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Advaxis Receives Orphan Drug Designation in the European Union for Axalimogene Filolisbac for the Treatment of Anal Cancer

PRINCETON, N.J., Dec. 14, 2015 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, announced that the European Medicines Agency (EMA) has granted Orphan Drug Designation to axalimogene filolisbac for the treatment of anal cancer.

“We’re pleased to announce Advaxis’ second EMA Orphan Drug Designation within four weeks, which strengthens our pipeline and confirms the potential that *Lm* Technology™ immunotherapies may offer to patients with high unmet medical needs,” said Daniel J. O'Connor, CEO of Advaxis. “Our clinical program in anal cancer is building momentum as a result of this designation, the encouraging preliminary data in patients with anal cancer, as well as the honor of receiving the Farrah Fawcett Foundation’s ‘Medical Visionary Angel Award’ for our commitment to innovative research in anal cancer and HPV-related cancers. Receiving Orphan Drug Designation moves us one step closer to our goal of bringing a valuable new treatment to patients as quickly as possible.”

Orphan Drug Designation in the European Union (EU) is granted to drugs or biologics that treat a life-threatening or chronically debilitating rare disease affecting fewer than five in 10,000 individuals in the EU. Products receiving orphan drug designation are eligible to receive market exclusivity for a period of up to ten years, as well as development incentives such as regulatory and protocol assistance and scientific advice.

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.

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 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's 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.

Clinical trials of axalimogene filolisbac, ADXS-PSA and ADXS-HER2 have been placed on clinical hold by the FDA. Advaxis is working closely with the FDA and expects this clinical hold will be resolved expeditiously and without significant interruption to the Company's clinical development programs.

For additional information on Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook, YouTube and Google+.

Forward-Looking Statements

This media statement 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 immunotherapies. 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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