Advaxis Announces Updated Prolonged Survival Data In Phase 1/2 ADXS-PSA Trial

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Median overall survival for ADXS-PSA in combination with KEYTRUDA ® increased to 33.6 months from previously reported 21.1 months

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (Nasdaq: ADXS), a clinical-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, today announced updated median overall survival data from its 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.

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At the final data cutoff of September 16, 2019, median overall survival for 37 patients in the combination arm was 33.6 months (95% CI, range 15.4-33.6 months). This updated median overall survival is an increase from the previous data presented at the American Association for Cancer Research (AACR) Annual Meeting in April, where median overall survival was 21.1 months in the combination arm. These new data, along with additional details from this final predetermined look at the trial results, will be presented at an upcoming medical conference.

"We are excited to report these updated data which show a meaningful increase in median overall survival for patients in the combination arm of the KEYNOTE-046 study," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "We believe that ADXS-PSA in combination with KEYTRUDA ® has the potential to be an important new treatment option for patients with advanced metastatic, castration-resistant prostate cancer, which based on these data, warrants further evaluation. We are currently assessing next steps for a potential new study for ADXS-PSA in combination with KEYTRUDA ® in mCRPC and we look forward to providing additional details about the program's path forward."

Mark N. Stein M.D., FACS, Associate Professor of Medical Oncology at Columbia University Medical Center and lead investigator of the study, said, "Patients with metastatic castration-resistant prostate cancer who have failed next generation hormonal agents and/or docetaxel have limited treatment options. The updated survival data in a patient population with advanced prostate cancer suggests this generally well tolerated vaccine should be evaluated in larger studies. I look forward to the continued evaluation of ADXS-PSA in combination with KEYTRUDA ® as a potential new treatment regimen that can improve patient outcomes while preserving quality of life."

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, progression-free survival and overall survival, and exploratory endpoints that include associations between biomarkers of immunologic response (serum PSA) with clinical outcomes. Enrollment in the study has been completed. 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 KEYTRUDA® has appeared to be well-tolerated, to date, with no additive toxicity observed.

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 Advaxis, Inc.

Advaxis, Inc. is a clinical-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 three programs in various stages of clinical development: ADXS-NEO, a personalized neoantigen-directed therapy designed, in principle, for any solid tumor; 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.

Forward-Looking Statements

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 impact of the discontinuation on relationships related to the AIM2CERV

Study; the success and timing of our clinical trials, including subject accrual; our ability to avoid and quickly resolve any clinical holds; 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, including to support current and planned clinical activities; 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 our existing 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.

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