



AVI BioPharma Reports Confirmation of Efficacy against Influenza Strains

1/20/06

NEUGENE Antisense Efficacy against Influenza Strains, Including Avian Influenza, to Lead to IND Filing with the FDA

PORTLAND, Ore.--(BUSINESS WIRE)--Jan. 20, 2006--AVI BioPharma, Inc. (Nasdaq:AVII) today announced confirmation from three independent laboratories of NEUGENE(R) antisense efficacy in preclinical experiments against multiple strains of influenza, including avian influenza strain H5N1.

- Dr. P. Puthavathana at Mahidol University in Bangkok, Thailand, confirmed NEUGENE antisense efficacy against an H5N1 viral isolate in her assay system.

- Dr. Darwyn Kobasa at the Public Health Agency of Canada in Winnipeg, Manitoba, completed an initial dose-response study in cell culture demonstrating NEUGENE efficacy against both the H1N1 and H3N2 strains.

- Dr. Manoj Pastey at Oregon State University in Corvallis, Ore., confirmed efficacy using the same NEUGENE antisense agents against the H7N7 and H3N8 strains.

Taken together, these data confirm efficacy observed with the H1N1 strain previously reported from Drs. Jianzhu and Chen Qin Ge at Massachusetts Institute of Technology in Boston and now represent positive reports from four laboratories using different endpoints and methodologies.

"These confirmations validate our approach to blocking replication of influenza viruses. We now believe that a single NEUGENE drug could be effective against most influenza subtypes, including the H5N1 avian strain," said Patrick L. Iversen, Ph.D., senior vice president of research and development at AVI. "By targeting regions of the viral genetic code that are common to all influenza A subtypes, we expect that our NEUGENE drugs will be effective against avian flu and the far more common influenza A viruses, which kill an average of 35,000 Americans every year."

AVI is also conducting collaborative animal studies evaluating NEUGENE efficacy against influenza strains at Tulane University in New Orleans and at the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) in Frederick, Maryland.

"Based on these recent findings and other results from additional studies, AVI now plans to file an Investigative New Drug (IND) application with the FDA for the treatment of influenza A virus with NEUGENE antisense drugs," said Denis R Burger, Ph.D., chief executive officer of AVI. "We feel confident in the safety, efficacy and potency of our NEUGENE drugs targeting influenza and plan to move forward into the clinical trial process later this year."

AVI's NEUGENE antisense drug development program against the influenza A virus specifically targets genetic regions of the virus that are highly conserved between six viral subtypes that cause human disease. These include three subtypes that caused pandemics in the 20th century -- the 1918 Spanish flu (H1N1), the 1957 Asian flu (H2N2) and the 1968 Hong Kong flu (H3N2) -- and three subtypes of avian flu that have been reported to cause disease in humans (H5N1, H7N7 and H9N2).

AVI's Antiviral Program

AVI's proprietary NEUGENE antisense drug candidates have demonstrated efficacy in preclinical studies against SARS coronavirus, West Nile virus (WNV), hepatitis C virus (HCV), dengue virus, Ebola virus, and Marburg virus. AVI has filed IND applications with the U.S. Food and Drug Administration and has ongoing clinical trials in WNV and HCV.

Showing how versatile NEUGENE drugs can be across viral subtypes, AVI demonstrated in its collaboration with the Centers for Disease Control and Prevention that NEUGENE agents are efficacious against all four immunologically distinct subtypes of the dengue virus. This outcome was achieved by targeting a highly conserved region of the dengue viral genetic code. In collaborative work with the USAMRIID targeting the Ebola virus, NEUGENE drugs protected three animal species from lethal challenges with this virus (see PLoS Pathog 2(1): e1). Additional clinical development efforts targeting dengue virus and Ebola virus are planned for 2006.

The speed with which effective NEUGENE drugs can be designed and manufactured exceeds any other modern drug development timeframe. For example, NEUGENE compounds targeting SARS, WNV and Ebola were developed within days to weeks of obtaining the appropriate genetic sequences for the viruses.

AVI's Clinical Experience

AVI's NEUGENE antisense drugs have a well-defined safety record in human clinical trials. Approximately 300 patients have been dosed with NEUGENE drug candidates targeting host and viral gene targets in 12 clinical studies under multiple INDs. Five routes of administration have been employed in AVI's clinical studies, and doses up to 450 mg have been administered without a single drug-related, serious adverse event. The combination of AVI's NEUGENE chemistry with conserved viral targets that are not expressed in the human genome makes a strong case for the

potential for success in the development of candidates to address influenza, including the possible emergence of a transmittable avian flu.

About Influenza A Viruses

Influenza, or flu, is a contagious respiratory illness caused by influenza viruses. On average 5 percent to 20 percent of the U.S. population is infected with the flu each year. Influenza A virus is an enveloped negative-strand RNA virus, with eight genome segments that code for 10 proteins. Influenza strains are subtyped according to the antigenic and genetic nature of their surface glycoproteins: hemagglutinin (HA or H) and neuraminidase (NA or N). Fifteen H and nine N subtypes have been identified, with three associated with widespread human disease (H1N1, H2N2 and H3N2). In addition, several subtypes of avian influenza virus -- H5N1, H7N7 and H9N2 -- can infect and cause disease in humans.

The current influenza pandemic in birds throughout Asia, Eastern Europe and Turkey is caused by the H5N1 subtype. It is thought that co-infection of humans or certain animals (such as pigs) with both H1N1 and H5N1 can lead to a reassortment or recombination of viral particles, resulting in the emergence of a virus with dangerous public health properties, namely one to which the human population has no natural immunity and which has the ability to spread easily from person to person. It is believed that emergence of avian flu by this general mechanism may have led to the worldwide pandemics of 1918, 1957 and 1968.

About AVI BioPharma

AVI BioPharma develops therapeutic products for the treatment of life-threatening diseases using third-generation NEUGENE antisense drugs. AVI's lead NEUGENE antisense compound is designed to target cell proliferation disorders, including cardiovascular restenosis, cancer and polycystic kidney disease. In addition to targeting specific genes in the body, AVI's antiviral program uses NEUGENE antisense compounds to combat disease by targeting single-stranded RNA viruses, including West Nile virus, hepatitis C virus, dengue virus and Ebola virus. AVI has introduced a NEUGENE-based exon-skipping technology called ESPRIT therapy. More information about AVI is available on the company's Web site at <http://www.avibio.com>.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: The statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including, but not limited to, the results of research and development efforts, the results of preclinical and clinical testing, the effect of regulation by the FDA and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, and other risks detailed in the company's Securities and Exchange Commission filings.

CONTACT: AVI BioPharma, Inc.
Michael Hubbard, 503-227-0554
hubbard@avibio.com
or
Lippert/Heilshorn & Associates Inc.
Bruce Voss, 310-691-7100 (Investors)
bvoss@lhai.com
Jody Cain, 310-691-7100 (Investors)
jcain@lhai.com
or
Waggener Edstrom Worldwide
Bioscience and Healthcare Practice
Jenny Moede, 503-443-7000 (Press)
jmoede@waggeneredstrom.com

SOURCE: AVI BioPharma, Inc.