Zydus receives final approval and 180 days shared exclusivity from the USFDA for Selexipag Tablets

Ahmedabad, India, 22 December, 2022

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) subsidiary Zydus Worldwide DMCC (Zydus) has received final approval from the United States Food and Drug Administration (USFDA) to market Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, and 1,600 mcg (USRLD: Uptravi® tablets).

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, and 1,600 mcg and therefore is eligible for 180 days of shared generic drug exclusivity for Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, and 1,600 mcg.

Selexipag tablet is indicated in adults for the treatment of pulmonary arterial hypertension (PAH, high blood pressure in the vessels that carry blood to the lungs) to delay disease progression and reduce the risk of hospitalization for PAH. The drug will be manufactured in the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Selexipag tablet had annual sales of USD 577 million in the United States according to IQVIA data (IQVIA MAT Sept. 2022).

The group now has 338 approvals and has so far filed over 431* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th September 2022)*

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PRESS RELEASE

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