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# Advaxis Lead Product Candidate ADXS-HPV in Combination with PD-1 Antibody Significantly Improves Immune and Therapeutic Efficacy in Preclinical Study

-- Demonstrates significant inhibition of tumor growth and prolonged survival/complete regression of tumors in an animal model --

PRINCETON, N.J.-- Advaxis, Inc. (OTCQB: ADXS) ("Advaxis" or the "Company"), a leader in developing the next generation of immunotherapies for cancer and infectious diseases, announced the publication of preclinical research with ADXS-HPV, Advaxis' *Lm*-LLO lead drug candidate, for the treatment of HPV-associated cancers in combination with PD-1 antibody.

The research was conducted by Dr. Samir N. Khleif and his research team at the Georgia Regents University Cancer Center. Advaxis provided the *Lm*-LLO immunotherapies and partial research funding. The paper titled "Anti-PD-1 antibody significantly increases therapeutic efficacy of *Listeria monocytogenes* (*Lm*)-LLO immunotherapy" by Drs. Mkrtichyan, Chong, Eid, Wallecha, Singh, Rothman, and Khleif, has been e-published in the Journal for Immunotherapy of Cancer.

The studies demonstrated that treatment with an *Lm*-LLO immunotherapy, in combination with an anti-PD-1 antibody, significantly improved immune and therapeutic efficacy in preclinical mouse models. In addition, the study showed that a significant reduction of regulatory T cells (Treg) and myeloid-derived suppressor cells (MDSC) in both the spleen and the tumor microenvironment were mediated solely by the *Lm*-LLO immunotherapy. The addition of anti-PD-1 antibody to the *Lm*-LLO immunotherapy treatment resulted in a significant increase in antigen-specific immune responses in the periphery and in CD8 T cell infiltration into the tumor. As a result, this treatment combination led to significant inhibition of tumor growth and prolonged survival/complete regression of tumors in treated animals.

Given the findings in the mouse model, additional studies were conducted to evaluate activity in human cells. In separate studies, *Lm*-LLO immunotherapy treatment was found to significantly upregulate surface PD-L1 expression on human monocyte-derived dendritic cells isolated from healthy volunteers. This finding suggests that the combination of *Lm*-LLO immunotherapy with an anti-PD-1 antibody could have clinical application.

"Previous studies with *Lm*-LLO immunotherapies have established the ability to combine with chemotherapy and radiation. Dr. Khleif's data are first to show the potential of combining Advaxis constructs with promising immune modulator (PD-1) in active clinical

development,” commented Dr. Petit.

The [provisional publication](#) is available online.

### **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.

ADX-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 [National Cancer Institute](#), [Cancer Research – UK](#), the [University of Pennsylvania](#), the [Georgia Regents University Cancer Center](#), the [Karolinska Institutet](#), and others.

For more information please visit: [www.advaxis.com](http://www.advaxis.com)

### **Forward-Looking Statements**

**This news release contains forward-looking statements, including, but not limited to: statements regarding the potential clinical application of combining *Lm-LLO* immunotherapy with an anti-PD-1 antibody. 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>. The Company 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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