February 25, 2008
AnGes MG, Inc.

Status Updates of NDA application of Naglazyme for the Treatment of Mucopolysaccharidosis VI

The NDA for Naglazyme ("Naglazyme for intravenous infusion 5 mg") for the treatment of mucopolysaccharidosis VI (MPS IV), submitted by AnGes MG, Inc., has passed the First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) on February 22nd held by the Ministry of Health, Labour and Welfare (MHLW).

Passing the First Committee on New Drugs, the application for approval of Naglazyme will be deliberated by the Pharmaceutical Affairs Department before the MHLW reaches a final decision on the granting of manufacturing and marketing approval.

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 bone marrow transplantation is an option for MPS VI patients, it is associated with the problem of finding a suitable donor and risks of transplantation; thus, there is a need for a safer and more effective treatment. Naglazyme is already sold in the US and Europe. In Japan, patient advocacy groups and academic societies are strongly calling for the early use of Naglazyme.

AnGes MG obtained exclusive rights from BioMarin Pharmaceutical Inc., US, to market Naglazyme in Japan; and in August 2007, submitted the NDA for Naglazyme. Accelerated processing of the application by the MHLW and the Pharmaceutical and Medical Devices Agency (PMDA) has enabled deliberations of the PAFSC to begin approximately six months following application. AnGes MG, will continue its efforts to bring Naglazyme to the market and to the patients in the shortest time frame possible.

Naglazyme was granted orphan-drug designation by the MHLW in June 2007.

<Reference>

1. Mucopolysaccharidosis VI (MPS VI)

Mucopolysaccharidosis VI (or Maroteaux-Lamy syndrome) is an inherited, degenerative disease caused by a deficiency of the enzyme N-acetylgalactosamine-4-sulfatase. The deficiency of this enzyme causes the accumulation of certain complex carbohydrates and glycosaminoglycans (GAGs) in the lysosomes, leading to progressive cellular, tissue, and organ system dysfunction.

2. Naglazyme

Naglazyme is the first approved enzyme replacement treatment (ERT) for MPS VI in the world. In clinical trials in the US and Europe, Naglazyme has shown efficacy in improving walking ability among others, and has also demonstrated an acceptable safety profile.