
**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 15, 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 15, 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 15, 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-HPV (ADXS11-001) with MedImmune's MEDI4736, in patients with advanced, recurrent, or refractory human papillomavirus ("HPV")-associated cervical cancer and HPV-associated head and neck cancer. The clinical trial is expected to begin patient enrollment in early 2015.

Exhibit No.	Description
99.1	Press Release dated December 15, 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 17, 2014

EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release issued by the Company on December 15, 2014.



Advaxis Announces FDA Acceptance of its Investigational New Drug Application to Commence Clinical Trials of ADXS-HPV in Combination with MedImmune's MEDI4736 for the Treatment of HPV-Associated Cancers

Companies Plan to Immediately Initiate Phase 1/2 Clinical Trial in Cervical and Head & Neck Cancer

PRINCETON, NJ, December 15, 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 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. The trial is expected to begin patient enrollment in early 2015.

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

The Phase 1 part of the study will be a dose-confirmation study of ADXS-HPV and MEDI4736 combination therapy. The Phase 2 portion of the study is designed to assess the safety and develop an estimate of clinical activity for the combination and monotherapy treatments, including tumor responses and progression-free survival (PFS) by immune-related response evaluation criteria (irRECIST). Patients will be randomized into three arms: ADXS11-001 monotherapy, MEDI4736 monotherapy, or ADXS-HPV in combination with MEDI4736.

"We are pleased to have received FDA acceptance for both of our IND applications to evaluate two of our investigational Lm-LLO immunotherapies in combination with two novel checkpoint inhibitors," stated Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "Since entering into the clinical trial collaboration with MedImmune in July, we have progressed rapidly from initial agreement to IND, and we now expect to initiate the ADXS-HPV plus MEDI4736 study by early 2015."

ADXS-HPV and MEDI4736 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 checkpoint inhibitor, such as MEDI4736, could enhance the anti-tumor immune response.

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 over expressing cancers. Her2 is over expressed 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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