Zydus receives tentative approval from USFDA for Selexipag Tablets

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Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) subsidiary Zydus Worldwide DMCC has received tentative approval from the United States Food and Drug Administration (USFDA) to market Selexipag Tablets in the strengths of 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, and 1,600 mcg (USRLD: Uptravi®). Selexipag is used in adults to treat pulmonary arterial hypertension (PAH) to delay disease progression and reduce the risk of hospitalization for PAH. Selexipag is a prostacyclin receptor agonist. The drug will be manufactured at group's formulation facility at SEZ, Ahmedabad.

Uptravi® (Selexipag) Tablets had annual sales of USD 551mn in the United States (as per IQVIA MAT Mar-22 data).

The group now has 331 approvals and has so far filed over 400 ANDAs since the commencement of filing process in FY 2003-04.

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 23000 people worldwide and is driven by its mission to unlock new possibilities in life-sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking discoveries. For more details visit www.zyduslife.com.

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PRESS RELEASE

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