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Phase 1/2 Combination Trial of AXAL and Durvalumab Completes Second Dose-Escalation Cohort

Part A expansion and Part B now enrolling for AXAL in combination with durvalumab for the treatment of advanced, recurrent or refractory HPV-associated cervical cancer and head & neck cancer

PRINCETON, N.J., July 26, 2016 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, today announced its combination study of axalimogene filolisbac (AXAL) with AstraZeneca's anti-PD-L1 durvalumab has completed the second dose-escalation cohort and has commenced enrollment for the Part A expansion and Part B phases of the study.

The study is evaluating the safety and efficacy of combination treatment with AXAL and durvalumab in patients with advanced, recurrent or refractory human papillomavirus (HPV)-associated cervical cancer and HPV-associated head and neck cancer.

The goal of the Part A expansion is to enroll 20 patients with HPV-associated head and neck cancer to receive AXAL at $1x10^9$ cfu plus 10 mg/kg of durvalumab. Part B of the trial will evaluate AXAL at $1x10^9$ cfu with 10mg/kg of durvalumab in patients with cervical cancer, with the goal to randomize 45 patients to a durvalumab monotherapy and 45 patients for the combination therapy.

Data from the first dose-escalation cohort will be submitted as an abstract for an upcoming major medical meeting this fall. Further information about the Phase 1/2 study can be found on ClinicalTrials.gov, using Identifier NCT02291055.

About Cervical Cancer

Cervical cancer is the fourth most common cancer in women worldwide. In the United States, nearly 13,000 new cases are diagnosed annually and approximately 4,100 deaths are reported because of cervical cancer. According to the WHO/ICO Information Centre on HPV and Cervical Cancer, about 3.9 percent of women in the U.S. are estimated to harbor high-risk cervical HPV infection at a given time, and 71.7 percent of invasive cervical cancers are attributed to high-risk HPV strains.

About Axalimogene Filolisbac

Axalimogene filolisbac (AXAL) is Advaxis' lead *Lm* Technology™ immunotherapy candidate for the treatment of HPV-associated cancers and is in clinical trials for three

potential indications: invasive cervical cancer, head and neck cancer, and anal cancer. In a completed randomized Phase 2 study in recurrent/refractory cervical cancer, AXAL showed apparent prolonged survival, objective tumor responses, and a manageable safety profile alone or in combination with chemotherapy, supporting further development of the company's *Lm* Technology™. AXAL has Orphan Drug Designation in the U.S. for the treatment of invasive cervical cancer, head and neck, and anal cancer.

About Durvalumab

Durvalumab is a selective, high-affinity human IgG1 mAb that blocks PD-L1 binding to PD-1 and CD80. The PD-1/PD-L1 pathway is an important checkpoint used by tumour cells to inhibit antitumour responses. PD-L1 upregulation is observed on tumour cells from a broad range of human cancers and may cause tumor immune evasion. Targeting and blocking the inhibitory effects of PD-L1 with durvalumab is an important immunotherapeutic approach designed to boost anti-tumor immune responses in patients with cancer. Durvalumab is being investigated in an extensive clinical trial program, as monotherapy or in combination with other immunotherapeutic and small molecules, in NSCLC, head and neck, bladder, gastric, pancreatic, HCC and blood cancers

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' lead *Lm* Technology™ immunotherapy, axalimogene filolisbac, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three potential indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The U.S. Food and Drug Administration (FDA) has granted axalimogene filolisbac orphan drug designation for each of these three clinical settings. Advaxis has two additional immunotherapy products: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, in human clinical development.

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

Forward-Looking Statements

This media statement contains forward-looking statements, including, but not limited to: statements regarding Advaxis' ability to develop 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, 2015, which is available at http://www.sec.gov. 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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