Zydus receives final approval from USFDA for Bosentan tablets for oral suspension, 32 mg

Ahmedabad, India, 18 February, 2026

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) for Bosentan tablets, oral suspension, 32 mg (USRLD: Tracleer® Tablets for Oral Suspension, 32 mg).

Bosentan 32 mg tablets for oral suspension are indicated for the treatment of Pulmonary Arterial Hypertension (PAH), specifically to improve exercise ability and reduce clinical worsening in children (aged 3 years and older) with idiopathic or congenital PAH. It is a dual endothelin receptor antagonist that lowers high blood pressure in the lungs, typically administered based on body weight.

Bosentan 32 mg tablets will be manufactured at the group's formulation manufacturing facility at SEZ, Ahmedabad.

Bosentan 32 mg tablets had annual sales of USD 9.3 mn in the United States (IQVIA MAT December 2025).

The group now has 432 approvals and has so far filed 505* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31-Dec-2025)*

PRESS RELEASE

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