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Shire biologics facility gets FDA clearance

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Singapore: Shire, global specialty biopharmaceutical company, has recieved US FDA approval for production of VPRIV drug substance (velaglucerase alfa for injection) in Shire's manufacturing facility at 400 Shire Way, Lexington, Massachusetts, US.

The facility was previously approved by the European Medicines Agency (EMA) for production of VPRIV drug substance. VPRIV, used for the long-term treatment of patients with type 1 Gaucher disease, is made in a human cell line using Shire's gene activation technology. The enzyme produced has the exact human amino acid sequence as that found in the naturally occurring human enzyme.

"FDA approval of Shire's manufacturing facility in Lexington provides greater assurance that Gaucher patients will receive consistent and uninterrupted access to enzyme replacement therapy for the treatment of type 1 Gaucher disease," said Mr Rhonda Buyers, CEO and executive director, National Gaucher Foundation.

Shire has invested over $200 million in manufacturing infrastructure and technology to establish a consistent drug supply chain to patients that use this treatment. The 400 Shire Way facility is the first commercially licensed facility in the world to utilize single-use bioreactor and disposable technology throughout cell culture processing designed to reduce manufacturing risk.

"Shire has always been committed to providing uninterrupted treatment for all VPRIV patients at the dose and frequency prescribed by their physicians. We continue to deliver on this commitment," said Mr Bill Ciambrone, executive VP, Technical Operations, Shire.

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