Advaxis Licenses ADXS-HER2 to OS Therapies for Evaluation in the Treatment of Osteosarcoma

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PRINCETON, N.J. and FAIRFAX, Va.--(BUSINESS WIRE)--**Advaxis, Inc.** (NASDAQ: ADXS), a late-stage biotechnology company focused on the discovery, development and commercialization of immunotherapy products, and OS Therapies LLC, a clinical-stage therapeutic company focused on the identification, development and commercialization of treatments for osteosarcoma, today announced that Advaxis has granted a license to OS Therapies for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans.

Osteosarcoma is an aggressive cancerous tumor that forms in bone. Although it is rare, osteosarcoma is the most common type of bone cancer, and is most frequently found in children and young adults. Current treatment options are limited and there have been no new treatment options in more than thirty years.

Under the terms of the license agreement, OS Therapies, in collaboration with the Children's Oncology Group (COG)[1], will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Advaxis will receive an upfront payment, reimbursement for product supply and other support, clinical, regulatory, and sales-based milestone payments, and royalties on future product sales. Additional details of the financial terms have not been disclosed.

"As Advaxis is primarily focused on developing neoantigen-directed therapeutics, this license agreement will allow for the clinical potential of ADXS-HER2 to be explored in osteosarcoma without financial support from Advaxis, building on earlier work performed by us with ADXS-HER2 in a Phase 1 clinical trial."

"Advaxis is pleased to license ADXS-HER2 to OS Therapies for human clinical trials in osteosarcoma. ADXS-HER2, which is already approved in the U.S. for the adjuvant treatment of osteosarcoma in canines, has the potential to provide a new treatment option for human osteosarcoma patients," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis. "As Advaxis is primarily focused on developing neoantigen-directed therapeutics, this license agreement will allow for the clinical potential of ADXS-HER2 to be explored in osteosarcoma without financial support from Advaxis, building on earlier work performed by us with ADXS-HER2 in a Phase 1 clinical trial."

"The OS Therapies mission is to develop and commercialize new therapeutics for the treatment of osteosarcoma, a deadly and extremely underserved pediatric cancer. We are excited about the opportunity to evaluate ADXS-HER2 in this indication, as its clinical profile has shown promise to date," said Paul Romness, Chief Executive Officer of OS Therapies. "Our initial focus is on the most common genetic mutation found in osteosarcoma, and we believe that HER2, and more specifically ADXS-HER2, holds potential to impact the treatment paradigm."

1 The Children's Oncology Group (www.childrensoncologygroup.org), a member of the NCI National Clinical Trials Network (NCTN), is the world's largest organization devoted exclusively to childhood and adolescent cancer research with over 10,000 experts worldwide working in over 200 COG member institutions. COG's mission is to improve the cure rate and outcome for all children with cancer.

About OS Therapies

OS Therapies was founded by concerned parents and friends of children with osteosarcoma, and is innovatively funded by public, non-profit, and private funding. OS Therapies CEO Paul Romness, formerly of Johnson & Johnson, Amgen and Boehringer Ingelheim, has brought together a group of industry veterans including Cerecor CEO Peter Greenleaf, as well as an internationally recognized Osteosarcoma Scientific Advisory Board.

To learn more about OS Therapies, visit www.ostherapies.com.

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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