
**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): **June 1, 2015**

ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-28489
(Commission
File Number)

02-0563870
(IRS Employer
Identification No.)

**305 College Road East
Princeton, New Jersey, 08540**
(Address of Principal Executive Offices)

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

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:

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

A copy of the press release of Advaxis, Inc. (the "Company") dated June 1, 2015 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 June 1, 2015, the Company announced that the U.S. Food and Drug Administration had cleared the Investigational New Drug application to conduct a Phase 2 clinical study of ADXS-HPV (ADXS11-001) alone or in combination with Incyte Corporation's investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), for the treatment of Stage I-IIIb human papillomavirus (HPV)-associated cervical cancer. The proposed Phase 2 protocol is designed as a multicenter, open-label, preoperative window-study designed to evaluate the safety and efficacy of ADXS-HPV as monotherapy and in combination with epacadostat in approximately 30 patients with Stage I-IIIb HPV-associated cervical cancer. The results will be used to determine whether further clinical development of this combination is warranted.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as a part of this report

99.1 Press Release dated June 1, 2015.

SIGNATURES

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

ADVAXIS, INC.
(Registrant)

By: /s/ Daniel J. O'Connor

Daniel J. O'Connor

President and Chief Executive Officer

Date: June 2, 2015

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release dated June 1, 2015.

ADVAXIS

IMMUNOTHERAPIES™

Advaxis Announces FDA Clearance of Investigational New Drug Application for Phase 2 Study of ADXS-HPV and Incyte's epacadostat for the Treatment of HPV-Associated Early Stage Cervical Cancer

PRINCETON, NJ, June 1, 2015 — **Advaxis, Inc.** (NASDAQ: ADXS), a clinical-stage biotechnology company developing cancer immunotherapies, today announced the clearance of the Investigational New Drug (IND) application by the United States Food and Drug Administration (FDA) to conduct a Phase 2 study of ADXS-HPV (ADXS11-001) alone or in combination with Incyte Corporation's (NASDAQ: INCY) investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) inhibitor, epacadostat (INCB24360), for the treatment of Stage I-IIIb human papillomavirus (HPV)-associated cervical cancer.

In February 2015, Advaxis and Incyte entered into a non-exclusive clinical trial collaboration agreement to evaluate the combination of ADXS-HPV with epacadostat for the treatment of cervical cancer. The proposed Phase 2 protocol is designed as a multicenter, open-label, preoperative window-study designed to evaluate the safety and efficacy of ADXS-HPV as monotherapy and in combination with epacadostat in approximately 30 patients with Stage I-IIIb human papillomavirus (HPV)-associated cervical cancer. The results will be used to determine whether further clinical development of this combination is warranted.

"The FDA clearance of the ADXS-HPV plus epacadostat IND for HPV-associated early stage cervical cancer adds to Advaxis's rapidly advancing pipeline in cervical cancer," stated Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "Additionally, the acceptance of this IND strengthens our pipeline of combination studies involving our *Lm-LLO* platform and aligns our technology with another potentially best-in-class immunotherapy technology. We look forward to the initiation of this study with Incyte."

"We are very pleased that the IND for this Phase 2 study has been cleared by the FDA," said Rich Levy, MD, Chief Drug Development Officer at Incyte. "Epacadostat is currently in multiple combination proof-of-concept trials with immune checkpoint inhibitors, and this new study may provide us with important translational data for epacadostat in combination with an immunotherapeutic vaccine."

About epacadostat (INCB24360)

Indoleamine 2,3-dioxygenase 1 (IDO1) is an immunosuppressive enzyme that has been shown to induce regulatory T cell generation and activation, and allow tumors to escape immune surveillance. Epacadostat is an orally bioavailable small molecule inhibitor of IDO1 that has nanomolar potency in both biochemical and cellular assays, and has demonstrated potent activity in enhancing T lymphocyte, dendritic cell and natural killer cell responses in vitro, with a high degree of selectivity. Epacadostat has shown proof-of-concept clinical data in patients with unresectable or metastatic melanoma in combination with the CTLA-4 inhibitor ipilimumab, and is currently in four proof-of-concept clinical trials with PD-1 and PD-L1 immune checkpoint inhibitors in a variety of cancer types.

About ADXS-HPV

ADXS-HPV is Advaxis's lead *Lm*-LLO 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 completed Phase 2 study, ADXS-HPV demonstrated prolonged survival, objective tumor responses, and a manageable safety profile alone or in combination with chemotherapy, supporting further development of this *Lm*-LLO immunotherapy. The U.S. Food and Drug Administration granted an orphan drug designation for ADXS-HPV for HPV-associated Stage II-IV cervical cancer, head and neck cancer, and for anal cancer.

About Incyte Corporation

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics, primarily for oncology. For additional information on Incyte, please visit the Company's website at www.incyte.com.

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^(R) (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 about our cancer immunotherapies please visit www.advaxis.com.

Advaxis Forward-Looking Statements

This news release contains forward-looking statements of Advaxis, including, but not limited to: statements regarding Advaxis's ability to develop the next generation of cancer immunotherapies; and the safety and efficacy of Advaxis's proprietary immunotherapy, ADXS-HPV. 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, 2014, 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.

Incyte Forward-Looking Statements

Except for the historical information set forth herein regarding Incyte, the matters set forth in this press release regarding Incyte contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: the potential efficacy, safety and therapeutic value of Incyte's epacadostat and its potential for treatment of Stage I-IIIb HPV-associated cervical cancer in combination with Advaxis's ADXS-HPV compound; the design, safety, potential results and potential timing of the phase 2 study of ADXS-HPV in combination with epacadostat; and whether data from this phase 2 study will provide Incyte with translational data for epacadostat in combination with an immunotherapeutic vaccine.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to the efficacy or safety of epacadostat or Incyte's other products and product candidates, the results of further research and development, the risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, other market or economic factors, competitive and technological advances, and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended March 31, 2015. Incyte disclaims any intent or obligation to update these forward-looking statements.

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

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