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Advaxis Announces First Patient Dosed in Phase 2 Trial Evaluating AXAL in Anal Cancer

FAWCETT study named to honor Farrah Fawcett, who passed away from HPV-associated anal cancer

PRINCETON, N.J., June 08, 2016 (GLOBE NEWSWIRE) -- [Advaxis, Inc.](#) (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, today announced dose administration for the first patient in the first stage of its Phase 2 clinical trial of their FAWCETT study, testing the Company's lead immunotherapy candidate, axalimogene filolisbac (AXAL), in patients with persistent or recurrent metastatic anal cancer.

The multi-center, open-label, two-stage study is designed to evaluate the efficacy and safety of AXAL as a monotherapy in patients with HPV-associated metastatic anal cancer who have received at least one prior treatment regimen for the advanced disease. Stage 1 of the trial will enroll 31 patients with anal cancer whose disease recurred after receiving treatment. Patients will receive AXAL 1×10^9 colony forming unit (CFU) doses every three weeks for up to two years.

In collaboration with Brown University Oncology Research Group, AXAL has been evaluated in high-risk, locally advanced anal cancer with concurrent standard chemotherapy and radiation treatment. Preliminary data show treatment with AXAL indicated a clinical complete response and no recurrence in all 10 patients who completed the treatment regimen.

"The FAWCETT study is an important step in the development program for AXAL," said Daniel J. O'Connor, President and Chief Executive Officer at Advaxis. "People living with anal cancer desperately need new treatment options, which is why Advaxis is pursuing two areas of evaluation, including monotherapy with AXAL and a second study with an immune checkpoint inhibitor in combination with AXAL."

The FAWCETT (**F**ighting **A**nal-Cancer **w**ith **CT**L **E**nhancing **T**umor **T**herapy) study was named in honor of Farrah Fawcett, who passed away due to HPV-associated anal cancer. In 2015, the Farrah Fawcett Foundation honored Advaxis with its inaugural "Medical Visionary Angel Award" based on the Company's clinical research and efforts to treat this disease, initiating a partnership among the organizations.

About Anal Cancer

Anal cancer is a fairly rare form of cancer in the United States, but the number of new anal

cancer cases has been rising for years. The risk of being diagnosed with anal cancer in one's lifetime is about 1 in 500. According to the American Cancer Society, approximately 7,270 new cases of anal cancer were diagnosed and about 1,010 people died of the disease in 2014.

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 Designations in the U.S. for the treatment of invasive cervical cancer, head and neck cancer and anal cancer.

About the Farrah Fawcett Foundation

The mission of the Farrah Fawcett Foundation is to provide funding for cutting edge cancer research, to support prevention and awareness, and to help those struggling with cancer today. Farrah Fawcett was diagnosed with anal cancer in 2006 and established the Foundation before her death in 2009. For more information, visit www.thefarrahfawcettfoundation.org and follow them on [Facebook](#).

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 (AXAL), 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 AXAL orphan drug designation for each of these three clinical settings. Advaxis has two additional immunotherapy products in human clinical development: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2-expressing solid tumors.

For additional information on Advaxis, visit www.advaxis.com and connect on [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#) and [Google+](#).

Advaxis Forward-Looking Statement

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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