

# Advaxis Announces First Patient Dosed with ADXS-HPV in Head and Neck Cancer Study

PRINCETON, N.J.-- Advaxis, Inc., (NASDAQ:ADXS)(NASDAQ:ADXSW), a leader in developing the next generation of immunotherapies for cancer and infectious diseases, announced that the first patient has been dosed in *REALISTIC*, a Phase 1 study being funded by Cancer Research UK (CRUK) to investigate the use of ADXS-HPV for the treatment of HPV-positive head and neck cancer.

This trial is sponsored by the University of Liverpool and Aintree University Hospitals NHS Foundation Trust, Liverpool, UK and is being conducted at the The Royal Liverpool University Hospital, Liverpool, UK, the Royal Marsden Hospital, London, UK, and the University Hospital of Wales, Cardiff, UK. The study will investigate the safety and efficacy of ADXS-HPV in patients presenting with HPV related oropharynx cancer and who have been treated with surgery, radiotherapy, and/or chemotherapy; alone or in combination. A maximum of 27 patients are to be enrolled in this study, and the study is funded by Cancer Research UK.

"This important milestone is the first step in understanding the potential of ADXS-HPV, our lead drug candidate, in the fight against the growing epidemic of HPV-associated head and neck cancer," commented Dr. Robert Petit, Chief Scientific Officer of Advaxis.

### **About Head and Neck Cancer**

Cancer of the head and neck includes cancers arising from the tissues lining the oral cavity, throat, nose, and sinuses. Excessive tobacco and alcohol are important risk factors for HNSCCs overall, but human papillomavirus (HPV) is now recognized as the causative agent in a growing subset of HNSCCs arising from the tonsil and base of tongue.

While the incidence of head and neck cancers not caused by HPV has fallen in the past three decades, in the United States the incidence of HPV-associated head and neck cancer has been increasing. The increase is highest among young individuals (<60 years of age), men, and Caucasians. Studies have shown that oral HPV infection is most 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 at approximately 12,000 new cases per year.

### **About Cancer Research UK**

Cancer Research UK is the largest single funder of cancer research in the UK and the world's largest charity dedicated to cancer research. It funds research on all aspects of cancer, from basic cell biology to large clinical studies of entire populations. The organization funds the work of more than 4,500 scientists, doctors, and nurses across the UK and runs specialized institutes dedicated to cancer research. Cancer Research UK currently funds more than 180 clinical trials.

Since the early 1980s, Cancer Research UK has taken over 100 new drugs into clinical trials with more than 100,000 patients taking part in trials since 1995.

For more information, please visit: <a href="http://www.cancerresearchuk.org">http://www.cancerresearchuk.org</a>.

## 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 <a href="National Cancer Institute">National Cancer Institute</a>, Cancer Research – UK, the <a href="University of Pennsylvania">University Of Pennsylvania</a>, the <a href="Georgia Regents University Cancer Center">Georgia Regents University Cancer Center</a>, 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 fight against the growing epidemic of HPV-associated head and neck cancer. 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 <a href="http://www.sec.gov">http://www.sec.gov</a>. 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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