
**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): **July 6, 2016**

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 July 6, 2016 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 July 6, 2016, the Company announced that it reached an agreement with the U.S. Food and Drug Administration (the “FDA”), under the Special Protocol Assessment (the “SPA”) process, for the Phase 3 AIM2CERV trial evaluating the Company’s lead *Lm* immunotherapy candidate, axalimogene filolisbac (“AXAL”), in patients with high-risk, locally advanced cervical cancer. AIM2CERV is a multinational, randomized, controlled clinical trial.

A successfully concluded SPA provides an agreement with FDA’s review division that a pivotal trial design, conduct, and planning analysis adequately address the scientific and regulatory objectives in support of a regulatory submission for drug approval. Final marketing approval depends upon the efficacy results, safety profile and an evaluation of the risk/benefit of treatment demonstrated in the Phase 3 clinical trial.

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 July 6, 2016.

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: July 6, 2016

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release dated July 6, 2016.



FDA Grants Special Protocol Assessment to Advaxis' Phase 3 Study of AXAL in Patients with Cervical Cancer

Enrollment to commence this summer

PRINCETON, N.J., July 6, 2016 – Advaxis, Inc. (NASDAQ:ADXS), a clinical stage biotechnology company developing cancer immunotherapies, today announced that it reached an agreement with the U.S. Food and Drug Administration (FDA), under the Special Protocol Assessment (SPA) process, for the Phase 3 AIM2CERV trial evaluating the Company's lead *Lm* immunotherapy candidate, axalimogene filolisbac (AXAL), in patients with high-risk, locally advanced cervical cancer (HRLACC). AIM2CERV is a multinational, randomized, controlled clinical trial conducted in collaboration with The GOG Foundation, Inc. Trial enrollment will commence this summer.

A successfully concluded SPA provides a binding agreement with FDA's review division that a pivotal trial design, conduct, and planned analysis adequately address the scientific and regulatory objectives in support of a regulatory submission for drug approval. Final marketing approval depends upon the efficacy results, safety profile and an evaluation of the risk/benefit of treatment demonstrated in the Phase 3 clinical trial.

In the 10-year period ending in 2013, only 25 percent of the requests for a SPA of oncology trials concluded with an FDA agreement.

"Receiving a SPA for the AIM2CERV trial is a testament to the promising AXAL results we have seen in cervical cancer patients," said Bradley Monk, M.D., Professor and Director of the Division of Gynecologic Oncology at Creighton University School of Medicine at St. Joseph's Hospital and Medical Center and Lead Cervical Cancer Advisor to Advaxis. "The AIM2CERV trial will be a critical step in demonstrating that AXAL can be successful as an immunotherapy, with the trial's goal to cure more women, and prevent disease recurrence."

"Collaborative discussions with the FDA led to a positive outcome with a SPA that clearly defines the clinical and regulatory pathway for the approval and commercialization of AXAL for the treatment of patients with HRLACC," said Daniel J. O'Connor, President and Chief Executive Officer. "Obtaining a SPA for the AIM2CERV Phase 3 protocol was our number one priority this year and it has now been achieved."

AXAL is a live attenuated *Listeria monocytogenes* bacteria bioengineered to target HPV-associated cancer. The primary objective of AIM2CERV is to compare the disease free survival of AXAL to placebo administered in the adjuvant setting following concurrent chemotherapy and radiotherapy (CCRT) administered with curative intent to patients with HRLACC. Secondary endpoints include examining overall survival and safety.

About Special Protocol Assessment

A SPA is an agreement with the FDA that the proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support the submission of an application for FDA's determination of regulatory approval. For further information regarding the SPA process, please visit the FDA website, www.fda.gov.

About Cervical Cancer

Cervical cancer is the third most common malignancy in women worldwide. In the United States, nearly 13,000 new cases are diagnosed, and approximately 4,100 deaths are reported due to cervical cancer. According to the WHO/ICO Information Centre on HPV and Cervical Cancer, about 3.9 percent of women in the United States are estimated to harbor high-risk cervical HPV infection at a given time, and 71.7 percent of invasive cervical cancers are attributed to high-risk HPV strains.

About Axalimogene Filolisbac

Axalimogene filolisbac (AXAL) is Advaxis' lead *Lm* Technology™ immunotherapy candidate for the treatment of patients with HPV-associated cancers and is in clinical trials for three potential indications: invasive cervical cancer, head and neck cancer, and anal cancer. In a completed randomized Phase 2 study in recurrent/refractory cervical cancer, AXAL showed apparent prolonged survival, objective tumor responses, and a manageable safety profile alone or in combination with chemotherapy, supporting further development of the Company's *Lm* Technology™. AXAL has Orphan Drug Designation in the U.S. for the treatment of anal cancer.

About GOG Foundation, Inc.

The GOG Foundation, Inc. (GOG Foundation) is an independent international non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials development, execution, analysis and distribution of results. Continuous evaluation of the GOG Foundation's processes is utilized in order to constantly improve the quality of patient care. The GOG Foundation conducts clinical trials for patients with a variety of gynecologic malignancies, including cancers that arise from the ovaries, uterus, cervix, vagina, and vulva. The GOG Foundation is a separate entity from the National Clinical Trials Network groups that are funded by the National Cancer Institute.

About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary *Lm* Technology™. The *Lm* Technology™, using bioengineered live attenuated *Listeria monocytogenes* (*Lm*) bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancer-fighting T cells directed against cancer antigens and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis' lead *Lm* Technology™ immunotherapy, axalimogene filolisbac (AXAL), targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three potential indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The U.S. Food and Drug Administration (FDA) has granted AXAL orphan drug designation for each of these three clinical settings. Advaxis has two additional immunotherapy products in human clinical development: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2-expressing solid tumors.

For additional information on Advaxis, visit www.advaxis.com and connect on [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#) and [Google+](#).

Advaxis Forward-Looking Statement

This media statement contains forward-looking statements, including, but not limited to: statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies; and the safety and efficacy of Advaxis' proprietary immunotherapies. These forward-looking statements are subject to a number of risks, including the risk factors set forth from time to time in Advaxis' SEC filings, including but not limited to its report on Form 10-K for the fiscal year ended October 31, 2015, 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.

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