May 1, 2014

Advaxis Receives Orphan Drug Designation for Treatment of Invasive Cervical Cancer

PRINCETON, N.J., May 1, 2014 (GLOBE NEWSWIRE) -- Advaxis, Inc., (Nasdaq:ADXS), a leader in developing cancer immunotherapies, announced today that it has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD) for ADXS-HPV, its lead immunotherapy drug candidate, for the treatment of Stage II-IV invasive cervical cancer.

Orphan Drug Designation is granted to drug therapies intended to treat diseases or conditions that affect fewer than 200,000 people in the United States. Orphan Drug Designation entitles the sponsor to clinical protocol assistance with the FDA, as well as annual grant funding, tax credits, waiver of PDUFA filing fees, and potentially a seven year market exclusivity period.

"We are very pleased that the FDA has granted Orphan Drug Designation for ADXS-HPV in Stage II-IV invasive cervical cancer," stated Daniel J. O'Connor, Chief Executive Officer of Advaxis. "ADXS-HPV is our most advanced product candidate with encouraging Phase 2 data, the potential to proceed along a registrational pathway, and now the benefits of orphan drug status."

"Advaxis will continue to aggressively pursue all available regulatory programs and incentives that can assist us in bringing our cancer immunotherapies to patients as quickly as possible," stated Chris French, Vice President, Regulatory and Medical Affairs.

About Orphan Drug Designation

Under the Orphan Drug Act (ODA), the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. The benefits of orphan drug designation can be substantial and include federal grants, tax credits, and potentially a seven year market exclusivity period once the product is approved, provided that the product is first to market.

In order for a sponsor to obtain orphan designation for a drug or biological product, an application must be submitted to OOPD, and the designation approved. The approval of an application for orphan designation is based upon the information submitted by the sponsor. A drug that has obtained orphan designation is said to have "orphan status." Each designation request must stand on its own merit. Sponsors requesting designation of the same drug for the same indication as a previously designated product must submit their own data in support of their designation request. The approval of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and efficacy of a compound must be established through adequate and well-controlled studies.

About ADXS-HPV

ADXS-HPV is an immunotherapy that is designed to target cells expressing the HPV gene E7. Expression of the E7 gene from high-risk HPV variants is responsible for the transformation of infected cells into dysplastic and malignant tissues. Eliminating these cells can eliminate the dysplasia or malignancy. ADXS-HPV is designed to infect antigen-presenting cells and direct them to generate a powerful, cellular immune response to HPV E7. The

resulting cytotoxic T cells infiltrate and attack the tumors while specifically inhibiting tumor Tregs and MDSCs in the tumors that are protecting it.

About Cervical Cancer

According to the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2010, there are 500,000 new cases of cervical cancer caused by HPV worldwide every year. Current preventative vaccines cannot protect the 20 million women who are already infected with HPV; and of the high risk oncogenic strains, only HPV 16 and 18 are present in these vaccines. Challenges with acceptance, accessibility, and compliance have resulted in only a third of young women being vaccinated in the United States and even less in other countries around the world. 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 cases of cervical cancer and continues to increase in frequency. HPV is associated with 80-100% of anal cancers and is also increasing in frequency.

About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing the next generation of cancer immunotherapies. Advaxis' immunotherapies are based on a novel platform technology using live, attenuated bacteria to stimulate the immune system to selectively target cancer cells while reducing tumor defenses.

ADXS-HPV, Advaxis' lead immunotherapy for the treatment of HPV-associated cancers, has demonstrated improved survival and objective tumor responses in a Phase 2 trial in 110 patients with recurrent cervical cancer. Advaxis is now planning the registrational program for ADXS-HPV. ADXS-HPV is also being evaluated in other HPV-associated cancers including a Phase 2 in advanced cervical cancer, a Phase 1/2 in head and neck cancer, and a Phase 1/2 in anal cancer. ADXS-HPV has orphan drug status for invasive cervical, anal, and head and neck cancers. As part of its global commercialization strategy to enter into regional licensing deals with other market dominant biopharmaceutical companies in territories where there is a high prevalence of HPV-associated cancers, Advaxis has granted exclusive licenses for the development and commercialization of ADXS-HPV in Asia and India.

ADXS-cHER2 is an immunotherapy for the treatment of HER2 overexpressing cancers (such as breast, gastric, esophageal, and other cancers in humans and for osteosarcoma in canines). Advaxis's lead animal-health immunotherapy, ADXS-cHER2, has demonstrated encouraging survival data in a Phase 1 trial in canine osteosarcoma. These data provide the rationale to advance this same immunotherapy into a Phase 1 clinical trial in patients with HER2 overexpressing cancers.

Advaxis has created more than 15 distinct immunotherapies based on its platform, either directly or through strategic collaborations with recognized cancer centers of excellence such as: the University of Pennsylvania, Brown University, the Georgia Regents University Cancer Center, the Icahn School of Medicine at Mount Sinai, and others.

For more information please visit www.advaxis.com or connect with us on

- Facebook: https://www.facebook.com/advaxisinc
- Twitter: https://twitter.com/Advaxis
- LinkedIn: http://www.linkedin.com/company/advaxis-inc.
- Google+: https://plus.google.com/b/115126287957745987074/115126287957745987074/posts

Forward-Looking Statements

This news release contains forward-looking statements, including, but not limited to: statements regarding

Advaxis' ability to develop the next generation of cancer immunotherapies; the safety and efficacy of Advaxis' proprietary immunotherapy, ADXS-HPV; whether Advaxis immunotherapies can redirect the powerful immune response all human beings have to the bacterium to cancers. 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, 2013, 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.

CONTACT: Advaxis Contact:
Lisa Caperelli
Senior Director of Investor Relations and Corporate Communications
Advaxis, Inc.
caperelli@advaxis.com
215.206.1822

Media Contact:
Tiberend Strategic Advisors, Inc.
Amy S. Wheeler
awheeler@tiberend.com
646.362.5750

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