Late Breaking Data at AACR Annual Meeting from Advaxis Phase 2 Study of AXAL Highlights Potential of the Company’s Lm Technology™ Platform

First clinical data with AXAL to show evidence of cytotoxic T cell infiltration into the tumor immune microenvironment or TME for HPV-Positive oropharyngeal cancer

PRINCETON, N.J., April 18, 2016 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, today announced immunological and pathologic data from the Company’s ongoing Phase 2 study of its lead immunotherapy candidate, axalimogene filolisbac (AXAL), in patients with late-stage HPV-associated oropharyngeal cancer (HPVOPC). This phase 2 “window of opportunity” trial was designed to evaluate the effect of AXAL on anti-tumor immunity in the tumor immune microenvironment (TME) of patients with HPVOPC by conducting an analyses and comparison of the TME between pre-treatment tumor biopsy and post-treatment resected tumor tissue, as well as pre and post AXAL treatment blood samples.

The data were selected for “Late Breaking Abstract” status and will be presented in the poster session of the American Association for Cancer Research (AACR) Annual Meeting on April 18, 2016 from 8:00 AM to 12:00 PM CT in Hall H of the New Orleans Memorial Convention Center in New Orleans, Louisiana. The poster (abstract LB-095) titled “HPV E7 antigen-expressing Listeria-based immunotherapy (AXAL) prior to robotic surgery for HPV-positive oropharyngeal cancer enhances HPV-specific T cell immunity” will be available at www.advaxis.com on Monday, April 18 at 9:00 AM ET.

The Phase 2 study, led by Andrew G. Sikora, M.D., Associate Professor of Otolaryngology and Co-Director of the Head and Neck Cancer Program in the NCI Comprehensive-Designated Dan L. Duncan Cancer Center at Baylor College of Medicine, supported by key investigators Brett Miles, M.D. and Marshall Posner, M.D. at the Icahn School of Medicine at Mount Sinai, and presented at AACR by Rosemarie Krupar, M.D. from Baylor College of Medicine, evaluates the immunogenicity and differential mechanism of AXAL as preoperative treatment prior to robotic surgery in patients with HPVOPC.

The trial has enrolled eight AXAL-treated patients and six no-treatment observational patients to date, with stage II-IV HPVOPC. The trial uniquely leveraged a 5-6 week “window of opportunity” between diagnosis and TORS (trans-oral robotic surgery) with curative intent, to administer two doses of AXAL treatment at $1 \times 10^9$ CFU 2 weeks apart.
This unique clinical setting or “window of opportunity”, makes it possible to analyze and compare changes to the TME after the compressed regimen of AXAL treatment as well as pre and post treatment blood samples. In this limited timeframe, patients received two doses of AXAL separated by only two weeks, followed by TOR surgery 1-2 weeks after the second dose.

The data presented showed that HPV E7- and/or E6-specific T cell responses increased in the peripheral blood in five of the study patients. Increased infiltration of both CD4+ and CD8+ T cells were observed in the TME of four patients, with a reduction of FOXP3+ regulatory T cells within the tumors of 3/6 patients. Increased T cell responses to HPV E6 supports enhanced immune activity against additional tumor targets. Changes to the TME included cytotoxic T cell infiltration into the post-resection tumor, increased immune activation, a reduction of regulatory T cells, infiltration of cytotoxic T cells, and increased expression of inflammatory activation markers. In addition, fluctuations of circulating serum cytokine (IL-15, IL-9, TNfa, IL-2 and MIP-1b) levels were observed potentially suggesting consumption by activated T cells and migration of T cells to the TME.

“While our data is preliminary, in several patients we saw increased T cell response, evidence of epitope spreading, and signs of increased immune activation consistent with expansion and infiltration of activated T cells into the tumor. We also saw trends towards a reduction in immuno-suppressive Tregs. Importantly, in several patients when compared to pre-treatment tumor tissue, post-treatment tissue analysis showed conversion of the TME into a site of active inflammation characterized by infiltration of activated T cells, and increased expression of activation markers including PD-1, PD-L1,” said Andrew Sikora, M.D., Ph.D., Associate Professor of Otolaryngology at the Baylor College of Medicine. “The fact that we are seeing these trends at this preliminary point in the study is very encouraging, and suggests that AXAL has the potential to generate beneficial immunologic responses in patients with HPV+ head and neck cancer.”

“The biggest challenge for an effective cancer immunotherapy is to overcome the mechanisms tumors use to protect themselves from immunological attack and destruction. Researchers refer to this as ‘immunosuppression in the tumor microenvironment (or TME).’ It has been demonstrated and published in peer review journals that Advaxis’ Lm Technology™ enables cytotoxic T cells to infiltrate into the TME. The late breaking AXAL data shows – for the first time in a human clinical trial – the potential of the Lm Technology™ platform to elicit a targeted anti-cancer immune response with clear infiltration into the TME by cytotoxic T cells,” said Daniel J. O’Connor, President and Chief Executive Officer of Advaxis.

“This is the first human clinical data that replicates the multiple beneficial immunologic and tumor microenvironment-modifying aspects of treatment with Advaxis’ immunotherapies that have been consistently demonstrated in several research models. It’s impressive that these changes occurred so consistently despite being obliged to use a shortened treatment schedule without the usual follow-up period to fit within the ‘window.’ Immunotherapies are generally understood to work better over time, and we would expect these early beneficial effects to deepen and contribute to tumor-controlling immunity over time,” said Robert Petit, Chief Scientific Officer and EVP of Advaxis. “These data points are the first clear demonstration of the reduction of Tregs in human tumors associated with
Advaxis’ immunotherapy. Inhibition of Tregs has been clearly associated with the Advaxis tLLO fusion peptide in many publications. Immune activation through TLRs and PAMPS, including STING and the subsequent infiltration of tumor fighting T cells into the TME along and simultaneous reduction in tumor protection by Tregs, are the cornerstones of successful immunotherapies. Every Advaxis immunotherapy product candidate, including AXAL, has these elements built into it.”

The study received a three-year $1.1 million grant from the U.S. Food and Drug Administration’s Office of Orphan Products Development, which funds research for the development of products for rare diseases.

For additional information, Advaxis will host a Research Reception at AACR at 6:30 PM CT on April 18, 2016 at the Sheraton New Orleans Hotel in New Orleans, Louisiana.

About Axalimogene Filolisbac

Axalimogene filolisbac (AXAL) is Advaxis’ 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 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+.

Advaxis Forward-Looking Statement

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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