Shire drug approved by European regulators for Lexington manufacturing

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Shire [1] plc's new Lexington manufacturing site has won approval from the European Medicines Agency for the purification of the company's Fabry disease treatment Replagal. The drug, an enzyme replacement treatment, already has EMA approval for purification at Shire's Cambridge facility.

The approval adds more pressure to Genzyme Corp., which was bought in April by Sanofi SA [2]; The Cambridge biotech had its own Fabry disease treatment, Fabrazyme, affected by a temporary shutdown of its Allston plant in 2010 and the subsequent FDA enforcement action [3]. Since then, Shire has taken progressive steps to push its own Fabry disease and type 1 Gaucher disease treatments forward, showing in March that patients can safely transition from Genzyme's treatments [4] to Shire's own treatments, the company said.

SOURCE [5]

Links:
[1] http://www.masshightech.com/search.html?q=Shire&t=1
[2] http://www.masshightech.com/stories/2011/02/14/daily28-Sanofi-paying-20B---and-then-some---for-Genzyme.html
[3] http://www.masshightech.com/stories/2010/03/22/daily34-FDA-plans-penalties-against-Genzyme-.html
[4] http://www.masshightech.com/stories/2011/03/21/daily10-Shire-data-shows-safe-switch-from-Genzyme-drugs.html
[5] http://www.masshightech.com/stories/2011/06/20/daily57-Shire-drug-approved-by-European-regulators-for-Lexington-manufacturing.html