

Genzyme Pompe Program Update June 2007

Genzyme would like to take this opportunity to provide a brief update to the Pompe patient community regarding the US supply of Myozyme® (alglucosidase alfa). As planned, Genzyme submitted the necessary documentation to the FDA this month for the licensure of the larger scale manufacturing process and continues to anticipate an FDA decision in the fourth quarter of 2007.

As you know, Genzyme implemented the Myozyme Temporary Access Program (MTAP) in April of this year. The goal of MTAP is to help optimize the supply of Myozyme during this FDA review period to ensure that patients currently on therapy stay on an uninterrupted course of therapy and to ensure that new patients in most urgent clinical need have access to Myozyme. As part of Genzyme's ongoing evaluation of the MTAP program, Genzyme would like to notify patients and physicians that, at this time, the age criteria for MTAP enrollment have been changed. Moving forward, all patients 17 years of age and younger will have access to Myozyme through the regular commercial route. This change to the MTAP protocol has been made to help ensure that the Genzyme clinical research team can focus their efforts on both enrolling new patients who are in urgent medical need and transitioning adult patients who are currently on treatment to help optimize the supply of Myozyme. By changing the age criteria, Genzyme is able to limit the complexity of the program in relation to required scheduled assessments. New patients who are 18 years of age or older will continue to need to meet the pre-defined medical criteria (require ventilation assistance for breathing or require a wheelchair for ambulation) in order to initiate treatment with Myozyme.

Additionally, because of the time it is taking to transition patients into MTAP who had previously been receiving commercial Myozyme, Genzyme strongly encourages people 18 years of age and older who are currently receiving commercial treatment and their treating physicians to consider enrolling into MTAP to help optimize supply availability. Genzyme anticipates that additional patients will be needed to make this transition in order to ensure that there is enough Myozyme from the smaller scale manufacturing process to avoid interruptions to treatment in the US. Although we are urging enrollment into MTAP, it remains voluntary at this time, and Genzyme will notify the Pompe community if that changes. If you are interested in learning more about how to participate in MTAP, please contact your treating physician or your Genzyme Treatment

Support Case Manager or physicians can contact Genzyme Medical Information.

As previously stated, 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 US with the availability of Myozyme produced through the larger scale manufacturing process to help provide a continuous and sustainable supply of Myozyme for US patients.

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