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# Advaxis Announces Initiation of Phase 1/2 Trial of ADXS-HPV in Head and Neck Cancer Conducted by Icahn School of Medicine at Mount Sinai

PRINCETON, N.J.-- Advaxis, Inc., (NASDAQ:ADXS), a leader in developing the next generation of cancer immunotherapies, announced that the Icahn School of Medicine at Mount Sinai (ISMMS) will initiate a Phase 1/2 study of ADXS-HPV in 25 patients with Human Papilloma Virus (HPV)-positive head and neck cancer, a type of cancer which is increasing at an epidemic rate. This clinical trial will be the first study to evaluate the effects of ADXS-HPV in patients when they are initially diagnosed with HPV-associated head and neck cancer, prior to receiving any chemotherapy or radiation. This study will be an important first step toward understanding ADXS-HPV's potential to treat this type of cancer before chemotherapy and/or radiation and its potential to reduce the need for these treatments.

In early November, Advaxis announced that it received Orphan Drug Designation from the US Food and Drug Administration for ADXS-HPV for HPV-associated head and neck cancer.

ADXS-HPV is Advaxis' lead immunotherapy product candidate for the treatment of HPV-associated cancers and has achieved proof-of-concept, demonstrating encouraging clinical activity and a manageable safety profile in patients with recurrent cervical cancer in a recently completed Phase 2 study.

"We are excited to be partnering with Mount Sinai in their search for improved treatment of head and neck cancers," commented Dr. Robert Petit, Chief Scientific Officer of Advaxis. "This will be the first study in which we can evaluate the effects of ADXS-HPV in patients when they are newly diagnosed with cancer and treat them with ADXS-HPV immunotherapy prior to any chemotherapy and/or radiation. Evaluating ADXS-HPV in this clinical trial is an important first step toward understanding the potential role of ADXS-HPV immunotherapy in treating these patients' cancer early and altering the course of their disease before any treatment with or radiation and/or chemotherapy which can have difficult, life altering consequences."

Dr. Andrew Sikora, Assistant Professor of Otolaryngology, Director of Head and Neck Translational Research at ISMMS, and principal investigator, commented, "We are really excited to carry out this study because it is a great opportunity to apply a new treatment approach to HPV-related head and neck cancer which has already been shown to be promising in cervical cancer. The approach we have chosen allows us to study the immune response in great detail not just in the patient's blood, but at the front lines of battle in the tumor itself."

Dr. Marshall Posner, Director, Head and Neck Medical Oncology, The Tisch Cancer Institute ISMMS, and co-principal investigator, commented, "We hope that this trial of a therapeutic HPV vaccine can help us set the stage for future immunotherapies that can eliminate the standard use of chemotherapy and radiotherapy as adjuvant treatments for HPV-caused oropharynx cancer. This is an exciting first step."

This non-randomized investigator-initiated study has been designed to evaluate the safety and immunogenicity of ADXS-HPV in patients with HPV-positive stage II-IV squamous cell carcinoma of the oropharynx (OPCSC). In this study, 15 patients will receive ADXS-HPV treatment followed by ablative transoral robotic surgery (TORS), and 10 patients will serve as the control group and receive only TORS. TORS is FDA-approved for head and neck cancer and is considered to be the standard of care therapy for OPCSC in appropriate patients.

Mount Sinai is a leader in the application of TORS to head and neck cancer, and studies have shown the potential

of TORS to minimize or avoid the morbidity associated with chemotherapy and radiation in appropriate patients.

**About ADXS-HPV in Head and Neck Cancer**

The incidence of HPV-associated head and neck cancers has been increasing at an epidemic rate, while head and neck cancers from other causes has been decreasing. According to the WHO, approximately 15-20% of the 400,000 new cases of head and neck cancer are HPV-related. In the US, there are about 12,000 new cases of HPV-associated head and neck cancer per year. ADXS-HPV has previously demonstrated clinical benefit as a single agent or in combination with chemotherapy in a Phase 2 clinical trial for HPV-associated recurrent cervical cancer.

**About Advaxis, Inc.**

Advaxis is a clinical-stage biotechnology company developing the next generation of cancer immunotherapies. 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 Phase 1 and 2 clinical trials for HPV-associated cancers: recurrent cervical cancer (completed Phase 2 study conducted in 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 U.S. 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, Icahn School of Medicine at Mount Sinai, 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 Advaxis' ability to develop the next generation of cancer immunotherapies; enrollment in the proposed study of ADXS-HPV in patients with HPV-positive stage II-IV squamous cell carcinoma of the oropharynx (OPCSC); the ability of the study to evaluate the safety and immunogenicity of ADXS-HPV in the patients to be studied, including generating important data documenting immunologic responses and changes to the tumor microenvironment resulting from ADXS-HPV treatment of HPV-associated head and neck cancer prior to surgical treatment; and whether immunotherapies can eliminate the standard use of chemotherapy and radiotherapy as adjuvant treatments for HPV-caused OPCSC. 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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