

**Genzyme Fabrazyme® (agalsidase beta) Supply Update**  
**Frequently Asked Questions**  
**October 3, 2011**

**FABRAZYME GLOBAL ALLOCATIONS**

**How is Fabrazyme supply allocated?**

Fabrazyme is approved and used by patients in over 50 countries worldwide. Globally, Genzyme has tried to maintain product allocations (amount of vials, types of vials or product) that are, overall, proportional to available supply and demand (the number of patients currently using the product, irrespective of commercial or charitable status) in a particular country.

**Are all countries affected by Fabrazyme supply constraints?**

All countries where Fabrazyme is used continue to experience significantly restricted supply of Fabrazyme. Genzyme is currently unable to meet worldwide patient demand. Each country manages their limited supply allocation in different ways.

**Why are patients treated differently in different regions globally? Why are patients in Europe treated on full dose and not in the USA?**

Fabry disease is a complex condition presenting differently in different patients. The choice of treatment where available, remains the decision of the treating physician and patient; as a manufacturer of a product, Genzyme does not make treatment recommendations. Differences in regional distribution logistics, availability of alternative treatment options, treatment practices and regulatory guidelines mean that the timing and amount of Fabrazyme available to patients may vary significantly from country to country.

- In the European Union, regulatory authorities recommend that patients be treated at a full dose or switched to an alternative product. Genzyme has worked to accommodate such a request within the region or country's allocation. Approximately 70% of European patients treated with Fabrazyme as of mid-2009 have by now been switched to an alternative treatment. This allowed for a smaller number of patients to be treated with a full dose of Fabrazyme. In turn this led to an overall decrease in the proportion of Fabrazyme supplied to Europe. Currently there are a handful of European patients who are on a reduced dose of Fabrazyme.
- In the USA, where no other approved treatment for Fabry disease is currently available, the FSWG (Fabry Stakeholders Working Group) recommended that no group of Fabry patients should be designated to receive full dose, as this would require a significant further reduction in dose or no treatment at all for other US patients treated with Fabrazyme.

**Why did I miss my recently scheduled infusion?**

Because there is very low inventory, supply is vulnerable and delays are possible. A recent example is the delay in the shipment of August 2011 Fabrazyme allocation for patients in the US due to a manufacturing release delay; Genzyme supplied the product allocated for August in September 2011. When such delays occur Genzyme will try to inform the Fabry community as quickly as possible.

## **MANUFACTURING & SUPPLY**

### **Genzyme previously communicated a return to full doses in Q4 2011, now this has been postponed until Q1 2012. Why the delay?**

In order to increase the supply of Fabrazyme, a new manufacturing plant with additional bioreactor capacity has been built in Framingham, Massachusetts. This plant is undergoing validation and the current expectation is that Genzyme will begin to be able to supply Fabrazyme produced at this plant to patients beginning in the first quarter of 2012. This timeline depends on successful completion of validation procedures and also requires subsequent regulatory approvals.

### **When will Fabrazyme supply return to normal?**

The new Framingham facility remains on track to supply product from that facility in the first quarter of 2012. The approval of this plant will allow the return to “normal” supply of Fabrazyme (that is, no restrictions on dose or patient numbers and a reduced risk of supply disruptions). However, due to the complexities of global regulatory approvals, global distribution, and release timing, approval to release product from Framingham is not expected to immediately enable return to full dose treatment for all Fabrazyme patients globally; such increase to full dose is expected to be gradual.

Genzyme is following a conservative approach and need to be confident that they can sustain higher levels before increasing supply levels - i.e., they do not want to increase supply and then have to decrease it in subsequent months.

### **What is Genzyme’s contingency plan if approval of the Framingham plant is delayed?**

Approval of the Framingham plant is necessary to restore and sustain normal, uninterrupted supply of Fabrazyme (that is, no restrictions on dose or patient numbers and a reduced risk of supply disruptions).

### **What is the plan for the Allston and Framingham facilities in the future?**

Genzyme will continue to support global markets with Fabrazyme originating from both the Allston and Framingham facilities until they can establish significant inventory levels and have the necessary regulatory approvals and a plan to consistently supply global markets. Only then would the Framingham facility become the sole production site for Fabrazyme.

### **Can Genzyme switch bioreactors around to make more Fabrazyme?**

Given the ongoing supply constraints of Thyrogen® (thyrotropin alfa for injection), Fabrazyme and Cerezyme® (imiglucerase for injection), Genzyme are unable at this time to change the allocation of bioreactors. They are continuously assessing their long-term manufacturing capacity plans and are taking this into consideration.

### **Cautionary Statement Regarding Forward-Looking Statements**

*This update contains forward-looking statements regarding Genzyme’s business plans and operations including, without limitation, expectations regarding future supply of Fabrazyme and the approval of Genzyme’s new manufacturing facility in Framingham. These statements are subject to risks and uncertainties that may cause actual results to differ materially. These risks and uncertainties include, among others, that Genzyme’s demand forecasts and estimates are inaccurate; that production of Fabrazyme does not continue as planned due to any reason, including bacterial or viral contamination, equipment failures, cell growth at lower than expected levels, fill-finish inefficiencies, power outages or*

*other disruptions of utility services, human error or regulatory issues; that compliance with the May 2010 FDA Consent Decree, including third-party oversight and/or the implementation of the remediation plan, results in additional or unexpected delays in product releases; that Genzyme cannot obtain on expected timetables or maintain regulatory approval of its new Framingham manufacturing facility; and the risks and uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2010. The statements in this update speak only as of October 3, 2011 and, other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*