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# Advaxis Announces GOG-0265 12-month Overall Survival Rate of 37.5% in Stage 2

*Data in 50 patients with recurrent metastatic carcinoma of the cervix demonstrates a 52% increase in 12-month overall survival rate*

PRINCETON, N.J., Oct. 24, 2016 (GLOBE NEWSWIRE) -- [Advaxis, Inc.](#) (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, today announced topline results from the early closure of stage 2 of the Phase 2 GOG-0265 trial, conducted by the Gynecologic Oncology Group (GOG, now part of NRG Oncology) and supported by the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI).

GOG-0265 is a single-arm, open-label Phase 2 multicenter study (NCT01266460) designed to evaluate the safety and activity of axalimogene filolisbac in patients with persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC) in a standard Simon two-stage design. The first stage of the study included a six-patient safety run-in and enrolled 26 patients. The first stage of the study was previously completed, meeting the predetermined safety and efficacy criteria required to proceed into the second stage of patient enrollment. The second stage enrolled 24 patients prior to the clinical hold that affected Advaxis' clinical development programs last year. The second stage was not completed as designed due to the clinical hold.

A preliminary analysis of 12-month overall survival data from 24 patients enrolled in the second stage prior to the clinical hold showed that treatment with axalimogene filolisbac resulted in a 37.5 percent 12-month overall survival rate. These preliminary findings are consistent with earlier data that showed a 38.5 percent 12-month overall survival rate in 26 patients enrolled in the first stage of the study, despite modest differences in dosing schedules between the two stages.

Based on protocol defined prognostic factors of patients who enrolled in the study (n=50), a 12-month survival rate of 25 percent would have been expected. Comparing this 25 percent 12-month overall survival rate to the 38 percent 12-month overall survival rate actually observed across the total study population, treatment with axalimogene filolisbac resulted in a 52 percent increase in the expected 12-month overall survival rate.

"These data demonstrate a meaningful improvement in 12-month overall survival rate compared to historical GOG studies," said Warner K. Huh, M.D., division director of Gynecologic Oncology at the University of Alabama at Birmingham, and lead investigator of the study. "Historical survival rates for patients with PRmCC underscore the need for additional treatment options for patients and these results illustrate the promising therapeutic potential for axalimogene filolisbac in women with this rare cancer."

In the second stage of the study, 15 out of 24 patients experienced a Grade 1 or Grade 2 treatment-related adverse event (TRAE). The most common Grade 1 or Grade 2 TRAEs were hypotension and symptoms related to cytokine release (e.g., nausea, chills, fever). Nine out of 24 patients experienced a Grade 3 TRAE and two out of 24 patients experienced a Grade 4 TRAE, which were hypotension and symptoms related to cytokine release.

“We are very encouraged by these data and look forward to presenting and discussing a more detailed analysis of the trial results at an upcoming medical society meeting,” said Daniel J. O’Connor, president and chief executive officer of Advaxis. “We believe that a more than 50 percent increase in 12-month overall survival rate is clinically meaningful, and Advaxis plans to pursue registrational opportunities in Europe in 2017.”

Axalimogene filolisbac was recently classified as an advance therapy medicinal product (ATMP) in the EU, has received U.S. Food and Drug Administration (FDA) Fast Track Designation as an adjuvant therapy for treating high risk, locally advanced cervical cancer (HRLACC), and has been granted U.S. orphan drug designation for the treatment of invasive cervical cancer.

### **About Cervical Cancer**

Cervical cancer is the fourth most common cancer in women worldwide.<sup>2</sup> An estimated 13,000 new cases will be diagnosed in the United States in 2016, and 4,100 people will die of the disease, according to the National Cancer Institute. Persistent HPV infection is the most important factor in the development of cervical cancer, research shows.<sup>3,4</sup> According to the ICO Information Centre on HPV and Cervical Cancer, about 4.4 percent of women in the United States are estimated to harbor high-risk cervical HPV infection at a given time, and about 72 percent of cervical cancers are attributed to high-risk HPV strains.<sup>5</sup> The prognosis for women with advanced and recurrent cervical cancer remains poor, with survival of only 4 to 7 months following failure of first-line treatment, research has shown.<sup>6</sup> According to the American Cancer Society, the 5-year mortality rate for metastatic disease is at just 17 percent, with the area continuing to be a high unmet medical need.<sup>7</sup>

### **About The GOG Foundation, Inc.**

The GOG Foundation, Inc. (GOG), now part of NRG Oncology, is a non-profit international organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies. The GOG is committed to maintaining the highest standards in clinical trials development, execution, analysis and distribution of results. Continuous evaluation of its processes is utilized in order to constantly improve the quality of patient care. The GOG conducts clinical trials for patients with a variety of gynecologic malignancies, including cancers that arise from the ovaries, uterus, cervix, vagina and vulva. General information on many of these trials for medical professionals and the lay public can be obtained from [ClinicalTrials.gov](http://ClinicalTrials.gov).

NRG Oncology is one of four adult US Network groups funded under the newly structured NCI National Clinical Trials Network. NRG Oncology is comprised of three legacy

cooperative groups, the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group (RTOG), and the Gynecologic Oncology Group (GOG).

### **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 3 in invasive cervical cancer, Phase 2 in head and neck cancer, and Phase 2 in anal cancer. The FDA has granted axalimogene filolisbac 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. axalimogene filolisbac 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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