Lupin gets USFDA nod to launch generic tablet to treat overactive bladder



Lupin Ltd (NSE: LUPIN) has announced the launch of Mirabegron, a generic version of Mybetriq used to treat overactive bladder in the United States, it informed the BSE in a filing late Saturday evening. The announcement from the Mumbai-headquartered pharma major came after it received approval from the United States Food and Drug Administration (USFDA).

Mirabegron is the generic equivalent of Myrbetriq and is manufactured by Astellas Pharma Global Development. Lupin had earlier informed that the product would be manufactured at its facility in Nagpur, India.

Myrbetriq, a prescription medicine, is used in the treatment of an overactive bladder with symptoms of frequent or urgent urination and urinary incontinence. It is also used to treat neurogenic detrusor overactivity (NDO) in children.

According to IQVIA MAT February 2024, Mirabegron had estimated annual sales of \$1,019 million in the United States, the company's exchange filing said.

Lupin's Executive Director and Global CFO, and Head of Corporate Affairs, Ramesh Swaminathan, expects the pharmaceutical company to clock quarterly US sales in the range of \$200–210 million this year, given the lineup of existing and upcoming products. The North American market contributes roughly 37% to Lupin's sales, while India is around 34%.

Lupin launched the first generic version of Oracea (Doxycycline capsules, 40 mg) on April 9 in the United States. Oracea capsules are used in the treatment of inflammatory lesions (papules and pustules) of rosacea in adult patients.

Lupin also recently announced the successful closure of inspections by the USFDA at its manufacturing facility located in Vadodara, Gujarat.

Lupin develops and commercialises a wide range of branded and generic formulations, biotechnology products, and APIs in over 100 markets in the US, India, South Africa, and across the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions.

Lupin shares settled nearly 3% lower on Friday, quoting at ₹1,547 apiece on the NSE. So far this year, Lupin stock price has surged nearly 18%, while the one-year gain on the stock is 120%.

News Source:

https://www.cnbctv18.com/market/stock-in-focus-lupin-share-price-co-launches-mirabegron-generic-myrbetriq-for-overactive-bladder-treatment-usfda-19399835.htm