

AVI BioPharma Presents Safety Data in Duchenne Muscular Dystrophy at 14th Annual International Congress of the World Muscle Society

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AVI-4658 Demonstrates Encouraging Human Safety Profile, Targeted Exon Skipping and New Dystrophin Production in Phase 1 Intramuscular Injection Study; Preliminary Data from Ongoing Phase 1b/2 Systemic Study Support Safety and Potential for Long-Term Dosing

For Immediate Release

BOTHELL, WA — September 14, 2009 — AVI BioPharma, Inc. (Nasdaq: AVII), a developer of RNA-based drugs, today announced that full data from its completed Phase 1 clinical trial of its splice skipping oligomer (SSO) AVI-4658 in patients with Duchenne Muscular Dystrophy (DMD) was presented at the 14th Annual International Congress of the World Muscle Society in Geneva, Switzerland. These data, presented by Dr. Virginia Arechavala-Gomez, a member of the MDEX Consortium at the University College London Institute of Child Health, showed that AVI-4658 was safe when injected intramuscularly and successfully induced the production of dystrophin protein in patients in a dose-responsive manner. This safe and well-tolerated production of new dystrophin is believed to be the key to restoring muscle function and successfully treating patients with DMD - a condition for which there is no currently approved disease modifying therapy.

Preliminary safety data from AVI's current systemic Phase 1b/2 clinical trial of AVI-4658 in patients with DMD was also presented by Dr. Stephen B. Shrewsbury, Chief Medical Officer and Senior Vice President of Preclinical, Clinical and Regulatory Affairs of AVI at the World Muscle Society (WMS) in Geneva on September 12, 2009. This presentation highlighted the study's early findings, which showed AVI-4658 to be well tolerated in patients in the first two completed dosing cohorts and the study's three ongoing dosing cohorts, where there have been no confirmed, drug-related adverse events or safety issues. These preliminary data further support the study's dose escalation to the final patient cohort at 20 mg/kg, which has been agreed in principal by the UK Regulatory Authority (MHRA) and the Ethics Committee and will be preceded by a Data Safety Monitoring Board review of data from the highest dose cohort currently being treated (10 mg/kg).

"These positive safety findings are exciting and promising, both for AVI-4658 and, most importantly, for patients and their families living with DMD," said Dr. Shrewsbury. "With no currently approved disease modifying therapies available to treat this fatal genetic disease, the progress being made in SSO-induced exon skipping is key. Insights into long-term safety and chronic dosing regimens could represent a crucial step forward in developing a safe and effective lifelong treatment for patients living with DMD."

The Phase 1 proof of principle, single dose escalation study tested the effect of an intramuscular injection of AVI-4658 in boys with DMD. The primary and secondary endpoints were safety and efficacy of AVI-4658, respectively. Each patient received an injection of 0.09 mg or 0.9 mg of AVI-4658, which is a novel phosphorodiamidate morpholino oligomer (PMO), into the exterior digitorum brevis muscle of one foot and an injection of saline as placebo into the corresponding muscle of the opposite foot to provide an internal treatment comparison. Three to four weeks later, each injected muscle was biopsied and examined for evidence of dystrophin production. Results demonstrated that injection of AVI-4658 elicited exon 51 skipping and dystrophin production in a dose dependent manner in all treated patients. Specifically, 44-79% of EDB fibers were dystrophin-positive, relative to contralateral muscle background and dystrophin levels seen in patients treated with AVI-4658 (equivalent to 42% of the dystrophin levels seen in each normal muscle cell) exceeded the levels achieved in a recent 2'O-methyl-phosphorothioate oligomer (2'O-Me P) DMD clinical trial. Importantly, AVI-4658 was well tolerated, with no adverse events related to the administration of the drug. These findings were also recently published in *Lancet Neurology* online and will appear in the journal's October 2009 print issue.

The currently ongoing Phase 1b/2 dose-finding clinical trial is evaluating the systemic delivery of AVI-4658. This is an open label, 12-week safety trial that includes measures of drug efficacy and pharmacokinetics. To date, four of the six dosing cohorts have been successfully completed and the fifth dosing cohort (10 mg/kg) is ongoing. Preliminary data presented at the WMS show that AVI-4658 has been well tolerated with very few mild and transient drug-related adverse events and no serious adverse events. Further, the independent Data Safety Monitoring Board (DSMB) has approved each of the trial's dose escalations and - with

DSMB approval - AVI could begin dosing on the sixth and final cohort (20 mg/kg) shortly. Importantly, dosing of the fifth and sixth cohort out to 12 weeks will exceed both dose level and duration of dosing previously studied by other researchers with the alternative 2'O-Me P approach. AVI believes that this encouraging and growing safety profile, duration of exposure and approved dose escalations are extremely important clinical advances for its PMO chemistry approach as any dose-limiting toxicity for any drug, could severely limit the effectiveness of a DMD therapy in this chronic condition where treatment must start in childhood and probably continue for life.

"It has been very pleasing to work on this project from its beginning and to be part of its early clinical success - showing the safety and efficacy of AVI-4658 when administered intramuscularly," said Professor Francesco Muntoni, the study's lead investigator and head of the MDEX consortium in the UK, which performed the study. "We are delighted to be recruiting DMD patients into the ongoing systemic study and to see that treatment is being well tolerated. The children in this trial and their families have been enthusiastic in their participation in these studies and we would like to thank them for taking part in this important clinical work."

The Phase 1b/2 clinical trial is being conducted in London, UK at the UCL Institute of Child Health / Great Ormond Street Hospital NHS Trust facilities and at the Royal Victoria Infirmary, Newcastle-Upon-Tyne, UK, which is the coordinating center for the European Treat Neuromuscular Diseases (Treat-NMD) initiative. The clinical costs for the trial are provided, in part, by the UK Medical Research Council.

About Duchenne Muscular Dystrophy (DMD)

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 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 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 are confined to a wheelchair by age 12. Eventually, this progresses to complete paralysis and increasing difficulty in breathing requiring ventilatory support. 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 ever, there are promising therapies in or moving into development.

About AVI BioPharma

The MDEX consortium led by Professor Francesco Muntoni, is a multidisciplinary enterprise to promote translational research into muscular dystrophies, and is formed by the clinical groups of Professor Francesco Muntoni (UCL Institute of Child Health) and Professor Kate Bushby and Professor Volker Straub (Newcastle University), and scientists from Imperial College London (Professor Dominic Wells), UCL Institute of Child Health (Dr. Jennifer Morgan), Royal Holloway University of London (Professor George Dickson), Oxford University (Dr. Matthew Wood) and University of Western Australia (Professor Steve Wilton). In addition, the charities Muscular Dystrophy Campaign (MDC), Action Duchenne and Duchenne Family Support Group also participate in the Consortium. For more information, visit www.mdex.org.uk.

About AVI BioPharma

AVI BioPharma is focused on the discovery and development of RNA-based drugs 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 as well as for the treatment of cardiovascular restenosis through our partner Global Therapeutics, a Cook Group Company. 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 HCV or Dengue viruses. For more information, visit www.avibio.com.