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Zydus gets 180 days shared exclusivity for Roflumilast Tablets

Ahmedabad, 14 February, 2022

Zydus' U.S. subsidiary Zydus Pharmaceuticals (USA) Inc. has received final approval from the USFDA to market Roflumilast Tablets in the strength of 500 mcg and a tentative approval for Roflumilast Tablets, 250 mcg (US RLD - DALIRESP®). Zydus being one of the first applicants for Roflumilast Tablets, 500 mcg is eligible for 180 days of shared generic drug exclusivity under section 505(j)(5)(B)(iv) of the FD&C Act. Zydus' Roflumilast Tablets are indicated as a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. The drug will be manufactured at the group's formulation manufacturing facility at the SEZ, Ahmedabad.

The group now has 327 approvals and has so far filed over 400 ANDAs since the commencement of the 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 pharmaceutical 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 become a global life-sciences company transforming lives through pathbreaking discoveries.

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