AVI BioPharma Initiates NEUGENE Antisense Clinical Program in Coronary Artery Bypass Grafting

10/18/06

PORTLAND, Ore.--(BUSINESS WIRE)--Oct. 18, 2006--AVI BioPharma, Inc. (Nasdaq:AVII), today announced the initiation of a clinical program to assess the safety and effectiveness of AVI-5126, a new generation of NEUGENE(R) antisense drug for treating coronary vascular disease.

The first clinical study in this program will assess the therapeutic benefit of exposing an excised saphenous vein, one of two principal veins running near the surface of the leg, to NEUGENE drug AVI-5126 immediately before connecting it to the coronary artery circulation of patients undergoing coronary artery bypass graft (CABG) procedures.

The pivotal study will be multicenter, double-blinded, randomized and placebo-controlled, with 600 patients managed similarly, except for variations in the immersion solutions for the veins. The control group will have the removed saphenous vein immersed in saline, while the veins of those in the experimental group will be immersed in AVI-5126 mixed with saline before connection of the vein graft into the coronary artery circulation.

Principal investigators for the study include Anatoliy Rudenko, M.D., Ph.D., director of the Amosov Institute of Cardiovascular Surgery, Department of Coronary Failure in Kiev, Ukraine, and Jerzy Sadowski, M.D., Ph.D., chairman of the Department of Cardiovascular Surgery and Transplantology at Jagiellonian University in Krakow, Poland.

"AVI's first step in the development of AVI-5126 for CABG is to conduct pivotal studies in Ukraine and Poland at reputable cardiovascular surgery sites that perform a high volume of procedures. We consider this critical in expediting patient recruitment in a cost-effective manner, without sacrificing the universal quality of care for subjects," said Denis R. Burger, Ph.D., chief executive officer of AVI. "If there are promising efficacy results in Ukraine and Poland in late 2007, AVI will then initiate a worldwide clinical program to bring AVI-5126 to the market in all major markets within five years."

AVI-5126 silences a gene known as c-myc, a key regulatory gene involved in cardiovascular restenosis. C-myc is believed to regulate the many downstream genes that produce the pathology of restenosis, namely cell migration and adhesion, collagen formation, secretion of extra-cellular matrix, and cell proliferation, among others.

Preclinical studies have shown that silencing c-myc just at the time of injury may be enough to prevent late-term consequences of intimal hyperplasia, considered the primary cause of vessel obstruction after CABG and intra-coronary artery stent placement.

AVI has shown in a previous Phase II clinical study that its drug AVI-4126 (Resten-NG(R)), also targeting the c-myc gene, reduced the restenosis rate after balloon angioplasty and stent placement by approximately 75 percent. AVI-5126 has the same NEUGENE antisense component as Resten-NG, but in addition it incorporates AVI's proprietary CytoPorter(TM) delivery peptide, a transporter tail to enhance drug delivery to the saphenous vein ex vivo before use in bypass surgery. This is the first clinical use of this delivery strategy, and the enhanced product is referred to as Resten-CP(TM).

Initial patient recruitment for the Phase Ib/II portion of the study will occur in November 2006. There will be periodic safety evaluations for patients participating in the study, including primarily assessment of major adverse events (e.g., death, myocardial attacks, or emergency need for repeat CABG) and 4-D coronary artery CAT scans. After a safety evaluation at three months of the first 110 patients enrolled, the study becomes a Phase III program.

Patients will be under study surveillance for one year after the CABG procedure. During this period they will be evaluated systematically by standard coronary angiography criteria (i.e., blockage of the saphenous vein graft of greater than or equal to 75 percent as measured by quantitative coronary artery angiography).

About Coronary Artery Bypass Grafting

CABG surgery is performed about 350,000 times annually in the United States, making it one of the most commonly performed major operations. CABG surgery is advised for selected groups of patients with significant narrowings and blockages of the heart arteries (coronary artery disease). CABG surgery creates new routes around narrowed and blocked arteries, allowing sufficient blood flow to deliver oxygen and nutrients to the heart muscles.

Each year, approximately 800,000 CABG procedures are performed worldwide for life-threatening cardiovascular disease. Although bypass surgery is effective in restoring blood flow, 30 percent to 50 percent of bypass grafts eventually become blocked or fail. Within the first year after a CABG procedure, it is estimated that between 15 percent and 30 percent of saphenous vein grafts fail (i.e., greater than or equal to 75 percent reduction in flow within the graft). In addition, vein graft failure significantly increases the risk of recurrent angina, late myocardial infarction, and the need for a repeat CABG on the same vessels.

About AVI BioPharma

AVI BioPharma develops therapeutic products for the treatment of life-threatening diseases using third-generation NEUGENE antisense drugs. AVI's lead NEUGENE antisense compound is designed to target cell proliferation disorders, including cardiovascular restenosis, cancer and polycystic kidney disease. In addition to targeting specific genes in the body, AVI's antiviral program uses NEUGENE antisense compounds to combat disease by targeting single-stranded RNA viruses, including hepatitis C virus, influenza A virus, dengue virus, West Nile virus and Ebola virus. AVI has introduced a NEUGENE-based exon-skipping technology called ESPRIT therapy. More information about AVI is available on the company's Web site at http://www.avibio.com.

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efforts, the results of preclinical and clinical testing, the effect of regulation by the FDA and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, and other risks detailed in the company's Securities and Exchange Commission filings.

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