Advaxis Announces Updated Positive Clinical Data in Ongoing Phase 1/2 ADXS-503 Trial in NSCLC at I/O 360° Conference

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First two patients treated in the combination arm who previously progressed on KEYTRUDA® *showed substantial tumor shrinkage with ADXS-503 treatment in combination with* KEYTRUDA®

Partial response observed in one patient and the other patient achieved stable disease with a 25% reduction in a target lesion

PRINCETON, N.J., Feb. 27, 2020 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announced updated results from the 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 Immuno-oncology 360° Conference in New York, New York. 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 Dr. Andres Gutierrez, Chief Medical Officer of Advaxis, include:

- Demonstrated substantial tumor shrinkage in the first two evaluable patients in the combination arm, Part B; with one patient who achieved a partial response (PR) and the other patient who achieved stable disease (SD) with 25% reduction in a target lesion
- These new data build upon previous results presented at the IASLC 2020 Targeted Therapies of Lung Cancer Meeting from seven evaluable patients demonstrating:
  — 50% (3 of 6) of evaluable patients from the monotherapy arm, from Part A, showed stable disease (SD)
  — 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

"The first two patients treated in the combination arm of ADXS-503 and pembrolizumab were older patients with up to four prior lines of therapy," said Dr. Jonathan W. Goldman, Director of Clinical Trials in Thoracic Oncology at UCLA. "These data are very encouraging as they preliminarily demonstrate the ability of ADXS-503 to enhance or restore sensitivity to checkpoint inhibitors as we had hypothesized during the design of the study based on preclinical data." He added, "We will follow the durability of the responses to therapy and look forward to moving into Part C in ADXS-503 later this year, which will enroll patients for first line therapy in combination with pembrolizumab."

Dr. Andres A. Gutierrez, Chief Medical Officer and EVP at Advaxis, said, "These initial signals of anti-tumor activity in non-small cell lung cancer correlate with the clinical benefit observed with ADXS-PSA and pembrolizumab in our KEYNOTE-046 study in advanced prostate cancer, highlighting the potential synergistic effects of *Lm* immunotherapies and checkpoint inhibitors."

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 KEYNOTE-046
KEYNOTE-046 (NCT02325557) is a Phase 1/2 open-label, multicenter, dose-determination and expansion trial that evaluates the safety, tolerability and preliminary clinical activity of ADXS-PSA as monotherapy (Part A; n=14 [13 treated]), and in combination with KEYTRUDA® (Part B; n= 37) in heavily pretreated patients with progressive and refractory metastatic castration-resistant prostate cancer (mCRPC).

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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

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