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Advaxis Provides Clinical Update for Phase 1/2 Trial of ADXS-HPV Immunotherapy Product Candidate in Anal Cancer

Open-Label Study Conducted by Brown University Oncology Group Shows Promising Preliminary Data, Triggering Study Expansion to Two Additional Sites

PRINCETON, N.J., Oct. 15, 2014 (GLOBE NEWSWIRE) --**Advaxis, Inc.** (Nasdaq:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, today announced preliminary data from its Phase 1/2 study of ADXS-HPV in human papillomavirus (HPV) associated anal cancer that indicate a "clinical complete response" in all 7 patients who have completed the treatment regimen.

"We are pleased with this preliminary data," commented Dr. Howard Safran, Medical Director of Brown University Oncology Research Group (BrUOG) and principal investigator of the study. "We are now in the process of opening this study at other institutions."

Conducted by BrUOG, the Phase 1/2 trial is a non-randomized, open-label, multi-center study of 25 patients designed to determine the safety and effectiveness of ADXS-HPV when combined with standard chemotherapy and radiation treatment for anal cancer in patients who have a high risk of recurrence based on their disease. The primary efficacy objective of the study is to assess the proportion of patients maintaining a clinical complete response at the 6 month mark. Based on historical clinical experience in similar high risk patients and pursuant to the study protocol, the addition of ADXS-HPV will be considered promising if the 6 month complete response rate is greater than 80%.

At present, 7 of 8 patients out of the planned total accrual of 25 patients have completed the treatment regimen. The 7 patients are without evidence of disease. Preliminary safety findings indicate flu-like symptoms were the most common adverse reaction lasting for about 24 hours.

Patients have been treated at Rhode Island Hospital and The Miriam Hospital (the main teaching hospitals of The Warren Alpert Medical School of Brown University). With these results, the study is being expanded to Ohio State University and Rutgers University, and these sites are in the process of activation.

Daniel J. O'Connor, President and CEO of Advaxis, remarked, "Though we recognize that the data is preliminary, it suggests a positive therapeutic response in the treated patients

that warrants further investigation. Our strategy is to provide an immunotherapeutic treatment option to patients with HPV-associated anal, cervical and head & neck cancer - each of which Advaxis has obtained orphan drug status."

About HPV and Anal Cancer

According to the American Cancer Society, most squamous cell anal cancers seem to be linked to infection by the human papilloma virus (HPV), the same virus that causes cervical cancer. In fact, women with a history of cervical cancer (or pre-cancer) have an increased risk of anal cancer. Anal cancer is fairly rare – much less common than cancer of the colon or rectum. About 7,210 new cases will be diagnosed and about 950 people are expected to die of anal cancer in the United States during 2014.

About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary platform intended to redirect the immune system to kill cancer and extend survival. The Advaxis *Lm*-LLO technology, using bioengineered live attenuated *Listeria monocytogenes* 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 MSDCs, that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis's lead immunotherapy, ADXS-HPV, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The FDA has granted Advaxis orphan drug designation for each of these three indications. The Company plans to initiate a registrational clinical program for cervical cancer in 2015 and has established licensing partners in India and Asia for commercialization in those regions. Advaxis is planning to evaluate the combination of ADXS-HPV with an anti-PD-L1 immune checkpoint inhibitor in HPV-associated cervical cancer and head and neck cancer.

Advaxis's second *Lm*-LLO immunotherapy candidate in clinical testing will be ADXS-PSA, which is being developed to address prostate cancer. Advaxis is planning to file an IND with the FDA and initiate a Phase 1-2 clinical study with ADXS-PSA alone and in combination with a PD-1 checkpoint inhibitor. Advaxis is also developing *Lm*-LLO immunotherapy ADXS-cHER2, to target the Her2 receptor overexpressing cancers. Her2 is overexpressed in certain solid-tumor cancers, including pediatric bone cancer (or osteosarcoma), breast cancer, esophageal, and gastric cancer. Advaxis is developing ADXS-cHER2 for both human and animal-health, and has seen promising results in canine osteosarcoma, which is considered a model for human osteosarcoma. Advaxis is planning to file an IND for ADXS-cHER2 in Her2 overexpressing cancers and to conduct a clinical program in pediatric osteosarcoma. Advaxis has licensed ADXS-cHER2 and three other immunotherapy constructs to Aratana Therapeutics, Inc. for veterinary use in companion animals (pets).

For more information please visit www.advaxis.com.

Forward-Looking Statements

This news release contains forward-looking statements, including, but not limited to: statements regarding Advaxis's ability to develop the next generation of cancer immunotherapies; the safety and efficacy of Advaxis's proprietary immunotherapy, ADXS HPV; whether Advaxis immunotherapies can redirect the powerful immune response all human beings have to the bacterium to cancers. 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, 2013, 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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