AnGes MG, Inc. Launched Naglazyme in Japan

AnGes MG, Inc. (AnGes) announced that on April 14, the company launched Naglazyme (galsulfase) for patients with the genetic disease mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome). Naglazyme is the first product commercialized by AnGes.

AnGes established a marketing and distribution agreement with BioMarin Pharmaceutical Inc. (BioMarin) in December 2006, through which AnGes obtained exclusive rights to market Naglazyme in Japan.

Naglazyme was developed to supplement the deficient enzyme in MPS VI by providing an exogenous enzyme in a therapeutic approach known as enzyme replacement therapy (ERT). Although hematopoietic stem cell transplant is an option for MPS VI patients, there are issues such as finding appropriate donors and risks of transplantation; thus, there is a need for a safer and more effective treatment. Naglazyme is already being sold in the US and Europe. In Japan, patient advocacy groups and academic societies have expressed strong interest for the early use of Naglazyme. AnGes and BioMarin have made efforts for the timely launch of Naglazyme.

Details of Naglazyme are as follows,

Date of marketing approval	March 28, 2008
Brand name:	Naglazyme Intravenous Infusion 5mg
Generic name:	Galsulfase (Genetical Recombination)
Indication:	MPS VI
Drug dosage	1mg/kg of body weight administered once weekly as an intravenous
	infusion
NHI price	256,775 Japanese yen/ 1 vial
Date of launch	April 14, 2008

<Reference>

About BioMarin Pharmaceutical Inc.

Headquarters: 105 Digital Drive, Novato, CA 94949, U.S.A. CEO: Jean-Jacques Bienaimé Founded: 1997 Number of employees: 520 (as of Jan. 2008) Business: Manufacture, develop and commercialize drugs Marketed Products:

- Aldurazyme (laronidase) for MPS I
- Naglazyme (galsulfase) for MPS VI
- Kuvan (sapropterin dihydrochloride) for phenylketonuria (PKU)

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.

About Naglazyme

Naglazyme is the first and only enzyme replacement therapy indicated for the treatment of MPS VI. As the first drug approved for MPS VI, regulatory agencies in both the United States and European Union have granted Naglazyme orphan drug status, which confers seven years and 10 years of market exclusivity, respectively.

