

## **AVI BioPharma's RNA-Based Therapeutics for Treatment of Ebola and Marburg Viruses Show Positive Safety Data in First Five of Six Cohorts of Phase 1 Clinical Studies**

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### **Data From Clinical Study of Marburg Candidate to Be Presented at 49th Annual Meeting of Infectious Diseases Society of America**

BOTHELL, WA, Oct 21, 2011 (MARKETWIRE via COMTEX) --

AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based therapeutics, today announced positive safety results from the first five cohorts of Phase I single ascending dose trials of AVI-6002 and AVI-6003, AVI's lead drug candidates being evaluated for the treatment of Ebola virus and Marburg virus, respectively.

Data from five cohorts of the AVI-6002 and AVI-6003 studies were evaluated by an independent Data and Safety Monitoring Board (DSMB), which issued recommendations for both studies to progress as planned to the next highest dosing level after no safety concerns were identified. The Phase I single ascending dose trials are designed to characterize the safety, tolerability and pharmacokinetics of each therapeutic candidate in healthy adult volunteers.

"We are very encouraged that these two drugs, which use our advanced PMOplus(R) chemistry, have demonstrated a favorable safety profile through five cohorts in our dose-escalation studies. These data also suggest that our backbone chemistry may be safe, independent of the specific sequence that is being targeted, and may support applications to other viral targets," said Chris Garabedian, president and CEO of AVI BioPharma.

To date, 25 healthy human subjects (five per group) have been enrolled into five sequential dose groups (0.01, 0.1, 1.0, 3.0 or 6.0 mg/kg) in each of the two studies. Within each group, four subjects received the indicated dose of the therapeutic and one subject received placebo. For each group, safety, clinical laboratory and renal biomarker results through five days after treatment were reviewed by a DSMB. Subjects enrolled in the sixth group for the drug studies will receive 9.0 mg/kg of the therapeutic or placebo. Final, unblinded safety and pharmacokinetic results for all subjects will be available upon completion of the trial.

AVI will present the data from the company's Marburg program at the 49th Annual Meeting of the Infectious Diseases Society of America in Boston, MA.

Tim Axtelle, senior director of clinical operations at AVI, will deliver a poster presentation titled "A Phase 1, Single Ascending-Dose Study of AVI-6003, a Combination of Two PMOplus(R) Compounds with Activity against Marburg Virus" at 11:45 a.m. EDT on Saturday, Oct. 22. The presentation will be given during poster session 149, called "New Approaches to Anti-Viral Therapy."

The presentation will be posted on the AVI BioPharma website in the "Events & Presentations" section after the session is completed.

AVI-6002 and AVI-6003 are AVI's lead therapeutic candidates for the Ebola and Marburg viruses, respectively. Both candidates employ AVI's patented PMOplus(R) technology that selectively introduces positive charges to its phosphorodiamidate morpholino oligomer (PMO) backbone to improve interaction between the drug and its target.

#### **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(R) Chemistry

PMOplus(R) 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(R) chemistry includes specific molecular charges positionally inserted into the PMO's inherent charge-neutral backbone. The PMOplus(R) 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

The Joint Project Manager Transformational Medical Technologies (JPM-TMT) Program supports the overall mission of the U.S. Department of Defense (DoD) by protecting the Warfighter and the nation from emerging, genetically engineered or unknown biothreats. Chartered within the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD), JPM-TMT partners with the DoD, other government agencies, academia, and industry for the advanced development of adaptable platform technologies that can be rapidly tailored and deployed to mitigate the effects of the unknown threat, whether it be naturally occurring or man-made. Program investments target the most difficult challenges of medical capability development and fill gaps not currently addressed by the biodefense community. For more information, visit [www.jpmtmt.mil](http://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](http://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 (the non-proprietary name assigned to AVI-4658), 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 diseases. For more information, visit [www.avibio.com](http://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 and their potential to treat a broad number of human diseases.

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; 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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