Advaxis Announces Business And Pipeline Update

October 24, 2019

Cash balance anticipated to extend into 2021

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 the following updates to its clinical programs.

"At Advaxis, we are committed to unlocking the potential benefits of our Lm TechnologyTM platform to improve outcomes for cancer patients"

ADXS-HOT: Cancer Type-Focused Hotspot/Off-the-Shelf Neoantigen-Directed Therapies – The ADXS-HOT program is a cancer-type specific immunotherapy that targets hotspot mutations, cancer testis antigens and oncofetal antigens. The first drug candidate from this program, ADXS-503, is designed to target most types of non-small cell lung cancer (NSCLC) and is currently being evaluated in a Phase 1/2 clinical trial, enrolling patients at five sites. The first dose level with monotherapy in Part A, (1 $X10^8$ CFU) has been completed and the Part A-second dose level (5 $X10^8$ CFU) and Part B in combination with a checkpoint inhibitor are currently open to enrollment. The Company plans to report immune response data from Part A monotherapy by the end of 2019.

Advaxis intends to file an investigational new drug (IND) application for its ADXS-504 (HOT Prostate) program by the end of 2019 and has completed manufacturing of its ADXS-506 (HOT Bladder) construct, enabling the construct to enter clinical development in the future.

ADXS-NEO: Personalized, Neoantigen-Directed Therapy – ADXS-NEO is a personalized neoantigen-directed immunotherapy designed to activate a patient's immune system in a range of cancers. The company has enrolled its last patient in Part A, the monotherapy portion of its Phase 1 dose-escalation study, which was planned to be followed by Part B, dose escalation in combination with a checkpoint inhibitor. Data previously released on the ADXS-NEO program demonstrated the tolerability, to date, of this construct at 1 $X10^8$ CFU and indicated signals of a robust anti-tumor immune response. Additionally, the signals of anti-tumor immune responses included a strong CD8+ T cell reactivity generated against personalized as well as hotspot mutations, which provided valuable insight for the company's HOT constructs. As the company moves into the combination arm of its HOT NSCLC study, it has determined that the information gained from the HOT NSCLC study will provide an opportunity to demonstrate the effects of its neoantigen constructs used in combination with a checkpoint inhibitor, thereby minimizing the benefits of entering Part B of the ADXS-NEO study. Therefore, the company has elected to not continue into Part B of the ADXS-NEO study in combination with a checkpoint inhibitor. The company plans to continue to dose the last patient enrolled in Part A in accordance with the protocol and cease further enrollment. The company intends to publish the final results from Part A of the ADXS-NEO study at a future medical meeting and close its ADXS-NEO program IND thereafter.

ADXS-PSA: Prostate Cancer – The company recently reported updated data for its Phase 1/2 KEYNOTE-046 study of ADXS-PSA, alone and in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, for unselected and advanced patients with metastatic castration-resistant prostate cancer ("mCRPC").

The median overall survival for this patient population in the combination arm was 33.6 months (95% CI, range 15.4-33.6 months). These results are encouraging as the patient population in the combination arm (n=37) had high Gleason scores (9), MSI-high negative status, visceral metastatsis in 30%, prior chemotherapy in 57% and one to two prior next generation hormonal agents in >80% of patients. The company is in discussions with potential partners regarding opportunities to expand or advance this mCRPC program.

ADXS-HPV: A xalimogene filolisbac (AXAL):

- *Cervical Cancer* – As announced in July, the company is in the process of winding down its Phase 3 AIM2CERV study evaluating AXAL for the treatment of patients with high-risk, locally advanced cervical cancer. As a result of the closure of this study, the company will be unblinding the data and anticipates reporting the results of the 110 patients that had been dosed with AXAL in this study by the end of 2019.

- *Lung Cancer* – Global BioPharma, Inc. (GBP), the company's partner in certain Asian and African territories, anticipates initiating its Phase 2, open-label controlled trial in HPV-associated NSCLC in patients following first-line chemotherapy by the end of 2019. The study will be assessing the effects of AXAL when combined with pemetrexed in patients with HPV+ NSCLC, following first line induction therapy.

"At Advaxis, we are committed to unlocking the potential benefits of our *Lm* Technology^{TM} platform to improve outcomes for cancer patients," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "The NEO trial has provided us with valuable proof-of-mechanism data for our HOT program, with clinical signals of generation of CD8+ T cells against hotspot mutations, antigen spreading and stable disease in two patients. While discontinuing the NEO program was a difficult decision, we ultimately believe that the off-the-shelf approach of our HOT program will allow us to more effectively evaluate our platform in a broad patient population with a more economical, commercial-ready manufacturing process while also extending our cash runway until early 2021. I want to personally thank the patients, employees and collaborating physicians who participated in or assisted with this study." He concluded, "The strength of our technology and pipeline leave us well positioned to explore a variety of strategic opportunities heading into 2020."

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.

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

Forward-Looking Statements

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 and quickly resolve 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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