



## **AVI BioPharma Files IND for Clinical Trial of Marburg Virus Treatment**

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### **Preclinical results with AVI-6003 demonstrate uniform survival in non-human primates following lethal virus challenge**

#### **For Immediate Release**

PORTLAND, OR — December 3, 2008 — AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based drugs, today announced the filing of an Investigational New Drug application with the U.S. Food and Drug Administration for a clinical trial to evaluate the Company's antisense drug AVI-6003 for the treatment of Marburg virus infection. AVI plans to conduct the trial as part of its continued collaboration with the US Army Medical Research Institute of Infectious Diseases (USAMRIID). Preclinical results of AVI-6003 demonstrated a reproducible and high rate of survival in non-human primates challenged with a lethal infection of Marburg virus.

"The outstanding results demonstrated in preclinical studies of AVI-6003 for the treatment of Marburg infection warrant its advancement to studies that may ultimately lead to the development of the first effective therapeutic for this lethal infection," said Leslie Hudson, Ph.D., President and Chief Executive Officer of AVI. "We are excited by the potential shown by AVI's RNA therapeutics for the treatment of infectious diseases including bioterrorism agents such as Marburg and Ebola virus."

COL John P. Skvorak, Commander, USAMRIID, added, "There is a significant need for the development of a therapeutic for Marburg virus and the promising preclinical results demonstrated by AVI-6003 support moving this candidate drug into clinical development".

In repeated trials, monkeys were dosed with well-tolerated amounts of drug and survived a challenge of roughly 1000 times the minimum lethal dose of virus. This level of infectious challenge normally results in uniform death of untreated monkeys within 7 to 10 days. Treatment of Marburg infected animals with AVI-6003 resulted in 100 percent survival at 15 days.

AVI-6003 is a novel analog based on AVI's PMO antisense chemistry in which anti-viral potency is enhanced by the addition of positively-charged components to the morpholino oligomer linkage.

AVI is conducting this research pursuant to the FDA's Animal Efficacy Rule, which is designed for the development of new drug products for indications in which clinical studies in humans cannot be conducted ethically. According to this rule, marketing approval may be granted based on the demonstration of efficacy in relevant animal species and additional supporting data.

The majority of the collaborative research effort between AVI and USAMRIID has been supported by a two year research contract from the Department of Defense's Transformational Medical Technologies Initiative with the goal of developing a new antiviral (antisense) platform targeting hemorrhagic fever viruses. In addition to development of antiviral agents for Marburg and Ebola, AVI is receiving government funds to develop antiviral agents to treat Junin virus under this contract. Under separate government agreements, AVI is receiving support for programs in Dengue virus, anthrax and ricin, as well as for additional applications in Ebola and Marburg.

#### **AAbout Marburg Virus**

Marburg virus is the cause of Marburg hemorrhagic fever, a rare disease that occurs naturally in sub-Saharan Africa. Marburg hemorrhagic fever was first described in 1967 when outbreaks in Germany and the former Yugoslavia were linked to monkeys imported from Uganda. The symptoms include fever, diarrhea, vomiting, massive bleeding from multiple organs and shock. Death generally occurs between 5 and 10 days after the onset of symptoms. For more information about Marburg virus, visit [www.cdc.gov](http://www.cdc.gov).

#### **AAbout USAMRIID**

USAMRIID, located at Fort Detrick, Maryland, is the lead medical research laboratory for the U.S. Department of Defense 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 [HYPERLINK www.usamriid.army.mil](http://www.usamriid.army.mil).

#### **About AVI BioPharma**

AVI BioPharma is focused on the discovery and development of RNA-based drugs utilizing proprietary derivatives of its antisense chemistry (morpholino-modified phosphorodiamidate oligomers or PMOs) that can be applied to a wide range of diseases and genetic disorders through several distinct mechanisms of action. Unlike other RNA therapeutic approaches, AVI's antisense technology has been used to directly target both messenger RNA (mRNA) and its precursor (pre-mRNA), allowing for both up- and down-regulation of targeted genes and proteins. AVI's RNA-based drug programs are being evaluated for the treatment of Duchenne muscular dystrophy as well as for the treatment of cardiovascular restenosis through our partner Global Therapeutics, a Cook Group Company. AVI's antiviral programs have demonstrated promising outcomes in Ebola Zaire and Marburg Musoke virus infections and may prove applicable to other viral targets such as HCV or Dengue viruses. For more information, visit [www.avibio.com](http://www.avibio.com).