Zydus receives final approval from the USFDA for Olmesartan Medoxomil and Hydrochlorothiazide Tablets

Ahmedabad, India, 28 February, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates hereafter referred to as "Zydus") has received final approval from the United States Food and Drug Administration (USFDA) for Olmesartan Medoxomil and Hydrochlorothiazide Tablets, 20 mg/12.5 mg, 40 mg/12.5 mg, and 40 mg/25 mg (USRLD: Benicar HCT ® Tablets).

Olmesartan Medoxomil and Hydrochlorothiazide, as the name suggests is a combination of two medicines: Olmesartan and Hydrochlorothiazide. Olmesartan is an angiotensin II receptor blocker (sometimes called an ARB blocker) while hydrochlorothiazide is a diuretic (water pill). This combination medicine is used to treat high blood pressure (hypertension). Lowering blood pressure may lower risk of a stroke or heart attack. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Olmesartan Medoxomil and Hydrochlorothiazide Tablets, 20 mg/12.5 mg, 40 mg/12.5 mg, and 40 mg/25 mg had annual sales of USD 41.7 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 346 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2022)

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PRESS RELEASE

For further information please contact :
The Corporate Communications Department

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