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Aurobindo receives FDA approval for Eptifibatide injection

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Aurobindo Pharma has received final approval from the US Food & Drug Administration (US FDA) to manufacture and market Eptifibatide Injection USP, 20 mg/10 mL, 75 mg/100 mL, and 200 mg/100 mL single-use vials. This product is expected to be launched in this month.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Integrilin Injection, 20 mg/10 mL, 75 mg/100 mL, and 200 mg/100 mL of Schering Corporation.

The approved product has an estimated market size of $137 million for the twelve months ending October 2015 according to IMS.