Advaxis Submits Investigational New Drug Application for Phase 1/2 Study of ADXS-HPV and MedImmune's MEDI4736 for the Treatment of HPV-Associated Cervical and Head & Neck Cancer

Dose Confirmation Safety Study of ADXS-HPV and MEDI4736 Combination Therapy to Initiate in Early 2015

PRINCETON, N.J., Nov. 12, 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 a Phase 1/2 study of ADXS-HPV (ADXS11-001) alone or in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, for the treatment of advanced, recurrent or refractory human papillomavirus (HPV)-associated cervical cancer and HPV-associated head and neck cancer.

This follows the press release issued in July 2014 announcing the clinical trial collaboration between Advaxis and MedImmune, the global biologics research and development arm of AstraZeneca.

ADXS-HPV is Advaxis's lead Lm-LLO immunotherapy designed for the treatment of HPV-associated cancers. Preclinical evidence suggests that the combination of ADXS-HPV with a checkpoint inhibitor, such as MEDI4736, can enhance overall anti-tumour response.

Pending FDA's acceptance of the IND submission, the proposed Phase 1/2 protocol is designed to evaluate the safety and efficacy of ADXS-HPV as monotherapy and in combination with MEDI4736. Specifically, the Phase 1 part of the trial is expected to establish a recommended dose regimen of ADXS-HPV with MEDI4736, and the Phase 2 portion will assess the safety and efficacy of the combination. The study is planned to begin in early 2015.

"The filing of our ADXS-HPV + MEDI4736 IND for HPV associated cervical and head and neck cancers is another significant advance in Advaxis's clinical strategy as it adds to our rapidly growing pipeline and positions Advaxis as a clear leader in the immunotherapy-checkpoint inhibitor combination therapy market," commented Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "Additionally, the filing of this IND and the recently announced filing of the ADXS-PSA + KEYTRUDA® (pembrolizumab) IND demonstrate Advaxis's ability to rapidly transition partnering agreements to clinical
programs. Since announcing our agreements with MedImmune and Merck in July and August, respectively, we have worked diligently with both companies' research teams to develop IND filings involving each company's checkpoint inhibitor that, upon acceptance by FDA, should enable us to initiate two Phase 1/2 trials in early 2015."

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.

About cervical cancer

There are 500,000 new cases of cervical cancer caused by HPV worldwide every year, according to the WHO Human Papillomavirus and Related Cancers in the World Summary Report 2010. Current preventative vaccines cannot protect the 20 million women who are already infected with HPV; and of the high risk oncogenic strains, only HPV 16 and 18 are present in these vaccines. Challenges with acceptance, accessibility, and compliance have resulted in only a third of young women being vaccinated in the United States and even less in other countries around the world. HPV is associated with 20-50% of oral squamous cell carcinomas.

About HPV-associated head and neck cancer

The incidence of HPV-associated head and neck cancers has been increasing at an epidemic rate, while head and neck cancers from other causes have been decreasing. According to the WHO, approximately 15-20% of the 400,000 new cases of head and neck cancer are HPV-related. In the US, there are about 12,000 new cases of HPV-associated head and neck cancer per year and it affects men about 3 times more frequently than women. HPV-associated head and neck cancer is growing fastest in developed countries like the US.

About ADXS-HPV

ADXS-HPV is Advaxis's lead immunotherapy product candidate for the treatment of HPV-associated cancers. It is currently under investigation in three HPV-associated cancers: invasive cervical cancer, head and neck cancer, and anal cancer. In cervical cancer, a recently completed Phase 2 study of ADXS-HPV demonstrated improved survival and a manageable safety profile alone or in combination with chemotherapy, which warrants further development of the molecule. Clinical trials in head and neck cancer and in anal cancer are ongoing. Advaxis has received Orphan Drug Designation from the US Food and Drug Administration for ADXS-HPV for HPV-associated Stage II-IV cervical cancer, head and neck cancer, and for anal 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.

CONTACTS: Company:
   Advaxis, Inc.
   Greg Mayes, Executive Vice President and COO
   mayes@advaxis.com
   609.452.9813 ext. 102

   Media Contact:
   Tiberend Strategic Advisors, Inc.
   Amy S. Wheeler
   awheeler@tiberend.com
   646.362.5750

Source: Advaxis