Zydus receives tentative approval from the USFDA for Bosentan Tablets for Oral Suspension

Ahmedabad, India, 15 February, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates hereafter referred to as "Zydus") has received tentative approval from the United States Food and Drug Administration (USFDA) to market Bosentan Tablets for Oral Suspension, 32 mg (USRLD: Tracleer® Tablets for Oral Suspension).

Bosentan Tablet for oral suspension is indicated for the treatment of pulmonary arterial hypertension (PAH) in pediatric patients aged 3 years and older with idiopathic or congenial PAH to improve pulmonary vascular resistance (PVR). The drug will be manufactured at the group's formulation manufacturing facility at SEZ, Ahmedabad.

Bosentan Tablets for Oral Suspension had annual sales of USD 16 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 341 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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