

August 25, 2014



Advaxis and Merck Form Collaboration to Evaluate Investigational Combination of Two Novel Immunotherapy Candidates for Advanced Prostate Cancer

PRINCETON, N.J., Aug. 25, 2014 (GLOBE NEWSWIRE) --[Advaxis, Inc.](#) (Nasdaq:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, has entered into a clinical trial collaboration agreement with 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 investigational anti PD-1 antibody, 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.

Both ADXS-PSA and pembrolizumab are investigational members of a new class of cancer treatments known as immunotherapies that are designed to enhance the body's own defenses in fighting cancer. Preclinical evidence suggests that Advaxis *Lm*-LLO immunotherapies in combination with a PD-1 inhibitor may lead to an enhanced anti-tumor immune response.

"We are excited to be working with Merck. Equally as exciting is the combination potential of our *Lm*-LLO immunotherapy with Merck's anti-PD-1 immune checkpoint inhibitor," commented Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "We believe the combination of Advaxis *Lm*-LLO cancer immunotherapies and checkpoint inhibitors holds significant promise for the treatment of prostate and other cancers."

Under the terms of the agreement, Advaxis and Merck will collaborate to evaluate the ADXS-PSA/pembrolizumab combination as a treatment for prostate cancer. The Phase 1 part of the trial is designed to establish a recommended dose regimen for ADXS-PSA alone and combined with pembrolizumab, and the Phase 2 portion will assess the safety and efficacy of the combination. Advaxis will sponsor and fund the study and Merck will provide pembrolizumab. The companies will collaboratively oversee the conduct of the study, which is planned to begin in early 2015. Results from the study will be used to determine the path for further clinical development of the combination.

"Collaborations such as this are an integral part of Merck's strategy to evaluate the potential of pembrolizumab in multiple combinations for a broad range of cancers," said Dr. Eric Rubin, vice president Oncology, Merck Research Laboratories. "We look forward to working with Advaxis to evaluate this novel investigational combination immunotherapy for the treatment of advanced prostate cancer."

About Prostate Cancer

According to the American Cancer Society, prostate cancer is the most common type of cancer found in American men, other than skin cancer. Prostate cancer is the second leading cause of cancer death in men, behind only lung cancer. One man in six will get prostate cancer during his lifetime, and one man in 36 will die of this disease.

About ADXS-PSA

ADXS-PSA is an *Lm*-LLO immunotherapy that is designed to target the PSA antigen 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. The Advaxis approach is also designed to inhibit the Treg and MDSC cells 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 we believe promotes immunologic tolerance of prostate cancer.

About Pembrolizumab

Pembrolizumab (MK-3475) is an investigational, humanized, monoclonal antibody against PD-1 designed to reactivate anti-tumor immunity. Pembrolizumab exerts dual ligand blockade of the PD-1 pathway by inhibiting the interaction of PD-1 on T cells with its ligands PD-L1 and PD-L2.

Pembrolizumab is currently being evaluated across more than 30 types of cancers, as monotherapy and in combination. It is anticipated that by the end of 2014, the pembrolizumab development program will grow to more than 24 clinical trials, enrolling an estimated 6,000 patients at nearly 300 clinical trial sites worldwide. For information about Merck's oncology clinical studies, please visit <http://www.merck.com/clinical-trials/index.html>.

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 MSDCs, 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 registrational clinical program for cervical cancer in 2014 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 cancers.

Advaxis's second 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. Advaxis is also developing 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 pursuing a clinical program in pediatric osteosarcoma and has licensed ADXS-cHER2 and three other immunotherapy constructs to a major animal-health company. Advaxis is planning to file an IND for ADXS-cHER2 in Her2 overexpressing cancers.

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

- Facebook: <https://www.facebook.com/advaxisinc>
- Twitter: <https://twitter.com/Advaxis>
- LinkedIn: <https://www.linkedin.com/company/advaxis-inc>.
- Google+:
<https://plus.google.com/b/115126287957745987074/115126287957745987074/posts>

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.

CONTACT: Advaxis Contact:

Lisa Caperelli
Senior Director of Investor Relations and
Corporate Communications
Advaxis, Inc.
caperelli@advaxis.com
215.206.1822

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

Advaxis Logo

Source: Advaxis