November 8, 2013

Advaxis Reports Final 18-Month Survival Data for ADXS-HPV in Patients with Recurrent Cervical Cancer at the 2013 Society for Immunotherapy of Cancer Annual Meeting

--Final 18 Month Survival Data Has Increased to 28% from the 22% Previously Reported--

PRINCETON, N.J.-- Advaxis, Inc., (NASDAQ:ADXS), a leader in developing the next generation of cancer immunotherapies, announced today final 18-month survival data from *Lm*-LLO-E7-15, a randomized Phase 2 study evaluating the safety and efficacy of ADXS-HPV ($1x10^9$ cfu) (ADXS11-001) with and without cisplatin (40 mg/m2, weekly x5) in 110 patients with recurrent cervical cancer in two treatment arms of 55 patients each. The primary endpoint of the study is overall survival. These data will be presented at the 2013 Society for Immunotherapy of Cancer (SITC) Annual Meeting in National Harbor, MD, on November 9, 2013 (Poster #258).

The last patient last visit (Day 545) occurred on October 18, 2013. The final 18-month survival data are 28% (31/110) which is updated from the preliminary18-month survival of 22% (16/73) reported at the 2013 ASCO Annual Meeting on June 2, 2013. The final 12-month survival was 36% (39/110). These data are comparable to the results for the landmark 2004 Phase 3 study conducted by the Gynecologic Oncology Group of cisplatin alone and cisplatin plus paclitaxel in recurrent cervical cancer patients with the same initial performance (health) status (0-2).[1] In that study, 12 month survival was presented as 35% for cisplatin alone and 32% for the combination and 18 month survival was presented as 20% for combination therapy and 12% for cisplatin, alone.

“The final 18 month survival outcome of 28% suggests that ADXS-HPV is an active treatment in recurrent cervical cancer. Achieving this promising 18 month survival with a single treatment cycle at the lowest effective dose, further suggests that higher doses and repeated cycles of immunotherapy might extend the lives of patients even further beyond the data presented here,” commented Dr. Robert Petit, Chief Scientific Officer of Advaxis. “To achieve this survival by giving an immunotherapy associated with only transient and low grade side effects in advanced cancer, supports that ADXS-HPV could provide an important new treatment option in the management of recurrent cervical cancer.”

Median overall survival in the Advaxis study was approximately 8.5 months which is indicative of the late stage of disease and baseline performance status of the patients. Those patients that completed the study will continue to be followed for survival. Survival results were not significantly different between treatment groups with or without cisplatin chemotherapy or who had previous therapy comprised of a combination of chemotherapy and radiation, radiation alone, or chemotherapy alone.

The tumor response rate was 11% with 6 complete responses and 6 partial responses/110 patients and was similar in both treatment groups per RECIST 1.1 criteria. Stable disease >3 months was observed in 35 additional patients, for a disease control rate of 43% (47/110). Average duration of response after 12 month minimum follow-up was 10.5 months for both treatment groups. In those patients treated with ADXS-HPV alone who had stable disease, the average duration of response was 6 months compared to 4.1 months in patients treated with ADXS-HPV plus cisplatin. Activity was observed against all high risk HPV strains detected, including 16, 18, 31, 33, and 45.

Subset analyses showed that the combination arm (addition of cisplatin to ADXS-HPV) did not significantly

improve survival or tumor response; and survival and tumor response were equally strong in patients with aggressive disease (defined as recurrence ≤2 years from initial diagnosis) versus non-aggressive disease (defined as recurrence >2 years from initial diagnosis).

The tolerability of ADXS-HPV continues to compare favorably with single agent and combination chemotherapies active in this disease setting. 110 patients received 264 doses of ADXS11-001 at $1x10^9$ cfu per dose. 42% (46/110) of patients experienced 104 mild-moderate Grade 1-2 adverse events and 2% (2/110) of patients experienced a serious adverse event (1 Grade 3 and 1 Grade 4) related/possibly related to ADXS11-001. This compares to published serious adverse event rates of 100%-400% related to treatment in studies on a range of chemotherapy regimens for cervical cancer.

Dr. Poonam Molli, Senior Scientist at Advaxis, will also present data on initial biomarker analysis of a subset of serum samples collected from patients in *Lm*-LLO-E7-15, pre- and post-dosing with ADXS11-001. Administration of ADXS11-001 immunotherapy resulted in increased expression of cytokines (IL6, IL-8, IL10, INF-γ and TNF-α) and chemokines (MIP-1α, MIP-1β and MCP-1) indicating activation of innate immunity. An association was also found between changes in the expression of cytokine and/or other serum factors and the severity of adverse events. These data may provide future screening tools to assist in predicting clinical efficacy and to monitor and manage side effects.

“We are pleased with the encouraging results and fully support continuing the path towards registration for our lead product candidate, ADXS-HPV, in invasive cervical cancer,” added Daniel J. O’Connor, Chief Executive Officer of Advaxis. “The completion of this study is a considerable step in demonstrating the potential of our technology to have a positive impact in an unmet medical need.”

These posters will be available on the Advaxis website at http://www.advaxis.com.

About The *Lm*-LLO-E7-15 Study

Lm-LLO-E7-15 was a randomized Phase 2 study being conducted in India in 110 women with recurrent cervical cancer designed to evaluate the safety and efficacy of ADXS-HPV +/- cisplatin. All patients were treated previously with chemotherapy, radiotherapy, or both; and had an ECOG performance status of 0-2. The ADXS-HPV treatment group received ADXS-HPV ($1x10^9$ cfu) as 3 IV infusions 4 weeks apart, each dose followed by antibiotic at 3 days post-dosing. The ADXS-HPV + cisplatin treatment group received ADXS-HPV as an IV infusion ($1x10^9$ cfu), followed by antibiotic beginning 3 days post-dosing, followed 4 weeks later with 5 weekly IV administrations of cisplatin (40 mg/m^2) followed 4 weeks later by 3 IV infusions of ADXS11-001 one month apart with antibiotic beginning 3 days after each ADXS11-001 dose. Naproxsyn 500 mg BID, (Day -1, 0) and promethazine 25 mg PO, BID (pre-dose, 8 hours) were administered as premedications. Ampicillin 500 mg QID (Days 3-9) was administered post-infusion. Safety was assessed at every visit. Efficacy was determined from overall survival and scans taken at baseline (before the first treatment dose) and at 3, 6, 9 12, and 18 months after treatment began.

About ADXS-HPV

ADXS-HPV is an immunotherapy that is designed to target cells expressing the HPV gene E7. Expression of the E7 gene from high-risk HPV variants is responsible for the transformation of infected cells into dysplastic and malignant tissues. Eliminating these cells can eliminate the dysplasia or malignancy. ADXS-HPV is designed to infect antigen-presenting cells and direct them to generate a powerful, cellular immune response to HPV E7. The resulting cytotoxic Tcells infiltrate and attack the tumors while specifically inhibiting tumor Tregs and MDSCs in the tumors that are protecting it.

About Cervical Cancer

According to the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2010, there are 500,000 new cases of cervical cancer caused by HPV worldwide every year. Current preventative vaccines cannot protect the 20 million women who are already infected with HPV; and of the high risk oncogenic strains, only HPV 16 and 18 are present in these vaccines. Challenges with acceptance, accessibility, and compliance have resulted in only a third of young women being vaccinated in the United States and even less in other countries around the world. HPV is associated with 20-50% of oral squamous cell carcinomas. HPV-associated head and neck cancer is growing at an epidemic rate in western countries; and occurs more frequently (3:1) in men than women. In the United States, the number of HPV-positive head and neck cancer cases has already equaled the number of cases of cervical cancer and continues to increase in frequency. HPV is associated with 80-100% of anal cancers and is also increasing in frequency.

About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing the next generation of immunotherapies for cancer. Advaxis immunotherapies are based on a novel platform technology using live, attenuated bacteria that are bio-engineered to secrete an antigen/adjuvant fusion protein(s) that is designed to redirect the powerful immune response all human beings have to the bacterium to the cancer itself.

ADXS-HPV is currently being evaluated in four clinical trials for human papillomavirus (HPV)-associated cancers: recurrent/refractory cervical cancer (India), locally advanced cervical cancer (GOG/NCI U.S. study, Clinical Trials.gov Identifier NCT01266460), head & neck cancer (CRUK study, Clinical Trials.gov Identifier NCT01598792), and anal cancer (BrUOG study, Clinical Trials.gov Identifier NCT01671488). Advaxis has over 15 distinct immunotherapies in various stages of development, developed directly by Advaxis and through strategic collaborations with recognized centers of excellence such as: the University of Pennsylvania, the Georgia Regents University Cancer Center, Brown University Oncology Group, and others.

For more information please visit: www.advaxis.com

[1]Moore et. al. “Phase III Study of Cisplatin With or Without Paclitaxel in Stage IVB, Recurrent, or Persistent Squamous Cell Carcinoma of the Cervix: A Gynecologic Oncology Group Study.” *Journal of Clinical Oncology*, 2004; 22:3113-3119.

Forward-Looking Statements

This news release contains forward-looking statements, including, but not limited to: statements regarding Advaxis' development of the next generation of cancer immunotherapies; the suggestion that ADXS-HPV is active in invasive cervical cancer; whether higher doses and repeated cycles of immunotherapy might further extend the lives of patients with cervical cancer beyond the data presented here; whether ADXS-HPV could provide an important treatment option in the management of recurrent cervical cancer; the potential registration of ADXS-HPV, having a positive impact in an unmet medical need. 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, 2012, 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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