AVI BioPharma Reports Favorable Safety and Pharmacokinetic Data From Its Clinical Trial Targeting Hepatitis C Virus

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NEUGENE Antisense Compound Was Well-Tolerated and Exhibited Favorable Pharmacokinetic Parameters

PORTLAND, Ore., Jan 10, 2006 (BUSINESS WIRE) -- AVI BioPharma, Inc. (Nasdaq:AVII), today announced favorable safety and pharmacokinetic results from the first phase of its clinical trial for chronic active hepatitis C virus (HCV). The multicenter study is designed to assess the safety, tolerability, pharmacokinetics (PK) and viral response to daily subcutaneous administration of its proprietary NEUGENE(R) antisense compound AVI-4065 among healthy volunteers and patients with HCV.

"There is a large, unmet medical need for effective HCV treatments, as the current therapy is successful in less than half of the patients infected with genotype 1 HCV, the most common form of the virus in the U.S.," said Denis R. Burger, Ph.D., chief executive officer of AVI. "In addition, the current treatment regimen with interferon and ribavirin is expensive, has a plethora of side effects, and is not well-tolerated by many patients. The favorable safety and PK data reported today provide further evidence for the large potential therapeutic window for NEUGENE antisense drugs. This is in sharp contrast to previous antisense failures by other companies with other antisense chemistries, which have been primarily due to dose-limiting toxicity."

The first phase of this study has been completed by enrolling and evaluating approximately 30 healthy volunteers at three dosage levels of AVI-4065. Trial participants have received 50 mg, 100 mg or 300 mg of study drug by subcutaneous injection daily for 14 days, with each dose level evaluated for safety and tolerability, and a PK analysis conducted.

No serious drug-related adverse events occurred at any dosage level. All dosages were well-tolerated with no injection site reactions or events that required intervention. The apparent plasma elimination half-life ranged from 10 hours to 12 hours with a peak concentration at about four hours after subcutaneous injection. The PK profile suggests that the target dosage for efficacy phase of this trial will fall between the 100 mg and 300 mg dosages.

Dr. Mark Holodniy, FACP, professor of medicine at Stanford University School of Medicine and director of the Department of Veterans Affairs Public Health Research & Consultation Program in Palo Alto, Calif., principal investigator for the trial, said, "I am pleased to participate as an investigator at one of many study sites in the rigorous clinical testing of AVI's lead compound targeted to the HCV virus. The study should provide a better understanding of the compound's safety, pharmacokinetics and potential biological effects against HCV."

In addition to this clinical trial, a supporting safety and PK study has been completed in nonhuman primates. Groups of primates received daily injections of up to 40 mg/kg AVI-4065 for 28 days or about 15 times the largest human dose used, and for twice the duration. No serious adverse events, toxicities or tolerability issues were observed. Importantly, the liver accumulation of AVI-4065 was found to be approximately three times the plasma concentration. These data allowed for a direct calculation of the potential liver concentration of drug in humans from the clinical cohorts.

Together with the primate data, calculations from the first phase of the clinical study provide the basis for a dosage regimen for the second efficacy phase. The second phase will include up to 40 patients with chronic active HCV, stratified into two cohorts, one composed of patients who have not received previous treatment and the other composed of patients who have failed conventional interferon and ribavirin treatment.

The study will continue to assess the safety, tolerability and pharmacokinetics in addition to efficacy, as measured by HCV virological responses over a minimum of 14 days of treatment. Patients will also be monitored following treatment to assess the duration of the HCV virological response to AVI-4065. Preliminary data from the second phase of this program are expected in the first quarter of 2006.

HCV is a single-stranded RNA virus. Because HCV and other single-stranded RNA viruses have relatively simple genetic structures, they are attractive targets for AVI's NEUGENE antisense, which is designed to target conserved portions of the viral genetic code that are not likely to mutate over time.

About Hepatitis C Infection

Chronic HCV infection causes an inflammation of the liver that can result in the development of cirrhosis, liver cancer or liver failure. According to the World Health Organization, approximately 170 million people worldwide are chronically infected with HCV. It is the most common chronic blood-borne infection in the developed world and the leading cause of liver transplants in the U.S. The Centers for Disease Control estimates that approximately 3.9 million Americans have been infected with HCV, of whom 2.7 million are chronically infected.

The Hepatitis Foundation International estimates that between 8,000 and 10,000 people die annually in the U.S. from HCV-related cirrhosis or liver cancer. The current treatment for HCV, 24 to 48 weeks of therapy with pegylated interferon alpha and ribavirin, is successful in less than half of the patients infected with genotype 1 HCV, the most common form of the virus in the U.S. Furthermore, this treatment has numerous side effects, some of them severe, which make it difficult for nearly half of initially treated patients to tolerate the recommended dosages and duration of treatment.

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 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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