# Advaxis Presents Updated Data from Ongoing ADXS-503 Phase 1/2 Lung Cancer Trial at the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting

November 9, 2020

*Disease control rate of 67% and overall response rate of 17% in first six evaluable patients with immediate prior progression on KEYTRUDA®*

*Biomarker data confirms on-mechanism activation of innate and adaptive immune responses to ADXS-503*

*ADXS-503 appeared safe and well tolerated as a monotherapy and in combination with KEYTRUDA®*

PRINCETON, N.J., Nov. 09, 2020 (GLOBE NEWSWIRE) -- **Advaxis, Inc. (Nasdaq: ADXS)**, a clinical-stage biotechnology company focused on the development and commercialization of immunotherapy products today announced the presentation of data from the Company's ongoing Phase 1/2 study evaluating ADXS-503 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy in non-small cell lung cancer (NSCLC) at the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting. ADXS-503 is the first drug construct from the Company's 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.

The data presented across three cohorts; Part A monotherapy, Part B combination with KEYTRUDA® and Part C combination with KEYTRUDA® in the first line setting for patients with NSCLC with PD-L1 expression ≥ 1% or who are unfit for chemotherapy, together, demonstrate that ADXS-503 was safe and well tolerated, and may restore or enhance sensitivity to checkpoint inhibitors as an off-the-shelf, neoantigen immunotherapy.

"The results observed thus far in Part B of this study, with ADXS-503 added to KEYTRUDA ® without intervening treatment or a change in the checkpoint inhibitor at the time of progression on KEYTRUDA®, provide encouraging proof-of-concept that ADXS-503 may re-sensitize or enhance the response to KEYTRUDA®," said Jonathan W. Goldman, M.D., Department of Medicine, Ronald Regan UCLA Medical Center, UCLA Health Santa Monica Medical Center, and Lead Study Investigator. "The results in Part B also demonstrate an improved disease control rate compared to other checkpoint rechallenge studies. We are equally intrigued with the duration and quality of the clinical benefit, as four patients have been safely treated and done well with the combination therapy, two of them for more than 10 months as of today. Importantly, the immune correlative data support the thesis that ADXS-503 is synergizing well with KEYTRUDA® by activating cytotoxic and memory CD8+ T cells. We are eagerly collecting additional data to better define the role of ADXS-503 and KEYTRUDA® in this setting and in Part C of the study in first line therapy of NSCLC patients."

**Key presentation highlights:**

Poster presentation titled, "*Phase 1/2 Study of an Off-the-Shelf, Multi-Neoantigen Vector (ADXS-503) Alone and in Combination with Pembrolizumab in Subjects with Metastatic Non-Small Cell Lung Cancer (NSCLC*)" presented by Jonathan W. Goldman, M.D., Department of Medicine, Ronald Reagan UCLA Medical Center, UCLA Health Santa Monica Medical Center, and lead study investigator

- ADXS-503 alone (Part A) and in combination with Pembrolizumab (Part B-DL1 and Part C) appeared safe and tolerable.
  - There were no added toxicities from combining ADXS-503 with Pembrolizumab
- In Part A, ADXS-503 alone achieved stable disease in 50% (n=6) of heavily pre-treated patients including prior treatment with checkpoint inhibitors in all but one patient
- In Part B, the overall response rate (17%) and disease control rate (67%) (n=6) suggest that adding on ADXS-503 after immediate prior progression on Pembrolizumab may re-sensitize or enhance response to Pembrolizumab
- The first two patients treated in the Part B that had achieved SD and PR have now lasted 10 months
- In Part B, one patient with squamous histology also achieved stable disease, suggesting this regimen may be broadly applicable across NSCLC
- Biomarker data from 9 patients to date, 6 from Part A and 3 from Part B, show:
  - Activation of cytotoxic- and/or memory-CD8+ T cells in patients treated with monotherapy and in combination therapy
  - 100% efficient priming by ADXS-503 with generation of CD8+ T cells against neoantigens in the vector as well as antigen spreading observed
  - Patients with known KRAS mutations in tumor samples have achieved stable disease in the study, including KRAS G12D in 2 out of 6 patients in Part A and KRAS G12V in 1 out of 3 in Part B DL1. Mutational analysis is ongoing across all patients.

Ken Berlin, Chief Executive Officer of Advaxis, said, “We are increasingly confident that ADXS-503, as an off-the-shelf neoantigen therapy, may be an important new approach to expand the benefit and durability of treatment with checkpoint inhibitors. These expanded biomarker data serve as in important proof-of-mechanism of ADXS-503 activity, stimulating both innate and adaptive immune responses with measured responses to neoantigens in our vector and antigen spreading observed. These encouraging efficacy and immune response data, in combination with a favorable safety and tolerability profile, suggest that our unique approach to neoantigen immunotherapy may be broadly applicable in lung cancer and potentially in other solid tumors. We look forward to increased momentum in the program as we continue to enroll patients in the Part B efficacy expansion and Part C expansion to the first line setting.”

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.

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