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Glenmark receives US FDA approval for Icatibant Injection

25 May 2021 | News

The injection will be manufactured in their North American manufacturing facility based in Monroe, North Carolina



Glenmark Pharmaceuticals (Glenmark) has received final approval by the United States Food & Drug Administration (US FDA) for Icatibant Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe, the generic version of Firazyr 1 Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe, of Shire Human Genetic Therapies. This marks Glenmark's first synthetic decapeptide injectable approval and will be manufactured in their North American manufacturing facility based in Monroe, North Carolina.

According to IQVIA sales data for the 12 months ending March 2021, the Firazyr Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe market2 achieved annual sales of approximately $223.4 million.

Glenmark's current portfolio consists of 172 products authorised for distribution in the US marketplace and 44 ANDA's pending approval with the US FDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.