

October 4, 2022

BSE Limited 1st Floor, P J Towers, Dalal Street, <u>Mumbai-400001</u> Code: 532321

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> Code: Zyduslife

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated October 4, 2022 titled "Zydus receives tentative approval from the USFDA for Amantadine Extended-Release 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



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 tentative approval from the USFDA for Amantadine Extended-Release Capsules

Ahmedabad, India, 04 October, 2022

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) U.S. subsidiary Zydus Pharmaceuticals (USA) Inc. has received tentative approval from the United States Food and Drug Administration (USFDA) to market Amantadine Extended-Release Capsules USP 68.5 mg and 137 mg (USRLD: Gocovri[®]).

Amantadine is indicated for the treatment of dyskinesia (sudden uncontrolled movements) in patients with Parkinson's disease who are treated with levodopa therapy, with or without dopaminergic medicines. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Amantadine Extended-Release Capsules had annual sales of USD 2.7 mn in the United States according to IQVIA data (IQVIA MAT Aug 2022).

The group now has 325 approvals and has so far filed over 428* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 30th June 2022)



For further information please contact : The Corporate Communications Department

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