AVI BioPharma Receives Orphan Drug Designation for AVI-4658 for Treatment of Duchenne Muscular Dystrophy

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PORTLAND, Ore.--(BUSINESS WIRE)--Nov. 1, 2007--AVI BioPharma, Inc. (Nasdaq:AVII), announced today that the U.S. Food and Drug Administration's (FDA) Office of Orphan Products Development has granted orphan drug designation to AVI-4658 for the treatment of Duchenne muscular dystrophy (DMD). AVI-4658 uses AVI's ESPRIT technology (Exon Skipping Pre-RNA Interference Technology) and is designed to benefit patients with certain mutations in the dystrophin gene. By "skipping" exon 51, the proper RNA reading frame can be restored in suitable patients, resulting in the production of functional dystrophin.

AVI is planning clinical development of AVI-4658 including a dose-ranging trial using systemic administration of the drug. This trial will be conducted in conjunction with the company's DMD cross-licensing and development partner, Ercole Biotech, Inc.

"The orphan drug designation for AVI-4658 is a significant step in AVI's development of this drug candidate," said K. Michael Forrest, interim CEO of AVI. "DMD is a devastating disease that currently has no viable treatment or cure. Patients deserve the hope of a longer and higher quality of life through innovative therapeutics."

As announced Oct. 26, 2007, clinical researchers at the Imperial College of London received approval to begin enrollment for a proof-of-principle study evaluating AVI-4658 in a single-dose, intramuscular administration study. This study is being conducted in collaboration with the United Kingdom-based MDEX Consortium.

About Orphan Drug Designation

The Orphan Drug Act (ODA) provides economic incentives to encourage biotechnology and pharmaceutical companies to develop drugs for rare diseases, those affecting fewer than 200,000 people in the United States. Orphan drug designation entitles AVI to seven years of market exclusivity for AVI-4658 for the treatment of patients with DMD. Additional incentives for orphan drug development include tax credits related to development expenses, reduction in FDA user fees and FDA assistance in clinical trial design.

About Duchenne Muscular Dystrophy

DMD, one of the muscular dystrophies, is the most common fatal genetic disorder to affect children around the world. It is a devastating and incurable muscle-wasting disease associated with specific inborn errors in the gene that expresses dystrophin, a protein that plays an important structural role in muscle fibers. When dystrophin is missing or nonfunctional due to a mutation in the dystrophin gene, as it is in DMD, the result is membrane leakage and fiber damage, ultimately leading to degeneration and death of the muscle fiber. In two-thirds of DMD cases, the genetic mistake is hereditary, but one-third of cases arise spontaneously. There is no cure for DMD. Approximately one in 3,500 boys is born with DMD, and an estimated 15,000 to 20,000 children have DMD in the United States alone.

About ESPRIT Technology

In normal genetic function, gene transcription produces a full-length pre-RNA that is then processed to a much shorter and functional messenger RNA. The mRNA is the template for creating a protein. During pre-RNA processing, packets of useful genetic information, called exons, are snipped out of the full-length RNA and spliced together to make the functional mRNA template. AVI's proprietary third-generation NEUGENE(R) chemistry can be used to target splice-joining sites in the pre-RNA, thus forcing the cell machinery to skip over targeted exons, providing altered mRNA, which in turn produces altered proteins. When the skipped exon contains a disease-causing mutation, the altered protein may restore function and potentially overcome the devastating clinical consequences of the mutation.

About AVI BioPharma

AVI BioPharma develops therapeutic products for the treatment of life-threatening diseases using third-generation NEUGENE(R) antisense drugs and ESPRIT exon skipping technology. AVI's ESPRIT technology is initially being applied to potential treatments for Duchenne muscular dystrophy. AVI's lead NEUGENE compound is designed to target cell proliferation disorders, including cardiovascular restenosis. 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 dengue virus, Ebola virus and H5N1 avian influenza viruses. 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.

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