Advaxis Submits Conditional Marketing Authorization Application for Axalimogene Filolisbac for the Second-Line Treatment of Metastatic Cervical Cancer in European Union

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- Advaxis reaches important regulatory milestone for axalimogene filolisbac with submission of Conditional MAA to treat metastatic cervical cancer in patients who progress beyond first-line therapy
- The MAA submission is centered around the encouraging results from the GOG-0265 study
- Each year, more than 24,000 women in Europe die from metastatic cervical cancer[1]

PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of cancer immunotherapies has submitted a conditional Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the company's lead *Lm* Technology product candidate, axalimogene filolisbac, for the treatment of adult women who progress beyond first-line therapy of persistent, recurrent or metastatic carcinoma of the cervix (PRmCC).

"Despite the availability of preventative measures, metastatic cervical cancer continues to be a major public health concern associated with high mortality rates within Europe"

"The submission of the MAA represents a significant regulatory milestone for Advaxis and the ongoing development of our *Lm* Technology Platform," stated Anthony Lombardo, interim Chief Executive Officer of Advaxis. "The submission is based on the improvement in 12-month survival rates observed in the Phase 2 GOG-0265 study. We feel that these data support axalimogene filolisbac as a potential therapeutic option for patients living with PRmCC who are in desperate need of new treatment options beyond first-line therapy," added Lombardo.

The MAA submission is built around data from the GOG-0265 study which examined overall survival rates in 50 women and showed a 12-month overall survival rate (primary efficacy endpoint) of 38% (n=19/50) in women with PRmCC, representing a 55% improvement over an expected, model-predicted,12-month survival rate of 24.5%.[2] More than 50% of treated women in this study had previously received multiple prior lines of therapy including treatment with bevacizumab and subsequently experienced progression of their disease.[2]

"Despite the availability of preventative measures, metastatic cervical cancer continues to be a major public health concern associated with high mortality rates within Europe," said Mansoor Mirza, M.D., Chief Oncologist at the Copenhagen University Hospital in Denmark and Medical Director of the Nordic Society of Gynaecological Oncology (NSGO). "The results from GOG-0265 are encouraging and could represent a meaningful step forward in the care of women suffering from PRmCC, which has seen very little innovation in almost 30 years."

In the GOG-0256 study, axalimogene filolisbac was generally well-tolerated with mostly Grade 1 and 2 flu-like adverse events associated with cytokine release which were managed with standard medical care. This safety profile is consistent with the ongoing clinical experience of axalimogene filolisbac across all clinical trials.

The EMA will evaluate the totality of the data, including results from GOG-0265 as well as supportive data from other clinical trials evaluating axalimogene filolisbac. In parallel with the MAA review process, the company will continue assessing partnership opportunities for the potential commercialization of axalimogene filolisbac in Europe.

The company has also decided to align and simplify its strategy by using axalimogene filolisbac exclusively in all ongoing and planned HPV-related cancer clinical trials, including the upcoming ADVANCE trial, previously planned with ADXS-DUAL. The strategic decision to harmonize all trials to axalimogene filolisbac is based on its clinical profile to date in over 250 patients, and its demonstration of similar activity in both HPV 16 and 18 subtypes in GOG-0265. The company believes that harmonizing to a single product candidate for all HPV-related programs will streamline developmental, regulatory and commercialization strategies.

About Axalimogene Filolisbac

Axalimogene filolisbac is a targeted *Listeria monocytogenes (Lm)*-based investigational 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.

Axalimogene filolisbac has already 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). In addition, axalimogene filolisbac will be studied in combination with nivolumab in the ADVANCE trial, a potential registrational trial for patients with PRmCC, which is planned to begin in 2018.

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.

References

1. Ferlay J, et al. *Eur J Cancer* 2013;49:1374-403.
2. Huh W, et al. Presented at the Annual Meeting on Women's Cancer. March 12-15, 2017.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements regarding Advaxis' ability and strategies to develop and commercialize cancer immunotherapies, timing of planned clinical trials and regulatory milestones, potential partnership opportunities 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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