



September 6, 2021

BSE Limited Code: 532321

1st Floor, P J Towers, Dalal Street, Mumbai-400001

National Stock Exchange of India Limited Code: Cadilahc

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

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated September 6, 2021 titled "Zydus Cadila's Sitagliptin base tablets receives Tentative Approval from FDA".

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, **CADILA HEALTHCARE LIMITED**

DHAVAL N. SONI COMPANY SECRETARY

Encl.: As above



Zydus Cadila's Sitagliptin base tablets receives Tentative Approval from FDA

September 6, 2021, Ahmedabad India

Zydus Cadila today announced that its subsidiary has received tentative approval from the United States Food and Drug Administration (FDA) for its new drug application for Sitagliptin base 25, 50 and 100 mg tablets. Zydus' Sitagliptin base contains the active moiety Sitagliptin in a different form than used in the branded reference product, Januvia[®] (Sitagliptin Phosphate).

On October 31, 2020, Zydus filed a New Drug Application (NDA) under Section 505(b)(2) of the Federal Food and Drug Cosmetic Act (FD&C Act) with the United States Food and Drug Administration (FDA) seeking approval to market Sitagliptin base 25, 50 and 100 mg tablets. Zydus' NDA received tentative approval upon completion of the first review cycle on September 2, 2021.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies including small molecule drugs, biologic therapeutics, and vaccines. The group employs 23000 people worldwide and is dedicated to creating healthier communities globally. For more information, please visit www.zyduscadila.com/

Januvia® is a registered trademark of the Merck.

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