

# AVI BioPharma Files IND for Clinical Trial of Ebola Virus Treatment

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# Preclinical results with AVI-6002 demonstrate excellent survival in the face of 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 evaluating the Company's antisense drug AVI–6002 for the treatment of Ebola virus. 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–6002 demonstrated a reproducible and high rate of survival in non–human primates challenged with a lethal infection of Ebola.

"We are extremely pleased to be advancing AVI–6002 into clinical development for the treatment of Ebloa virus based on the unprecedented results demonstrated by this product candidate in preclinical studies conducted in collaboration with USAMRIID," said Leslie Hudson, Ph.D., President and Chief Executive Officer of AVI. "The clinical development pathway for biodefense agents like AVI–6002 provides for approval of a product based upon animal efficacy data and supporting human safety data. Our success with this drug candidate demonstrates the strength of AVI's biodefense program and the potential for RNA–based therapeutics in the treatment of infectious diseases, including bioterrorism agents."

"AVI–6002 has been shown to be very effective in our animal models. USAMRIID is excited about advancing this product into clinical studies and the possibility for the development of a therapeutic product that will effectively treat individuals suffering from Ebola infection," said COL John P. Skvorak, Commander, USAMRIID.

In repeated trials, monkeys were dosed with well-tolerated amounts of drug and survived a challenge of roughly 1000 times the minimum lethal dose. This level of infectious challenge normally results in uniform death of untreated monkeys within 7 to 10 days. Treatment of Ebola infected animals with AVI–6002 resulted in 75 percent survival of the infected animals at 15 days post infection when the treatment period ended and circulating viral titer was below detectable levels.

AVI-6002 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 appropriate 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 Ebola and Marburg, AVI is receiving government funds to develop antiviral agents to treat Junín 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.

#### About Ebola Zaire Virus

Ebola Zaire virus has been the most frequent cause of field outbreaks of Ebola hemorrhagic fever and is endemic to sub–Saharan Africa. Ebola hemorrhagic fever is a rare and often fatal disease. Outbreaks first occurred in 1976 in Zaire and in western Sudan. A recent outbreak occurred in November of 2007 in Uganda ending in January of 2008. Infected individuals develop high fevers, headache, muscle aches, vomiting, and abdominal cramping. In fatal infections, bleeding is observed from the nose, eyes, rectum and urethra. There is uniform mortality once hemorrhagic signs appear as a result of exposure to the Ebola Zaire virus. For more information about Ebola Zaire virus, visit www.cdc.gov.

### About 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 <u>www.usamriid.army.mil</u>.

## 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.