Advaxis Presents Translational Biomarker Data from Ongoing ADXS-503 Phase 1/2 Lung Cancer Trial at the American Associated for Cancer Research (AACR) 2021 Annual Meeting

April 10, 2021

Collaboration with Precision for Medicine to develop novel flow cytometry PD-1 expression assay as a pharmacodynamic biomarker in T cells during PD-1 blockade

Assay enables determination of PD-1 expression independent of PD-1 receptor status, accounting for both free and drug-bound PD-1

Results confirm on-mechanism activation of innate and adaptive immune responses in patients with demonstrated clinical benefit from ADXS-503 treatment in combination with pembrolizumab

PRINCETON, N.J., April 10, 2021 (GLOBE NEWSWIRE) -- **Advaxis, Inc. (Nasdaq: ADXS**), a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products, and Precision for Medicine, a specialized services company supporting next generation approaches to drug development and commercialization, today announced data on the development of a novel flow immunophenotyping assay to accurately evaluate total PD-1 expression as a pharmacodynamic marker during PD-1 blockade, and translational data demonstrating immune responses correlated to observed clinical benefit from the Company's ongoing Phase 1/2 study evaluating ADXS-503 in combination with KEYTRUDA®, presented as a poster at the American Association for Cancer Research (AACR) Annual Meeting 2021. 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 presented data suggest this novel immunophenotyping assay has the potential to more accurately measure pharmacodynamic biomarkers in immunotherapy," said Ken Berlin, Chief Executive Officer of Advaxis. "This assay enables the detection of both free and drug-bound PD-1 expression, independent of PD-1 receptor status or interference due to PD-1 blockade, enabling the accurate evaluation of PD-1 expression in patients undergoing treatment with pembrolizumab. We believe this is another important step forward in further understanding immune responses in patients treated with immunotherapy agents, and may provide important translational insights specific to PD-1 expression and immune modulation which may help shape treatment strategies moving forward."

Mr. Berlin continued, "The flow cytometry data confirmed the on-mechanism activation of the innate and adaptive immune systems in patients with observed clinical benefit following treatment with ADXS-503 in combination with pembrolizumab. The demonstrated proliferation and activation of NK cells and CD8 + T cells, plus increased PD-1 expression in diverse immune cells in patients achieving clinical benefit, add to the growing body of evidence which demonstrate the potential of ADXS-503 to re-sensitize or enhance responses to pembrolizumab, even in patients with prior progression. We will continue these analyses with Precision for Medicine on additional patients from our ongoing Phase 1/2 study in NSCLC, and look forward to continued progress as we build upon our previously reported efficacy results which show promising and durable clinical benefit after treatment with ADXS-503, our first off-the-shelf neoantigen immunotherapy candidate."

Key presentation highlights:

Poster presentation titled, "*Evaluation of total PD-1 expression using multi-color flow cytometry in metastatic non-small cell lung cancer patients treated with multi-neoantigen vector (ADXS-503) alone and in combination of pembrolizumab to assess T-cell & T-cell memory subsets*" presented by Dr.Venkat Mohanram, Senior Scientist at Precision for Medicine.

- A novel multi-color flow cytometry analysis was developed to accurately identify PD-1 expression on peripheral blood mononuclear cells (PBMCs) of NSCLC patients receiving PD-1/PD-L1 blockade therapy with pembrolizumab and ADXS-503
- No interference in PD-1 detection due to pembrolizumab blockage was observed, enabling the determination of PD-1 expression independent of PD-1 receptor status, with both free and drug-bound PD-1 detected
- Preliminary flow cytometry data demonstrated on-mechanism activation of innate and adaptive immune responses to ADXS-503. Three patients from the ongoing Phase 1/2 with demonstrated clinical benefit of stable disease showed:
    - Proliferation and activation of NK cells
    - Increased PD-1 expression on circulating CD4+, CD8+ and NK cells
    - Increased counts of CD8+ T cells including proliferative, cytotoxic and memory CD8+ T cells

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 15 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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