Press Release

Zydus Cadila receives Final Approval from USFDA for Ursodiol Capsules and Tentative Approval for Linagliptin and Metformin Hydrochloride Tablets

Ahmedabad, 17 October, 2020

Zydus Cadila has received final approval from the USFDA to market Ursodiol Capsules USP, 300 mg (US RLD: Actigall®Capsules). Ursodiol is in a class of medications called gallstone dissolution agents. It is used to treat people with primary biliary cirrhosis (PBC; an autoimmune liver disease).

The company also received tentative approval from the USFDA to market Linagliptin and Metformin Hydrochloride Tabs (US RLD: Jentadueto® Tablets) in the strengths of 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1,000 mg. It is used along with diet and exercise to improve control of blood sugar levels in adults with type 2 diabetes mellitus.

Both drugs will be manufactured at the group's formulation manufacturing facility at the SEZ, Ahmedabad.

The group now has 307 approvals and has so far filed over 390 ANDAs since the commencement of the filing process in FY 2003-04.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs nearly 25000 people worldwide and is dedicated to creating healthier communities globally.

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For further information please contact :
The Corporate Communications Department

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, India.
Phone : +91-079-71800000, +91-079-48040000 www.zyduscadila.com
CIN : L24230GJ1995PLC025878