Advaxis' Phase 3 AIM2CERV Study Placed on Partial Clinical Hold by FDA Related to CMC Requests

January 23, 2019

Enrolled Patients Continue to be Treated

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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 receipt of notification from the U.S. Food and Drug Administration (FDA) that the Company's ongoing Phase 3, randomized, double-blinded, placebo-controlled, pivotal study of axalimogene filolisbac (AXAL) in high-risk, locally advanced cervical cancer (AIM2CERV) has been placed on partial clinical hold. The FDA's recent communication, received late last week, states that the partial hold is related to their requests for additional information pertaining to certain AXAL chemistry, manufacturing and controls (CMC) matters. The Agency did not cite any safety issues related to the trial and all currently enrolled patients will continue to receive treatment, per the trial protocol. However, no new patients can enroll in AIM2CERV until resolution of this partial hold.

"FDA's review of the AXAL Investigational New Drug (IND) application was prompted by our proposal to modify the AIM2CERV trial's analysis plan to include, among other things, allowance for a second formal interim analysis for both safety and efficacy," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "The primary focus of the items raised by the Agency relates to providing additional clarifying details for CMC information previously provided in support of Phase 3 development and which will help support a future Biologics License Application. We have already begun efforts to address the Agency's requests for information and are working to respond as promptly as we can." He concluded, "Our AXAL product has demonstrated a manageable safety profile in the over 400 patients we have dosed to date and we look forward to enrolling new patients in our AIM2CERV trial after FDA agrees that the information we submit is responsive to its requests."

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 subject accrual; our ability to avoid any clinical holds; 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 to resolve FDA's partial clinical hold, the ability to get FDA approval for study amendments, the timing of data read-outs, the ability of our product candidates to successfully perform in clinical trials; our ability to initiate, enroll, and execute pilots and clinical trials; our ability to maintain collaborations; ; 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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