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 Zituvimet™ 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).

Zituvimet™ 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.

****

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences 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