AVI BioPharma Provides Cardiovascular Program Update; Notice of Allowance of Two Patents Strengthens Cardiovascular Restenosis Program

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PORTLAND, Ore.--(BUSINESS WIRE)--Aug. 3, 2006--AVI BioPharma, Inc. (Nasdaq:AVII), today issued an update on its licensed and internal cardiovascular programs, both of which have been strengthened by notices of allowance from the U.S. Patent Office.

AVI licensed its vascular disease program to the Cook Group Inc. (Cook) in March 2006 for device delivery of the NEUGENE(R) antisense drug AVI-4126, while the company is focusing internal development on coronary artery bypass graft (CABG) using AVI-5126.

The following patents were the subject of the U.S. Patent Office's notification:

- "Antisense Restenosis Composition and Method" covers the broad use of AVI-4126 to treat any vascular injury including balloon angioplasty alone or in combination with a stent. The patent also includes the use of an intravascular stent that delivers AVI-4126 either via a coating or any other method. This patent protects the AVI-Cook program through January 2020.

- "Microbubble Compositions and Methods for Oligonucleotide Delivery" covers the administration of a broad range of drugs, including any antisense drugs, via microbubbles to damaged vascular tissues. The patent also covers a range of proteins and gases used to make and administer the bubbles. This patent protects this delivery method until October 2017.

"These two patents strengthen the foundation of protection for both our licensed and internal cardiovascular programs," said Denis R. Burger, Ph.D., chief executive officer of AVI. "With Cook's device expertise and AVI's long-term patent position for these technologies, our partnership is now a formidable combination to address vascular diseases on many fronts. Internally, we are prioritizing our coronary artery bypass graft program."

Cook has licensed AVI's NEUGENE antisense technology for down-regulating c-myc gene expression in vascular disease. Joseph B. Horn, formerly AVI vice president of cardiology, rejoined Cook to advance related programs through clinical development and into commercialization, including AVI's Resten-NG(R) drug-eluting stent (DES) program, Resten-MP(TM) microparticle delivery program (APRAISAL trial) and a program for catheter delivery of Resten-NG.

"I'm pleased with the progress made in the very short time since I rejoined Cook," said Horn. "These two patent allowances provide us with new long-term protection for both the drug and various methods of delivery. The microparticle delivery has early promising results in the ongoing Resten-MP APRAISAL clinical trial that we took over from AVI. As has been the case in the past, Cook will look to provide an update on clinical progress at the Transcatheter Cardiovascular Therapeutics Meeting in October."

In addition to assuming all program costs, Cook has entered into a supply agreement to purchase the drugs for development, clinical studies and commercialization from AVI.

"As a clinical investigator in Essen, Germany, one of the three active sites for the APRAISAL trial, I am very pleased with the systemic microbubble delivery of c-myc antisense for my patients," said Sebastian Philipp, M.D. "This allows our clinical group to provide balloon angioplasty and stent placement without the potential long-term problems associated with the current drug-eluting stents. Thus far there have not been any safety issues with the administration of antisense or the bubble formulation. Our early findings are very encouraging."

Resten-NG (AVI-4126) is a third-generation antisense agent that targets the key regulatory gene involved in cardiovascular restenosis, the transcription factor referred to as c-myc. It 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.

The c-myc gene expression is immediately activated by the injury to the vascular lining during angioplasty and stent placement, and peaks at 24 hours to 48 hours before subsiding. NEUGENE antisense drugs are particularly suited to prevent this process because they can be delivered immediately following injury to the angioplasty site by a variety of means including catheter and stent elution, or by systemic delivery using AVI's microparticle delivery system, Resten-MP.

AVI has finished preclinical studies with Resten-CP (AVI-5126) for coronary artery bypass grafting. This drug is AVI-4126 with transporter tail (CytoPorter(TM), CP) attached to enhance delivery to the saphenous vein ex vivo before use in bypass surgery. Based on both positive results from animal studies and positive Phase II clinical results with NEUGENE antisense targeting c-myc for restenosis, AVI is moving into Phase II clinical trials in CABG later this year.

About Coronary Artery Bypass Grafting (CABG)

Coronary artery bypass graft (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.

About the APRAISAL Study

The primary therapeutic endpoint of the study is the subsequent reduction in luminal diameter (late loss) from the time of intervention to follow-up at six months, as measured by quantitative angiography and intravascular ultrasound. Reduction in late loss is the standard indicator cardiologists use to gauge long-term stent efficacy.

The University of Essen, in Germany, is the principal investigative center. Prof. Dr. med. Raimund Erbel, director of cardiology at the center, has appointed PD Dr. Stefan Sack as the principal investigator to coordinate the study, with the other German centers participating in the trial including the University of Heidelberg and the Coburg Clinical Center.

AVI is conducting this study in collaboration with Harvard Clinical Research Institute (HCRI), an internationally recognized specialist in the management of coronary artery disease and stents under the direction of Donald Cutlip, M.D., chief medical officer.

About Cook Group

The world's largest privately held manufacturer of medical devices with international headquarters in Bloomington, Ind., COOK(R) (www.cookmedical.com) is a leading designer, manufacturer and global distributor of minimally invasive medical device technology for diagnostic and therapeutic procedures. Since its founding in 1963, Cook has created innovative technologies for drug-eluting and bare metal stents, aortic and vascular endografts, catheters, wire guides, introducer needles and sheaths, embolization coils, medical biomaterials and contract manufacturing of biopharmaceuticals, vena cava filters and other minimally invasive medical devices for radiology, cardiology, urology and OB/GYN, critical care medicine, surgery, gastroenterology, bone access and endovascular therapies.

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 West Nile virus, hepatitis C virus, dengue virus, Ebola virus and influenza A 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.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: The statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including, but not limited to, the results of research and development 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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