Advaxis to Present Survival Data of Lm-LLO Cancer Immunotherapies in Recurrent Cervical Cancer and Canine Osteosarcoma at the Society for Immunotherapy of Cancer 29th Annual Meeting

Immunotherapy Candidate for Pediatric Osteosarcoma, ADXS-cHER2, Delays Metastatic Disease and Prolongs Overall Survival in Canine Osteosarcoma

Bivalent Lm-LLO Immunotherapies Demonstrate Increased Anti-Tumor Effects when Compared to Monovalent Lm-LLO Immunotherapies in Preclinical Studies

ADXS-HPV Treatment Results in Long-term Survival, Tumor Responses, and Stabilization of Disease in Phase 2 Study in Recurrent Cervical Cancer

PRINCETON, N.J., Nov. 4, 2014 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq:ADXS), a cancer immunotherapy company, today announced the abstracts of three preclinical and clinical studies highlighting the survival outcomes and anti-tumor effects of its proprietary Lm-LLO cancer immunotherapy technology at the Society for Immunotherapy of Cancer (SITC) 29th Annual Meeting, November 6-9, 2014 at the Gaylord National Hotel and Convention Center in National Harbor, Maryland.

Daniel J. O'Connor, Chief Executive Officer of Advaxis, stated, "The studies being presented at SITC demonstrate the potential that our Lm-LLO immunotherapies offer in the treatment of a wide range of cancers and, collectively, the value that Advaxis is continuing to build as a company."

O'Connor continued, "Of note, the data from Dr. Mason's research in canine osteosarcoma supports our rationale to pursue a clinical development program with ADXS-cHER2 in pediatric osteosarcoma, based on the known similarities between canine and human osteosarcoma, as well as other HER2 overexpressing cancers, such as breast, gastric, and esophageal cancers. Meanwhile, the Phase 2 data with ADXS-HPV supports further development of this Lm-LLO immunotherapy. Additionally, Advaxis's preclinical research with bivalent constructs demonstrates the ability of the platform to address multiple targets within the same Lm-LLO cancer immunotherapy and lays the groundwork to potentially expand our pipeline."

On Friday, November 7, Nicola J. Mason, BVetMed, Ph.D., DACVIM, and Pamela Cole, Chair in Companion Animal Medicine, Assistant Professor of Medicine, University of Pennsylvania's School of Veterinary Medicine, will present the preliminary data from an ongoing Phase 1 clinical study in dogs with osteosarcoma (poster #69). The data indicates that ADXS-cHER2 is able to delay or prevent metastatic disease, with all 17 treated dogs failing to develop lung metastasis. Additionally, ADXS-cHER2 has been found to significantly prolong overall survival following standard of care (amputation and follow-up chemotherapy). 14 of the treated dogs remain alive with median survival having not yet been reached; median survival in control dogs (n=13) was 316 days.

Anu Wallecha, Ph.D., Director Research and Development at Advaxis, will be also be delivering a poster presentation on Friday, November 7, on a preclinical study evaluating the therapeutic efficacy of two bivalent Lm-LLO immunotherapies (HER2/HMW-MAA and HER2/CA9) in comparison to monovalent Lm-LLO immunotherapies (poster #77). The poster will also provide possible mechanisms of action that could be responsible for the observed anti-tumor effects.
On Saturday, November 8, Robert Petit, Ph.D., Chief Scientific Officer of Advaxis, will present data that was previously reported at ASCO 2014 on the final results from the randomized Phase 2 clinical study of 110 patients with recurrent cervical cancer treated with a single cycle (three doses) of ADXS-HPV (poster #106). Long-term survival was 18% >24 months, 18 month survival was 22%, and 12 month survival was 32%. The overall tumor response rate was 11% (complete and partial responses), with a median duration of response of 9.5 months. A disease control rate (≥ three months) was observed for 38% of patients. ADXS-HPV was well-tolerated with 62% of patients reporting no adverse events (AE) and 38% of patients reporting mild transient adverse events (Grade 1 or 2) that occurred on the day of infusion. One Grade 3 fever was reported and there were no Grade 4 or Grade 5 AE.

About SITC

The Society for Immunotherapy of Cancer (SITC) is a 501 (c)(3) non-profit medical professional society of influential scientists, academicians, researchers, clinicians, government representatives, and industry leaders from around the world dedicated to improving cancer patient outcomes by advancing the science and application of cancer immunotherapy. Currently, SITC has more than 800 members representing 17 medical specialties and are engaged in research and treatment of at least a dozen types of cancer.

Through emphasis on high-caliber scientific meetings, dedication to education and outreach activities, focus on initiatives of major importance to the field, and commitment to collaborations with like-minded organizations and patient advocacy groups, SITC brings together all aspects of the cancer immunology and immunotherapy community in an effort to make cancer immunotherapy one of the four standards of care and the word "cure" a reality for cancer patients living with this disease.

About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary platform intended to redirect the immune system to kill cancer. The Advaxis Lm-LLO 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 immunotherapy, ADXS-HPV, targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The FDA has granted Advaxis orphan drug designation for each of these three indications. The Company plans to initiate a registration clinical program for cervical cancer in 2015 and has established licensing partners in India and Asia for commercialization in those regions. Advaxis is planning to evaluate the combination of ADXS-HPV with an anti-PD-L1 immune checkpoint inhibitor in HPV-associated cervical cancer and head and neck cancer.

Advaxis's second Lm-LLO immunotherapy candidate in clinical testing will be ADXS-PSA, which is being developed to address prostate cancer. Advaxis is planning to file an IND with the FDA and initiate a Phase 1/2 clinical study with ADXS-PSA alone and in combination with a PD-1 checkpoint inhibitor. Advaxis is also developing Lm-LLO immunotherapy ADXS-cHER2, to target the Her2 receptor overexpressing cancers. Her2 is overexpressed in certain solid-tumor cancers, including pediatric bone cancer (or osteosarcoma), breast cancer, esophageal, and gastric cancer. Advaxis is developing ADXS-cHER2 for both human and animal-health, and has seen promising results in canine osteosarcoma, which is considered a model for human osteosarcoma. Advaxis is planning to file an IND for ADXS-cHER2 in Her2 overexpressing cancers and to conduct a clinical program in pediatric osteosarcoma. Advaxis has licensed ADXS-cHER2 and three other immunotherapy constructs to Aratana Therapeutics, Inc.

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

- Facebook: https://www.facebook.com/advaxisinc
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; the safety and efficacy of Advaxis's 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's 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.

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