Advaxis Presents Updated Clinical Data from Ongoing Phase 1/2 Trial of ADXS-503 in NSCLC at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting

May 19, 2021

Updated data show disease control rate of 44% with durable clinical benefit observed beyond one year in patients with disease progression on pembrolizumab

Translational data support potential of ADXS-503 to restore and/or enhance sensitivity to checkpoint inhibitors

PRINCETON, N.J., May 19, 2021 (GLOBE NEWSWIRE) -- **Advaxis, Inc. (Nasdaq: ADXS**), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announced updated data from the Company's ongoing Phase 1/2 study evaluating ADXS-503 in combination with KEYTRUDA® which will be presented as a poster at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting. ADXS-503 is the first drug construct from the ADXS-HOT off-the-shelf, 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.

"These early results, which include a disease control rate of 44% in the first 9 evaluable patients treated with ADXS-503 as an add on therapy at progression with pembrolizumab, are particularly encouraging given the durable nature of disease control in 3 patients," said Suresh Ramalingam, M.D., Roberto C. Goizueta Chair for Cancer Research, Director, Division of Medical Oncology and Deputy Director of the Winship Cancer Institute at Emory University School of Medicine. "The translational results from the study provide interesting insights on the potential mechanism of action by which the addition of ADXS-503 may may be effective in this patient population."

Ken Berlin, Chief Executive Officer of Advaxis, said, "We are encouraged by these updated results which continue to support the potential of ADXS-503 to enhance and/or restore sensitivity to checkpoint inhibitors. The clinical activity observed to date in this challenging patient population, combined with a favorable safety profile, suggest that ADXS-503 may be an important new off-the-shelf immunotherapy treatment option. We look forward to continued progress in the clinic with our ADXS-HOT products which includes the ongoing Phase 1/2 study of ADXS-503 in NSCLC, and the expansion of the program to our planned Phase 1 Study of ADXS-504 for the treatment of early prostate cancer."

Key presentation highlights:

Highlights from the poster presentation titled, "*A phase 1 study of an off-the-shelf, multi-neoantigen vector (ADXS-503) in patients with metastatic non-small-cell lung cancer (NSCLC) progressing on pembrolizumab as last therapy*" presented by Missak Haigentz, M.D., Section Chief of Hematology and Oncology at Morristown Medical Center and Medical Director of Hematology and Oncology for Atlantic Health, and Study Investigator, include:

- 10 patients have been treated with ADXS-503 as an add on therapy to patients failing pembrolizumab as last therapy with 10 patients evaluable for safety and 9 patients evaluable for efficacy
- Combination therapy was well tolerated with no DLTS or added toxicity of the two drugs. Grade 1 and 2, transient and reversible events included chills, fever, fatigue, in approximately half of the patients
- The Disease Control Rate (DCR) was 44% (4/9)
- Clinical benefit was durable, with an observed partial response (PR) and stable disease (SD) sustained for over a year, and another observed SD lasting over 6 months. An additional PR was maintained for approximately 4 months
- Biomarker data demonstrate that patients who seem to achieve clinical benefit include those with PD-L1 expression ≥50%, secondary resistance disease to pembrolizumab and those who show proliferation and/or activation of NK and CD8+ T cells within the first weeks of therapy
- Translational studies show:
    - Antitumoral T-cell responses elicited against hot-spot mutation antigens and/or tumor associated antigens (TAAs)
    - Emergence of naive CD8+ Tcell clones, suggesting reactivity against novel antigens
    - Induction of proliferation and/or activation of pre-existing CD8+ T-cell clones, including PD-1 upregulation

- Enrollment in Part B of the ongoing study will continue to further evaluate the clinical benefit and immune effects of adding on ADXS-503 to patients progressing on pembrolizumab

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. Part B with ADXS-503 (1 $X10^8$ CFU) in combination with KEYTRUDA® is currently enrolling its efficacy expansion for up to 18 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. Part C, which is evaluating ADXS-503 in combination with KEYTRUDA® (1 $X10^8$ CFU + KEYTRUDA®) as a first line treatment for patients with NSCLC with PD-L1 expression ≥ 1% or who are unfit for chemotherapy is currently enrolling patients.

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 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, statements about the Company's balance sheet position, and statements related to the goals, plans and expectations for the Company's ongoing clinical studies. 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 January 22, 2021, 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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