BioMarin Submits U.S. Biologics License Application for Marketing Authorization of Aryplase for MPS VI

PRNewswire-FirstCall
NOVATO, Calif.

BioMarin Pharmaceutical Inc. (Nasdaq and SWX: BMRN) today announced that it has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for Aryplase(TM) (galsulfase), an investigational enzyme replacement therapy for the treatment of mucopolysaccharidosis VI (MPS VI).

"This BLA submission represents a significant milestone in our effort to bring people with MPS VI the first specific treatment option for this debilitating, progressive and life-threatening disease," stated Stuart Swiedler, M.D., Ph.D., Vice President of Clinical Affairs at BioMarin. "We look forward to continuing to work with the FDA during the review process and to submitting a marketing application for Aryplase to the European Medicines Agency by the end of the year."

At a pre-BLA meeting in September of this year BioMarin met with FDA to discuss key information on Aryplase to be included in the BLA. Consistent with this meeting, the fully electronic BLA filing includes a comprehensive set of preclinical, clinical and manufacturing related information on Aryplase. As part of the BLA submission, BioMarin has requested priority review, a request considered by the FDA for new product applications that address unmet medical needs. If the FDA accepts the BLA and grants the request for priority review, the FDA is expected to complete all aspects of the review and to take action on the application within six months of its submission. Aryplase has received fast track status and orphan drug designation. Orphan drug

designation is conferred upon investigational products for diseases that affect fewer than 200,000 people in the United States. Products with orphan drug status that are the first to be approved for a specific indication have seven years of market exclusivity within the United States.

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.

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 FDA, 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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