Lupin receives US FDA tentative approval for Emtricitabine, Tenofovir Alafenamide Tablets, 200 mg/25 mg

This product will be manufactured at Lupin's Nagpur facility in India and will be supplied to low and middle-income countries. Emtricitabine and Tenofovir Alafenamide Tablets are indicated to treat or prevent HIV-1 infection in adults and children who weigh at least 35 kg.

Mumbai: Lupin Limited announced that it has received tentative approval from the United States Food and Drug Administration (US FDA) under the US President's Emergency Plan for AIDS Relief (PEPFAR) for its abbreviated new drug application for Emtricitabine and Tenofovir Alafenamide Tablets, 200 mg/25 mg, to market a generic equivalent of Descovy Tablets, 200 mg/25 mg, of Gilead Sciences, Inc.

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Naresh Gupta, President - API and Global Institution Business, Lupin said, "The tentative approval from the US FDA for our Emtricitabine and Tenofovir Alafenamide Tablets significantly enhances our HIV medicine offering."

News Source:

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