BioMarin Submits Marketing Authorization Application in European Union for Aryplase to Treat MPS VI

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BioMarin Pharmaceutical Inc. (Nasdaq and SWX: BMRN) today announced that it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency for Aryplase(TM) (galsulfase), an investigational enzyme replacement therapy for the treatment of mucopolysaccharidosis VI (MPS VI).

Emil Kakkis, M.D., Ph.D., Senior Vice President of Business Operations at BioMarin, commented, "This milestone represents an important step in our goal to bring the first specific therapeutic treatment option to MPS VI patients around the world. Our ability to submit this European application just seven days after filing for Aryplase marketing authorization in the United States demonstrates our ability to prepare separate and comprehensive marketing authorization applications simultaneously. This accomplishment is a tribute to our dedicated employees who worked diligently to make this happen."

BioMarin has received orphan medicinal product designation for Aryplase in the European Union. Orphan medicinal product designation is conferred upon investigational products for diseases that affect fewer than five in 10,000 patients in the European Union. Products with orphan medicinal product designation that are the first to be approved for a specific indication have 10 years market exclusivity within the European Union.

About Aryplase

Aryplase is an investigational enzyme replacement therapy for the treatment of MPS VI. Aryplase is designed to address the underlying deficiency of MPS VI disease and provide the enzyme that people with MPS VI are lacking.

About MPS VI

MPS VI, also known as Maroteaux-Lamy Syndrome, is an inherited debilitating, life-threatening disease for which no drug therapies are currently available. MPS VI is caused by the deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B), a lysosomal enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs). This enzyme deficiency leads to the accumulation of GAGs in the lysosomes of cells, giving rise to progressive cellular, tissue and organ system dysfunction. Debilitating symptoms can include impaired cardiac and pulmonary function, delayed physical development, skeletal and joint deformities, impaired vision and hearing, sleep apnea, and reduced endurance. The majority of people with MPS VI die from disease-related complications between childhood and early adulthood.

BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. The company's product portfolio is comprised of two approved products, Orapred(R) (prednisolone sodium phosphate oral solution) for severe asthma and Aldurazyme(R) (laronidase) for MPS I, and multiple investigational product candidates including Aryplase(TM) (galsulfase), a Phase 3 product candidate for the treatment of MPS VI, and Phenoptin(TM) (sapropterin hydrochloride) a Phase 2 product candidate for the treatment of phenylketonuria (PKU). 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: the development of Aryplase; and filings with and actions by regulatory authorities. 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 clinical trials; the content and timing of decisions by the European Medicines Agency and other regulatory authorities concerning Aryplase; and those factors detailed in BioMarin's filings with the Securities and Exchange Commission, including, without limitation, the factors contained under the caption "Factors That May Affect Future Results" in BioMarin's 2003 Annual Report on Form 10-K and the factors contained in BioMarin's reports on Forms 10-Q and 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.

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