ADXS-PSA in Combination with KEYTRUDA® Prolonged Survival in Metastatic Castration-Resistant Prostate Cancer

April 1, 2019

Updated Results from Phase 1/2 Study to be Presented Today at the AACR Annual Meeting

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. **(NASDAQ: ADXS)**, a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, today announced updated data from the Phase 1/2 KEYNOTE-046 study in metastatic, castration-resistant prostate cancer (mCRPC). This trial is being conducted in conjunction with Merck (known as MSD outside the U.S. and Canada) and is evaluating ADXS-PSA, one of Advaxis' *Listeria monocytogenes* (*Lm*)-based immunotherapies, alone and in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy.

"We are very excited to report the updated ADXS-PSA data today at the AACR meeting"

Findings will be highlighted in a poster discussion entitled *"Effects of ADXS-PSA with or without Pembrolizumab on Survival and Antigen Spreading in Metastatic, Castration-Resistant Prostate Cancer Patients"* at the American Association for Cancer Research (AACR) Annual Meeting underway in Atlanta. The poster discussion will be held today from 1:00-5:00 p.m. ET and will be led by lead author Mark N. Stein M.D., FACS, Associate Professor of Medical Oncology at Columbia University Medical Center.

KEYNOTE-046 is an open-label, multicenter, dose-determining safety and tolerability Phase 1/2 trial of 50 heavily pretreated patients conducted in two parts (Part A and Part B), with a Phase 2 expansion cohort. The objective of the study is to evaluate ADXS-PSA alone (Part A) and in combination with KEYTRUDA® (Part B) for primary endpoints that include safety, tolerability and dosing. Secondary endpoints include anti-tumor activity and progression-free survival, and exploratory endpoints include associations between biomarkers of immunologic response (serum PSA) with clinical outcomes.

"There is a pressing need to improve the care and treatment of patients with metastatic, castration-resistant prostate cancer," said Dr. Stein. "Data from 37 patients in the combination arm of KEYNOTE-046 are promising as a median overall survival of 21.1 months was observed. These results compare favorably to standard-of-care therapy and to study results from similar unselected patient populations with bone-predominant disease, which indicates that this combination warrants further investigation."

Key findings from the combination arm of KEYNOTE-046 include the following:

- The majority of treatment-related adverse events consisted of transient and reversible Grade 1-2 chills/rigors, fever, hypotension, nausea and fatigue. The combination of ADXS-PSA and pembrolizumab has been well-tolerated, to date, with no additive toxicity observed.
- Median overall survival was 21.1 months at data cutoff (February 1, 2019) (95% CI, range 16.0 months to not-yet-reached) in this dataset of 37 patients.
- Correlative immune analyses showed T-cell responses against PSA in 75% of subjects and antigen spreading in 85% of subjects.
- Broader immune stimulation, including B-cell activation, was observed in the combination arm (n=37) than in the ADXS-PSA monotherapy arm (n=13).

"We are very excited to report the updated ADXS-PSA data today at the AACR meeting," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "These data show the clinical potential of ADXS-PSA both alone and in combination with KEYTRUDA®. It is meaningful that the combination has been well-tolerated in the study population because dose-related toxicities can present challenges for cancer patients, and an additive therapy with a favorable safety and tolerability profile may offer an attractive option for clinicians if developed further in this indication." He concluded, "Based on the prolonged survival data and strong safety profile to date, we believe that continued clinical development of ADXS-PSA in combination with KEYTRUDA® is warranted and represents a potentially significant opportunity for Advaxis."

The full abstract is available at www.advaxis.com and the poster will be available on the Company's website today at 1:00 p.m. ET.

About KEYNOTE-046

KEYNOTE-046 (NCT02325557) is a Phase 1/2 open-label, multicenter, dose-determination and expansion trial that evaluates the safety, tolerability and preliminary clinical activity of ADXS-PSA as monotherapy (Part A; n=14 [13 treated]), and in combination with KEYTRUDA® (Part B; n=37) in heavily pretreated patients with progressive and refractory mCRPC.

About ADXS-PSA

ADXS-PSA, one of Advaxis' *Lm*-based immunotherapies, utilizes live, attenuated, bioengineered *Lm* as a vector to deliver PSA directly to antigen presenting cells. Development is being pursued in a clinical trial collaboration and supply agreement with Merck.

About Advaxis, Inc.

Advaxis, Inc. is a late-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. Advaxis has four programs in various stages of clinical development: ADXS-HPV for cervical cancer; ADXS-NEO, a personalized neoantigen-directed therapy for multiple cancers; ADXS-503 for non-small cell lung cancer, from its ADXS-HOT off-the-shelf neoantigen-directed program; and ADXS-PSA for prostate cancer.

To learn more about Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook and YouTube.

Advaxis Forward-Looking Statement

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the success and timing of our clinical trials, including subject accrual; our ability to avoid any clinical holds and to resolve FDA's partial clinical hold; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our ability to obtain the appropriate labeling of our products under any regulatory approval; our plans to develop and commercialize our products; the successful development and implementation of our sales and marketing campaigns; the size and growth of the potential markets for our product candidates and our ability to serve those markets; our ability to successfully compete in the potential markets for our product candidates, if commercialized; regulatory developments in the United States and other countries; the rate and degree of market acceptance of any of our product candidates; new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements; market conditions in the pharmaceutical and biotechnology sectors; our available cash; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our ability to obtain additional funding; our ability to obtain and maintain intellectual property protection for our product candidates; the success and timing of our preclinical studies including IND-enabling studies; the timing of our IND submissions; our ability to get FDA approval for study amendments; the timing of data read-outs; the ability of our product candidates to successfully perform in clinical trials; our ability to initiate, enroll, and execute pilots and clinical trials; our ability to maintain collaborations; our ability to manufacture and the performance of third-party manufacturers; the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; our ability to successfully implement our strategy; and, other risk factors identified from time to time in our reports filed with the SEC. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

CONTACT:

Investors:
LHA Investor Relations
Miriam Weber Miller, (212) 838-3777
mmiller@lhai.com