AVI BioPharma Discusses Phase II Cardiovascular Clinical Study

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PORTLAND, Ore.--(BUSINESS WIRE)--Oct. 31, 2006--Clinicians involved in the performance of the APPRAISAL Phase II clinical study sponsored by AVI BioPharma, Inc. (Nasdaq: AVII) and AVI's partner Cook Group Inc. presented promising preliminary observations at the 18th Annual Transcatheter Cardiovascular Therapeutics conference in Washington, D.C. last week. The multi-center APPRAISAL study is designed to evaluate Resten-MP(TM) delivered intravenously via microparticle technology, in conjunction with placement of one or more bare-metal stents.

AVI and partner Cook Group, which licensed AVI's NEUGENE(R) antisense technology for down-regulating c-myc gene expression in the field of cardiovascular disease, expect independently reviewed core lab data to be presented at the EuroPCR conference in May 2007.

"We are enthusiastic about these early observations that have been made thus far in the APPRAISAL study," said Joseph B. Horn, president, Global Therapeutics, a Cook Group Company. "The presentations made last week provide enthusiasm for a rapid progression of the trial with commercialization of AVI-4126 as the goal."

"We have demonstrated that our microparticle delivery system for Resten-MP is effective at delivering therapeutic concentrations of the drug to the sites of vessel injury," said Patrick L. Iversen, Ph.D., senior vice president of research and development at AVI. "That, coupled with the outstanding safety profile demonstrated by all of our compounds, make this a promising approach in the ongoing battle against restenosis. Together with Cook, we look forward to seeing continued rapid progress in this program."

The drug component in Resten-MP, AVI-4126 (Resten-NG(R)), was found to reduce restenosis in the AVAIL Phase II clinical trial. In that multicenter study, for which Martin Leon, M.D., was the principal investigator, Resten-NG was injected directly into the coronary artery using a special drug delivery catheter at the time of stent placement. Resten-NG in the therapeutic dose arm demonstrated statistically significant efficacy in preventing restenosis determined by both quantitative angiography and intravascular ultrasound compared with a control arm and a subtherapeutic dose arm. Further, Resten-NG significantly reduced the neointimal growth that contributes to the failure of angioplasty intervention. The binary restenosis rate was reduced by 75 percent among patients who received a therapeutic dose.

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. C-myc is believed to regulate the many downstream genes that produce the pathology of restenosis, including cell migration and adhesion, collagen formation, secretion of extra-cellular matrix, and cell proliferation.

About the Study

The primary therapeutic endpoint of the APPRAISAL 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 organization specializing in the management of coronary artery disease and stents. A validated historical database with over 20,000 patients will be used by HCRI as the comparator in this initial advanced clinical phase study.

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.

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