

BioMarin Announces That FDA Has Advised it Will Not Take Action on the Kyndrisa™ (drisapersen) New Drug Application by the PDUFA Date

SAN RAFAEL, Calif., Dec. 18, 2015 (GLOBE NEWSWIRE) -- BioMarin Pharmaceutical Inc. (Nasdaq:BMRN) announced today that the U.S. Food and Drug Administration (FDA) has notified the Company that they had not yet completed their review process and would be unable to take an action by the Prescription Drug User Fee Act (PDUFA) action date for Kyndrisa™(drisapersen) of December 27, 2015, and anticipate taking action in early January 2016.

About BioMarin

BioMarin is a global biotechnology company that develops and commercializes innovative therapies for patients with serious and life-threatening rare and ultra-rare genetic diseases. The company's portfolio consists of five commercialized products and multiple clinical and pre-clinical product candidates. For additional information, please visit www.BMRN.com.

Forward-Looking Statement

This press release contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: expectations regarding the FDA's review of the Kyndrisa NDA, outcomes of the review of such filings; and the possible approval of Kyndrisa. These forward-looking statements are predictions and involve risks and uncertainties such that actual results may differ materially from these statements. These risks and uncertainties include, among others: results and timing of current and planned clinical trials of Kyndrisa; the content and timing

of decisions by the FDA, and EMA concerning Kyndrisa; and those factors detailed in BioMarin's filings with the Securities and Exchange Commission, including, without limitation, the factors contained under the caption "Risk Factors" in BioMarin's 2014 Annual Report on Form 10-K, as amended, and the factors contained in BioMarin's reports on Form 8-K. Stockholders are urged not to place undue reliance on forward-looking statements, which speak only as of the date hereof. BioMarin is under no obligation, and expressly disclaims any obligation to update or alter any forward-looking statement, whether as a result of new information, future events or otherwise. Kyndrisa™ is our trademark, and BioMarin® is a registered trademark of BioMarin Pharmaceutical Inc.

Contacts:

Investors

Traci McCarty

BioMarin Pharmaceutical Inc.

(415) 455-7558

Media

Debra Charlesworth

BioMarin Pharmaceutical Inc.

(415) 455-7451

Source: BioMarin Pharmaceutical Inc.

<https://investors.biomarin.com/2015-12-18-BioMarin-Announces-That-FDA-Has-Advised-it-Will-Not-Take-Action-on-the-Kyndrisa-drisapersen-New-Drug-Application-by-the-PDUFA-Date>