

Sarepta Therapeutics Announces Plans to Submit Rolling NDA for Eteplirsen following Today's Pre-NDA Meeting with the FDA

- *Held pre-NDA meeting and agreed on rolling submission with the Agency -*
- *Will submit first two components of the NDA this week -*
- *Plans to complete the submission by mid-year -*

CAMBRIDGE, Mass. --(BUSINESS WIRE)--May 19, 2015-- Sarepta Therapeutics, Inc. (NASDAQ: SRPT), a developer of innovative RNA-targeted therapeutics, today announced that the Company held a pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding its lead product candidate, eteplirsen, for the treatment of Duchenne muscular dystrophy (DMD). Sarepta has agreed with the Agency to initiate a rolling NDA submission and will submit the non-clinical and CMC components of the NDA by the end of this week. As previously announced, Sarepta plans to submit the final component of the NDA by mid-year 2015.

"We will initiate a rolling NDA submission to facilitate the regulatory review of the NDA," said Edward Kaye, M.D., Sarepta's interim chief executive officer and chief medical officer. "The initiation of our NDA submission for eteplirsen marks a significant milestone for the Duchenne community and we look forward to completing the submission by the middle of the year and to continuing to work with the Agency towards the goal of providing treatments to patients as quickly as possible."

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 drug-resistant bacteria and infectious, rare and other human diseases. For more information, please visit us at www.sarepta.com.

Forward-Looking Statements

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,” “may,” “intends,” “prepares,” “looks,” “potential,” “possible” and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements relating to Sarepta’s plans to initiate a rolling NDA for eteplirsen, facilitate the regulatory review process, submit the non-clinical and CMC components of the NDA by end of this week, complete the final component of the NDA by mid-year 2015 and the Company’s plans to continue working with the Agency towards the goal of providing treatments to patients as quickly as possible.

These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta’s control. Actual results could materially differ from those stated or implied by these forward-looking statements as a result of such risks and uncertainties. Known risk factors include the following: we may be delayed in or may not be able to complete our planned NDA submission for eteplirsen; even if we complete our eteplirsen NDA submission we may not be able to comply with all FDA requests in a timely manner or at all and the FDA may determine that the submission does not qualify for filing or approval; the additional information and data we collect or have collected for the eteplirsen NDA submission may not be consistent with prior data or results or may not support an eteplirsen NDA filing or approval; there may be delays in our projected timelines and our expectations may not be accurate with respect to a potential commercialization of eteplirsen for various reasons, including possible limitations of Company resources and regulatory or agency decisions, scale-up of manufacturing may not be successful, we may lack the funding necessary to commercialize eteplirsen or any of our product candidates, the results of the additional eteplirsen trials the Company conducts may not support an NDA filing or approval for eteplirsen and those risks identified under the heading “Risk Factors” in Sarepta’s most recent Annual and Quarterly Reports on Forms 10-K and 10-Q, respectively, filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by Sarepta, 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. You should not place undue reliance on forward-looking statements. Sarepta does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof, except to the extent required by applicable law or SEC rules.

Internet Posting of Information

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

Source: Sarepta Therapeutics, Inc.

Media and Investors:

Sarepta Therapeutics, Inc.

Ian Estepan, 617-274-4052

iestepan@sarepta.com

W2O Group

Ryan Flinn

Office: 415-946-1059

Mobile: 510-207-7616

rflinn@w2ogroup.com