Advaxis Provides Update on MAA Filing and ADXS-HOT Program

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PRINCETON, N.J.--(BUSINESS WIRE)--Advaxis, Inc. (NASDAQ:ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, today announced a clinical update, as follows:

- Plans to withdraw its Conditional Marketing Authorization Application (MAA) in the European Union for axalimogene filolisbac to treat metastatic cervical cancer in patients who progress beyond first-line therapy
- Submission of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to study its first ADXS-HOT drug candidate for the treatment of non-small cell lung cancer (NSCLC)
- Selection of prostate cancer as the second cancer type within its ADXS-HOT program to move towards the clinic, with an IND filing anticipated within the next six months

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Advaxis' regulatory action in Europe is based on European Medicines Agency (EMA) feedback following its initial review indicating the application will likely need additional data to support a conditional approval. The February 2018 submission included data from the Phase 2 GOG-0265 study in 50 patients, which showed a 12-month overall survival rate (primary efficacy endpoint) of 38% (n=19/50) in women with persistent, recurrent or metastatic carcinoma of the cervix, representing a 55% improvement over a model-predicted 12-month overall survival rate of 24.5%. As more than half of the women treated in this study had received multiple prior lines of therapy including with bevacizumab treatment, the 38% 12-month overall survival rate was unprecedented when compared against historical data.

The Company continues to believe that the results from the GOG-0265 study are clinically meaningful and provide proof-of-concept that axalimogene filolisbac demonstrated clinical activity in metastatic cervical cancer. The withdrawal of this application does not impact the ongoing clinical trials of axalimogene filolisbac. As previously communicated, Advaxis is actively seeking a partner to support the late-stage cervical cancer program.

The Company also announced that it has submitted an IND with the FDA to study its first product candidate from the ADXS-HOT program, ADXS-503, for the treatment of NSCLC. Upon allowance of the IND for ADXS-503, the Company plans to initiate an open-label, Phase 1/2 clinical trial. Further details of the study design will be provided after the IND is allowed. Advaxis expects the first patient will be dosed by the end of 2018. Additionally, Advaxis anticipates submitting a second IND from the ADXS-HOT program within the next six months, for its drug candidate referred to as ADXS-504, for the treatment of prostate cancer.

"We are pleased to submit the ADXS-503 IND and look forward to advancing our ADXS-HOT NSCLC drug candidate into the clinic. Our ADXS-HOT program leverages both the benefits of our *Lm* technology platform, which has shown clinical activity in earlier generation drug candidates, and the use of neoantigen targets. We believe that neoantigen-based treatments have the potential to transform cancer care, and the ADXS-HOT program allows us to develop cancer-type specific therapies across a broad range of tumor types," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "With our announcement today of plans for a second IND submission for an ADXS-HOT construct in prostate cancer, we feel confident we can reach proof-of-concept for these off-the-shelf therapeutics in a relatively rapid and cost-effective manner."

Advaxis affirms plans to submit a total of four INDs for drug candidates from its ADXS-HOT program by the end of calendar year 2019, resulting in Phase 1/2 studies evaluating safety, immune responses and preliminary clinical activity of four different constructs addressing four different tumor types. Beyond NSCLC and prostate cancer, the next two ADXS-HOT product candidates will be selected from breast, colorectal, bladder, ovarian and head and neck cancers.

About ADXS-HOT

ADXS-HOT is a program that leverages the Company's proprietary *Lm* technology to target hotspot mutations that commonly occur in specific cancer types. ADXS-HOT drug candidates are designed to target acquired shared or "public" mutations in tumor driver genes along with other cancer-testes and oncofetal tumor-associated antigens that also commonly occur in specific cancer types. Although ADXS-HOT drug candidates have not yet been tested in patients, each product candidate has been designed to potentially treat all patients with a specific cancer type, without the need for pre-treatment biomarker testing, biopsy, DNA sequencing or diagnostic testing.

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 preclinical development: HPV-associated cancers, neoantigen therapy, hotspot/ cancer antigens and prostate cancer.

To learn more about Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook and YouTube.

Advaxis Forward-Looking Statement

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the success and timing of our clinical trials, including patient accrual; our ability to release the clinical hold and reduce the impact to our trials; our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing; our ability to obtain the appropriate labeling of our products under any regulatory approval; our plans to develop and commercialize our products; the successful development and implementation of our sales and marketing campaigns; the size and growth of the potential markets for our product candidates and our ability to serve those markets; our ability to successfully compete in the potential markets for our product candidates, if commercialized; regulatory developments in the United States and other countries; the rate and degree of market acceptance of any of our product candidates; new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements; market conditions in the pharmaceutical and biotechnology sectors; our available cash; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our ability to obtain additional funding; our ability to obtain and maintain intellectual property protection for our product candidates; the success and timing of our preclinical studies including IND-enabling studies; the timing of our IND submissions, the ability of our product candidates to successfully perform in clinical trials; our ability to execute clinical trials; our ability to maintain collaborations; our ability to initiate pilot studies and clinical trials, enroll our trials, obtain and maintain approval of our product candidates; our ability to manufacture and the performance of third-party manufacturers; the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators; our ability to successfully implement our strategy; and other risk factors identified from time to time in our reports filed with the SEC. 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.

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