

Advaxis and SELLAS Announce Licensing Agreement for Development of WT1 Antigen-Targeting Immunotherapy

PRINCETON, N.J., and HAMILTON, Bermuda, Feb. 27, 2017 (GLOBE NEWSWIRE) -- Advaxis, Inc. (NASDAQ:ADXS) and SELLAS Life Sciences Group, both late-stage biopharmaceutical companies focused on developing cancer immunotherapies, today announced that Advaxis has granted SELLAS a license to develop a novel cancer immunotherapy agent using Advaxis' proprietary *Lm*-based antigen delivery technology with SELLAS' patented WT1 targeted heteroclitic peptide antigen mixture (galinpepimut-S).

Advaxis' proprietary technology generates innate immune stimulation, alongside potent and sustained T-cell responses. When combined with SELLAS' WT1 antigens, this has the potential to precisely direct an immune response, yielding improved clinical activity against many cancer types that express WT1. SELLAS' future clinical studies will investigate this capability in the presence of measurable residual or recurrent disease.

Galinpepimut-S has demonstrated positive phase 2 clinical results in acute myeloid leukemia and malignant pleural mesothelioma and positive early clinical data in multiple myeloma. It has been shown to induce strong immune responses (CD4+/CD8+) against the WT1 antigen and to access a broad range of HLA types. Advaxis' *Lm*-based antigen delivery technology has demonstrated the potential to induce an enhanced innate immune stimulation and generate specific T cells while reducing immune tolerance in the tumor microenvironment.

Under the terms of the collaboration, Advaxis will conduct all pre-clinical activities required for an IND filing. Thereafter, SELLAS will be responsible for all clinical development and commercial activities. Advaxis will receive future payments of up to \$358 million from SELLAS if certain development, regulatory, and commercial milestones are met. Following any regulatory approval of the product candidate emanating from this particular program, SELLAS has agreed to pay Advaxis single-digit to low double-digit royalties based on worldwide net sales upon commercialization.

"WT1 is one of the most widely expressed cancer antigens and was named a top target for cancer immunotherapy by the National Cancer Institute," said Daniel J. O'Connor, President and Chief Executive Officer of Advaxis. "SELLAS' proprietary galinpepimut-S therapy has already demonstrated clinical benefit and a strong immune response against WT1 expressing cancer cells. We believe that the use of our proprietary *Lm*-based antigen delivery technology with SELLAS' proprietary technology could result in a very compelling WT1-targeted cancer immunotherapy."

Angelos Stergiou, MD, ScD h.c., Vice Chairman and Chief Executive Officer of SELLAS, added: "The combined Advaxis-SELLAS *Lm*-WT1 active immunotherapy candidate has the potential to deliver SELLAS' WT1 proprietary peptide antigens in a novel way, taking advantage of our antigen's ability to target a wide variety of tumors of diverse immune system HLA genotypes. The delivery afforded by the Advaxis technology expands upon our current programs and should substantially enhance the clinical utility seen with galinpepimut-S, and eventually, the cancer immunotherapy armamentarium for a variety of tumors."

About SELLAS Life Sciences Group

SELLAS Life Sciences is a late-stage biopharmaceutical company focused on the development of novel cancer immunotherapies and therapeutics for a broad range of cancer indications. The Company's lead product candidate, galinpepimut-S, is a cancer immunotherapeutic agent licensed from Memorial Sloan Kettering Cancer Center that targets a broad spectrum of hematologic cancers and solid tumor indications. Galinpepimut-S is poised to enter Phase 3 clinical trials in patients with acute myeloid leukemia (AML) and mesothelioma in the first and second half of 2017, respectively. SELLAS recently received orphan drug designations by the US FDA, as well as the EMA, for galinpepimut-S in AML and MPM; as well as Fast Track Designation for AML and mesothelioma (MPM) by the US FDA.

Galinpepimut-S also is in various development phases in multiple myeloma, ovarian cancer, and soon in other indications as monotherapy or in combination with other immuno-oncology agents.

SELLAS was founded in 2012 and is headquartered in Bermuda, with additional offices in New York. For more information, visit www.sellaslifesciences.com.

About SELLAS' WT1 Immunotherapeutic Anti-cancer Treatment, Galinpepimut-S

SELLAS' WT1 immunotherapeutic anti-cancer treatment, galinpepimut-S, which was licensed by Sellas from Memorial Sloan Kettering Cancer Center, is a clinical-stage cancer immunotherapy being developed to target hematologic cancers and solid tumors, including AML, MPM, multiple myeloma, ovarian cancer, and multiple other cancers. The WT1 antigen is a transcription factor that is not generally expressed in normal adult cells, but appears in a large number of cancers, as well as in certain cancer stem cells. WT1 has been ranked by the NCI as the number 1 target for cancer immunotherapy. While WT1 has not been druggable by traditional approaches, it can be targeted by the immune system. Specifically, a number of different peptide sequences from the WT1 antigen have been identified as immunogenic and capable of stimulating cytotoxic T cells that can target and kill WT1-expressing cancer cells. Studies also have shown that WT1 does not provoke tolerization and that patients' T cells can remain reactive to the antigen over time.

Galinpepimut-S, originally developed by MSK and licensed to SELLAS, comprises four modified heteroclitic peptide chains that induce a strong innate immune response (CD4+/CD8+ T cells) against the WT1 antigen. Galinpepimut-S is administered in combination with an adjuvant and an immune modulator to improve the immune response to the target. Based on its mechanism and the accumulating evidence of activity in mid-

stage trials, galinpepimut-S may have the potential to complement currently available therapies by destroying residual tumor cells of cancers in remission and providing ongoing immune surveillance for recurrent tumors. Overall, SELLAS' galinpepimut-S could target over 20 cancers that over-express WT1, many of which are associated with relapse rates of up to 80 percent or more, as seen in patients with AML and MPM.

About Advaxis, Inc.

Located in Princeton, N.J., Advaxis, Inc. is a clinical-stage biotechnology company developing multiple cancer immunotherapies based on its proprietary *Lm* Technology™. The Lm Technology, using bioengineered live attenuated Listeria monocytogenes (Lm) bacteria, is the only known cancer immunotherapy agent shown in preclinical studies to both generate cancer fighting T cells directed against cancer antigens and neutralize Tregs and myeloid-derived suppressor cells (MDSCs) that protect the tumor microenvironment from immunologic attack and contribute to tumor growth. Advaxis' lead Lm Technology immunotherapy, AXAL, targets HPV-associated cancers and is in clinical trials for three potential indications: Phase 3 in invasive cervical cancer, Phase 2 in head and neck cancer, and Phase 2 in anal cancer. The FDA has granted AXAL orphan drug designation for each of these three clinical settings, as well as Fast Track designation for adjuvant therapy for high-risk locally advanced cervical cancer (HRLACC) patients and a Special Protocol Assessment for the Phase 3 AIM2CERV trial in HRLACC patients. AXAL has also been classified as an advanced therapy medicinal product for the treatment of cervical cancer by the European Medicines Agency's Committee for Advanced Therapies. Advaxis has two additional immunotherapy products: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2 expressing solid tumors, in human clinical development. In addition, Advaxis and Amgen are developing ADXS-NEO, a preclinical investigational cancer immunotherapy treatment designed to activate a patient's immune system to respond against the unique mutations, or necepitopes, contained in and identified from each individual patient's tumor, with plans to enter the clinic in 2017.

For additional information on Advaxis, visit http://www.advaxis.com/ and connect on Twitter, LinkedIn, Facebook, and YouTube.

Advaxis Forward-Looking Statement

This press release contains forward-looking statements, including, but not limited to, statements regarding Advaxis' ability to develop the next generation of cancer immunotherapies, and the safety and efficacy of Advaxis' proprietary immunotherapy, axalimogene filolisbac. 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, 2016, which is available at http://www.sec.gov.

Any forward-looking statements set forth in this presentation speak only as of the date of this presentation. 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.

CONTACTS:

Advaxis Inc.:

Ranya Dajani, Vice President, Business Development dajani@advaxis.com
609.250.7559

Media Contact:

JPA Health Communications
David Connolly
dconnolly@jpa.com
617.945.9316

SELLAS Life Sciences Group:

Jonathan Eckard, PhD, Chief Business & Strategy Officer jeckard@sellaslife.com 917.334.7284

Jane Searle jane.searle@mbsvalue.com 212.710.9686



Source: Advaxis