AVI BioPharma Initiates Clinical Studies for Two RNA-Based Therapeutic Candidates for Treatment of Ebola and Marburg Viruses

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Studies of AVI-6002 and AVI-6003 Are the First to Evaluate Safety and Tolerability of AVI's PMOplus Platform Chemistry in Humans

BOTHELL, WA, May 04, 2011 (MARKETWIRE via COMTEX) -- AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based therapeutics, today announced that it initiated dosing in two Phase 1 clinical studies for AVI-6002 and AVI-6003, its lead drug candidates being evaluated for the treatment of Ebola virus and Marburg virus, respectively. AVI is developing AVI-6002 and AVI-6003 under a competitively awarded contract for up to $291 million from the U.S. Department of Defense through the Joint Project Manager Transformational Medical Technologies (JPM-TMT) program. Both candidates utilize AVI's advanced and proprietary PMOplus(TM) chemistry.

"These are the first drug candidates employing our PMOplus chemistry to be evaluated in humans, and they are the first AVI programs to enter the clinic based on our prior studies supported by the JPM-TMT program," said Chris Garabedian, president and CEO of AVI BioPharma. "Additionally, we look forward to new and continued opportunities to earn further government support through JPM-TMT."

Each Phase 1 study will be randomized, double-blind, placebo-controlled and involve single escalating doses of AVI-6002 or AVI-6003 to assess the safety, tolerability and pharmacokinetics of each drug candidate in healthy adult volunteers. In each study, five volunteers will be enrolled in one of six cohorts for a total of up to 30 volunteers. The cohorts will include four volunteers who receive the therapeutic, and one who will receive a placebo.

Preclinical studies of AVI-6002 and AVI-6003 have been a collaborative effort between AVI and scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the U.S. Department of Defense's (DOD) lead medical research laboratory for biological defense. All preclinical studies were conducted at USAMRIID, which has the DOD's only Biosafety Level 4 (BSL4), or maximum containment capability, and is essential for studying the Ebola and Marburg viruses.

Data from preclinical studies published in Nature Medicine demonstrate that AVI-6002 and AVI-6003 provide post-exposure efficacy in non-human primates against Ebola and Marburg viruses, respectively. In multiple studies evaluating treatment of Ebola virus-infected primates with AVI-6002 and treatment of Marburg-infected primates with AVI-6003, USAMRIID scientists have observed up to 80% survival and 100% survival, respectively, when the viruses were inoculated at 1000 times the lethal dose within the confines of a BSL4 laboratory, compared to control groups where both viruses were universally lethal.

About Ebola and Marburg Viruses

Ebola hemorrhagic fever is a severe and often fatal disease in humans. The disease was first recognized in 1976 and is one of two members of a family of RNA viruses called Filoviridae. The disease is generally understood to be endemic to parts of Africa. Onset of illness from Ebola virus is abrupt with symptoms that include fever, headache, muscle ache, vomiting and stomach pain. Internal and external bleeding may also be observed in some patients. There are currently no treatments for Ebola virus infection beyond supportive care.

Marburg hemorrhagic fever is another severe and potentially fatal disease in humans first recognized in 1967. It is also caused by an RNA virus of the filovirus family and is understood to be endemic to Africa. Onset of the disease is often sudden, and the symptoms include fever, chills, nausea, vomiting, chest pain and diarrhea. Increasingly severe symptoms may also include massive hemorrhaging and multiple organ dysfunctions. There are currently no treatments for Marburg virus infection beyond supportive care.

About AVI's PMOplus Chemistry

PMOplus chemistry is an advanced generation of AVI's phosphorodiamidate morpholino oligomer, or PMO, technology pioneered by AVI. The PMO platform is designed to provide a stable chemistry backbone with superior drug-like characteristics for AVI's advanced RNA-based therapeutics. PMOplus chemistry includes specific molecular charges positionally inserted into the PMO's inherent charge-neutral backbone. The PMOplus modifications are intended to specifically enhance drug performance characteristics on two key parameters: targeted cell penetration and the maintenance of antiviral performance in the presence of viral mutation.

About JPM-TMT

Joint Project Manager Transformational Medical Technologies (JPM-TMT) is a U.S. Department of Defense (DOD) program created to protect the Warfighter from emerging, genetically altered and unknown biological threats. As the premier partner to DOD, other government agencies, academia, biotechnology and pharmaceutical industries, JPM-TMT delivers a cutting-edge and agile, end-to-end translational process for developing and providing novel response capabilities to protect the Warfighter from biological threats. Pursuant to Homeland Security Presidential Directives 10, 18, 21 and National Security Presidential Directive 33, JPM-TMT integrates early scientific discovery with the advanced development and acquisition capabilities of the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD).

About USAMRIID

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), located at Fort Detrick, Maryland, is the lead medical research laboratory for the U.S. Department of Defense's Biological Defense Research Program, and plays a key role in national defense and in infectious disease research. The Institute conducts basic and applied research on biological threats resulting in medical solutions (such as vaccines, drugs and diagnostics) to protect the Warfighter. While USAMRIID's primary mission is focused on the military, its research often has applications that benefit society as a whole. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command. For more information, visit

www.usamriid.army.mil

About AVI BioPharma

AVI BioPharma is focused on the discovery and development of novel RNA-based therapeutics for rare and infectious diseases, as well as other select disease targets. Applying pioneering technologies developed and optimized by AVI, the Company is able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. Unlike other RNA-based approaches, AVI's technologies can be used to directly target both messenger RNA (mRNA) and precursor messenger RNA (pre-mRNA) to either down-regulate (inhibit) or up-regulate (promote) the expression of targeted genes or proteins. By leveraging a highly differentiated RNA-based technology platform, AVI has built a pipeline of potentially transformative therapeutic agents, including eteplirsen, which is in clinical development for the treatment of Duchenne muscular dystrophy.

Forward-Looking Statements and Information

This press release contains statements that are forward-looking, including statements about the development of AVI's product candidates, the efficacy, potency and utility of AVI's product candidates in the treatment of rare and infectious diseases, and AVI's expectations about new and continued funding from the government. These forward-looking statements involve risks and uncertainties, many of which are beyond AVI's control. Known risk factors include, among others: clinical trials may not demonstrate safety and efficacy of any of AVI's drug candidates; any of AVI's drug candidates may fail in development, may not receive required regulatory approvals, or be delayed to a point where they do not become commercially viable; and AVI may not qualify for additional or continued government funding in support of its product development programs. Any of the foregoing risks could materially and adversely affect AVI's business, results of operations and the trading price of its common stock. For a detailed description of risks and uncertainties AVI faces, you are encouraged to review the official corporate documents filed with the Securities and Exchange Commission. AVI does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

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