September 17, 2015

Advaxis's Axalimogene Filolisbac (ADXS-HPV) Showed 38.5 Percent 12-Month Survival in Patients With Persistent/Recurrent Metastatic Cervical Cancer

Data From Stage 1 of a Phase 2 Study Conducted by GOG Presented at AGOS 2015

Advaxis to Host Conference Call and Webcast Today, September 17, at 4:30 p.m. ET, to Discuss Stage 1 Data

PRINCETON, N.J., Sept. 17, 2015 (GLOBE NEWSWIRE) -- **Advaxis, Inc.** (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, and the Gynecologic Oncology Group (GOG, now part of NRG Oncology), today announced clinical data from Stage 1 of an ongoing two-stage Phase 2 study (GOG-0265) of Advaxis's lead *Lm* Technology™ immunotherapy, axalimogene filolisbac (ADXS-HPV), in patients with persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC) who have progressed on at least one prior line of systemic therapy. The Stage 1 data showed that treatment with axalimogene filolisbac resulted in a 38.5 percent 12-month overall survival rate in 26 patients.

Evaluation of safety data showed that Grade 1 or 2 adverse events occurred in 19 out of 26 patients (73 percent), with fatigue, chills and fever being the most common. Four patients (15 percent) experienced a Grade 3 adverse event (hypotension and cytokine release syndrome) and one patient (4 percent) experienced a Grade 4 adverse event (lung infection and sepsis). The results were presented at the American Gynecological & Obstetrical Society (AGOS) annual meeting in Half Moon Bay, Calif. by Tom Herzog, M.D., Clinical Director at the University of Cincinnati Cancer Institute.

"Patients with PRmCC who have failed at least one line of therapy face a life threatening condition with an estimated survival of 4 to 7 months and no available treatment options," said Dr. Herzog. "The Stage 1 results for axalimogene filolisbac, which show 12-month survival, are a meaningful step forward in meeting the needs of women who require second-line treatment for PRmCC."

The GOG has conducted over 17 studies of a diverse set of investigational agents and regimens, but never has the 12-month overall survival rate exceeded 30 percent in people with PRmCC. Stage 2 of the GOG-0265 study is currently enrolling and the protocol has been amended by GOG to allow for continuous cycles of treatment until disease

recurrence (the Stage 1 protocol provided for 3 doses of axalimogene filolisbac over 3 months).

"The axalimogene filolisbac data presented at AGOS by the GOG and Dr. Herzog represent some of the most encouraging Phase 2 data to date in metastatic cervical cancer and support the results previously observed in Advaxis's own Phase 2 study," said Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "Advaxis is grateful to NRG Oncology and the GOG for having the foresight several years ago to design, sponsor and conduct this study."

Advaxis has submitted a Special Protocol Assessment (SPA) request to the U.S. Food and Drug Administration (FDA) for a Phase 3 study evaluating the safety and efficacy of axalimogene filolisbac in high-risk, locally advanced cervical cancer (HRLACC). The SPA review process remains ongoing. The planned Phase 3 trial will be conducted in collaboration with the GOG Foundation, Inc. and is intended to begin enrollment by the end of 2015, depending on the length of the FDA's SPA review process.

A completed randomized Phase 2 trial of axalimogene filolisbac with or without cisplatin chemotherapy in Indian patients with PRmCC (0-2 prior lines of therapy) also demonstrated promising activity (12-month overall survival rate of 32 percent) and acceptable tolerability with chills and flu-like symptoms the most common treatment-related adverse events. Results from this trial were featured in a poster at the American Society of Clinical Oncology (ASCO) annual meeting in 2014.

Business Update & Webcast

Advaxis will hold a business update conference call today, September 17, at 4:30 p.m. ET/ 1:30 p.m. PT to provide Advaxis investors and stakeholders with a review of the Stage 1 clinical data from the GOG-0265 study presented at AGOS 2015. Dr. Herzog will be the featured presenter on the call.

A live broadcast of the conference call will be available by direct dial at 1-888-364-3109 in the U.S. or 1-719-325-2455 outside of the U.S, or by live webcast with slides available online at this URL: http://public.viavid.com/index.php?id=116099.

The call will be recorded and available for playback through October 1 by dialing 1-877-870-5176 in the U.S. and 1-858-384-5517 outside of the U.S.; Replay Passcode 2197270. In addition, the webcast will be available for replay at the URL above.

About the GOG-0265 Study

GOG-0265 is an open-label, single-arm, two-stage Phase 2 study designed to evaluate the safety, tolerability and efficacy of axalimogene filolisbac in approximately 67 patients with PRmCC who have received at least one prior line of systemic therapy. The primary efficacy endpoint is 12-month overall survival rate, with secondary efficacy endpoints of progression-free survival, overall survival and objective tumor response. The primary safety endpoints are the number of patients with dose-limiting toxicities and the frequency and severity of adverse effects.

The trial is being conducted in the United States by GOG, now part of NRG Oncology, under the sponsorship of the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI). Further information about the study can be found on ClinicalTrials.gov, using Identifier NCT01266460.

About Cervical Cancer

Cervical cancer is the fourth most common cancer and the most common cause of mortality in women worldwide. In the United States, nearly 13,000 new cases are diagnosed 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 (ADXS-HPV) is Advaxis's 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, axalimogene filolisbac 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™.

About the Gynecologic Oncology Group

The Gynecologic Oncology Group (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.

NRG Oncology is one of four adult cooperative 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 GOG Foundation, Inc.

The GOG Foundation, Inc. is an independent international non-profit 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 Foundation is committed to

maintaining the highest standards in clinical trials development, execution, analysis and distribution of results. Continuous evaluation of our processes is utilized in order to constantly improve the quality of patient care. The GOG Foundation conducts clinical trials for patients with a variety of gynecologic malignancies, including cancers that arise from the ovaries, uterus, cervix, vagina, and vulva. The GOG Foundation is a separate entity from the National Clinical Trials Network groups that are funded by the National Cancer Institute.

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 a cancer antigen and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis's 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. 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's ability to develop the next generation of cancer immunotherapies; and the safety and efficacy of Advaxis's 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's SEC filings, including but not limited to its report on Form 10-K for the fiscal year ended October 31, 2014, 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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