

March 16, 2024

BSE Limited Code: 532321

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

**National Stock Exchange of India Limited** 

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

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated March 16, 2024 titled "Zydus receives final approval from USFDA and 180 days CGT exclusivity for Finasteride and Tadalafil Cap Capsules".

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 final approval from USFDA and 180 days CGT exclusivity for Finasteride and Tadalafil Cap Capsules

Ahmedabad, India, 16 March, 2024

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) has received final approval from the United States Food and Drug Administration (USFDA) to market Finasteride and Tadalafil Capsules USP 5 mg/5 mg. (USRLD: ENTADFI TM).

Zydus is the "first approved applicant" for Finasteride and Tadalafil Capsules, 5 mg/5 mg, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act and therefore is eligible for 180 days of CGT exclusivity. Finasteride and Tadalafil is used to treat benign prostatic hyperplasia. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ II, India.

The group now has 392 approvals and has so far filed over 460\* ANDAs since the commencement of the filing process in FY 2003-04.

(\*as of 31st December 2023)

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For further information please contact: The Corporate Communications Department

Zydus Lifesciences Limited

(formerly known as Cadila Healthcare Limited)
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