



Advaxis Announces Publication of Phase 2 Results Evaluating Axalimogene Filolisbac for the Treatment of Recurrent Metastatic Cervical Cancer in the International Journal of Gynecological Cancer

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Peer-reviewed published article shows treatment with axalimogene filolisbac resulted in an overall 12-month survival rate of approximately 35%

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, announces that data from an earlier Phase 2 clinical study of axalimogene filolisbac (ADXS11-001) as a treatment for persistent or recurrent metastatic (squamous or non-squamous cell) carcinoma of the cervix (PRmCC) was accepted for publication in the May edition of peer-reviewed *International Journal of Gynecological Cancer*. The article is titled, "A Randomized Phase 2 Study of ADXS11-001 *Listeria monocytogenes*-Listeriolysin O Immunotherapy With or Without Cisplatin in Treatment of Advanced Cervical Cancer."

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This multicenter, randomized Phase 2 study conducted in India compared axalimogene filolisbac as a monotherapy with axalimogene filolisbac in combination with chemotherapy (cisplatin) in 110 patients with PRmCC. The primary endpoint was overall survival (OS), and patients were followed every three months for up to 18 months for tumor response and survival status.

The 12-month OS rate was approximately 35% (n = 38/109). Median OS was 8.28 months in the axalimogene filolisbac monotherapy arm and 8.78 months in the combination arm (p=non-significant). Overall, approximately 25% of patients (n = 27/109) reached the 18-month survival milestone. There were 3 confirmed complete responses (RECIST 1.1) and 1 confirmed partial response.

The most commonly reported treatment related adverse events were mild-to-moderate and related to cytokine release symptoms (chills, fever, vomiting and nausea), consistent with the observed safety profile in later clinical studies.

"These compelling results led to the conduct of the Phase 2 GOG-0265 study, where the 12-month OS rate with axalimogene filolisbac was subsequently replicated in a more heavily-pretreated PRmCC population in the U.S. In addition, these data are supportive of our upcoming planned submission of a conditional Marketing Authorization Application with the European Medicines Agency for axalimogene filolisbac for the treatment for metastatic cervical cancer, and give us added confidence in our immunotherapy as a treatment for these patients with limited treatment options," stated Anthony Lombardo, interim Chief Executive Officer of Advaxis.

About Axalimogene Filolisbac

Axalimogene filolisbac is a targeted *Listeria monocytogenes (Lm)*-based immunotherapy that attacks HPV-associated cancers by altering a live strain of *Lm* bacteria to generate cancer-fighting T cells against cancer antigens while neutralizing the tumor's natural protections that guard the tumor microenvironment from immunologic attack. In a Phase 2 trial evaluating axalimogene filolisbac for the treatment of PRmCC, the product candidate showed a 12-month overall survival rate of 38% observed in 50 patients in the trial. This is a 55% improvement over an expected, model-predicted, 12-month survival rate of 24.5%.

Axalimogene filolisbac has achieved multiple regulatory milestones, including classification as an EMA advanced therapy-medicinal product for the treatment of cervical cancer, receipt of the U.S. Food and Drug Administration (FDA) Fast Track Designation as an adjuvant therapy for treating high-risk, locally advanced cervical cancer (HRLACC), receipt of a Special Protocol Assessment agreement with the FDA for the Phase 3 AIM2CERV trial, and orphan drug designations in three HPV-associated indications (PRmCC, head and neck, and anal cancer).

About Advaxis, Inc.

Advaxis, Inc. is a late-stage biotechnology company focused on the discovery, development and commercialization of proprietary *Lm*-based antigen delivery products. These immunotherapies are based on a platform technology that utilizes live attenuated *Listeria monocytogenes (Lm)* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy and are designed to access and direct antigen presenting cells to stimulate anti-tumor T-cell immunity, activate the immune system with the equivalent of multiple adjuvants and simultaneously reduce tumor protection in the tumor microenvironment to enable the T cells to eliminate tumors. Advaxis has four franchises in various stages of clinical and near-clinical development: HPV-associated cancers, individualized neoantigen immunotherapy, cancer-specific hotspot mutation immunotherapies and prostate cancer.

To learn more about Advaxis, visit www.advaxis.com and connect on [Twitter](#), [LinkedIn](#), [Facebook](#), and [YouTube](#).

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements regarding Advaxis' ability to develop and commercialize 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, 2017, which is available at www.sec.gov.

Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

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