# Advaxis' ADXS-503 (HOT Lung) Demonstrates Pronounced and Sustained Tumor Control in Ongoing Phase 1/2 Lung Cancer Trial

October 26, 2020

*Disease control rate of 67% in first six evaluable patients who had progressed on KEYTRUDA*

*Approximate 50% improvement in disease control rate versus the rates reported in other checkpoint rechallenge studies*

*Durable, sustained tumor control of over 43 and 33 weeks observed in first two evaluable patients*

PRINCETON, N.J., Oct. 26, 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 results from the combination arm of the Company's ongoing Phase 1/2 study evaluating ADXS-503 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy in non-small cell lung cancer (NSCLC). 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.

Key data updates for the first 6 evaluable patients who have received ADXS-503 as an add-on therapy immediately following progression with KEYTRUDA®, include:

- Disease control rate of 67% (4/6 patients) and overall response rate of 17% (1/6 patients) achieved after immediate prior progression on KEYTRUDA® with previous best responses of stable disease
- Sustained clinical benefit with the first two treated patients remaining on treatment for over 43 and 33 weeks
- Updated and new patient level data for the four patients with observed disease control, all of whom remain on study, include:
  - Previously reported partial response (PR) with 60% tumor reduction seen on 8-week scan and sustained at 33-week scan in an elderly patient with non-squamous NSCLC who had received Pembrolizumab for approximately 30 months with a best overall response (BOR) of stable disease
  - Previously reported stable disease (SD) with a 25% reduction in target lesion sustained at 43-week scan in an elderly patient with non-squamous NSCLC who had received Pembrolizumab for ~32 months with a BOR of stable disease.
  - Stable disease (SD) confirmed on 13 week-scan in a patient with squamous NSCLC who had received Pembrolizumab for approximately 15 months with a BOR of stable disease
  - Stable disease (SD) on 6 week-scan in a patient with non-squamous NSCLC who had received Pembrolizumab for approximately 14 months, including combination therapy with chemotherapy in the beginning

"I am highly encouraged by these data which suggest that treatment with ADXS-503 has the potential to re-sensitize or enhance response to KEYTRUDA®, even in patients with immediate prior progression on treatment," said Dr. Andres Gutierrez, Chief Medical Officer of Advaxis. "Other checkpoint inhibitor rechallenge studies have reported disease control rates of approximately 45 percent, with these studies typically including bridging therapy, a change in checkpoint inhibitor, or an interruption in treatment of varying intervals. The 67% disease control rate demonstrated thus far in this ongoing study represents an impressive 50 percent improvement versus the disease control rate observed in other studies in similar settings. This improvement in the setting of uninterrupted treatment on KEYTRUDA® is promising and suggests that ADXS-503 may be capable of re-stimulating the immune system to drive clinically meaningful benefit. The sustained durability of responses is also noteworthy, and I look forward to the continued evaluation of ADXS-503 in additional patients as we advance through the efficacy expansion phase of the study."

Ken Berlin, Chief Executive Officer of Advaxis, said, "We are pleased that the growing and maturing data from our ongoing ADXS-503 clinical trial suggest that this drug candidate may represent an important new treatment option for patients who have progressed on checkpoint inhibitors. Notably, all patients with disease control were on treatment with KEYTRUDA® for over one year at the time of progression, with prior best responses that were limited to stable disease throughout their treatment. In addition, one patient with squamous histology also achieved stable disease, suggesting this regimen may be broadly applicable across NSCLC. As to the durability of tumor control, the first 2 evaluable patients remain on treatment with sustained clinical benefit for over 10 months, suggesting treatment with ADXS-503 is capable of providing long-term resensitization or enhancement to checkpoint inhibitors after disease progression."

Mr. Berlin continued, "Our belief is that ADXS-503, as an off-the-shelf neoantigen therapy that to date has a favorable safety and tolerability profile, may be broadly beneficial to lung cancer patients in diverse treatments settings and specifically, those with limited treatment options. These results, paired with our recent biomarker data that show on-mechanism activation of an immune response to ADXS-503 antigens, leave us increasingly confident that ADXS-503 has the potential to restore or enhance sensitivity to checkpoint inhibitors. We look forward to continued progress in our expanded clinical program, now evaluating patients in Part B, the efficacy expansion arm, and Part C, our expansion to the first line setting, both of which are continuing to enroll patients."

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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