

AVI BioPharma Announces Positive Results Against Human Pandemic H1N1 Influenza Virus in Preclinical Studies of AVI-7100

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AVI-7100 Demonstrates Statistically Significant Activity Versus Saline and Tamiflu(R) Controls, Up to 3.9 Log Greater Reduction in Average Viral Titer AVI BioPharma and US Department of Defense Conduct Successful Rapid Response Exercise Against Real-World Threat, Pandemic H1N1 Virus

BOTHELL, WA, Aug 24, 2010 (MARKETWIRE via COMTEX) --

AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based drugs, today announced positive results from two preclinical studies evaluating the therapeutic potential of AVI-7100 against a fully virulent pandemic H1N1 virus, also known as swine flu or swine origin influenza virus. An analysis of the data from the studies demonstrated statistically significant reductions in average viral titer versus a saline control and a control with Tamiflu(R), a standard of care drug. The studies of AVI-7100, which used AVI's proprietary PMOplus(TM) chemistry, were supported by the Transformational Medical Technologies program (TMT) of the U.S. Department of Defense to identify RNA-based drug candidates against pandemic H1N1 virus. The studies were undertaken as part of a rapid response exercise demonstrating TMT's ability, in partnership with AVI, to rapidly respond to a real-world emerging viral threat.

"These H1N1 results build on the significant success we've had applying our RNA-based technologies and advanced proprietary chemistries, such as PMOplus(TM), to anti-infective therapeutic candidates," said J. David Boyle II, interim President and CEO of AVI BioPharma. "Based on these results, TMT continues to support AVI-7100, funding an accelerated IND enabling program and Phase 1 study, as well as expanded preclinical evaluation that explores AVI-7100's potential as a broad spectrum influenza therapeutic. We look forward to continuing to work closely with TMT to support our national preparedness against biological threats."

Study Results An analysis of the results from the two preclinical studies evaluating AVI-7100 against a fully virulent strain of pandemic H1N1 virus in a ferret model demonstrated potent, statistically significant reductions in the average viral titer in the upper respiratory region versus saline and Tamiflu controls. In the analysis of these two studies, AVI-7100 administered intraperitoneally at 10 mg/kg resulted in statistically significant reductions in the combined daily average viral titer through peak viral load (days 1-3) versus saline control ($p=0.0012$) and Tamiflu control ($p=0.0103$) by up to 3.9 log. Maximum reductions in the cumulative average viral titer of 5.1 log versus saline control and 4.52 log versus Tamiflu control were observed through day 5, but statistical analysis at this time point was not possible due to limited animal numbers.

Microscopic examination of the lungs of the infected ferrets seven days after infection evaluated the extent of regional tissue damage. Pathology scores in each study revealed only mild damage in the AVI-7100 treated ferrets versus severe damage in both saline controls and Tamiflu controls. The gross examination of the lung and spleens of the AVI-7100 treated ferrets appear normal, but obvious damage was observed in these tissues in the saline and Tamiflu controls. Finally, the number of infiltrating macrophages in the bronchiolar space was reduced in the AVI-7100 treated ferrets compared to the saline or the Tamiflu controls.

Presentation of the final data from these studies is planned for a medical conference in 2010.

About The TMT/AVI H1N1 Rapid Response Exercise As part of its ongoing evaluation of programs being conducted in cooperation with AVI, the U.S. Department of Defense Transformational Medical Technologies program established a contract with AVI to conduct a rapid response exercise against a real-world emerging threat, the pandemic H1N1 virus. The intent of the exercise was to demonstrate the capability of AVI to efficiently respond to a real-world emerging viral threat by rapidly designing and producing multiple therapeutic candidates and evaluating preclinical efficacy.

Initially the exercise involved identifying target sequences against H1N1, designing several drug candidates utilizing proprietary derivatives of AVI's antisense phosphorodiamidate morpholino oligomers (PMO) chemistry, and then manufacturing the candidates in sufficient quantity for preclinical testing. This was successfully accomplished in approximately one week, demonstrating AVI's ability to rapidly respond to a real-world viral threat utilizing the AVI's RNA based therapeutics platform.

Subsequently, AVI evaluated its RNA-based drug candidates in preclinical studies using a mouse model of seasonal flu and identified two lead candidates, including AVI-7100. The two lead candidates were tested in the more advanced ferret model utilizing a fully virulent human pandemic H1N1 virus. The ferret studies included various treatment groups employing the lead candidates administered via intraperitoneal and intranasal dosing routes, a saline control group, a scrambled RNA sequence control group and a control group dosed with Tamiflu, a standard of care drug. While both lead candidates and routes of administration were indicative of activity versus all controls, AVI-7100 administered intraperitoneally demonstrated overall superiority.

About AVI-7100 AVI-7100 employs AVI's patented PMOplus(TM) technology that selectively introduces positive charges to its phosphordiamidate morpholino oligomer (PMO) backbone to improve selective interaction between the drug and its target. The PMOplus(TM) chemistry platform previously generated two Investigational New Drugs (INDs) for AVI-6002 and AVI-6003, AVI's lead hemorrhagic fever virus therapeutic candidates for Ebola and Marburg viruses, respectively. These hemorrhagic fever virus therapeutic candidates are being developed under a July 2010 contract awarded through the U.S. Department of Defense Transformational Medical Technologies program (TMT). This contract provides funding to AVI of up to approximately \$291 million.

Activities to develop AVI-7100 as a medical countermeasure against the pandemic H1N1 influenza virus are being funded under a June 2010 contract awarded to AVI through the TMT program. The contract provides for funding of up to \$18 million to advance the development of AVI-7100, and includes studies enabling an Investigational New Drug (IND) application with the U.S. Food and Drug Administration, the study of an intranasal delivery formulation, and the funding of a Phase 1 clinical trial to obtain human safety data to support potential use under an Emergency Use Authorization.

Additional funding under an earlier contract awarded to AVI via the TMT program is supporting continued preclinical evaluation of AVI-7100 against H1N1 as well as expanded preclinical evaluation against H5N1 (avian flu) and drug resistant H1N1 and H3N2 flu strains. Funding from this earlier contract also supported the rapid response exercise and is valued at up to \$8.1 million.

About Pandemic H1N1 Influenza On June 11, 2009 the World Health Organization declared a pandemic of H1N1 influenza. The virus was first detected in people in the U.S. in April 2009 and was referred to as "swine flu" because many of the genes in the virus were very similar to those found in flu viruses that circulate in pigs (swine). Illness with the 2009 H1N1 virus has ranged from mild to severe. Symptoms include fever, cough, runny nose, headache, chills and fatigue. Many people infected with H1N1 also have respiratory symptoms without a fever. Severe illness and deaths have occurred as a result of illness associated with the virus. The Centers for Disease Control and Prevention (CDC) estimated that between April 2009 and April 2010 there were up to 89 million cases of H1N1 infection in the U.S. The CDC also estimated that there were up to 403,000 H1N1-related hospitalizations in the U.S. during the same time period.

About the Defense Threat Reduction Agency The Defense Threat Reduction Agency (DTRA) was founded in 1998 to integrate and focus the capabilities of the Department of Defense (DoD) that address the threat by weapons of mass destruction (WMD). DTRA's mission is to safeguard the United States and its allies from chemical, biological, radiological, nuclear and high-yield explosive WMDs by providing capabilities to reduce, eliminate and count the threat and mitigate its effects. DTRA combines DoD resources, expertise, and capabilities to ensure the United States remains ready and able to address the present and future WMD threats. For more information on DTRA, visit www.dtra.mil.

About the Transformational Medical Technologies Program (TMT) The TMT program was created by the U.S. Department of Defense to protect the Warfighter from emerging and genetically altered biological threats by discovering and developing a wide range of medical countermeasures through enhanced medical research, development, test and evaluation programs. The TMT Program Office is matrixed from the Joint Science and Technology Office -- DTRA and Joint Program Executive Office -- Chemical and Biological Defense, with oversight from the Office of the Secretary of Defense. For more information on TMT, visit <http://www.tmti-cbdefense.org>.

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, we are able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. Unlike other RNA-based approaches, our 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 our highly differentiated RNA antisense-based technology platform, we have built a pipeline of potentially transformative therapeutic agents, including a clinical stage Duchenne muscular dystrophy candidate and anti-infective candidates

for influenza and hemorrhagic fever viruses. For more information, visit www.avibio.com.

Forward-Looking Statements and Information

This press release contains statements that are forward-looking, including statements about the amount and timing of potential funding; the development of AVI 7100, AVI 6002 and AVI 6003, including preclinical development, filing of an IND application, completion of a Phase 1 human safety clinical trial, clinical development and FDA approval; AVI's PMOplus(TM) chemistry and other antisense-based technology and its ability to protect against the H1N1 virus, as well as its efficacy, potency and utility in the treatment of infectious diseases, and its 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: development of any of AVI 7100 , AVI 6002 and/or AVI 6003 may not result in funding from the TMT in the anticipated amounts or on a timely basis, if at all; clinical trials may not demonstrate safety and efficacy of any of our drug candidates and/or our antisense-based technology platform; any of our 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. The results and analysis of the AVI 7100 studies described in this press release are subject to interpretation, and may not be repeated in later preclinical and clinical trials. The AVI 7100 study described in this press release is subject to interpretation and included small numbers of animal subjects which may limit the utility of the statistical analysis conducted in predicting future results. Further, the AVI 7100 study results described in this press release is not predictive of future outcomes and may not be repeated in later preclinical and clinical trials.

SOURCE: AVI BioPharma, Inc.