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Advaxis Presents Oral Late-breaking Data on Phase 2 GOG-0265 Study of Axalimogene Filolisbac at SGO's Annual Meeting on Women's Cancer

- Achieved primary objective of 12-month survival rate, demonstrating axalimogene filolisbac is an active therapy in metastatic cervical cancer

- Unprecedented 12-month survival rate for metastatic cervical cancer observed

PRINCETON, N.J., March 15, 2017 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a biotechnology company developing cancer immunotherapies, presented data from the GOG-0265 study at the Society of Gynecologic Oncology's Annual Meeting on Women's Cancer in National Harbor, MD. GOG-0265 is a single arm, Phase 2 trial evaluating axalimogene filolisbac for the treatment of persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC). The primary endpoints of the study were to assess the safety and efficacy of axalimogene filolisbac in women with PRmCC. The primary efficacy endpoint was overall survival at 12 months from initial treatment with axalimogene filolisbac. The primary safety endpoints were to evaluate the number of patients with dose-limiting toxicities and the frequency and severity of adverse effects.

The final efficacy results of GOG-0265 demonstrated that 38% of patients (n = 19/50) with heavily pretreated PRmCC were alive 12 months following treatment with axalimogene filolisbac. The GOG-0265 study protocol used a logistic model-based calculation to establish the expected 12-month survival rate. The model identified the key prognostic factors of age, race and performance status significantly related to survival from a database of approximately 500 patients with PRmCC who participated in 17 previous phase 2 studies conducted by the Gynecologic Oncology Group (GOG), now part of NRG Oncology. Using this model, the expected 12-month survival rate of patients enrolled in the study was calculated to be 24.5%. As a result, the 38% 12-month survival rate of patients treated with axalimogene filolisbac represents a 52% improvement over the expected survival rate and is the highest 12-month survival rate achieved to date in this setting. The probability of this survival improvement being detected by chance versus a true treatment effect was calculated to be 0.02. A compelling and ongoing complete response of 18.5 months was observed and the longest ongoing survival is 40.6 months.

"The 12-month survival rate of axalimogene filolisbac reached unprecedented levels in this study, which is both impressive and important given the lack of innovation in metastatic cervical cancer," said Warner K. Huh, MD, Division Director of Gynecologic Oncology at the University of Alabama at Birmingham, and Lead Investigator of the study.

The safety profile was consistent with previous clinical experience. The most common Grade 1 or Grade 2 treatment-related adverse events (TRAEs) were hypotension and symptoms related to cytokine release (e.g., nausea, chills, fever). Eighteen out of 50 patients experienced a Grade 3 TRAE and two out of 50 patients experienced a Grade 4 TRAE, which were hypotension and symptoms related to cytokine release.

The abstract was selected by SGO for prominence as an oral late-breaking presentation by Charles A. Leath III, M.D., MSPH, Associate Professor of Obstetrics and Gynecology at the University of Alabama at Birmingham School of Medicine, entitled, "A prospective phase 2 trial of the *listeria*-based HPV immunotherapy axalimogene filolisbac in second and third-line metastatic cervical cancer: A NRG Oncology Group trial," on March 14 at 2:30 p.m. ET. Slides from the presentation are available at www.advaxis.com/sgo2017.

Highlights from Dr. Leath's presentation include:

- A 38% (n = 19/50) 12-month survival rate in second- and third-line PRmCC treated with axalimogene filolisbac, representing a 52% improvement over the expected 12-month milestone survival rate of 24.5%
- Eight patients remain alive as of January 31, 2017 (Range 12.02 – 40.6 months)
- Disease control (complete response, partial response, or stable disease) was achieved in 32% of patients based on investigator assessment of best response
- A durable complete response in a patient with PRmCC previously treated with chemotherapy and bevacizumab remains ongoing at 18.5 months
- Results compare favorably to GOG Study 227C of bevacizumab, which demonstrated a 12-month milestone overall survival (OS) rate of 30% in a similar patient population which subsequently supported regulatory approval in first-line treatment in combination with chemotherapy in 2014
- Consistent with its immunotherapy mechanism of action, axalimogene filolisbac demonstrated a promising plateau in the survival curve, indicating potential long-term clinical benefit for a subset of patients with PRmCC
- Axalimogene filolisbac was generally well-tolerated, with primarily infusion-associated, low grade, transient TRAEs (≥30%), such as fatigue, chills, anemia, nausea and fever
- Only 2 patients experienced grade 4 TRAEs

Advaxis plans to initiate a global, phase 3 randomized registration study in patients with metastatic cervical cancer later this year.

About the Phase 2 GOG-0265 Study

GOG-0265 is an open-label, single arm 2-stage study designed to evaluate the safety, tolerability and efficacy of axalimogene filolisbac to treat PRmCC as conducted by the Gynecologic Oncology Group (GOG), now part of NRG Oncology. Patients who progressed on or after at least 1 prior line of systemic-dose chemotherapy receive one cycle (three doses) of axalimogene filolisbac at 1 x 10^9 CFU every 28 days. The primary efficacy endpoint was the 12-month survival rate, with secondary efficacy objective to evaluate progression-free survival, overall survival and objective tumor response. The primary safety endpoints were to evaluate the number of patients with dose-limiting

toxicities and the frequency and severity of adverse effects.

The expected 12-month overall survival rate (null hypothesis) was established using a prospectively-defined logistic model-based calculation derived from 17 serially conducted GOG/NRG 2-stage studies in PRmCC involving approximately 500 patients, adjusting for prognostic factors (age, performance status, race) significantly related to survival. In accordance with the prior trials, GOG/NRG used a consistent protocol design/data collection methodology for the current 2-stage GOG-0265 study in PRmCC, which contributed to a robust and homogeneous patient dataset for the primary endpoint analysis.

About Cervical Cancer

Cervical cancer is the fourth most common cancer in women worldwide. 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. According to the ICO Information Centre on HPV and Cervical Cancer, about 4.4% of women in the United States are estimated to harbor high-risk cervical HPV infection at a given time, and about 72% of cervical cancers are attributed to high-risk HPV strains. PRmCC is a fatal disease, and 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. There is no therapy following failure of first-line treatment. According to the American Cancer Society, the five-year mortality rate for metastatic disease is at just 17%, with the area continuing to be a high unmet medical need.

About the GOG Foundation, Inc.

The GOG Foundation, Inc. (GOG) 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.

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 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 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 high risk locally advanced cervical cancer (HRLACC) patients and a SPA 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 EMA's CAT. 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 www.advaxis.com and connect on Twitter, LinkedIn, Facebook, and YouTube.

Advaxis Forward-Looking Statement

This press release 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 immunotherapy, axalimogene filolisbac. 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, 2016, which is available at http://www.sec.gov.

Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law.

You are cautioned not to place undue reliance on any forward-looking statements.

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