



Advaxis Announces Updated Data at ASCO from a Phase 2 Study of AXAL in Advanced Cervical Cancer Showing Promising Survival Rates Consistent with Earlier Reports

June 6, 2018

Durable complete response seen in a recurrent / metastatic cervical cancer patient previously treated with chemoradiation and systemic-dose chemotherapy plus bevacizumab

[Advaxis, Inc.](#) (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, announced today that the Gynecologic Oncology Group (GOG), now part of NRG Oncology (NRG) will present additional preliminary data from a two-stage Phase 2 study of its lead immunotherapy candidate, axalimogene filolisbac (AXAL), 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.

These data will be featured at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Ill., in the Gynecologic Cancer General Poster Session on June 6 at 1:00 PM CT and also in an Oral Poster Discussion Session at 4:45 PM. The poster ([abstract #5516](#)), "ADXS11-001 immunotherapy in squamous or non-squamous persistent/recurrent metastatic cervical cancer: Results from stage 1 [and stage 2] of the phase II GOG/NRG-0265 study" and presentation are available at www.advaxis.com. Warner K. Huh, M.D., Professor and Division Director of Gynecologic Oncology and Senior Scientist at the University of Alabama at Birmingham, is the lead author and principal investigator.

GOG/NRG-0265 is a single-arm two-stage, Phase 2 multicenter study (NCT01266460). Stage 1 of the trial enrolled 26 AXAL-treated patients who received up to three doses at 1×10^9 colony forming units administered in 28 day intervals. Results from Stage 1 demonstrated a twelve-month survival rate of 38.5 percent, which exceeds prior historical GOG trials in this patient population. The twelve-month survival rate among the 69 percent of patients who received the maximum three per protocol doses was 56 percent, with a 12.1-month median overall survival. Safety and efficacy results of Stage 1 met the criteria for the initiation of Stage 2, which was amended for continuous cycles of AXAL (greater than three doses).

Twenty-four patients were treated with AXAL in Stage 2. However, a temporary clinical hold limited overall exposure to the immunotherapy, which necessitated 10 patients who had not progressed to discontinue AXAL treatment. Further, only 12 of the 24 patients received three or more doses. Demographics in the truncated Stage 2 cohort were similar to Stage 1, but a substantially higher proportion of patients were pre-treated with bevacizumab (83 percent (Stage 2) vs. 31 percent (Stage 1)).

At a median follow-up of 8.7 months, these Stage 2 results demonstrate a 42 percent six-month overall survival rate, which increases to 67 percent in those 12 patients who received three or more doses of AXAL. Preliminary results from Stage 2 appear consistent with the promising survival results from Stage 1 in a more heavily bevacizumab pre-treated population.

Investigator assessment of tumor best response showed disease control rates (CR+PR+SD) of 27 percent and 37 percent in Stage 1 and 2, respectively. Of particular note, a patient in Stage 2 experienced a complete response following three doses of AXAL. This patient continues to be followed with no evidence of disease at 11 months. Treatment with AXAL will resume under a compassionate use single-patient IND.

The safety profile across both stages was similar, with primarily grade one and two treatment-related events such as fatigue, chills, fever, nausea. Grade three events (n = 4 in Stage 1) included hypotension and cytokine release syndrome. No grade four or five treatment-related adverse events were observed.

Given the substantial proportion of Stage 2 patients that discontinued treatment with AXAL as a result of the clinical hold, Advaxis and the GOG/NRG agreed to re-enroll a new cohort of Stage 2 patients. The re-enrollment of Stage 2 is expected to commence shortly.

"We are excited about the potential of AXAL to help women with recurrent cervical cancer as there are so few options available," said Daniel J. O'Connor, President and Chief Executive Officer of Advaxis.

The Company and the GOG Foundation plan to commence enrollment to an international Phase 3 adjuvant study, AIM2CERV, for patients with high risk, locally advanced cervical cancer.

About Cervical Cancer

Cervical cancer is the fourth most common cancer in women worldwide. In the U.S., 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 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

"ADXS11-001 immunotherapy in squamous or non-squamous persistent/recurrent metastatic cervical cancer: Results from stage 1 [and stage 2] of the phase II GOG/NRG-0265 study"

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 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 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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