# AVI BioPharma Presents Successful Trial Results Using NEUGENE Antisense to Alter Drug Metabolism in Humans

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Business Editors/Biotech Writers

PORTLAND, Ore.--(BUSINESS WIRE)--Oct. 19, 2006--AVI BioPharma, Inc. (Nasdaq:AVII), today presented data and analysis from four NEUGENE(R) antisense clinical studies at the second annual meeting of the Oligonucleotide Therapeutics Society at Rockefeller University in New York. The studies showed that AVI-4557 inhibited the metabolic enzyme cytochrome P450 (CYP), a liver enzyme responsible for the metabolism or breakdown of approximately half of currently marketed drugs.

The clinical briefing, titled "Human Clinical Trials With AVI-4557 Targeting Cytochrome P450 3A4," will be presented by Patrick L. Iversen, Ph.D., senior vice president of research and development at AVI.

"This is an important collection of clinical studies that demonstrate NEUGENE AVI-4557 predictably alters the pharmacokinetic profile (PK) of two drugs in humans when administered via different routes, including oral administration," said Dr. Iversen. "Controlling the rate of drug metabolism and reducing its variability among patients has the potential to reduce the amount of drug needed to improve therapeutic results. Among the many potential applications of this approach is the treatment of HIV and HCV patients with protease inhibitors, which are primarily metabolized by CYP, the gene silenced by AVI-4557."

Cytochrome P450 comprises a family of enzymes that break down thousands of compounds in the body. CYP3A4, a subset of P450, is perhaps the most important and widely implicated enzyme in the arena of drug metabolism and disposition. AVI-4557 is a NEUGENE antisense drug designed to silence the expression of CYP3A4.

In a series of four human clinical trials involving 128 subjects, AVI showed inhibition of CYP3A4 using doses of AVI-4557 ranging from 10 mg to 300 mg as either single or repeated daily doses by intravenous, subcutaneous or oral routes of administration.

The study design included eight patients per cohort. Six patients received AVI-4557, while two received a placebo in each group. All patients were dosed with one of two well-known drugs that are metabolized by CYP3A4: buspirone (an anti-anxiety drug) or midazolam (an anesthetic drug). The PK profiles of each drug were determined before administration of AVI-4557 and again 24 hours and 72 hours after administration.

The efficacy endpoint of the study was the change in the PK of the two test drugs as measured by changes in the maximum concentration (Cmax), total concentration over time (AUC) and half-life. Significant changes in Cmax, AUC and half-life of the test drugs were observed following silencing of CYP3A4 with AVI-4557. An additional key endpoint of the studies was safety and tolerability of AVI-4557. No serious adverse events were seen in the study, and the drug's bioavailability was shown to be excellent.

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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