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Survival Results with Advaxis HER2 Targeted Immunotherapy in Canine Osteosarcoma Published in Clinical Cancer Research

Data Shows Reduction in Metastatic Disease and Increased Survival

PRINCETON, N.J., March 21, 2016 (GLOBE NEWSWIRE) -- [Advaxis, Inc.](#) (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, today announced that data from a dose-escalation study of ADXS-HER2 in canine osteosarcoma (OSA) was published online March 18, 2016 in [Clinical Cancer Research](#), a journal of the American Association for Cancer Research (AACR).

The study by Nicola Mason, PhD, BVetMed, Associate Professor of Medicine at the University of Pennsylvania School of Veterinary Medicine, evaluated the immunogenicity, safety, and impact of attenuated, recombinant *Listeria monocytogenes* (*Lm*) transformed with a HER2/Neu fusion protein (ADXS-HER2) on survival in 18 dogs with surgically treated osteosarcoma. The research is part of Advaxis' ongoing ADXS-HER2 clinical program.

"This is promising and important research both for dogs and humans," said Dr. Mason. "We were able to use the Advaxis *Lm* Technology to induce an antigen-specific T-cell response against HER2/Neu which is expressed in both canine and pediatric osteosarcoma, with only low-grade, transient side-effects. I am very excited about these results and the potential this technology holds for treatment of cancer patients of either species."

In the study, 18 dogs received either 2×10^8 , 5×10^8 , 1×10^9 or 3.3×10^9 CFU of ADXS-HER2 post-completion of surgery and adjuvant chemotherapy with 15 dogs showing an induced antigen-specific response within 6 months of immunotherapy administration. Additionally, treatment with ADXS-HER2 reduced the incidence of metastatic disease and prolonged survival relative to a historical control group. The median survival time for the ADXS-HER2 treated dogs was 956 days which was significantly longer than the 423 day median survival time of the historical control group ($p=0.014$, HR 0.33; 95% CI 0.136-0.802).

Osteosarcoma is the most common primary bone tumor in dogs, with more than 10,000 dogs annually diagnosed. Osteosarcoma is also the most common bone cancer in children and teens. It is the third most common cancer in teens after lymphomas and brain tumors. HER2 is expressed in approximately 40 to 60 percent of pediatric and canine osteosarcomas and in pulmonary metastatic disease, providing strong rationale for HER2 targeted immunotherapy in these cancers.

About ADXS-HER2

ADXS-HER2 is an *Lm* Technology™ immunotherapy product candidate being developed by Advaxis to target HER2 expressing cancers. ADXS-HER2 has received orphan drug designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of osteosarcoma. Advaxis is developing ADXS-HER2 for both human and animal health, and has seen encouraging data in canine osteosarcoma, which is considered a model for human osteosarcoma. Advaxis has licensed ADXS-HER2 to Aratana Therapeutics, Inc. for animal health therapeutics. Aratana expects to receive a conditional USDA license by the end of 2016 to market and sell ADXS-HER2 for dogs with canine osteosarcoma.

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 cancer antigens 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+](#).

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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