Data Highlighting Advaxis' ADXS-PSA Presented at ASCO Annual Meeting

June 1, 2018

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 preliminary data from the ongoing metastatic, castration resistant prostate cancer (mCRPC) Phase 1/2 KEYNOTE-046 study, conducted in conjunction with Merck (known as MSD outside the United States and Canada) evaluating ADXS-PSA, Advaxis's *Listeria monocytogenes* (*Lm*)-based immunotherapy, alone and in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy.

"Improvements in the care and treatment of highly refractory prostate cancer, a traditionally difficult type of cancer to treat, are vital. These early results show a safe and tolerable profile for ADXS-PSA alone or in combination with KEYTRUDA"

Findings will be highlighted in a poster discussion at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting underway in Chicago, on Saturday, June 2, from 4:45 pm to 6:00 p.m. CDT (Location: Hall A; Poster #246; Abstract #5019). Principal Investigator and author Naomi Haas, MD, Director of the Prostate and Kidney Cancer Programs and Associate Professor of Medicine at the Hospital of the University of Pennsylvania will be presenting.

ADXS-PSA was tested alone or in combination with KEYTRUDA in an advanced and heavily pretreated patient population who had progressed on androgen deprivation therapy. A total of 13 and 37 patients were evaluated on monotherapy and combination therapy, respectively. Overall, the safety profile was consistent with findings from prior clinical studies using the *Lm* platform. Treatment-related adverse events (TRAEs) were mostly mild or moderate constitutional symptoms such as fever, chills, rigors, hypotension, nausea and fatigue, consistent with immune activation and manageable with standard care. One patient in the monotherapy arm was discontinued from the study due to a grade 4 TRAE related to cytokine release, which resolved within 24 hours using medical management. There were no new toxicities observed with the combination therapy. In all treated patients, those who received the combination therapy experienced the longest overall survival (OS) at data cut-off, with the median not having been reached at 13 months of follow-up.

"Improvements in the care and treatment of highly refractory prostate cancer, a traditionally difficult type of cancer to treat, are vital. These early results show a safe and tolerable profile for ADXS-PSA alone or in combination with KEYTRUDA," said Dr. Haas. "Albeit the study was not designed to compare monotherapy to combination therapy, the survival rates in the combination therapy arm are encouraging, especially given the reduction in PSA levels observed in this group, and mature data in the following 6 months will help better define the role of ADXS-PSA in combination with KEYTRUDA in mCRPC."

Key Findings from KEYNOTE-046 (as of March 30, 2018):

- The advanced patient population in the study had a median Gleason score of 8.3, and was heavily pretreated, with greater than 70% having received three or more prior lines of therapy.
- Median overall survival had not been reached in the combination arm after 13 months of follow-up (95%CI 7.16-NR), and was 7.79 months (95%CI 3.52-11.9) in the monotherapy arm.
- 56.8% of patients on combination therapy and 38.5% of patients on monotherapy did not experience disease progression.
- The percentage of patients with PSA declines from baseline in the combination therapy arm was 40.5%, and 15.4% in the monotherapy arm.
- In all treated patients, an improvement in survival was observed in patients with PSA declines from baseline of 50% or greater vs. those with PSA declines of less than 50%. There were 7 patients in the combination arm with 50% or greater declines in PSA from baseline, and none in the monotherapy arm.

Previously presented immunologic data from the monotherapy arm of this trial showed that ADXS-PSA induced or enhanced T cell responses not only to PSA, but also to other prostate cancer antigens that were not expressed by the *Lm*-based vector, which is indicative of antigen cascade or antigen spreading (SITC 2017; Hayes et al. *J Immunother Cancer.* 2017;5(Suppl 2)86:P2). Correlative immunologic analyses and overall survival for the combination therapy patients are underway.

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. Patient accrual in the study is complete, with 5 patients still receiving treatment, all in Part B, and being followed for survival analysis.

About ADXS-PSA

ADXS-PSA, one of Advaxis's *Listeria monocytogenes* (*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 the T cells to eliminate tumors. Advaxis has four franchises in various stages of clinical and preclinical development: HPV-associated cancers, neoantigen therapy, hotspot/ cancer antigens and prostate cancer.

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

Advaxis Forward-Looking Statement

This press release contains forward-looking statements, including, but not limited to, statements regarding Advaxis' ability to develop and commercialize the next generation of cancer immunotherapies, and the safety and efficacy of Advaxis' proprietary immunotherapies. These forward-looking statements are subject to a number of risks including the risk factors set forth from time to time in Advaxis' SEC filings including, but not limited to, its report on Form 10-K for the fiscal year ended October 31, 2017, and on Form 10-Q for the quarter ended January 31, 2018, which are available at www.sec.gov.

Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

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