



Dedicated To Life

February 20, 2023

Listing Department
BOMBAY STOCK EXCHANGE LIMITED
P J Towers, Dalal Street, Fort,
Mumbai-400 001

Code: **532321**

Listing Department
NATIONAL STOCK EXCHANGE OF INDIA LIMITED
Exchange Plaza, Bandra Kurla Complex,
Bandra (E),
Mumbai-400 051

Code: **ZYDUSLIFE**

Re.: **Press Release**

Dear Sir / Madam,

Please find enclosed two press releases, both dated February 20, 2023 titled (i) "**Zydus receives tentative approval from the USFDA for Gabapentin Tablets (Once-Daily), 300 mg and 600 mg**" and (ii) "**Zydus receives tentative approval from the USFDA for Canagliflozin and Metformin Hydrochloride Tablets**".

The contents of the press releases 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

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



Zydus receives tentative approval from the USFDA for Gabapentin Tablets (Once-Daily), 300 mg and 600 mg

Ahmedabad, India, 20 February, 2023

Zydus Lifesciences Limited's (including its subsidiaries/affiliates hereafter referred to as "Zydus") subsidiary Zydus Pharmaceuticals (USA) Inc. has received tentative approval from the United States Food and Drug Administration (USFDA) for Gabapentin Tablets (Once-Daily), 300 mg and 600 mg (USRLD: Gralise® Tablets).

Gabapentin tablets are indicated for the management of Postherpetic Neuralgia (PHN). The drug will be manufactured at the group's formulation manufacturing facility at Moraiya.

Gabapentin Tablets had annual sales of USD 90 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 343 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)



**PRESS
RELEASE**

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)

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Zydus receives tentative approval from the USFDA for Canagliflozin and Metformin Hydrochloride Tablets

Ahmedabad, India, 20 February, 2023

Zydus Lifesciences Limited's (including its subsidiaries/affiliates hereafter referred to as "Zydus") subsidiary Zydus Pharmaceuticals (USA) Inc. has received tentative approval from the United States Food and Drug Administration (USFDA) for Canagliflozin and Metformin Hydrochloride Tablets, 50 mg/500 mg, 50 mg/1,000 mg, 150 mg/500 mg, and 150 mg/1,000 mg_ (USRLD: Invokamet® Tablets).

Canagliflozin and metformin combination product is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients already being treated with both canagliflozin and metformin. The drug will be manufactured at the group's formulation manufacturing facility at Moraiya.

Canagliflozin and Metformin Hydrochloride Tablets had annual sales of USD 49.4 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 344 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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