Advaxis Announces Updated Positive Clinical and Biomarker Data from Ongoing Phase 1/2 ADXS-503 Trial in NSCLC

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Sustained clinical benefit seen in patients treated with ADXS-503 in combination with KEYTRUDA® *after 16 weeks, including a partial response and stable disease in patients who had most recently progressed on* KEYTRUDA®

Positive preliminary immunogenicity data with CD8+ T cells generated in all of the first seven patients evaluated for ADXS-503 antigens

PRINCETON, N.J., May 14, 2020 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announced updated clinical and biomarker 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). The trial is evaluating ADXS-503, alone and in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy. ADXS-503 is 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.

Key data updates:

- Sustained clinical benefit in the combination arm, Part B, in the first two evaluable patients who had previously progressed on KEYTRUDA® as last therapy whose best response while on KEYTRUDA® was stable disease.
    - One observed partial response and one response of stable disease with 25% reduction in a target lesion, as confirmed in the radiographic scans at 16 weeks of combination therapy
    - Responses achieved after immediate prior progression on KEYTRUDA® with previous best responses of stable disease suggests ADXS-503 may re-sensitize or enhance response to KEYTRUDA®
- Preliminary biomarker data from seven patients in monotherapy demonstrates:
    - Activation of cytotoxic and memory CD8+ and CD4+ T cells
    - CD8+ T cells generated in all seven patients evaluated
    - Antigen spreading observed in five of seven patients for epitopes not incorporated in ADXS-503
- Part A monotherapy has been completed (n=7) with three out of six (50%) evaluable patients showing stable disease.
- As a monotherapy, and in combination with KEYTRUDA®, ADXS-503 appeared safe and well tolerated with no dose limiting toxicities at the dose-levels evaluated.

"We are thrilled to see sustained clinical benefit with ADXS-503 in combination with KEYTRUDA® in these first two evaluable patients who had recently progressed on KEYTRUDA®," said Ken Berlin, Chief Executive Officer of Advaxis. "Importantly these responses were achieved in patients with prior best responses that were limited to stable disease during their two years on this checkpoint inhibitor. Taken together, these results leave us increasingly confident that ADXS-503 has the potential to restore or enhance sensitivity to checkpoint inhibitors. In addition, we believe our recent biomarker data, which shows the robust and specific activation of an immune response to ADXS-503 antigens, provides important understanding and validation of the mechanism of action of ADXS-503."

Dr. Andres Gutierrez, Chief Medical Officer at Advaxis, said, "With these promising clinical, safety and immunogenicity data, we have decided to expand Part B of the study, which will continue evaluating patients that have progressed on KEYTRUDA® as their last prior therapy. In addition, we will start Part C of the trial to evaluate ADXS-503 with KEYTRUDA® combination therapy as a first line treatment for NSCLC patients that cannot tolerate the standard of care regimen with KEYTRUDA® in combination with chemotherapy. With the recent dosing of the third patient in Part B, Dose Level 1 which completes this cohort, we anticipate beginning enrollment in the Part B expansion and Part C in early June and look forward to continued progress as we evaluate the ability of ADXS-503 to generate anti-tumor immune responses in advanced NSCLC patients with significant need for new treatment options."

The Phase 1/2 clinical trial of ADXS-503 is seeking to establish the recommended dose, safety, tolerability and clinical activity of ADXS-503 administered alone and in combination with a KEYTRUDA® 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 with ADXS-503 (1 $X10^8$ CFU) in combination with KEYTRUDA® is currently closed to enrollment. With preliminary encouraging safety and efficacy results, the Company is planning to expand Part B to additional patients at dose level 1 (1 $X10^8$ CFU + KEYTRUDA®) with the potential to proceed to dose level 2 (5 $X10^8$ CFU + KEYTRUDA®) at a later date. In addition, the Company intends to expand the study to Part C, which will evaluate ADXS-503 in combination with KEYTRUDA® (1 $X10^8$ CFU + KEYTRUDA®) as a first line treatment for patients that are medically unfit to receive the standard of care regimen with KEYTRUDA® in combination with chemotherapy.

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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