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Advaxis' Axalimogene Filolisbac Data Selected for Poster Presentation at ESGO 2017

PRINCETON, N.J.--(BUSINESS WIRE)-- [Advaxis, Inc.](#) (NASDAQ:ADXS), a late-stage biotechnology company developing cancer immunotherapies, today announced that the [European Society of Gynaecologic Oncology \(ESGO\)](#) has accepted an abstract for a poster presentation at its 2017 congress on the identification of potential baseline biomarkers indicative of survival benefit from treatment with the company's lead immunotherapy candidate, axalimogene filolisbac. ESGO is Europe's landmark gynecologic oncology meeting. Held biennially, ESGO congress brings together professionals to learn and discuss the latest medical and scientific developments in gynecologic cancers research, treatment and care.

Advaxis researchers identified certain pre-treatment baseline levels of serum proteins that were strongly associated with overall survival (OS) benefit in patients with persistent or recurrent metastatic carcinoma of the cervix (PRmCC) that were treated with axalimogene filolisbac in the Phase 2 GOG/NRG-0265 study. The 12-month survival rate in this study was 38 percent (19/50), and these results were presented at a medical meeting earlier this year.

This analysis of pre-treatment baseline serum proteins of 45 patients from the study showed that levels of a group of four closely-aligned proteins were strongly correlated with OS. One cluster of patients (n=25), had relatively lower levels of all four proteins and exhibited an OS of 56 percent, while the second cluster (n=20), with relatively higher levels, exhibited an OS of 15 percent. These data are statistically significant (HR=0.23; 95% CI: 0.10-0.48; P<.001) and suggest that the baseline levels of these analytes have prognostic value for OS, and high levels of these individual proteins were negatively associated with clinical outcomes in the trial.

Importantly, it was found that much of this effect was due to levels of one particular protein, which was found to be most highly correlated with OS in the study. This particular protein was previously not known to be associated with survival in cervical cancer. Advaxis will continue to evaluate this particular protein as a potential biomarker to help identify patients most likely to benefit from treatment with axalimogene filolisbac.

"In the field of cancer immunotherapy, biomarkers have been playing an increasing role in guiding patient selection and identifying early indicators of treatment response," said Robert Petit, Chief Scientific Officer of Advaxis. "The discovery of this potential biomarker, which previously has not been known to be associated with survival in cervical cancer, is significant and could be a biomarker to predict efficacy, similar to how PD-L1 expression is used as a biomarker for checkpoint inhibitors. PD-L1 testing has become an important and

routine strategy to guide treatment, and this biomarker has the promise to do the same for axalimogene filolisbac.”

Sandy Hayes, PhD, Associate Director of Research and Biomarker Lead at Advaxis, is the first author and presenter of “Baseline Serum Protein Levels Associated with Survival in Axalimogene Filolisbac (Axal)-Treated Metastatic Cervical Cancer Patients: The GOG/NRG-0265 Trial.” The poster will be presented at ESGO 2017, held Nov. 4 to 7 in Vienna, Austria, and will also be published in a supplement to the *International Journal of Gynecological Cancer*.

About Cervical Cancer

Cervical cancer is the fourth most common cancer affecting women worldwide. An estimated 13,000 cases were diagnosed in the United States in 2016, and 4,100 women will have this disease as their cause of death each year, according to the National Cancer Institute. Decades of research have shown that persistent HPV infection, particularly with high-risk virus types such as HPV-16 and HPV-18, is the most important factor in the development of cervical cancer. The prognosis for women with advanced and recurrent cervical cancer remains poor, with median survival of only six to seven months following initiation of palliative treatment with chemotherapy. According to the American Cancer Society, the five-year survival rate for stage IV disease is at 15 to 16 percent. There is no approved therapy following failure of first-line treatment, and there has been limited advancement in developing new therapeutics for advanced cervical cancer over the last 30 years.

About Axalimogene Filolisbac

Axalimogene filolisbac is a targeted *Listeria monocytogenes* (*Lm*)-based immunotherapy that attacks HPV-associated cancers by altering a live strain of *Lm* bacteria to generate cancer-fighting T cells against cancer while neutralizing the tumor’s natural protections that guard the tumor microenvironment from immunologic attack.

Axalimogene filolisbac has received Fast Track designation as an adjuvant therapy for high-risk locally advanced cervical cancer (HRLACC) patients and a Special Protocol Assessment for the Phase 3 AIM2CERV trial in HRLACC patients. Axalimogene filolisbac is the only active product candidate to have received the U.S. FDA orphan drug designation in cervical cancer.

Advaxis, in collaboration with Bristol-Myers Squibb, is evaluating ADXS-DUAL, the next generation immunotherapy candidate targeting HPV-associated cancers, with the PD-1 immune checkpoint inhibitor, *Opdivo* (nivolumab), as a potential combination treatment option for women with metastatic cervical cancer. Expected to start by the end of 2017, the study will evaluate this combination regimen in women with PRmCC who have failed at least one prior line of systemic chemotherapy.

About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a late-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary *Lm* Technology™. *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 immunotherapies axalimogene filolisbac and ADXS-DUAL target HPV-associated cancers and are in clinical trials for invasive and metastatic cervical cancer, head and neck cancer and 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 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, an 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.

To learn more about 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 immunotherapies, axalimogene filolisbac and ADXS-DUAL. 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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