



FDA Postpones Advisory Committee Meeting to Review Eteplirsen Due to Severe Weather Storm in the Washington D.C. Area

CAMBRIDGE, Mass.--(BUSINESS WIRE)--January 20, 2016--Sarepta Therapeutics, Inc. (NASDAQ:SRPT), a developer of innovative RNA-targeted therapeutics, today announced that the U.S. Food and Drug Administration's (FDA) Peripheral and Central Nervous System Advisory Committee meeting scheduled for Friday, January 22 has been postponed by the FDA due to an anticipated severe winter snowstorm forecasted to hit the Washington D.C. area. A future meeting date will be announced in the Federal Register. In the event of a change in the February 26, 2016 PDUFA date, the company will provide an update at that time.

The Advisory Committee was scheduled to review Sarepta's New Drug Application (NDA) for eteplirsen, for the treatment of Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping. The new drug application (NDA) for eteplirsen is being reviewed under the FDA accelerated approval pathway, which allows early approval of a drug for a serious or life-threatening illness that offers a benefit over current treatments.

About Duchenne Muscular Dystrophy (DMD)

DMD is an X-linked rare degenerative neuromuscular disorder causing severe progressive muscle loss and premature death. One of the most common fatal genetic disorders, DMD affects approximately one in every 3,500 – 5,000 boys born worldwide. A devastating and incurable muscle-wasting disease, DMD is associated with specific errors in the gene that codes for dystrophin, a protein that plays a key structural role in muscle fiber function. Progressive muscle weakness in the lower limbs spreads to the arms, neck and other areas. Eventually, increasing difficulty in breathing due to respiratory muscle dysfunction requires ventilation support, and cardiac dysfunction

can lead to heart failure. The condition is universally fatal, and death usually occurs before the age of 30.

About Eteplirsen

Eteplirsen is designed to address the underlying cause of DMD by restoring the dystrophin messenger RNA (mRNA) reading frame, thus enabling the production of a shorter, functional form of the dystrophin protein. Eteplirsen uses Sarepta's proprietary phosphorodiamidate morpholino oligomer (PMO) chemistry and exon-skipping technology to skip exon 51 of the dystrophin gene. Approximately 13 percent of the DMD population is amenable to exon 51 skipping. Data from clinical studies of eteplirsen in DMD patients have demonstrated a consistent safety and tolerability profile and have also shown measurable dystrophin protein expression. Promoting the synthesis of a shorter dystrophin protein is intended to slow the decline of ambulation and mobility seen in DMD patients. There currently is no approved treatment in the United States for DMD and eteplirsen has not been approved by the FDA or any regulatory authority for the treatment of DMD.

About Sarepta Therapeutics

Sarepta Therapeutics is a biopharmaceutical company focused on the discovery and development of unique RNA-targeted therapeutics for the treatment of rare, infectious and other diseases. The Company is primarily focused on rapidly advancing the development of its potentially disease-modifying DMD drug candidates, including its lead DMD product candidate, eteplirsen, designed to skip exon 51. Sarepta is also developing therapeutics for the treatment of infectious diseases, such as drug-resistant bacteria and other rare human diseases. For more information, please visit us at www.sarepta.com.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. 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 regarding the postponed Advisory Committee meeting date to review the NDA for eteplirsen, Sarepta's plans to provide an update if the PDUFA date is changed, and a potential accelerated approval.

These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Known risk factors include, among others: the FDA may further delay or cancel the Advisory Committee meeting and may also change the current PDUFA date for the eteplirsen NDA; the results of our ongoing research and development efforts and clinical trials for eteplirsen and our other product candidates may not be positive or consistent with prior results or demonstrate a safe treatment benefit; there may be delays in Sarepta's projected regulatory and development timelines relating to the eteplirsen NDA and plans for commercializing eteplirsen and developing Sarepta's other product candidates for various reasons including regulatory decisions or possible limitations of Sarepta's financial and other resources; Sarepta may not be able to successfully complete its planned commercialization of eteplirsen or continue developing its product candidates as planned for a variety of reasons including due to regulatory, court or agency decisions, such as decisions by the USPTO with respect to patents that cover Sarepta's product candidates, manufacturing issues, and any or all of Sarepta's product candidates may fail in development or may not receive required regulatory approvals for commercialization; and those risks identified under the heading "Risk Factors" in Sarepta's 2014 Annual Report on Form 10-K or and most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by the Company which you are encouraged to review.

Any of the foregoing risks could materially and adversely affect Sarepta's business, results of operations and the trading price of Sarepta's common stock. For a detailed description of risks and uncertainties Sarepta faces, you are encouraged to review the Company's filings with the SEC. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. Sarepta

does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

Internet Posting of Information

We routinely post information that may be important to investors in the 'For Investors' section of our website at www.sarepta.com. We encourage investors and potential investors to consult our website regularly for important information about us.

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