Pfizer and AVANT Enter into Licensing and Development Agreement for Novel Therapeutic Vaccine Candidate for Brain Cancer

Wednesday, April 16, 2008 - 03:07am

(BUSINESS WIRE)--Pfizer, Inc (NYSE: PFE) and AVANT Immunotherapeutics (Nasdaq: AVAN), acting through its wholly-owned subsidiary Celldex Therapeutics, Inc. today announced that they have entered into an agreement under which Pfizer will be granted an exclusive worldwide license to a therapeutic cancer vaccine candidate, CDX-110, in Phase 2 development for the treatment of glioblastoma multiforme (GBM). This agreement also gives Pfizer exclusive rights to the use of EGFRvIII vaccines in other potential indications.

CDX-110, which has been granted both Fast Track and Orphan Drug designations by the U.S. Food and Drug Administration (FDA), is an investigational immunotherapy that targets the tumor-specific molecule EGFRvIII, a functional variant of the epidermal growth factor receptor (EGFR), which is a protein that has been well validated as a target for cancer therapy in certain tumor types.

EGFRvIII is only expressed in cancer cells and not in normal tissue and is a transforming oncogene that can directly contribute to cancer cell growth, as it does in about 40 percent of GBM tumors.

“We are excited about the potential for CDX-110 and intend to partner with AVANT and academic physician-scientists to investigate this novel vaccine candidate with the hope of providing patients and doctors with a new treatment option for this devastating disease,” said Dr. Briggs Morrison, Senior Vice President for Clinical Development at Pfizer.

Under the licensing and development agreement, Pfizer will make an upfront payment to AVANT of $40 million and will make a $10 million equity investment in AVANT. Pfizer will fund all development costs for these programs. AVANT is also eligible to receive milestone payments exceeding $390 million for the successful development and commercialization of CDX-110 and additional EGFRvIII vaccine products, as well as double-digit royalties on any product sales. The agreement is subject to approval under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (as amended) and is expected to close in the second quarter of 2008.

“This partnership advances the therapeutic potential for CDX-110, particularly for patients with GBM. We are very pleased to initiate this relationship to expand our clinical development activities for GBM and toward other cancers,” said Ron Newbold, Ph.D., Senior Vice President of Business Development of AVANT Immunotherapeutics. Una Ryan, CEO of AVANT, added, “We see this as an important milestone for the immunotherapy field, and we look forward to Pfizer’s commitment to help even more cancer patients in the future.”

CDX-110 is designed to induce or enhance the body’s immune responses against EGFRvIII resulting in destruction of tumor cells that express the variant receptor. Early efficacy and safety data from single arm Phase 2 clinical trials of CDX-110 in combination with the current standard treatment for patients with GBM are very encouraging. Progression-free survival and overall survival data from these trials compare very favorably with historical control data. A randomized Phase 2 trial is ongoing.

GBM is the most common and aggressive form of primary brain tumor, with very poor prognosis. There are an estimated 10,000 new cases of GBM annually in the United States, which predominantly affects adults aged 45 to 70. The current standard treatment for patients with GBM includes surgical resection, radiotherapy with concurrent temozolomide and then adjuvant temozolomide chemotherapy.

About Pfizer Inc

Pfizer discovers and develops innovative medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality healthcare and health system support.

About AVANT Immunotherapeutics, Inc.

AVANT Immunotherapeutics and Celldex Therapeutics combined during the first quarter of 2008. AVANT is a NASDAQ-listed company discovering and developing innovative vaccines and targeted immunotherapeutics for the treatment of cancer, infectious and inflammatory diseases. AVANT focuses on the use of tumor-specific targets and human monoclonal antibodies (mAbs) to precisely deliver therapeutic agents through its novel “ targeted immunization” approach. In addition, AVANT is exploiting its access to proprietary human antibody technology for development of therapeutic monoclonal antibodies (mAbs). AVANT’s deep product pipeline consists of products in varying stages of development. Identification of the potential of EGFRvIII in cancer diagnosis, prevention and therapy was based on the collaborative efforts of Dr. Bert Vogelstein and Dr. Albert Wong at Johns Hopkins University and Dr. Darell Bigner at Duke University. Application of this discovery toward the development of the CDX-110 vaccine was further advanced by Dr. John Sampson and his colleagues at the Duke University Brain Tumor Center in collaboration with Dr. Amy Heimberger at the MD Anderson Cancer Center. AVANT also has several product candidates in its development pipeline including:

CDX-1307, a product based on its proprietary APC Targeting Technology™, which is in two Phase 1 clinical trials for patients with advanced pancreatic, bladder, breast and colon cancer; TP10, a complement inhibitor, in development for transplantation and other indications; and Three candidates based on its oral, rapidly-protecting, single-dose and temperature-stable vaccine technology, including combination vaccines for travelers, the military and global health needs.

AVANT has three commercialized products, including Rotarix® (partnered with GSK) for the prevention of rotavirus infection and two human food safety vaccines for reducing salmonella infection in chickens and eggs. Additional information on AVANT Immunotherapeutics, Inc. can be obtained through its web site http://www.avantimmune.com.

For more information on Pfizer or AVANT please visit www.pfizer.com or www.avantimmune.com

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of April 16, 2008. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a license agreement between Pfizer Inc. and AVANT Immunotherapeutics relating to a therapeutic cancer vaccine candidate, CDX-110, and other potential vaccines and the potential benefits thereof. This

information involves substantial risks and uncertainties including, among other things, the satisfaction of the condition to closing the agreement; the uncertainties inherent in research and development activities; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for CDX-110 and other potential vaccines as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential thereof; and competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and in its reports on Form 10-Q and Form 8-K.

AVANT DISCLOSURE NOTICE: Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995: This release includes forward-looking statements that are subject to a variety of risks and uncertainties and reflect AVANT's current views with respect to future events and financial performance. There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by AVANT. These factors include, but are not limited to: (1) the successful integration of the business post-merger, multiple technologies and programs; (2) the ability to adopt AVANT's APC Targeting TechnologyTM to develop new, safe and effective vaccines against oncology and infectious disease indications; (3) the ability to adapt AVANT's vectoring systems to develop new, safe and effective orally administered vaccines against disease causing agents; (4) the ability to successfully complete product research and further development, including animal, pre-clinical and clinical studies, and commercialization of CDX-110, CDX-1307, CholeraGarde® (Peru-15), Ty800, ETEC E. coli vaccine, and other products and AVANT's expectations regarding market growth; (5) the cost, timing, scope and results of ongoing safety and efficacy trials of CDX-110, CDX-1307, CholeraGarde® (Peru-15), Ty800, ETEC E. coli vaccine and other preclinical and clinical testing; (6) the ability to negotiate strategic partnerships or other disposition transactions for AVANT's cardiovascular programs, including TP10 and CETi; (7) the ability of AVANT to manage multiple clinical trials for a variety of product candidates; (8) the volume and profitability of product sales of Megan®Vac 1, Megan® Egg and other future products; (9) the process of obtaining regulatory approval for the sale of Rotarix® in major commercial markets, as well as the timing and success of worldwide commercialization of Rotarix® by our partner, GlaxoSmithKline or Glaxo; (10) Glaxo's strategy and business plans to launch and supply Rotarix® worldwide, including in the U.S. and other major markets and its payment of royalties to AVANT; (11) AVANT's expectations regarding its technological capabilities and expanding its focus to

broader markets for vaccines; (12) changes in existing and potential relationships with corporate collaborators; (13) the availability, cost, delivery and quality of clinical and commercial grade materials produced at AVANT's own manufacturing facility or supplied by contract manufacturers and partners; (14) the timing, cost and uncertainty of obtaining regulatory approvals; (15) AVANT's ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors; (16) AVANT's ability to retain certain members of management;(17) AVANT' s expectations regarding research and development expenses and general and administrative expenses; (18) AVANT's expectations regarding cash balances, capital requirements, anticipated royalty payments (including those from Paul Royalty Fund), revenues and expenses, including infrastructure expenses; (19) the ability to obtain substantial additional funding; (20) AVANT's belief regarding the validity of our patents and potential litigation;(21) Pfizer's and our strategy and business plans concerning the continued development and commercialization of CDX-110; and (22) certain other factors that might cause AVANT's actual results to differ materially from those in the forward-looking statements including those set forth under the headings "Business," "Risk Factors " and Management's Discussion and Analysis of Financial Condition and Results of Operations" in each of AVANT's Annual Report on Form 10-K, its current Reports on Form 8-K, as well as those described in AVANT's other press releases and filings with the Securities and Exchange Commission, from time to time. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences. These forward-looking statements were based on information, plans and estimates at the date of this press release, and AVANT does not promise to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

Pfizer Media: Shreya Jani, 212-733-4889 Investors: Jennifer Davis, 212-733-0717 or AVANT Investors: Una Ryan, 781-433-0771 President and CEO Ronald C. Newbold, 908-454-7120 x 312 SVP, Business Development or Media: Dan Budwick, 212-477-9007 x 14 BMC Communications