AVI BioPharma Opens Investigational New Drug (IND) Application for AVI-4658 in Duchenne Muscular Dystrophy

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BOTHELL, WA, Jul 07, 2010 (MARKETWIRE via COMTEX) --

AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based therapeutics, today announced that following review by the U.S. Food and Drug Administration the Company's Investigational New Drug (IND) application for AVI-4658 is open. AVI-4658 is AVI's lead drug candidate being developed as a systemically administered treatment for a substantial subgroup of patients with Duchenne muscular dystrophy (DMD), a genetic muscle wasting disease caused by failure to produce dystrophin. AVI plans to initiate a Phase 1b/2 clinical trial in DMD in the U.S. this year.

The intended site for the planned U.S. based study is Nationwide Children's Hospital in Columbus, Ohio, with Jerry R. Mendell, M.D. as the Principal Investigator. The clinical program design is being reviewed in consultation with Dr. Mendell, co-investigator Kevin Flanigan, M.D., and other DMD key opinion leaders. It is anticipated that future clinical evaluation will explore increasing doses of AVI-4658 considering the generally well tolerated nature of the drug candidate as exhibited in the clinical and preclinical studies to date, and the substantial, but variable, increases in dystrophin measurements demonstrated in patients with DMD in the U.K. based Phase 1b/2 clinical trial.

"We are actively working with scientific and medical experts and regulatory authorities to finalize plans for our U.S. based Phase 1b/2 study as we complete the collection and analysis of clinical data from the recent U.K. trial of AVI-4658," stated Stephen B. Shrewsbury, M.D., Senior Vice President and Chief Medical Officer, AVI BioPharma, Inc. "The results we have reported to date are very promising and suggest an overall very favorable safety profile. As we continue the clinical evaluation of systemically administered AVI-4658, I remain optimistic about its potential to induce consistent, substantial novel dystrophin protein expression in patients with DMD."

AVI-4658 is an RNA-based therapeutic employing AVI's novel phosphorodiamidate morpholino oligomer (PMO) based chemistry and exon skipping technologies. It is being developed as a systemic treatment for patients with DMD.

About Duchenne Muscular Dystrophy

Duchenne Muscular Dystrophy (DMD) is one of the most common fatal genetic disorders to affect children around the world. Approximately one in every 3,500 boys worldwide is affected with DMD. Girls are rarely affected by the disorder. DMD is a devastating and incurable muscle-wasting disease associated with specific inborn errors in the gene that codes for dystrophin, a protein that plays a key structural role in muscle fiber function. Symptoms usually appear in children by age three. Progressive muscle weakness of the legs and pelvis eventually spreads to the arms, neck, and other areas. By age 10, braces may be required for walking, and most patients require full-time use of a wheelchair by age 12. Eventually, this progresses to complete paralysis and increasing difficulty in breathing due to respiratory muscle dysfunction requiring ventilatory support, and cardiac muscle dysfunction leading to heart failure. The condition is terminal and death usually occurs before the age of 30. The outpatient cost of care for a non-ambulatory DMD patient is very high. There is currently no cure for DMD, but for the first time ever there are promising therapies in, or moving into, development.

About AVI BioPharma

AVI BioPharma is focused on the discovery and development of RNA-based medicines 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, including an ongoing systemic Phase 1b/2 clinical trial of exon skipping with AVI-4658. 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 Junin, influenza, HCV or Dengue viruses. For more information, visit 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.

SOURCE: AVI BioPharma, Inc.