combination arm, with a total of seven evaluable patients
- 50% (3 of 6) of evaluable patients from the monotherapy arm, from Part A, showed stable disease
- The first evaluable patient from the combination arm, Part B, who previously progressed on pembrolizumab, showed stable disease with a 25% reduction in a site lesion
- Stable disease was observed in a heavily pretreated patient population with patients failing up to six prior lines of therapy and most patients progressing on prior immunotherapy treatments
- ADXS-503 monotherapy and in combination with pembrolizumab appeared safe and tolerable in this heavily pretreated population of patients with no dose limiting toxicities observed
- Treatment-related adverse events were mostly Grade 1-2, with no additive toxicity observed with combination therapy

"The presented preliminary data on safety, tolerability and disease stabilization with ADXS-503 in patients with advanced NSCLC provides an important clinical proof-of-concept to the Company's first off-the shelf, hotspot neoantigen construct tested thus far," said Dr. Andres Gutierrez, Chief Medical Officer of Advaxis. "These data are important given the highly refractory patient population with most evaluated patients progressing on prior immunotherapies and, while early, we are particularly interested in documenting additional potential signals of synergy with KEYTRUDA®. We look forward to reporting additional clinical and immunogenicity data later this year in addition to starting Part C of the study which will evaluate ADXS-503 in combination with pembrolizumab as a first-line treatment for NSCLC patients."

The Phase 1/2 clinical trial of ADXS-503 will seek to establish the recommended dose, safety, tolerability and clinical activity of ADXS-503 administered alone and in combination with a checkpoint inhibitor in approximately 50 patients with NSCLC, in at least five sites across the U.S. The two dose levels with monotherapy in Part A, (1 $X10^8$ and 5 $X10^8$ CFU) have been completed and Part B in combination with a checkpoint inhibitor is currently open to enrollment.

About ADXS-HOT
ADXS-HOT is a program that leverages the Company's proprietary *Lm* technology to target hotspot mutations that commonly occur in specific cancer types. ADXS-HOT drug candidates are designed to target acquired shared or "public" mutations in tumor driver genes along with other proprietary cancer-testes and oncofetal tumor-associated antigens that also commonly occur in specific cancer types. ADXS-HOT drug candidates are an off-the-shelf treatment, designed to potentially treat all patients with a specific cancer type, without the need for pretreatment biomarker testing, DNA sequencing or diagnostic testing.

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.

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