June 20, 2007
AnGes MG, Inc.

Announcement on Acquisition of First-Class Drug Marketing Business License

On June 15, 2007, AnGes MG, Inc. was authorized by the Tokyo Metropolitan Government as a first-class drug marketing business license (hereinafter referred to as “license”) holder.

This license is indispensable for marketing prescription drugs in Japan under the Pharmaceutical Affairs Law. Compliance to the Standards on Methods of Quality Control (Good Quality Practice; GQP) and the Standards on Post-Marketing Safety Control (Good Vigilance Practice, GVP) is also indispensable for an applicant to receive this license. AnGes MG, having received this license, is now able to market prescription drugs in Japan.

At the end of last year, our company obtained the rights for development and distribution of Naglazyme (a drug for the treatment of mucopolysaccharidosis VI) in Japan. Naglazyme was developed as a means of enzyme replacement therapy, i.e., replenishment of the enzyme deficient in patients with mucopolysaccharidosis VI. At present, hematopoietic stem cell transplant is available as a means of treating mucopolysaccharidosis type VI. However, since hematopoietic stem cell transplant is frequently limited by the difficulty in finding an appropriate donor and the risks associated with the procedure, a new treatment that is safer and efficacious has been sought. In the USA and Europe, Naglazyme has already been launched. In Japan, patient advocacy groups and medical societies have shown a strong interest in obtaining access to Naglazyme for Japanese patients. AnGes MG is preparing to submit an application for approval of this drug to the Ministry of Health Labour and Welfare, by utilizing clinical data collected in the USA and Europe.

Having obtained the license mentioned above, AnGes MG will make further efforts to launch Naglazyme into the Japanese market as soon as possible.

Naglazyme was designated as an orphan drug by the Ministry of Health, Labour and Welfare on June 5, 2007.