Lupin receives tentative approval from US FDA for Raltegravir Tablets

Raltegravir Tablets USP, 600 mg are indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients and in pediatric patients weighing at least 40 kg.

Mumbai: Global pharma major Lupin Limited has announced that it has received tentative approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Raltegravir Tablets USP, 600 mg, to market a generic equivalent of Isentress® HD Tablets, 600 mg of Merck Sharp & Dohme LLC. Lupin is the exclusive first-to-file for this product and may be eligible to receive a 180-day exclusivity. This product will be manufactured at Lupin's Nagpur facility in India.

Raltegravir Tablets USP, 600 mg are indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients and in pediatric patients weighing at least 40 kg.

News Source:

https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/lupin-receives-tentative-approval-from-us-fda-for-raltegravir-tablets/115158366