Zydus receives two final approvals from the USFDA for Silodosin capsules and Pregabalin capsules

- *The drugs will be manufactured at the group's formulation manufacturing facility at Moraiya, Ahmedabad, India.*

Ahmedabad, India, 10 December, 2022

Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited) has received final approval from the United States Food and Drug Administration (USFDA) to market Silodosin Capsules, 4 mg and 8 mg (USRLD: Rapaflo® capsules). The company also received the final approval to market Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg (USRLD: Lyrica capsules).

Silodosin capsules are indicated to treat signs and symptoms of an enlarged prostate gland, which is also known as benign enlargement of the prostate (benign prostatic hyperplasia or BPH).

Silodosin capsules had annual sales of USD 14 mn in the United States according to IQVIA data (IQVIA MAT Sep 2022).

Pregabalin capsules are indicated to treat pain caused by nerve damage due to diabetes or to shingles (herpes zoster) infection. It is also used to treat nerve pain caused by spinal cord injury and pain in people with fibromyalgia.

Pregabalin capsules had annual sales of USD 242 mn in the United States according to IQVIA data (IQVIA MAT Sep 2022).

The group now has 338 approvals and has so far filed over 431* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th September 2022)*

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PRESS RELEASE

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