

AVI BioPharma Provides Update on Initiation of Eteplirsen Phase 2 Clinical Trial

June 9, 2011 8:04 AM ET

BOTHELL, WA, Jun 09, 2011 (MARKETWIRE via COMTEX) -- AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based therapeutics, today provided an update on the initiation of its Phase 2 clinical trial of eteplirsen, the Company's lead therapeutic candidate for the treatment of Duchenne muscular dystrophy (DMD).

On June 8th, following a meeting of the Institutional Review Board (IRB) of Nationwide Children's Hospital in Columbus, Ohio, the site of the Phase 2 clinical trial, AVI received an IRB request to modify the clinical trial protocol. AVI is reviewing the request, which is not related to the safety or expected activity of eteplirsen, and anticipates submitting a revised Phase 2 clinical trial protocol to the IRB later this month. The U.S. Food and Drug Administration (FDA) has not communicated any concerns regarding the original design of the Phase 2 clinical trial at this time and the Company intends to provide any updates on this protocol to the FDA.

"We will work quickly and deliberately to address the IRB's request, and we expect to initiate the Phase 2 trial in the third quarter," said Chris Garabedian, AVI's President and CEO. "Furthermore, we are confident that we will remain on track in initiating a pivotal trial in the second half of 2012. We remain fully committed to eteplirsen development and its potential as an important treatment for DMD."

Based on the expected initiation of the Phase 2 trial in the third quarter, AVI anticipates study results in the second quarter of 2012.

About Institutional Review Boards

Institutions conducting clinical trials must submit each trial protocol to an independent institutional review board for review and approval prior to trial initiation. Generally, the institutional review boards will consider, among other things, clinical trial design, participant informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. While institutional review boards are mandated and overseen by the U.S. Department of Health and Human Services and FDA, they are not affiliated with either of these governmental entities.

About Eteplirsen

Eteplirsen is AVI's lead systemically administered drug candidate for the treatment of a substantial subgroup of patients with Duchenne muscular dystrophy (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. AVI plans to initiate a Phase 2 study of eteplirsen in the third quarter of 2011 and is currently conducting NDA-enabling activities to support the initiation of a pivotal Phase 3 study in the second half of 2012.

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 a highly differentiated RNA-based technology platform, AVI has built a pipeline of potentially transformative therapeutic agents, including eteplirsen, 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.

Forward-Looking Statements and Information

This press release contains statements that are forward-looking, including statements about the development of AVI's product candidates, including the submission of a revised Phase 2 clinical trial protocol, the initiation of a Phase 2 clinical trial in the third

quarter of 2011, the availability of study results in the second quarter of 2012 and the initiation of a pivotal study in the second half of 2012 for eteplirsen, and the efficacy, potency and utility of AVI's product candidates in the treatment of rare and infectious diseases. These forward-looking statements involve risks and uncertainties, many of which are beyond AVI's control. Known risk factors include, among others: clinical trials may not demonstrate safety and efficacy of any of AVI's drug candidates; 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; and the IRB may not approve a revised Phase 2 protocol. Any of the foregoing risks could materially and adversely affect AVI's business, results of operations and the trading price of its 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.

"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.

AVI Media and Investor Contact:

David A. Walsey
Senior Director, Investor Relations & Corporate Communications
425.354.5140
Email Contact

AVI Media Contact:

David Schull
Russo Partners
858.717.2310 or 212.845.4271
Email Contact

SOURCE: AVI BioPharma, Inc.

<http://www2.marketwire.com/mw/emailprcntct?id=6384CD80F2E3D9D4>
<http://www2.marketwire.com/mw/emailprcntct?id=AE5D65ECE4A7601F>