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Advaxis Initiates Combination Portion of Phase 1/2 Study with Merck

KEYNOTE-046 study to evaluate KEYTRUDA® in combination with ADXS-PSA

Advaxis begins screening patients for Phase 3 AIM2CERV study in cervical cancer

PRINCETON, N.J., Oct. 20, 2016 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, today announced the commencement of Part B of the KEYNOTE-046 clinical trial evaluating Advaxis' *Lm* immunotherapy candidate, ADXS-PSA, in combination with KEYTRUDA (pembrolizumab) in patients with previously treated, metastatic castration-resistant prostate cancer (mCRPC). In Part A of the Phase 1/2 study, 14 patients were treated with ADXS-PSA monotherapy across three dose levels, with no dose limiting toxicities, paving the way for initiating Part B of the study.

KEYNOTE-046 is a multicenter, open-label, nonrandomized, dose determining, Phase 1/2 trial evaluating the safety of ADXS-PSA. Part B of the study is evaluating the tolerability of ADXS-PSA in combination with KEYTRUDA in 30 patients with mCRPC. Secondary objectives for this study are to evaluate antitumor activity and progression-free survival of ADXS-PSA. KEYNOTE-046 is the first-in-human study of Advaxis' *Lm* immunotherapy candidate for prostate cancer. It is the second study initiated to evaluate the use of KEYTRUDA in the treatment of advanced prostate cancer.

Advaxis also announced initiation of its Phase 3 AIM2CERV study, a multicenter, placebo-controlled, randomized study of axalimogene filolisbac, or AXAL, administered in the adjuvant setting following chemotherapy and radiation in women with high-risk, locally advanced cervical cancer (HRLACC). The primary objective of the trial is disease-free survival, with secondary objectives including examining overall survival and safety. In July 2016, Advaxis received a Special Protocol Assessment for the AIM2CERV trial, as well as Fast Track designation for AXAL as an adjuvant therapy for HRLACC patients.

Several trial sites have been opened for both studies and locations are currently screening patients for enrollment. For more information on Advaxis clinical trials, visit clinicaltrials.gov.

About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary *Lm* Technology. The *Lm* Technology, using bioengineered live attenuated *Listeria monocytogenes* (*Lm*) bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancer fighting T cells directed against cancer antigens and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor

microenvironment from immunologic attack and contribute to tumor growth. Advaxis' l e a d *Lm* Technology immunotherapy, AXAL, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three potential indications: Phase 3 in invasive cervical cancer, Phase 2 in head and neck cancer, and Phase 2 in anal cancer. The FDA has granted AXAL orphan drug designation for each of these three clinical settings, as well as Fast Track designation for adjuvant therapy for HRLACC patients and a Special Protocol Assessment for the Phase 3 AIM2CERV trial in HRLACC patients. AXAL has also been classified as an advanced therapy medicinal product for the treatment of cervical cancer by the European Medicines Agency's Committee for Advanced Therapies. Advaxis has two additional immunotherapy products: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, in human clinical development. In addition, Advaxis and Amgen are developing ADXS-NEO, a preclinical investigational cancer immunotherapy treatment designed to activate a patient's immune system to respond against the unique mutations, or neoepitopes, contained in and identified from each individual patient's tumor, with plans to enter the clinic in 2017.

For additional information on Advaxis, visit http://www.advaxis.com/ and connect on Twitter, LinkedIn, Facebook, YouTube and Google+.

Advaxis Forward-Looking Statement

This press release contains forward-looking statements, including, but not limited to: statements regarding the completion and timing of the offering of shares. 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, 2015, which is available at http://www.sec.gov, as well as the risks identified or incorporated by reference in the registration statement and the prospectus supplement relating to the offering. Advaxis undertakes no obligation to publicly release the result of any revision to these forward-looking statements, which may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

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