AVI Enters Into Collaborations for the Development of Two Additional Exon-Skipping Products for Duchenne Muscular Dystrophy (DMD)

November 15, 2011 8:05 AM ET

Collaborations Represent Key Inflection Point in AVI's Progress in Developing Treatments for Broader DMD Population

BOTHELL, WA, Nov 15, 2011 (MARKETWIRE via COMTEX) --

AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based therapeutics, today announced collaborations for the development of two additional exon-skipping drugs, one for exon 45 and one for exon 50, to support AVI's broad-based development program for the treatment of DMD. AVI's collaboration with Children's National Medical Center in Washington, D.C. and the Carolinas Medical Center (CMC) will support certain IND-enabling activities for an exon 45-skipping therapeutic. AVI's collaboration with the National Institutes of Health (NIH) will support IND-enabling activities for an exon 50-skipping therapeutic and will be supported through in-kind research conducted either by the Therapeutics for Rare and Neglected Diseases (TRND) program or by contract research organizations. AVI is currently conducting a Phase IIb trial of eteplirsen, its exon 51-skipping therapeutic candidate for the treatment of DMD.

"The initiation of these additional programs, with the financial support of, and in collaboration with, leading institutions, is a validation of AVI's exon-skipping drug platform and will help to accelerate the development of our DMD program," said Chris Garabedian, President and CEO of AVI BioPharma. "These collaborations will lay the foundation for AVI's pan exon strategy for the development of therapeutics to treat a majority of the DMD population."

Exon 45-Skipping Collaboration

The collaboration with Children's National and CMC will be funded primarily through two grants, one from the U.S. Department of Defense's (DoD) Congressionally Directed Medical Research Program to Children's National and the other from the National Institute of Neurological Disorders and Stroke to CMC. This funding is intended to pursue the most promising treatments for DMD. The collaboration will support a series of GLP toxicology studies for an exon 45-skipping drug candidate based on AVI's phosphorodiamidate morpholino oligomer (PMO) chemistry. The details of the research plan associated with this collaboration, as well as the details of the funding from the NIH and the DoD, will be finalized by the parties over the next few months.

"Children's National is committed to finding an effective treatment for Duchenne muscular dystrophy patients," said Eric Hoffman, PhD, Director of the Center for Genetic Medicine Research at Children's National Medical Center. "Working with partners like AVI and their PMO-based exon-skipping therapeutics may accelerate the clinical development of a specific exon 45-skipping therapeutic that could improve the care and quality of life for more boys with this disease."

Dr. Qi Long Lu, director of the McColl-Lockwood Laboratory at Carolinas Medical Center, added, "A strong pre-clinical GLP toxicology package is a critical part of a robust drug development program. Our collaboration with AVI is designed to help support the IND-enabling work necessary to advance AVI's exon-skipping drug candidates into the clinic."

Exon 50-Skipping Collaboration

The TRND program is a new initiative by NIH designed to assist in the development of new drugs for rare and neglected diseases. To develop new medicines, TRND establishes partnerships with leading academic, government, biopharmaceutical and patient advocacy groups to focus on the discovery, optimization and pre-clinical testing of new drugs. AVI was selected for the award through a national competitive process. Definitive details of the collaboration will be finalized upon execution of a Cooperative Research and Development Agreement (CRADA) between the two parties.

"TRND collaborates with researchers and companies with an aim of helping companies like AVI advance TRND's mission of accelerating the development of therapeutics for rare diseases like DMD," said John McKew, PhD, Chief of TRND's Therapeutic Development Branch. "TRND selected AVI because its innovative platform technology has the potential to move forward into later stage clinical trials in this disease for which there is little or no therapy."

About 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. A devastating and incurable muscle-wasting disease, DMD is associated with specific inborn errors in the gene that codes for dystrophin, a protein that plays a key structural role in muscle fiber function. Progressive muscle weakness eventually spreads to the arms, neck and other areas. Eventually, this progresses to complete paralysis and increasing difficulty in breathing due to respiratory muscle dysfunction requiring ventilatory support as well as cardiac muscle dysfunction leading to heart failure. The condition is terminal, and death usually occurs before the age of 30.

About AVI BioPharma AVI BioPharma is focused on the discovery and development of novel RNA-based therapeutics for rare and infectious diseases, as well as other select disease targets. Applying pioneering technologies developed and optimized by AVI, the Company is able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. Unlike other RNA-based approaches, AVI's technologies can be used to directly target both messenger RNA (mRNA) and precursor messenger RNA (pre-mRNA) to either down-regulate (inhibit) or up-regulate (promote) the expression of targeted genes or proteins. By leveraging its highly differentiated RNA -based technology platform, AVI has built a pipeline of potentially transformative therapeutic agents, including eteplirsen (the non-proprietary name for AVI-4658), which is in clinical development for the treatment of Duchenne muscular dystrophy, and multiple drug candidates that are in clinical development for the treatment of infectious diseases. For more information, visit www.avibio.com.

About Eteplirsen Eteplirsen is AVI's lead drug candidate that is systemically delivered for the treatment of a substantial subgroup of patients with DMD. Data from clinical studies of eteplirsen in DMD patients have demonstrated a broadly favorable safety and tolerability profile and restoration of dystrophin protein expression.

Eteplirsen uses AVI's novel phosphorodiamidate morpholino oligomer (PMO)-based chemistry and proprietary exon-skipping technology to skip exon 51 of the dystrophin gene. By skipping exon 51, eteplirsen may restore the gene's ability to make a shorter, but still functional, form of dystrophin from mRNA. Promoting the synthesis of a truncated dystrophin protein is intended to improve, stabilize or significantly slow the disease process and prolong and improve the quality of life for patients with DMD. AVI is also developing other PMO-based exon-skipping drug candidates intended to treat additional patients with DMD.

About Children's Research Institute / Children's National Medical Center Children's National Medical Center in Washington, DC, has been serving the nation's children since 1870. Home to Children's Research Institute and the Sheikh Zayed Institute for Pediatric Surgical Innovation, Children's National is consistently ranked among the top pediatric hospitals by U.S. News & World Report and the Leapfrog Group. With 303 beds, more than 1,330 nurses, 550 physicians, and seven regional outpatient centers, Children's National is the only exclusive provider of acute pediatric services in the Washington metropolitan area. Children's National has been recognized by the American Nurses Credentialing Center as a Magnet(R) designated hospital, the highest level of recognition for nursing excellence that a medical center can achieve. For more information, visit ChildrensNational.org, receive the latest news from the Children's National press room, or follow us on Facebook and Twitter.

About the Carolinas Medical Center Carolinas Medical Center (www.carolinasmedicalcenter.org) is an 874-bed tertiary care hospital located in Charlotte, N.C. It is one of 33 hospitals currently affiliated with Carolinas HealthCare System (www.carolinashealthcare.org) one of the nation's leading and most innovative healthcare organizations. CHS provides a full spectrum of healthcare and wellness programs throughout North and South Carolina. Its diverse network of more than 650 care locations includes academic medical centers, hospitals, healthcare pavilions, physician practices, destination centers, surgical and rehabilitation centers, home health agencies, nursing homes and hospice and palliative care. CHS works to improve and enhance the overall health and wellbeing of its communities through high quality patient care, education and research programs, and a variety of collaborative partnerships and initiatives.

About the Therapeutics for Rare and Neglected Diseases (TRND) Program The Therapeutics for Rare and Neglected Diseases (TRND) program (currently administered by the NIH Center for Translational Therapeutics, an intramural program of the National Human Genome Research Institute) is part of a congressionally mandated program to encourage and speed the development of new drugs for rare and neglected diseases. This program is specifically intended to stimulate drug discovery and development research collaborations between NIH and academic scientists, non-profit organizations, and pharmaceutical and biotechnology companies working on rare and neglected illnesses. The TRND program provides an opportunity to partner with and gain access to rare and neglected disease drug development capabilities, expertise, and clinical/regulatory resources in a collaborative environment with the goal of moving promising therapeutics into human clinical trials. TRND uses an application and evaluation process to select collaborators. Selected investigators provide the drug project starting points and ongoing biological/disease expertise throughout the project.

Forward-Looking Statements and Information In order to provide AVI's investors with an understanding of its current results and future prospects, this press release contains statements that are forward-looking. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements about the development of AVI's product candidates and their efficacy, potency and utility in the treatment of rare and infectious diseases, AVI's expectations regarding future success, and the ability of the exon 45 and exon 50 collaborations to accelerate AVI's DMD program and result in additional open INDs.

These forward-looking statements involve risks and uncertainties, many of which are beyond AVI's control. Known risk factors include, among others: preclinical studies may not result in open INDs; clinical trials may not demonstrate safety and efficacy of any of AVI's drug candidates and/or AVI's antisense-based technology platform; and any of AVI's drug candidates may fail in development, may not receive required regulatory approvals, or be delayed to a point where they do not become commercially viable.

Any of the foregoing risks could materially and adversely affect AVI's business, results of operations and the trading price of AVI's common stock. For a detailed description of risks and uncertainties AVI faces, you are encouraged to review the official corporate documents filed with the Securities and Exchange Commission. AVI does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

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