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Advaxis Announces FDA Acceptance of Its Investigational New Drug Application to Commence First-in-Human Clinical Trials of ADXS-HER2

Advaxis Plans to Immediately Initiate Phase 1 Clinical Trial in Patients With Metastatic HER2 Expressing Solid Tumors

PRINCETON, N.J., Jan. 22, 2015 (GLOBE NEWSWIRE) --[Advaxis, Inc.](#) (Nasdaq:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to conduct a Phase 1 clinical study of ADXS-HER2 (ADXS31-164) for the treatment of patients with metastatic HER2 expressing solid tumors. The clinical trial, which will be the first-in-human study of Advaxis's lead *Lm*-LLO immunotherapy product for HER2 expressing cancers, is expected to begin patient enrollment in the first half of 2015. [In May 2014](#), Advaxis was granted orphan drug designation by the FDA for ADXS-HER2 in osteosarcoma.

The Phase 1 clinical study is designed to evaluate the safety and tolerability of ADXS-HER2 as a monotherapy in patients with metastatic HER2 expressing solid tumors such as breast, gastric, esophageal, and osteosarcoma. Results from the study will be used to determine the future clinical development program of ADXS-HER2.

"We are very pleased to have received FDA acceptance for our ADXS-HER2 IND application and look forward to commencing the Phase 1 clinical study in HER2 expressing solid tumors," stated Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "This trial will provide important insights about the potential of ADXS-HER2 in HER2 expressing cancers such as breast, gastric, esophageal and osteosarcoma."

The safety and efficacy of ADXS-HER2 is currently being evaluated in an ongoing Phase 1/2 veterinary clinical study in pet dogs with osteosarcoma, conducted by Nicola Mason, BVet.Med, Ph.D., DACVIM, of the University of Pennsylvania School of Veterinary Medicine. To date, dogs treated (n=15) with ADXS-HER2 immunotherapy, after receiving standard of care (amputation and follow up chemotherapy), had a statistically significant overall survival benefit ($p=0.032$) compared to dogs (n=13) that only received standard of care. Additionally, the preliminary data suggests immune responses induced by ADXS-HER2 targeted pulmonary micrometastases and prevent the development of metastatic disease in the dog's lungs.

Advaxis has granted exclusive worldwide rights to Aratana Therapeutics (Nasdaq:PETX) to develop and commercialize ADXS-HER2 for the treatment of osteosarcoma in dogs. In

July 2014, Aratana filed a U.S. Department of Agriculture (USDA) product license application for ADXS-HER2 for the treatment of canine osteosarcoma and other cancers. While the USDA has no specific obligation to respond within a prescribed timeframe, the companies expect a response within 12 to 18 months from the date the application was filed.

About HER2 Expressing Solid Tumor Cancers

HER2 is expressed in a percentage of solid tumors such as breast, bladder, pancreatic, gastric, ovarian cancers and osteosarcoma. The American Cancer Society estimates that in 2015 in the United States (US) alone there will be 232,670 diagnoses of invasive breast cancer, 22,220 new cases of gastric cancer, 74,690 new cases of bladder cancer, 46,420 new cases of pancreatic cancer, 22,220 new cases of gastric cancer, 21,980 new cases of ovarian cancer, and 800 new cases of osteosarcoma.

About Advaxis, Inc.

Advaxis is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary *Lm*-LLO platform technology. The *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 *Lm*-LLO 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 registrational clinical program for cervical cancer in 2015 and has established licensing partners in India and Asia for commercialization in those regions. Advaxis entered into a clinical trial collaboration with MedImmune, the global biologics research and development arm of AstraZeneca, for a Phase 1/2 immunotherapy study to evaluate the safety and efficacy of MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with Advaxis's ADXS-HPV as a treatment for patients with advanced, recurrent or refractory HPV-associated cervical cancer and HPV-associated 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 entered into a clinical trial collaboration agreement with Merck & Co., Inc. ("Merck"), known as MSD outside the United States and Canada, through its subsidiaries, to evaluate the combination of Advaxis's *Lm*-LLO cancer immunotherapy, ADXS-PSA, with Merck's PD-1 checkpoint inhibitor KEYTRUDA® (pembrolizumab). The planned clinical trial will evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with pembrolizumab in a Phase 1/2 study of patients with previously treated metastatic, castration-resistant prostate cancer.

Advaxis is also developing *Lm*-LLO immunotherapy ADXS-HER2, to target the HER2 receptor expressing cancers. HER2 is expressed in certain solid-tumor cancers, including

pediatric bone cancer (or osteosarcoma), breast cancer, esophageal, and gastric cancer. ADXS-HER2 has received orphan drug designation by the U.S. Food and Drug Administration (FDA) 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 and three other immunotherapy constructs to Aratana Therapeutics, Inc. for pet therapeutics.

For more information about our cancer immunotherapies please visit www.advaxis.com.

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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