Zydus receives final approval from the USFDA for Roflumilast Tablets, 250 mcg

Ahmedabad, India, 19 April, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as "Zydus") has received final approval from the United States Food and Drug Administration (USFDA) to manufacture and market Roflumilast Tablets, 250 mcg (USRLD: Daliresp Tablets, 250 mcg).

Roflumilast reduces inflammation in the lungs that leads to chronic obstructive pulmonary disease (COPD). It is used to prevent worsening of symptoms in people with severe COPD. The drug will be manufactured at the group's formulation manufacturing facility in SEZ Ahmedabad, (India).

Roflumilast Tablets, 250 mcg had annual sales of USD 34 mn in the United States (IQVIA MAT Feb. 2023).

The group now has 363 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2022)

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PRESS RELEASE

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