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Advaxis' Axalimogene Filolisbac to be Developed and Commercialized in Latin America With Stendhal

20 Countries in Latin America and the Caribbean Covered by the Agreement

PRINCETON, N.J., Feb. 03, 2016 (GLOBE NEWSWIRE) -- [Advaxis, Inc.](#) (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, today announced that it has entered into a co-development and commercialization agreement with Especificos Stendhal SA de CV ("Stendhal"), for Advaxis' lead *Lm* Technology™ immunotherapy, axalimogene filolisbac (ADXS-HPV), in HPV-associated cancers. Stendhal is a privately held Latin American specialty pharmaceutical company that partners with leading drug companies to deliver effective solutions for life-threatening diseases in Latin American markets.

Under the terms of the Agreement, Stendhal will pay \$10 million toward the expenses of AIM2CERV, a planned global Phase 3 clinical trial in women with high-risk, locally advanced cervical cancer. This payment covers a significant portion of the total planned study costs. Stendhal will also work with Advaxis to complete the clinical trial of axalimogene filolisbac in Mexico, Brazil, Colombia, and other investigational sites in Latin American countries. Additionally, Stendhal will manage the regulatory approval process, promotion, commercialization and market access for axalimogene filolisbac in these markets. Advaxis and Stendhal will share profits on a pre-determined basis.

Stendhal has a long history of partnering with leading pharmaceutical companies to bring therapies for HIV, infectious disease, and neurologic and cardiovascular disease to its Latin American markets. This new partnership with Advaxis will expand its growing portfolio in oncology and is one of the first of its kind in Latin America to make cancer immunotherapies available in the region.

HPV-related cancer is a looming public health issue in Latin America. According to the World Health Organization, cervical cancer mortality rates are three times higher in Latin America and the Caribbean than in North America. More than 83,000 women are diagnosed annually and, without intervention, mortality is projected to increase to 45 percent by 2030. HPV is also prevalent in 90.4 percent of anal cancer in Latin America and the Caribbean.

"We're pleased to announce our agreement with Stendhal, which enables us to greatly expand the clinical program for, and the potential impact of, axalimogene filolisbac in HPV-related cancers," said Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "We now have the potential to address an important unmet medical need in an

area of the world where the rate of HPV-associated cancers is unfortunately extremely high.”

“Our mission is to bring new treatments to Latin America and ensure that patients have access to therapies that have the potential to save their lives. Women throughout our region are facing increasing rates of HPV and the burden of cervical cancer,” said Carlos Arenas, Chief Executive Officer of Stendhal. “It is through partnerships such as this one that we can alter the course of disease and address the health inequalities many in Latin America face.”

About Cervical Cancer

Cervical cancer is the fourth most common cancer in women worldwide. In the U.S., nearly 13,000 new cases are diagnosed annually and approximately 4,100 deaths are reported because of cervical cancer. According to the WHO/ICO Information Centre on HPV and Cervical Cancer, about 3.9 percent of women in the U.S. are estimated to harbor high-risk cervical HPV infection at a given time, and 71.7 percent of invasive cervical cancers are attributed to high-risk HPV strains.

About Anal Cancer

Anal cancer is a fairly rare form of cancer in the United States, but the number of new anal cancer cases has been rising for years. The risk of being diagnosed with anal cancer in one's lifetime is about 1 in 500. According to the American Cancer Society, approximately 7,270 new cases of anal cancer were diagnosed and about 1,010 people died of the disease in 2014.

HPV-Associated Head and Neck Cancers

More than 90 percent of head and neck squamous cell oropharyngeal cancers originate from the mucosal linings of the oral cavity, pharynx, or larynx. Currently, 60 to 80 percent of these cancers are caused by HPV. Head and neck cancers are treated by surgical removal of the cancer and lymph nodes, often followed by radiation and chemotherapy based on the extent of the disease. While patients may achieve good long-term survival, standard treatments can change their physical appearance and are associated with significant short and long-term toxicities which may interfere with salivary gland function, taste, smell, and the ability to swallow.

The incidence of HPV-associated head and neck cancers has been increasing at an epidemic rate, while head and neck cancers from other causes have been decreasing. According to the WHO, approximately 15 to 20 percent 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 and it affects men about 3 times more frequently than women. HPV-associated head and neck cancer is growing fastest in developed countries like the U.S.

About Axalimogene Filolisbac

Axalimogene filolisbac (ADX-HPV) is Advaxis' lead *Lm* Technology™ immunotherapy

candidate for the treatment of HPV-associated cancers and is in clinical trials for three potential indications: invasive cervical cancer, head and neck cancer, and anal cancer. In a completed randomized Phase 2 study in recurrent/refractory cervical cancer, axalimogene filolisbac showed apparent prolonged survival, objective tumor responses, and a manageable safety profile alone or in combination with chemotherapy, supporting further development of the company's *Lm* Technology™. Axalimogene filolisbac has Orphan Drug Designation in the U.S. for the treatment of anal cancer.

About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary *Lm* Technology™. The *Lm* Technology™, using bioengineered live attenuated *Listeria monocytogenes* (*Lm*) 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 myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis' lead *Lm* Technology™ immunotherapy, axalimogene filolisbac, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three potential indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The U.S. Food and Drug Administration (FDA) has granted axalimogene filolisbac orphan drug designation for each of these three clinical settings. Advaxis has two additional immunotherapy products: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, in human clinical development.

For additional information on Advaxis, visit www.advaxis.com and connect on [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#) and [Google+](#).

About Stendhal

Stendhal is a privately-held specialty pharmaceutical company based in Mexico City and operating in 14 countries in Latin America. Stendhal's business is developing strong partnerships and launching innovative branded products in the region in order to bring best-in-class products to patients in Latin America. Stendhal's success is based upon long-term partnerships with market leaders in the following therapeutic areas: HIV, Multiple Sclerosis, CNS, Genetic Disorders, Cardiovascular and Infectious Diseases and, most recently, Oncology. Stendhal is dedicated to being the best choice as a Latin American partner with expertise in local clinical trials, market access, regulatory strategy and commercialization in Latin America. Further information on Stendhal is available at <http://www.stendhalpharma.com>.

Forward-Looking Statements

This media statement contains forward-looking statements, including, but not limited to: statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies; and the safety and efficacy of Advaxis' proprietary immunotherapies. 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, 2015, 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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