AVI BioPharma Announces FDA Approval to Proceed With a Modified Dosing of AVI-6003 for Treatment of Marburg Virus

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AVI-7288, a Component of AVI-6003, Shows Efficacy Results in Standalone Treatment of Non-Human Primate Studies

BOTHELL, WA, Feb 28, 2012 (MARKETWIRE via COMTEX) --AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based therapeutics, today announced that it has received approval from the Food and Drug Administration (FDA) to proceed with a single oligomer, AVI-7288, in studies in both humans and non-human primates to support the safety and efficacy of post-exposure prophylaxis against Marburg virus infection. AVI-7288 is one of two components that make up AVI-6003. Studies conducted to date have shown that efficacy in non-human primates can be attributed to this single component, while the second component, AVI-7287, does not appear to contribute to efficacy. AVI is conducting this work under a Department of Defense contract managed by the Joint Project Manager Transformational Medical Technologies (JPM-TMT) Project Management Office, a component of the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD). The FDA approved proceeding with the Marburg program using the single oligomer AVI-7288 under the original IND.

"While we have not seen any toxicity in humans to date with AVI-6003, by removing AVI-7287 we have a simpler development path and may improve the therapeutic window by evaluating a single action agent," said Chris Garabedian, president and CEO of AVI BioPharma. "We are pleased to be able to explore this single oligomer as a potentially safe and effective treatment against this lethal hemorrhagic fever virus."

AVI will proceed with dosing AVI-7288 in the Phase I multiple ascending dose studies planned to characterize the safety, tolerability and pharmacokinetics of multiple doses of the drug in healthy adult volunteers. The randomized, double-blind placebo controlled study will be overseen by a DSMB, who will review safety and clinical laboratory data after each dose cohort prior to enrolling the next highest dose cohort. AVI will also proceed using AVI-7288 in non-human primate studies to continue to evaluate efficacy.

Patrick Iversen, Ph.D., Senior Vice President of Research and Innovation at AVI, will present the results of a non-human primate confirmatory study conducted to evaluate the optimal dose and components of AVI-6003 during the upcoming Association of Microbiology BioDefense and Emerging Diseases Research Meeting in Washington, DC. In the confirmatory study at higher doses of PMOplus(R) at 15 mg/kg/component, survival was 90%, 100% and 0% in the AVI-6003, AVI-7288 and placebo groups, respectively. Based on these results, AVI concluded that AVI-7288 is the active component in AVI-6003 and that further development would proceed accordingly with the single oligomer component AVI-7288. The presentation is titled "A Single PMOplus(R) Oligomer is Effective in a Cynomolgus Macaque Marburg Virus Lethal Challenge Model" and will be presented at 3:20 p.m. EST on Tuesday, February 28, 2012, during session 020/Therapeutics.

Dr. Iversen will also deliver a poster presentation titled "Restoring Antibiotic Sensitivity with Antisense Inhibitors of Gene Expression" at 1:00 p.m. EST on Tuesday, February 28, 2012, during poster session 018.

The presentation and poster will be posted on the AVI BioPharma website in the "Events & Presentations" section after the respective sessions are completed. The presentation and poster will be archived there following the presentation for 90 days.

AVI-7288 is a single oligomer, one of two composing AVI-6003. AVI-7288 employs AVI's patented PMOplus® technology that selectively introduces positive charges to its phosphorodiamidate morpholino oligomer (PMO) backbone to improve interaction between the drug and its target.

AVI-6003 has been AVI's lead therapeutic candidate to-date for the Marburg virus and is a combination of AVI-7287 and AVI-7288, both of which employ AVI's patented PMOplus® technology.

About Marburg Viruses
Marburg hemorrhagic fever is a severe and potentially fatal disease in humans first recognized in 1967. It is caused by an RNA virus of the Filoviridae family and is understood to be endemic to Africa. The Marburg virus is classified as a Category A bioterrorism agent by the Centers for Disease Control and Prevention, or CDC, and was determined to pose a material threat to

national security and public health by the Secretary of Homeland Security in 2006. 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. PMOplus® has potentially broad therapeutic applications and has thus far shown to be particularly effective in increasing the potency of PMO-based oligomers.

About JPM-TMT
JPM-TMT, an organization within the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) aims to protect the Warfighter from emerging infectious diseases, genetically altered and unknown biological threats. Through strategic investments and partnerships with innovative biotech firms, pharmaceutical corporations, other government agencies, and academic institutions, JPM-TMT facilitates the advanced development and acquisition of broad-spectrum medical countermeasures and systems to enhance our nation's biodefense response capability. For more information, visit www.jpmtmt.mil.

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 its 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, and multiple drug candidates that are in clinical development for the treatment of infectious disease. For more information, please visit www.avibio.com.

Forward-Looking Statements and Information

In order to provide AVI's investors with an understanding of its current results and future prospects, this press release contains statements that are forward-looking. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements about the development of AVI's product candidates, their efficacy, potency and utility in the treatment of rare and infectious diseases, their potential to treat a broad number of human diseases and AVI's plans to initiate Phase I multiple ascending dose studies and non-human primate studies of AVI-7288.

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 and/or AVI's antisense-based technology platform; development of AVI-7288 may not result in funding from JPM-TMT in the anticipated amounts or on a timely basis, if at all; and 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. Any of the foregoing risks could materially and adversely affect AVI's business, results of operations and the trading price of AVI's 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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