

February 15, 2023

BSE Limited Code: 532321

1st Floor, P J Towers, Dalal Street, <u>Mumbai-400001</u>

National Stock Exchange of India Limited

Exchange Plaza, 5th Floor, Plot No. C/1, G Block, Bandra-Kurla Complex, Bandra (East), <u>Mumbai-400051</u>

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated February 15, 2023 titled "Zydus receives tentative approval from the USFDA for Bosentan Tablets for Oral Suspension".

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors' at large.

Thanking you,

Yours faithfully,
For, ZYDUS LIFESCIENCES LIMITED

DHAVAL N. SONI COMPANY SECRETARY

Encl.: As above



Code: Zyduslife



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)



For further information please contact: The Corporate Communications Department

Zydus Lifesciences Limited

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