

Genzyme Pompe Program Update April 2007

As many of you are aware, a standard part of the biologics drug development process is to incrementally scale-up manufacturing capacity as demand for the product increases. During the development of Myozyme[®], Genzyme began the manufacturing process using a smaller scale, and has since scaled-up to produce larger quantities of product for commercial use worldwide. In addition to the use of this larger scale in multiple clinical trials, we've successfully transitioned to commercial use of the larger scale of Myozyme in over 29 countries where we have received regulatory approval. In the United States, we are still in the process of seeking regulatory approval for use of the larger scale manufacturing process, as it has taken time to produce the necessary data to support the submission to the FDA.

Genzyme plans to submit the necessary documentation to the FDA in June for the licensure of the larger scale manufacturing process and anticipates an FDA decision in the fourth quarter of 2007. Genzyme will not be able to sell product from the larger scale manufacturing process commercially in the USA during this FDA review period. Based on this timing and expected demand for Myozyme over the FDA review period, we anticipate that there will likely be a temporary supply shortage in the United States later this year. This situation does not affect the supply of Myozyme outside of the USA.

During this submission and FDA review period, Genzyme will proactively take a number of steps to ensure that patients currently on therapy stay on an uninterrupted course of therapy and that new patients in most urgent clinical need have access to Myozyme. Specifically, all children five years of age and under will continue to access Myozyme through the regular commercial route. Beginning immediately, Genzyme will initiate a clinical program called the Myozyme Temporary Access Program (MTAP) designed to help provide access to Myozyme produced by the larger scale process during the FDA review period. Patients enrolled in MTAP will be provided Myozyme at no cost during the course of the program. The goals of MTAP are two-fold: (a) to minimize any potential disruption in the treatment of patients already on therapy; and (b) to ensure that Myozyme is available for new patients who are in the most urgent clinical need. Under MTAP, new patients seeking Myozyme treatment who meet pre-specified age and medical criteria will be eligible for enrollment in the program. Additionally, Genzyme may invite some patients who are currently receiving treatment with Myozyme and are

over the age of 18 to enroll into MTAP to help optimize supply availability.

Following regulatory approval of the larger scale manufacturing process, we will work with physicians and their patients who are enrolled in MTAP to transition to commercial therapy through the regular route and will assist new patients who did not meet the MTAP criteria during this temporary period to expedite initiation of treatment. Genzyme remains committed to supporting the Pompe community in the USA and the ability to use Myozyme produced through the larger scale manufacturing process to help provide a continuous and sustainable supply of Myozyme for USA patients.

Genzyme recognizes and regrets the impact to those in the USA affected by this situation during this scale-up process review. We will continue to work with the FDA, physicians, and patient organization leaders to help minimize the impact and ensure a stable supply of Myozyme.