

# Naglazyme Approved by Brazil's National Health Surveillance Agency

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BioMarin Pharmaceutical Inc. announced today that ANVISA, Brazil's National Health Surveillance Agency, has granted BioMarin marketing approval for Naglazyme(R) (galsulfase) for the treatment of patients with Mucopolysaccharidosis VI (MPS VI).

"We are very pleased to receive marketing approval for Naglazyme in Brazil which has the largest known number of affected MPS VI patients in the world," said Stephen Aselage, Senior Vice President of Global Commercial Development at BioMarin. "Although there is no formal orphan drug designation in Brazil, ANVISA approved Naglazyme in just eight months based on a recent resolution that gives priority review for therapies that are developed for the treatment of neglected diseases or are considered orphan disorders. This emphasizes the need to rapidly bring life-altering therapies to patients around the world, and we remain dedicated to pursuing continued geographic expansion and are optimistic regarding the long-term potential of Naglazyme."

Naglazyme was approved by the U.S. Food and Drug Administration (FDA) in May 2005 and by the European Commission (EC) in January 2006. As the first drug approved for MPS VI, the FDA and EC have both designated Naglazyme as an orphan drug, conferring seven years of market exclusivity in the United States and 10 years of market exclusivity in the European Union.

## About MPS VI

MPS VI (also known as Maroteaux-Lamy syndrome) is a debilitating, life-threatening genetic disease caused by a deficiency of the enzyme N-acetylgalactosamine 4-sulfatase. This enzyme deficiency leads to the accumulation of certain complex carbohydrates, glycosaminoglycans (GAGs), in the lysosomes, giving rise to progressive cellular, tissue and organ system dysfunction. The majority of individuals with MPS VI die from disease-related complications between childhood and early adulthood. Additional information can be found at [www.mpsvi.com](http://www.mpsvi.com).

## About Naglazyme

Naglazyme is the first and only enzyme replacement therapy indicated for the treatment of MPS VI. Naglazyme is indicated for patients with MPS VI. Naglazyme has been shown to improve walking and stair-climbing capacity.

The most common adverse events observed in clinical trials in Naglazyme-treated patients were headache, fever, arthralgia, vomiting, upper respiratory infections, abdominal pain, diarrhea, ear pain, cough, and otitis media. Severe reactions included angioneurotic edema, hypotension, dyspnea, bronchospasm, respiratory distress, apnea, and urticaria. The most common symptoms of infusion reactions included fever, chills/rigors, headache, rash, and mild to moderate urticaria. Nausea, vomiting, elevated blood pressure, retrosternal pain, abdominal pain, malaise, and joint pain were also reported. No patients discontinued for adverse events and all patients who completed the double-blind portion of the trial continued to receive weekly infusions of Naglazyme. Nearly all patients developed antibodies as a result of treatment, but the level of the immune response did not correlate with the severity of adverse events. Because antihistamine use may increase the risk of apneic episodes, evaluation of airway patency should be considered prior to the initiation of treatment. Consideration to delay Naglazyme infusion should be given when treating patients who present with an acute febrile or respiratory illness. Additional information can be found at [www.naglazyme.com](http://www.naglazyme.com).

## About BioMarin

BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. The company's product portfolio comprises three approved products and multiple clinical and preclinical product candidates. Approved products include Naglazyme(R) (galsulfase) for mucopolysaccharidosis VI (MPS VI), a product wholly developed and commercialized by BioMarin; Aldurazyme(R) (laronidase) for mucopolysaccharidosis I (MPS I), a product which was developed through a 50/50 joint venture with Genzyme Corporation; and Kuvan(R) (sapropterin dihydrochloride) Tablets, a product for the treatment of phenylketonuria (PKU), developed in partnership with Merck Serono, a division of Merck KGaA of Darmstadt, Germany. Other product candidates include 6R-BH4 for cardiovascular indications, which is currently in Phase 2 clinical development for the treatment of sickle cell disease, and PEG-PAL (PEGylated recombinant phenylalanine

ammonia lyase), which is currently in Phase 1 clinical development for the treatment of PKU. For additional information, please visit [www.BMRN.com](http://www.BMRN.com). Information on BioMarin's website is not incorporated by reference into this press release.

#### Forward-Looking Statement

This press release contains forward-looking statements about the business prospects of BioMarin Pharmaceutical Inc., including, without limitation, statements about: the continued clinical development and commercialization of Naglazyme and BioMarin's other products and product candidates 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: our success in the continued commercialization of Naglazyme; the content and timing of decisions by the U.S. Food and Drug Administration, the European Commission and other regulatory authorities concerning each of the described products and product candidates; 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 2007 Annual Report on Form 10-K, as amended, and the factors contained in BioMarin's reports on Form 10-Q and 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.

BioMarin(R), Naglazyme(R) and Kuvan(R) are registered trademarks of BioMarin Pharmaceutical Inc.

Aldurazyme(R) is a registered trademark of BioMarin/Genzyme LLC.

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