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Advaxis and MedImmune Commence Enrollment in Phase I/II Study of Axalimogene Filolisbac (ADXS-HPV) in Combination With Durvalumab (MEDI4736) for the Treatment of HPV-Associated Cancers

PRINCETON, N.J. and GAITHERSBURG, Md., Aug. 20, 2015 (GLOBE NEWSWIRE) -- **Advaxis, Inc.** (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, and MedImmune, the global biologics research and development arm of AstraZeneca, today announced that enrollment has commenced in a Phase I/II clinical trial of axalimogene filolisbac (ADXS-HPV), Advaxis's investigational *Lm* Technology™ immunotherapy, in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), for the treatment of patients with advanced, recurrent or refractory human papillomavirus (HPV)-associated cervical cancer and HPV-associated head and neck cancer.

MedImmune logo

The two-part, open-label Phase I/II study is designed to evaluate the safety and efficacy of axalimogene filolisbac as a monotherapy and in combination with durvalumab in approximately 66 patients. Phase I is a dose-confirmation combination study with axalimogene filolisbac and durvalumab, which is expected to establish the maximum tolerated dose. The Phase II portion of the study will randomize patients to receive axalimogene filolisbac monotherapy, durvalumab monotherapy, or the combination. The primary efficacy endpoints include objective response rate and progression-free survival. Further information about the Phase I/II study can be found on ClinicalTrials.gov, using Identifier NCT02291055.

"We are pleased to have initiated patient enrollment for this combination immunotherapy study and look forward to evaluating this immunotherapy combination in the clinic, with the hopes of confirming the preclinical anti-tumor effects," said Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "The initiation of our combination immunotherapy study with MedImmune adds to what has become a rapidly expanding clinical development pipeline for Advaxis involving our *Lm* Technology™ immunotherapy platform alone and in combination with potentially synergistic technologies."

Axalimogene filolisbac and durvalumab are members of a new class of cancer treatments known as immunotherapies, which are designed to enhance the body's own defenses in fighting cancer. Data from preclinical studies suggest that Advaxis's *Lm* Technology™ immunotherapies in combination with a checkpoint inhibitor, such as durvalumab, may lead to an enhanced anti-tumor immune response. Results from the Phase I/II study will determine the future clinical development program for the combination.

About Cervical Cancer

Cervical cancer is the fourth most common cancer and the most common cause of mortality in women worldwide with 528,000 new cases reported annually and an estimated 266,000 deaths in 2012; the majority of which is diagnosed in less-developed countries. Within the U.S., approximately 12,900 cases of invasive cervical cancer are diagnosed annually and up to 30 percent are diagnosed with locally advanced disease. Despite a well-established and adopted standard of care for the treatment of locally advanced cervical cancer, consisting of cisplatin and radiotherapy administered concurrently, a large percentage of these patients, particularly those with high risk features and/or poor prognostic factors, will experience cancer recurrence and ultimately die of their disease. These patients represent a subpopulation of locally advanced cervical cancer with the highest unmet medical need and where the need for new therapeutic options is greatest as there are no approved therapies for this specific patient population.

About HPV-Associated 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 have been decreasing. According to the WHO, approximately 15-20 percent of the 400,000 new cases of head and neck cancer are HPV-related. In the U.S., there are about 12,000 new cases of HPV-associated head and neck cancer per year, affecting men about three 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 (ADXS-HPV) is Advaxis's 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 II 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™.

About Durvalumab

Durvalumab (MEDI4736) is an investigational human monoclonal antibody directed against programmed cell death ligand 1 (PD-L1). Signals from PD-L1 help tumors avoid detection by the immune system. Durvalumab blocks these signals, countering the tumor's immune-evading tactics.

Durvalumab was accelerated into Phase III clinical development in non-small cell lung cancer and head and neck cancer. The OCEANS clinical development program will evaluate durvalumab as monotherapy and in combination with a cytotoxic T-lymphocyte-associated protein-4 (CTLA-4) monoclonal antibody tremelimumab, in lung cancer, across the spectrum of the disease. In head and neck cancer, durvalumab is being investigated in three late stage studies (HAWK, CONDOR and EAGLE) as monotherapy and in combination with tremelimumab, looking at patients with different PD-L1 expression status who have failed on chemotherapy.

A comprehensive development program for durvalumab is underway across multiple tumor types, including gastric, pancreatic and bladder cancer, in addition to lung and head and neck cancers.

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 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's lead *Lm* Technology™ immunotherapy, axalimogene filolisbac, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three potential indications: Phase II in invasive cervical cancer, Phase I/II in head and neck cancer, and Phase I/II 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. For additional information on Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook, YouTube and Google+.

About MedImmune

MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, Md., one of AstraZeneca's three global R&D centers. For more information, please visit www.medimmune.com.

Forward-Looking Statements

This news release contains forward-looking statements, including, but not limited to: statements regarding Advaxis's ability to develop the next generation of cancer immunotherapies; and the safety and efficacy of Advaxis's proprietary immunotherapy, axalimogene filolisbac. These forward-looking statements are subject to a number of risks, including the risk factors set forth from time to time in Advaxis's SEC filings, including but

not limited to its report on Form 10-K for the fiscal year ended October 31, 2014, 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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