Amgen And Advaxis Enter Global Cancer Immunotherapies Collaboration

August 2, 2016

Collaboration Will Advance Highly Targeted, Patient-Specific Treatment Approach
Advaxis Will Hold a Teleconference at 9:30 a.m. ET Today

THOUSAND OAKS, Calif. and PRINCETON, N.J., Aug. 2, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Advaxis, Inc. (NASDAQ:ADXS) today announced a global agreement for the development and commercialization of Advaxis' ADXS-NEO, a novel, preclinical investigational cancer immunotherapy treatment that is designed to activate a patient's immune system to respond against the unique mutations, or neoepitopes, contained in and identified from each individual patient's tumor. This collaboration brings together Amgen's development expertise in immuno-oncology with Advaxis' MINE™ (My Immunotherapy Neo-Epitopes) program, which is uniquely positioned to develop a customized approach to cancer treatment.

Under the terms of the agreement, Amgen receives exclusive worldwide rights to develop and commercialize ADXS-NEO. Amgen will make an upfront payment to Advaxis of $40 million and purchase $25 million of Advaxis common stock. Amgen will be fully responsible for funding clinical and commercial activities. Advaxis will lead the clinical development of ADXS-NEO through proof-of-concept, retain manufacturing responsibilities, and receive development, regulatory and sales milestone payments of up to $475 million and potential high single digit to mid-double digit royalty payments based on worldwide sales.

"Amgen's collaboration with Advaxis leverages and enhances our development and commercialization expertise in novel immuno-oncology treatments," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We look forward to partnering with Advaxis to advance this highly targeted and patient-specific treatment option for patients."

"Amgen is a pioneer in the science of using living cells to develop biologic medicines, making them an incredibly strong partner to develop and commercialize Advaxis' MINE," said Daniel J. O'Connor, president and chief executive officer at Advaxis. "With Amgen's resources, worldwide reach and a culture that embraces science and innovation, we are positioned to accelerate the clinical development program for ADXS-NEO to improve the lives of those who suffer from cancer."

The Advaxis *Lm* Technology™ utilizes live attenuated *Listeria monocytogenes* (*Lm)* bioengineered to produce and deliver tumor antigen/adjuvant fusion proteins within antigen presenting cells with the goal of generating strong, T-cell-mediated immunity. For ADXS-NEO, DNA from each patient's primary tumor and/or metastases as well as normal cells, is sequenced and compared to identify mutations in genes coding for potential neo-antigens in the cancer. Advaxis then engineers and manufactures patient-specific *Lm*-LLO (listeriolysin O) vectors capable of immunizing them against neoepitopes exclusive to their cancer. After the ADXS-NEO infusion, neoepitope peptides corresponding to each patient's cancer-associated mutations are delivered directly into their antigen presenting cells by *Lm*-LLO, where they can stimulate cellular immune responses against multiple neoepitopes simultaneously. Clinical trials for ADXS-NEO are expected to begin in 2017.

About MINE™ (My Immunotherapy Neo-Epitopes) / ADXS-NEO
MINE™ (My Immunotherapy Neo-Epitopes) and ADXS-NEO are designed to activate a patient's immune system to respond against the unique mutations, or neoepitopes, contained in each individual patient's tumor. This strategy, using massive parallel sequencing, eliminates the need for predictive algorithms and enables the development of truly personalized immunotherapies that can be manufactured in a manner that is cost-effective and timely for patients.

MINE™ will evaluate the immunologic and anti-tumor activity of this patient tumor-specific, neoepitope-based immunotherapyAdvaxis and Amgen will use learnings from MINE to identify and target neoepitopes using *Lm* Technology™ and later develop patient specific immunotherapy constructs that incorporate the neoepitope sequences identified in the patient's tumor cells. Clinical studies using ADXS-NEO are in development.

Conference Call and Webcast
Advaxis will host a conference call today, Aug. 2, 2016, beginning at 9:30 a.m. ET. Please see below for details.

Conference call numbers:
Domestic/Canada: 888-466-4442
International: 719-325-2480
Conference ID: 2246109
Webcast: http://public.viavid.com/index.php?id=120644

Accessible via the Investor Relations section of Advaxis' website: http://ir.advaxis.com/

A replay of the conference call and webcast will be available beginning approximately one hour after the completion of the call. Access numbers for this replay are 1 (877) 870-5176 (U.S./Canada) and 1 (858) 384-5517 (international); conference ID: 2246109.

About Amgen
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

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, axalimogene filolisbac (AXAL), targets human papillomavirus (HPV)-associated cancers and is in clinical trials for three potential indications: Phase 2 in invasive cervical cancer, Phase 1/2 in head and neck cancer, and Phase 1/2 in anal cancer. The U.S. Food and Drug Administration (FDA) has granted AXAL orphan drug designation for each of these three clinical settings, as well as a Special Protocol Assessment for the Phase 3 AIM2CERV trial in patients with high risk, locally advanced cervical cancer. 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 in human clinical development: ADXS-PSA in prostate cancer and ADXS-HER2 in HER2-expressing solid tumors. Advaxis has received Fast Track Designation for ADXS-HER2 for the treatment of patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma and for AXAL for the treatment of high-risk locally advanced cervical cancer.

For additional information on Advaxis, visit www.advaxis.com and connect on Twitter, LinkedIn, Facebook, YouTube and Google+.

Amgen Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market.

Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing its products and global economic conditions. In addition, sales of Amgen's products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between it and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key manufacturing facilities and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all. Amgen is increasingly dependent on information technology systems, infrastructure and data security. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

Advaxis Forward-Looking Statement
This media statement 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 immunotherapies. 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, 2015, which is available at http://www.sec.gov. Advaxis undertakes no obligation to publicly release the result of any revision to these forward-looking statements, which may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

CONTACTS:

Amgen, Thousand Oaks
Kristen Neese, 805-313-8267 (media)
Trish Hawkins, 805-447-5631 (media)
Arvind Sood, 805-447-1060 (investors)

Advaxis, Inc.
Greg Mayes, Executive Vice President and COO
mayes@advaxis.com
609-250-7515

JPA Health Communications (media)
David Connolly
dconnolly@jpa.com
617-543-3915

Logo - http://photos.prnewswire.com/prnh/20081015/AMGENLOGO