



AVI BioPharma Receives Fast Track Designation for AVI-4658 for Treatment of Duchenne Muscular Dystrophy

12/3/07

PORTLAND, Ore.--(BUSINESS WIRE)--Dec. 3, 2007--AVI BioPharma, Inc. (Nasdaq:AVI), today announced that the U.S. Food and Drug Administration has granted Fast Track status to its product candidate, AVI-4658, for the treatment of Duchenne muscular dystrophy (DMD).

DMD 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.

AVI-4658 uses AVI's Exon Skipping Pre-RNA Interference Technology (ESPRIT) to potentially benefit DMD patients who have mutations in exon 51 of the dystrophin gene. In animal models, ESPRIT technology has demonstrated the ability to selectively bypass defective exons, thus restoring near-normal levels of dystrophin production. The company believes that by using AVI 4658 to skip exon 51, clinically relevant levels of dystrophin may be produced, limiting further muscle function decline in some patients. AVI-4658 was recently granted Orphan Drug status for the same indication.

AVI plans to initiate a clinical trial with systemically delivered AVI-4658 by mid-2008, to evaluate the safety and potential efficacy of the drug in ambulatory DMD patients.

"We expect that Fast Track designation will open the door to expedited clinical development and regulatory review of AVI-4658 in the United States. We welcome the opportunity to work closely with the FDA to determine the best and shortest path forward with our promising new approach for the treatment of this disease," said K. Michael Forrest, interim chief executive officer of AVI. "We look forward to fruitful and timely discussions with the FDA to agree on an approach that will accomplish these objectives."

About Fast Track Designation

Fast Track designation of a product candidate is intended to facilitate the development and to expedite the review of drugs for serious and life-threatening conditions so that an approved product can reach the market expeditiously. This designation provides for priority interactions with the FDA.

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 antisense drugs and ESPRIT exon skipping technology. AVI's ESPRIT technology is initially being applied to potential treatments for Duchenne muscular dystrophy. AVI's NEUGENE compounds are also designed to treat cardiovascular restenosis, and aid in Coronary Artery Bypass Graft (CABG) procedures. 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 Marburg virus, Ebola Zaire virus, and H5N1 avian influenza virus. 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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