



Dedicated To Life

December 1, 2023

BSE Limited

P J Towers,
Dalal Street,
Mumbai-400001

Code: 532321

National Stock Exchange of India Limited

Exchange Plaza,
C/1, Block G,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Code: Zyduslife

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated December 1, 2023 titled "**Zydus receives final approval from the USFDA for Ivabradine Tablets, 5 mg and 7.5 mg**".

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

Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited)

Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle,
S. G. Highway, Ahmedabad-382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000
website : www.zyduslife.com | CIN : L24230GJ1995PLC025878



Zydus receives final approval from the USFDA for Ivabradine Tablets, 5 mg and 7.5 mg

Ahmedabad, India, December 1, 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) for Ivabradine Tablets, 5 mg and 7.5 mg (USRLD: Corlanor[®] Tablets, 5 mg and 7.5 mg).

Ivabradine is indicated to reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction. It is also used in children aged 6 months and older for the treatment of stable symptomatic heart failure due to cardiomyopathy. The drug will be manufactured at the group’s formulation manufacturing facility at Ahmedabad SEZ, India.

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Ivabradine Tablets, 5 mg and 7.5 mg and therefore may be eligible for 180 days of shared generic exclusivity for Ivabradine Tablets, 5 mg and 7.5 mg.

Ivabradine Tablets, 5 mg and 7.5 mg had annual sales of USD 136.5 mn in the United States (IQVIA MAT October, 2023).

The group now has 382 approvals and has so far filed over 448* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 30th September 2023)

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**PRESS
RELEASE**

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)

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