Advaxis Submits Investigational New Drug Application for ADXS31-142 (ADXS-PSA) for the Treatment of Metastatic Castration Resistant Prostate Cancer

Advaxis to Initiate Dose Finding Study in Early 2015 in Preparation for PD-1 Combination Study With Merck's KEYTRUDA(R) (pembrolizumab)

PRINCETON, N.J., Nov. 5, 2014 (GLOBE NEWSWIRE) -- Advaxis, Inc. (Nasdaq:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, today announced that the Company has submitted an Investigational New Drug application (IND) to the United States Food and Drug Administration (FDA) to conduct the first-in-human study of ADXS31-142 for the treatment of metastatic castration resistant prostate cancer (mCRPC). ADXS31-142 is Advaxis's lead Lm-LLO immunotherapy designed to specifically target prostate-specific antigen (PSA).

Pending FDA's acceptance of the IND submission, the proposed Phase 1/2 protocol is designed to evaluate the safety and efficacy of ADXS31-142 as monotherapy and in combination with KEYTRUDA® (pembrolizumab), the first anti-PD-1 (programmed death receptor-1) therapy approved in the United States, by Merck, known as MSD outside the United States and Canada, through its subsidiaries.

The Phase 1 part of the trial is designed to identify a recommended dose for ADXS31-142 when used alone and when combined with KEYTRUDA. The Phase 2 part of the trial will assess the safety and efficacy of the combination regimen. Advaxis and Merck will collaboratively oversee the conduct of the study, which is planned to begin in early 2015. Results from the open-label study will be used to determine the future clinical development program for the combination.

Within 30 calendar days of the IND filing, FDA will notify Advaxis of any questions it has or protocol revisions it requests which may delay this timing. Advaxis plans to work with the FDA review team to address any questions or requests that arise within this 30-day window.

"With the filing of our ADXS31-142 IND, we are on track to begin a Phase 1/2 human clinical trial with a second Lm-LLO immunotherapy investigational new drug in early 2015," commented Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "This is another important milestone for Advaxis as we continue to advance our pipeline of immunotherapy candidates and investigate novel combinations with checkpoint inhibitors and other synergistic agents that we believe may offer new treatment options for patients with cancer."

Both ADXS31-142 and KEYTRUDA are members of a new class of cancer treatments known as immunotherapies, which are designed to enhance the body's own defenses in fighting cancer. Data from preclinical studies suggest that Advaxis Lm-LLO immunotherapies in combination with a PD-1 inhibitor may lead to an enhanced anti-tumor immune response. The goal of the Phase 1/2 trial is to begin examining that potential.

About Prostate Cancer

Prostate cancer is the second most common form of cancer affecting men in the United States: an estimated one in six will be diagnosed with prostate cancer in his lifetime. The American Cancer Society estimates that...
approximately 233,000 new cases of prostate cancer will be diagnosed and about 30,000 men are expected to die of the disease this year.

About ADXS-PSA

ADXS-PSA is an Lm-LLO immunotherapy that is designed to target the prostate-specific antigen (PSA), a protein produced exclusively by prostate cells that is associated with prostate cancer. ADXS-PSA secretes the PSA antigen, fused to the powerful immunostimulant tLLO, directly inside the antigen presenting cells that are capable of driving a cellular immune response to PSA expressing cells. This approach is also designed to inhibit the Treg and myeloid-derived suppressor cells (MDSCs) that contribute to immunologic tolerance of prostate cancer. In preclinical analysis, ADXS-PSA inhibits the immunosuppression caused by Treg and MDSC cells localized inside tumors that may promote immunologic tolerance of prostate cancer.

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-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. ADXS-cHER2 has received orphan drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of osteosarcoma. 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 pet therapeutics.

For more information 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.

KEYTRUDA is a registered trademark of Merck & Co., Inc.

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