

July 19, 2024

BSE Limited Code: 532321

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

National Stock Exchange of India Limited

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 July 19, 2024 titled "Zydus receives final approval from USFDA for its NDA ZituvimetTM XR (sitagliptin and metformin hydrochloride) extended-release tablets".

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

website: www.zyduslife.com | CIN: L24230GJ1995PLC025878



Code: Zyduslife



Zydus receives final approval from USFDA for its NDA Zituvimet[™] XR (sitagliptin and metformin hydrochloride) extended-release tablets

Ahmedabad, India, 19 July 2024

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as "Zydus") has received final approval for its New Drug Application (NDA) from the United States Food and Drug Administration (USFDA) to market ZituvimetTM XR (sitagliptin and metformin hydrochloride) extended-release tablets.

With this, Zydus has all three NDAs of Sitagliptin (base) and combination franchise approved through the 505(b)(2) route. Notably, all the three NDAs achieved First-Cycle Approval (FCA).

ZituvimetTM XR (sitagliptin and metformin hydrochloride) extended-release tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The product will be manufactured at the group's formulation manufacturing facility in Ahmedabad SEZ, India.

According to IQVIA (MAT May 2024), U.S. market for DPP-IV inhibitors and its combinations is US\$ 9.5 bn.



For further information please contact: The Corporate Communications Department

Zydus Lifesciences Limited

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