AVI BioPharma Presents Initial Results on Hepatitis C Virus Clinical Trial at the International Conference on Antiviral Research Annual Meeting

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PORTLAND, Ore.--(BUSINESS WIRE)--May 10, 2006--AVI BioPharma, Inc. (Nasdaq:AVII) will present initial data from the second phase of its multicenter study in patients with chronic active hepatitis C virus (HCV) infection at the prestigious International Conference on Antiviral Research (ICAR) annual meeting today. AVI's presentation titled "AVI-4065, An Antisense Approach to Active HCV Infection: Preclinical and Clinical Evaluation" will be presented by Patrick L. Iversen, Ph.D., AVI's senior vice president of research and development. See www.georgetown.edu/research/arc/ISAR for details.

The second phase of the trial has been designed to assess the safety, tolerability, pharmacokinetics (PK) and viral and clinical response to treatment with AVI's proprietary NEUGENE(R) antisense compound, AVI-4065, among HCV patients.

AVI-4065 exhibited favorable safety and tolerability profiles in all patients treated thus far, with no serious drug-related adverse events or tolerability issues observed during treatment or follow-up. Based on the relatively long elimination half-life of AVI-4065 and its mechanism of action, an irreversible binding to the viral genome preventing viral protein synthesis, a slow, steady liver loading with test drug was expected in patients with high levels of viral target in the liver. This correspondingly predicts a slow, steady decrease in viral load over the drug-loading period.

The PK analysis in patients treated thus far was consistent with this prediction; there was a significant decrease in the concentration of drug in the plasma (Cmax) in HCV patients compared with the normal subjects in the initial phase of the trial. This was consistent with an increased elimination of drug found in the urine, most likely bound to the virus in the HCV-infected patients. In addition, there was a significant correlation between viral titer at day one and the extent of reduction in Cmax, further supporting this mechanism of elimination. These observations demonstrate a significant and direct pharmacodynamic response to HCV infection.

Viral responses have been assessed in only a few patients out to the 28th day of the study. During the 14 days of treatment, three of five patients evaluated had an initial decrease in viral load, whereas two of five exhibited little initial change in viral titer. The mean viral titers of all patients tested thus far showed a slight decrease (0.30 log reduction) both during and after treatment, with no rebound effect observed out to 28 days. These are very preliminary results in a small number of patients, and active enrollment and evaluation is ongoing, with formal results expected around the end of the year.

"Based on the PK and mechanism-of-action of our drug, we expected a slow, steady accumulation of drug in the liver with a corresponding decrease in viral load," said Dr. Iversen. "The maximal tissue concentration of drug would be reached in three to five half-lives, or approximately 33 to 55 days. This indicates that an extension of treatment duration is required to reach maximum drug concentration and reduction of viral load in the liver. These preliminary results are consistent with that and very encouraging for ongoing drug development. Extending the treatment period would be expected to further reduce viral load in responding patients and may ultimately decrease viral load in those patients who are not early responders."

"We are pleased to have shown early signs of an anti-HCV response in our first human study," said Denis R. Burger, Ph.D., chief executive officer of AVI. "Because our drug has a significant therapeutic window, we have several options for modifying the therapeutic regimen to enhance the results. Our options include increasing the duration of treatment, increasing the dose, enhancing the delivery, fine-tuning the target, enhancing target affinity, and exploring combinations of antisense agents, or combinations of antisense agents with other drugs. We firmly believe that, after seeing initial trends, we can develop an optimal, viable drug therapy for HCV."

The first phase of this study was completed in March 2006 and evaluated 31 healthy volunteers who received 14 consecutive days of treatment with AVI-4065 at three dosage levels. In the second phase of this clinical trial, patients with HCV are stratified into two cohorts, one composed of patients who have not received previous treatment and the other composed of patients who failed conventional interferon and ribavarin treatment. In addition to efficacy as measured by HCV virological responses to treatment with AVI-4065, the study will continue to assess the safety, tolerability and pharmacokinetics of the compound. Patients will also be monitored for four months following treatment to assess the duration of the virological response to AVI-4065, and sequencing of the viral genome will be performed to assess potential resistance.

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, 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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