

US Pompe Program Update – December 3, 2009

Genzyme would like to provide an update to the US Pompe community about the status of the Alglucosidase Alfa Temporary Access Program (ATAP) and the application for Lumizyme™ (alglucosidase alfa) approval in the United States.

In a press release dated December 3, 2009, it was announced that Genzyme will reopen enrollment in ATAP to provide access to treatment for severely affected adults with Pompe disease prior to commercial approval of Lumizyme. Enrollment in the program will be available at currently active ATAP study sites to patients who meet the eligibility criteria. Please speak to your physician about ATAP or contact Genzyme Medical Information at 800-745-4447, option 2 for more information.

Genzyme and the Food and Drug Administration (FDA) also have agreed on a path toward approval of Lumizyme. In November, Genzyme received a Complete Response letter for its Biologic License Application (BLA) for Lumizyme. Genzyme had been seeking approval of Lumizyme produced at a 2000 L bioreactor scale, manufactured at its Allston plant. In its letter, the FDA stated that satisfactory resolution of deficiencies related to the Allston plant would be required before the Lumizyme application can be approved. Since receiving the Complete Response letter, Genzyme has had several discussions with the FDA on the most expeditious path toward approval. Based on these discussions, Genzyme will now seek approval of the product produced at a larger 4000 L bioreactor scale, in a resubmission to the agency. The 4000 L-scale product is produced at Genzyme's manufacturing plant in Geel, Belgium. Genzyme anticipates that the resubmission will be made this month.

Genzyme continues to produce Myozyme® (alglucosidase alfa) at the 160 L scale and this product is reserved for patients in the US who are 17 years old and younger.

We will continue to keep you informed of relevant updates as information becomes available. We appreciate your ongoing support as we continue to work to provide access to treatment for the full Pompe community.