



AVI BioPharma's Drug for Duchenne Muscular Dystrophy Recommended for Orphan Drug Status in EU and Receiving Provisional GTAC Approval for Clinical Trial in UK

10/14/08

For Immediate Release

CORVALLIS, OR — October 14, 2008 — AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based drugs, today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) adopted a positive opinion recommending orphan medicinal product designation for AVI-4658 to treat Duchenne muscular dystrophy (DMD). Additionally, the Company received notification from the Gene Therapy Advisory Committee (GTAC) in the UK granting provisional approval for the Company's planned clinical trial for systemic delivery of AVI-4658 to treat DMD. The conditions for final GTAC approval include certain wording changes in the patient and parent information documents and completion of normal site specific assessments. AVI expects to comply with the conditions for final approval this quarter.

The Company believes the positive COMP opinion will serve as the scientific basis for the European Commission to issue a European Union orphan designation pursuant to Regulation (EC) 141/2000. Orphan designation in the EU brings several benefits to the sponsor including certain fee waivers, protocol assistance in product development, and marketing exclusivity up to 10 years.

"The EMA Committee's positive recommendation on orphan status for AVI-4658 in DMD together with GTAC's favorable review of our clinical trial protocol for the same drug candidate adds further momentum to the development of AVI's portfolio of exon skipping drugs to treat this devastating and debilitating disease", said Dr. Leslie Hudson, President and Chief Executive Officer of AVI BioPharma. "These positive events are evidence of the Company's continuing commitment to advance potential new treatments for DMD. We expect to see results from our ongoing intramuscular administration trial shortly and to begin the intravascular administration trial once all approvals are finalized. We also look forward to advancing AVI-4658 towards the clinic in the US during 2009".

In June of 2008, the Medicine & Healthcare Product Regulatory Agency (MHRA) in the UK gave clearance for the Company to move forward with a Company-sponsored systemic clinical trial of AVI-4658 in the United Kingdom. This trial, which will involve an intravascular (IV) administration to sixteen ambulatory boys with DMD, is expected to start in the current quarter once GTAC approval is complete. The Company was granted an orphan drug designation for AVI-4658 by the U.S. Food and Drug Administration (FDA) in November of 2007.

AVI BioPharma is currently engaged in a clinical trial at the Imperial College of London where patients with DMD are receiving a single-dose, intramuscular (IM) administration of AVI-4658. This study is being conducted in collaboration with the United Kingdom-based MDEX Consortium. AVI-4658 is designed to skip exon 51 of the dystrophin gene, thus repairing the mutated reading frame in the mRNA sequence coding for dystrophin, a vital protein which is absent or virtually absent in boys with DMD. By skipping this exon, a truncated, yet functional, form of the dystrophin protein is produced and this could ameliorate the disease process, potentially prolonging and improving the quality of life in these patients.

Leading experts specializing in the fields of genetic disease and/or neuromuscular disorders believe that exon skipping is one of the most exciting and promising approaches to treat a majority of DMD patients. AVI has continued to demonstrate its scientific leadership in the application of exon skipping to DMD through the publication of preclinical results of studies demonstrating the ability of AVI's new class of drug candidates — termed PPMO-B — to induce sustained expression of dystrophin in the mdx mouse model of DMD. Treatment with this new class of AVI compound resulted in the sustained production of functional dystrophin in numerous tissues, including the heart, diaphragm and skeletal muscles. These are key organs for the treatment of the disease. The papers were published in peer-reviewed journals, *Molecular Therapy*, "Sustained Dystrophin Expression Induced by Peptide-Conjugated Morpholino Oligomers in the Muscles of mdx Mice", by Jearawiriyapaisarn N, Moulton HM, Buckley B, Roberts J, Sazani P, Fucharoen S, Iversen P, Kole R and *Proceedings of National Academy of Science* "Effective rescue of dystrophin improves cardiac function in dystrophin-deficient mice by a modified morpholino oligomer" by Wu B, Moulton HM, Iversen PL, Jiang J, Li J, Li J, Spurney CF, Sali A, Guerron AD, Nagaraju K, Doran T, Lu P, Xiao X, Lu QL.

See:

- <http://www.nature.com/mt/journal/vaop/ncurrent/abs/mt2008120a.html>
- <http://www.pnas.org/content/105/39/14814.full>

About Orphan Drug Designation

In the United States, the Orphan Drug Act provides economic incentives to encourage biotechnology and pharmaceutical companies to develop drugs for rare diseases...those affecting fewer than 200,000 people in the U.S. Orphan drug designation entitles AVI to 7 years of market exclusivity for AVI-4658 for the treatment of patients with DMD. Additional incentives include tax credits related to development expenses, reduction in FDA user fees and FDA assistance in clinical trial design. In the EU, Orphan Drug designation is provided to encourage the development of products that demonstrate promise for the diagnosis, prevention and/or treatment of life-threatening or very serious conditions that are rare and affect not more than 5 in 10,000 persons in the European Union. The EU designation of orphan drug status provides many of the same benefits as in the U.S.; however, the period of market exclusivity for an approved drug is 10 years.

About Duchenne Muscular Dystrophy (DMD)

DMD is the most common fatal genetic disorder to affect children around the world. Approximately one in every 3,500 boys worldwide is afflicted with Duchenne muscular dystrophy with 20,000 new cases reported each year. It 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 male children before age 6. 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 are confined to a wheelchair by age 12. Eventually, this progresses to complete paralysis and increasing difficulty in breathing. The condition is terminal and death usually occurs before the age of 30. The outpatient cost of care for a non-ambulatory DMD boy is among the highest of any disease. There is currently no cure for DMD, but for the first time in decades, there are promising therapies in or moving into development.

About AVI BioPharma

AVI BioPharma is focused on the discovery and development of RNA-based drugs using the company's expanded portfolio of proprietary antisense compounds (PMOs). The company's technology applications leverage distinct mechanisms of action in a range of genetic diseases, genetic disorders and the genetic code of disease-causing organisms. The emerging field of directed alternative RNA splicing represents AVI's newest and most exciting application based on the company's core antisense technology. Functional attributes of this approach may include correcting genetic defects (RNA mutations; which AVI believes could produce promising treatments for Duchenne muscular dystrophy), coding for novel soluble receptors (an exciting and novel approach which could have application in the treatment of inflammatory diseases such as rheumatoid arthritis), and the reduction in activity of immune modulators in disease states (currently being applied to IL-10). AVI's RNA-based drug programs also include blocking mRNA translation. In AVI's biodefense program, this application has been successful against the single-stranded RNA viruses Ebola Zaire and Marburg Musoke in non-human primates and may have value against other viral targets such as HCV, Dengue, Junin, influenza and RSV viruses. This application also will be evaluated in the clinic for the treatment of cardiovascular restenosis by our partner Cook Medical. More information about AVI is available at www.avibio.com.