Sarepta Receives Negative CHMP Re-examination Opinion for Eteplirsen

-- Relying upon Scientific Advisory Group input, Sarepta will seek further scientific advice from European Medicines Agency on a possible path to bring eteplirsen to patients in Europe --

CAMBRIDGE, Mass., September 21, 2018 (GLOBE NEWSWIRE) – Sarepta Therapeutics, Inc. (NASDAQ: SRPT), a commercial-stage biopharmaceutical company focused on the discovery and development of precision genetic medicine to treat rare neuromuscular diseases, announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), has confirmed its 31 May 2018 negative opinion for a Conditional Marketing Application for eteplirsen. Eteplirsen is designed to treat approximately 13% of the Duchenne muscular dystrophy community who have genetic mutations amenable to exon 51 skipping.

“While largely anticipated, we are disappointed with the outcome of the CHMP re-examination and firmly believe that eteplirsen should be made available to patients in Europe, as it is in the United States,” stated Doug Ingram, president and chief executive officer, Sarepta Therapeutics.

Mr. Ingram continued, “We were, however, encouraged by the openness of discussion with the SAG and CHMP and their willingness to engage on different approaches to provide additional data to support an eventual approval in Europe. Based on those discussions, Sarepta will work to explore a potential path forward that balances the needs of patients and their families to avoid lengthy and unnecessarily burdensome trials with those of European Regulators for additional supportive data consistent with existing European regulations. We will be seeking follow up Scientific Advice in 2019 in order to explore the approach to bring eteplirsen to Europe.”

The Company expects the European Commission (EC) to adopt the CHMP opinion by year-end 2018.

About Sarepta Therapeutics

Sarepta Therapeutics is a commercial-stage biopharmaceutical company focused on the discovery and development of precision genetic medicine to treat rare neuromuscular diseases. The Company is primarily focused on rapidly advancing the development of its potentially disease-modifying Duchenne muscular dystrophy (DMD) drug candidates. For more information, please visit www.sarepta.com.

Forward-Looking Statements

This press release contains "forward-looking statements." 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 Sarepta's plan to seek further scientific advice from EMA on a possible path to bring eteplirsen to patients in Europe; eteplirsen's potential to treat approximately 13% of the DMD community who have genetic mutations amenable to exon 51 skipping; Sarepta's belief that eteplirsen should be made available to patients in Europe; CHMP's willingness to engage on different approaches to provide additional data to support an eventual approval in Europe; Sarepta's plan to work to explore a potential path forward that balances the needs of patients and their families to avoid lengthy and unnecessarily burdensome trials with those of European Regulators for additional supportive data consistent with existing European regulations; Sarepta's intention to seek follow up Scientific Advice in 2019 in order to explore the approach to bring eteplirsen to Europe; and Sarepta's expectation that the EC will adopt the CHMP opinion by year-end 2018.

These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Known risk factors include, among others: Sarepta *may not be able to eventually obtain regulatory approval for eteplirsen, or any other product candidates, from EMA; Sarepta may not be able to execute on its business plans, including meeting its expectations with respect to EXONDYS 51 sales, meeting its expected or planned regulatory milestones and timelines, research and clinical development plans, and bringing its product candidates to market, for various reasons including possible limitations of Company financial and other resources, manufacturing limitations that may not be anticipated or resolved for in a timely manner, and regulatory, court or agency decisions, such as decisions by the CHMP on eteplirsen or the United States Patent and Trademark Office with respect to patents that cover our product candidates; and those risks identified under the heading "Risk Factors" in Sarepta's most recent Annual Report on Form 10-K for the year ended December 31, 2017 and most recent Quarterly Report on Form 10-Q 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 the Company'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 Sarepta's 2017 Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q filed with the SEC as well as other SEC filings made by Sarepta. 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.

Source: Sarepta Therapeutics, Inc.

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