
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 8, 2014

ADVAXIS, INC.
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

00028489

(Commission
File Number)

02-0563870

(IRS Employer
Identification No.)

**305 College Road East
Princeton, New Jersey**

(Address of principal executive offices)

08540

(Zip Code)

Registrant's telephone number, including area code: **(609) 452-9813**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure.

A copy of the press release of Advaxis, Inc. (the “Company”) dated December 8, 2014 relating to the announcement discussed in Item 8.01 below is attached hereto as Exhibit 99.1.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On December 8, 2014, the Company announced that the U.S. Food and Drug Administration has cleared its Investigational New Drug application to conduct a Phase 1/2 clinical study to evaluate the combination of ADXS-PSA (ADXS31-142) with KEYTRUDA® (pembrolizumab), marketed by Merck & Co., Inc., in patients with previously treated, metastatic castration-resistant prostate cancer (mCRPC). The clinical trial, which will be the first-in-human study of the Company’s lead *Lm-LLO* immunotherapy product candidate in prostate cancer, is expected to begin patient enrollment in the first quarter of 2015.

Exhibit No. Description

99.1 Press Release dated December 8, 2014.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ADVAXIS, INC.

By: /s/ Daniel J. O'Connor

Name: Daniel J. O'Connor

Title: Chief Executive Officer

Date: December 10, 2014

EXHIBIT INDEX

Exhibit No. **Description**

99.1 Press Release issued by the Company on December 8, 2014.



Advaxis Announces FDA Acceptance of its Investigational New Drug Application to Commence Clinical Trials of ADXS-PSA in Combination with Merck's KEYTRUDA® (pembrolizumab) for Prostate Cancer

Companies Plan to Immediately Initiate Phase 1/2 Clinical Trial

PRINCETON, NJ, December 8, 2014 — **Advaxis, Inc.** (NASDAQ:ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, announced today that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to conduct a Phase 1/2 clinical study to evaluate the combination of ADXS-PSA (ADXS31-142) with KEYTRUDA® (pembrolizumab), marketed by Merck & Co., Inc., in patients with previously treated, metastatic castration-resistant prostate cancer (mCRPC). The clinical trial, which will be the first-in-human study of Advaxis's lead *Lm-LLO* immunotherapy product candidate in prostate cancer, is expected to begin patient enrollment in the first quarter of 2015.

The open-label Phase 1/2 clinical trial is designed to evaluate the safety and efficacy of ADXS-PSA as a monotherapy and in combination with KEYTRUDA, the first anti-PD-1 (programmed death receptor-1) therapy approved in the United States. KEYTRUDA is developed and marketed by Merck.

The Phase 1 part of the study will be a dose-escalating study designed to establish the maximum tolerated dose of ADXS-PSA when used alone and in combination with KEYTRUDA. The Phase 2 portion will assess the safety and efficacy of the combination immunotherapy regimen. Advaxis and Merck will collaboratively oversee the conduct of the study and will use the results from the trial to determine the future clinical development program for the combination.

"Combinations of immunotherapies are the future of cancer research," stated Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "We are extremely pleased with FDA's acceptance of this IND because it gives us the opportunity to conduct clinical trials of ADXS-PSA in combination with an important, FDA approved PD-1 inhibitor, KEYTRUDA."

O'Connor continued, "This open-label study will provide Advaxis clinical data by which we can evaluate the potential of our proprietary *Lm-LLO* immunotherapy technology to enhance the activity of an anti-PD-1 antibody. During preclinical studies, our immunotherapies demonstrated a synergistic anti-tumor immune response when combined with a PD-1 inhibitor. We look forward to the possibility of seeing these encouraging results again, this time in a clinical setting, with the hopes of offering a promising alternative treatment option for patients diagnosed with an aggressive and difficult to treat form of prostate cancer."

ADXS-PSA 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.

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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