Advaxis Announces Increasing Focus on Neoantigen-Directed Immunotherapies and Closing of Its Phase 3 AIM2CERV Study

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PRINCETON, N.J.--(BUSINESS WIRE)--**Advaxis, Inc.** (NASDAQ:ADXS), a clinical-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, today announced that it is increasing its focus on neoantigen-directed immunotherapies and closing the AIM2CERV Phase 3 clinical trial with axalimogene filolisbac (AXAL) in high-risk locally advanced cervical cancer. Advaxis intends to continue to support the clinical development of AXAL, its single-antigen construct, in other HPV-related cancers while redirecting resources towards advancing its neoantigen-directed programs. Specifically, the company plans to continue developing ADXS-NEO, currently in a Phase 1 clinical trial, in patients with several types of advanced or metastatic solid tumors including melanoma, lung, colorectal, head and neck and bladder cancers, and ADXS-HOT, currently in a Phase 1/2 clinical trial, for non-small cell lung cancer. The company anticipates advancing additional drug constructs from its ADXS-HOT program into the clinic over the next 18 months.

"We remain firmly committed to our Lm Technology™ platform, including our personalized and off-the-shelf approaches for neoantigen-directed therapies, and the development of AXAL against HPV-related cancers"

“We remain firmly committed to our *Lm* Technology™ platform, including our personalized and off-the-shelf approaches for neoantigen-directed therapies, and the development of AXAL against HPV-related cancers,” said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. “While closing the AIM2CERV trial was a difficult decision due to the efforts of many individuals including the investigators and patients, the delays we incurred as a result of the recent FDA partial clinical hold and the estimated cost and time to completion for AIM2CERV led us to believe the best path forward for the company is to focus on our neoantigen programs. We believe this increased focus will enable a quicker and more cost-effective approach to demonstrate the strength and versatility of our *Lm* platform, thereby enhancing shareholder value.”

The estimated remaining cost to complete the AIM2CERV trial ranges from $80 million to $90 million, and initial efficacy data is not anticipated for at least three years. Therefore, results from the clinical trial were not the basis for the decision to close the study, nor was safety as the trial recently underwent its third Independent Data Monitoring Committee (IDMC) review with no safety issues noted. The company plans to unblind the AIM2CERV clinical data generated to date and anticipates submitting these data for publication. In addition, Advaxis will continue to pursue monetization opportunities for AXAL.

“The emerging data from our neoantigen programs look very promising, and therefore these programs merit an increased focus of the company’s resources,” stated Mr. Berlin. “With this redirection of resources to our neoantigen programs, we anticipate our cash usage for the next 12 months will be in the range of $33 million to $37 million, which includes $8 million to $9 million in non-recurring costs associated with prior AXAL studies including AIM2CERV. This reduction in our cash burn is a significant improvement over the past several years and also betters the goal we set of $45 million at the beginning of our fiscal year 2019.” He concluded, “We believe these changes will enable us to pursue a leadership position in the neoantigen field by building upon the early and exciting data from our ADXS-NEO and ADXS-HOT programs.”

About Advaxis, Inc.

Advaxis, Inc. is a clinical-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 T cells to eliminate tumors. Advaxis has four programs in various stages of development: ADXS-NEO, a personalized neoantigen-directed therapy in principle for any solid tumor; ADXS-503 for non-small cell lung cancer, from its ADXS-HOT off-the-shelf neoantigen-directed program, ADXS-PSA for prostate cancer and ADXS-HPV for HPV-associated cancers.

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 impact of the discontinuation on relationships related to the AIM2CERV Study; 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, including to support current and planned clinical activities; 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; our 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 our existing 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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