

Advaxis Announces ADXS-cHER2 Demonstrates Significant Survival Advantage in Ongoing Canine Osteosarcoma Study

PRINCETON, N.J.-- Advaxis, Inc., (OTCQB: ADXS and ADXSD), a leader in developing the next generation of immunotherapies for cancer and infectious diseases, announced updated preliminary data from a dose escalation Phase 1 study evaluating the safety and efficacy of ADXS-cHER2 in the treatment of dogs with osteosarcoma that overexpress human epidermal growth factor receptor-2, or HER2.

Osteosarcoma is an aggressive malignant bone tumor that affects dogs that overexpress HER2. Dogs undergoing standard of care (SOC) treatment (affected limb amputation and follow-up chemotherapy) have a median survival rate of only 1 year. Updated preliminary data from the first two of three dose groups (6 dogs/3 dogs per dose group) show a significant survival advantage for dogs that received SOC plus ADXS-cHER2 compared to 11 dogs whose owners elected not to participate in the trial but who were followed for survival ($p=0.04$). At this point in the study, 8 of 9 dogs treated with ADXS-cHER2 are alive (mean survival undefined), compared with 5 of 11 dogs in the control group (mean survival 265 days).

ADXS-cHER2 continues to be well-tolerated with the dogs experiencing only mild, easily managed side effects (fever, increased heart rate, and vomiting) consistent with immune activation (cytokine release syndrome) observed at the time of treatment. There is no evidence of any cumulative or long-term side effects on the dogs, including their cardiovascular systems.

“Preliminary results so far are very encouraging,” commented Dr. Nicola Mason, the lead investigator of the study at UPenn Veterinary School. “The side effects at the time of infusion are very mild and we are now treating the dogs on an outpatient basis.”

Once the dose has been selected, the study is intended to expand into Phase 2 and additional collaborative academic centers will be added.

“These early results are significant on several levels,” commented Dr. Robert Petit, Chief Scientific Officer of Advaxis. “This is the first demonstration of clinical activity with a second Advaxis immunotherapy (in addition to ADXS-HPV) in a naturally developing cancer. These data serve as the foundation for validating Advaxis immunotherapy constructs as a true platform technology, and set the groundwork for future development of a variety of immunotherapies targeting different cancers and infectious diseases. Improving survival in HER2 overexpressing canine osteosarcoma provides direct and important rationale supporting clinical studies in human HER2 overexpressing cancers. As we continue to find the best ways to treat canine osteosarcoma with ADXS-cHER2, the experience we gain will serve to accelerate our development of treatments for similar human cancers.”

Thomas A. Moore, Chairman and Chief Executive Officer of Advaxis added, “We believe there is a significant commercial opportunity for Advaxis in the veterinary medical market and we are discussing these data with several veterinary health companies.”

About ADXS-cHER2

ADXS-cHER2 is an *Lm*-LLO immunotherapy for HER2 overexpressing cancers (such as breast, gastric and other

cancers in humans and for osteosarcoma in canines). ADXS-cHER2 secretes the cHER2 antigen, fused to LLO, directly inside APC that are capable of driving a cellular immune response to cHER2 overexpressing cells. In preclinical analysis, localized effect is the inhibition of the Treg and MDSC cells that we believe may promote immunologic tolerance of the HER2 overexpressing cancer cells of the tumor. We currently are conducting a Phase 1 study in companion dogs evaluating the safety and efficacy of ADXS-cHER2 in the treatment of canine osteosarcoma and plan to meet with the U.S. Department of Agriculture, or USDA, to discuss the requirements to proceed forward with our first immunotherapy in the veterinary market.

About Canine Osteosarcoma

Osteosarcoma is the most common primary bone tumor in dogs, accounting for roughly 85% of tumors on the canine skeleton. Approximately 8,000-10,000 dogs a year (predominately middle to older-aged dogs and larger breeds) are diagnosed with osteosarcoma in the United States. This cancer initially presents as lameness and oftentimes visible swelling on the leg. Current standard of care treatment is amputation immediately after diagnosis, followed by chemotherapy and sometimes radiation for palliative care. Invariably, however, the cancer metastasizes to the lungs, eventually leading to death.

About the UPENN Canine Osteosarcoma Study

Nine dogs have been vaccinated in the Phase 1 portion of the study and seven additional dogs are due to be vaccinated within the next 2 months. Three dogs in each dose group received 3 doses of ADXS-cHER2 at 1×10^8 , 5×10^8 or 1×10^9 cfu three weeks apart. The primary endpoint of the study is to determine the maximum tolerated dose of ADXS-cHER2. Secondary endpoints for the study are progression-free survival and overall survival. The study has been amended to allow for maintenance dosing and is intended to expand to additional sites.

About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing the next generation of immunotherapies for cancer and infectious diseases. Advaxis immunotherapies are based on a novel platform technology using live, attenuated bacteria that are bio-engineered to secrete an antigen/adjuvant fusion protein(s) that is designed to redirect the powerful immune response all human beings have to the bacterium to the cancer itself.

ADXS-HPV is currently being evaluated in four clinical trials for human papillomavirus (HPV)-associated cancers: recurrent/refractory cervical cancer (India), locally advanced cervical cancer (GOG/NCI U.S. study, Clinical Trials.gov Identifier NCT01266460), head & neck cancer (CRUK study, Clinical Trials.gov Identifier NCT01598792), and anal cancer (BrUOG study, Clinical Trials.gov Identifier NCT01671488). Advaxis has over 15 distinct immunotherapies in various stages of development, developed directly by Advaxis and through strategic collaborations with recognized centers of excellence such as: the [National Cancer Institute](#), [Cancer Research – UK](#), the [Wistar Institute](#), the [University of Pennsylvania](#), the [University of British Columbia](#), the [Karolinska Institutet](#), and others. For more information please visit: advaxis.com | [Facebook](#) | [twitter](#) | [LinkedIn](#)

Forward-Looking Statements

This news release contains forward-looking statements, including, but not limited to: statements regarding expanding into Phase 2 with additional collaborative academic centers, future development of a variety of immunotherapies targeting different cancers and infectious diseases, clinical studies in human HER-2 overexpressing cancers, the acceleration of development of treatments for similar human cancers, and that there is a significant commercial opportunity for Advaxis in the veterinary medical market. 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, 2012, 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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