Advaxis’ ADXS-HPV Granted Orphan Drug Designation for Treatment of HPV-Associated Head and Neck Cancer

PRINCETON, N.J.--Advaxis, Inc., (NASDAQ:ADXS), a leader in developing the next generation of cancer immunotherapies, announced that it has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD) for ADXS-HPV, its lead drug candidate, for the treatment of human papillomavirus (HPV)-associated head and neck cancer.

Orphan Drug Designation is granted to drug therapies intended to treat diseases or conditions that affect fewer than 200,000 people in the United States. Orphan Drug Designation entitles the sponsor to clinical protocol assistance with the FDA, as well as federal grants, tax credits, and potentially a seven year market exclusivity period.

“We are very pleased to have been granted an orphan drug designation for ADXS-HPV in this unmet medical need,” commented Dr. Robert Petit, Chief Scientific Officer of Advaxis. “Patients with head and neck cancer have limited treatment options and we hope to improve their survival by developing ADXS-HPV for this indication. We plan to initiate an additional Phase 1/2 study in early stage head and neck cancer for ADXS-HPV with a nationally recognized center of excellence, and we will continue the ongoing Phase 1 study being sponsored by the University of Liverpool and Aintree University Hospitals NHS Foundation Trust that is evaluating the safety and efficacy of ADXS-HPV when combined with standard chemotherapy and radiation treatment in patients with head and neck cancer.”

“Receiving orphan drug designation for ADXS-HPV in head and neck cancer is excellent news for a technology that may offer the potential to treat an indication with few therapy options, and, importantly, it helps define a clear path forward to registration,” commented Daniel J. O’Connor, President and Chief Executive Officer of Advaxis.

About Orphan Drug Designation

Under the Orphan Drug Act (ODA), the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in
the United States for this type of disease or condition will be recovered from sales of the product. The benefits of orphan drug designation can be substantial and include federal grants, tax credits, and potentially a seven year market exclusivity period once the product is approved, provided that the product is first to market.

In order for a sponsor to obtain orphan designation for a drug or biological product, an application must be submitted to OOPD, and the designation approved. The approval of an application for orphan designation is based upon the information submitted by the sponsor. A drug that has obtained orphan designation is said to have “orphan status.” Each designation request must stand on its own merit. Sponsors requesting designation of the same drug for the same indication as a previously designated product must submit their own data in support of their designation request. The approval of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and efficacy of a compound must be established through adequate and well-controlled studies.

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 T cells infiltrate and attack the tumors while specifically inhibiting tumor Tregs and MDSCs in the tumors that are protecting it.

About Head and Neck Cancer

Cancer of the head and neck includes cancers arising from mucosa lining the oral cavity, oropharynx, hypopharynx, larynx, sinonasal tract, and nasopharynx. The most common histologic type observed is squamous cell carcinoma; therefore, the term “head and neck squamous cell carcinoma” (HNSCC) is frequently used to imply squamous cell carcinomas involving these anatomical sites. Excessive tobacco and alcohol are important risk factors for HNSCCs overall, but human papillomavirus (HPV) is now recognized as the causative agent in a subset of HNSCCs.

While the incidence of head and neck cancers that are linked to alcohol and tobacco use as the primary risk factor has fallen in the past three decades, a trend attributed to decreasing tobacco use in the United States, the incidence of HPV-associated head and neck cancer has been increasing. The increase was observed particularly among young individuals (<60 years of age), men, and Caucasians. Studies have shown that oral HPV infection is likely to be sexually acquired, as the increase in the incidence of HPV-associated head and neck cancers may be attributed to changing sexual practices. According to the World Health Organization’s Human Papillomavirus and Related Cancers in the World Summary Report 2010, 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 cervical cancer cases.

About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing the next generation of immunotherapies for cancer and infectious diseases. 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

Forward-Looking Statements

This news release contains forward-looking statements, including, but not limited to: statements regarding the potential of ADXS-HPV to treat an indication with few therapy options and improve survival of patients by developing ADXS-HPV for this indication. 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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