April 8, 2021

Listing Department **Code: *532 321***
**BSE LIMITED**
P J Towers, Dalal Street, Fort,
Mumbai – 400 001

Listing Department **Code: *CADILAHC***
**NATIONAL STOCK EXCHANGE OF INDIA LIMITED**
Exchange Plaza, Bandra Kurla Complex,
Bandra (E),
Mumbai – 400 051

**Re.:** Press Release

Dear Sir/Madam,

Please find enclosed a copy of press release dated April 8, 2021 titled "**Zydus Cadila announces USFDA approval for First Generic for Ibrutinib Capsules, 70 mg and gets eligibility for 180-day exclusivity**".

The contents of the press release 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, **CADILA HEALTHCARE LIMITED**

**DHAVAL N. SONI**
**COMPANY SECRETARY**

**Encl.:** As above

Zydus dedicated to life

Press Release Press Release Press Release Press Release Press Release Press Release Press Release Press Release

# Zydus Cadila announces USFDA approval for First Generic for Ibrutinib Capsules, 70 mg and gets eligibility for 180-day exclusivity

*Ahmedabad, 08 April, 2021*

Zydus Cadila has received final approval from the USFDA to market Ibrutinib Capsules, 70 mg and 140 mg (US RLD: Imbruvica Capsules). Ibrutinib belongs to a class of drugs known as kinase inhibitors and is used to treat certain cancers, such as mantle cell lymphoma or marginal zone lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, and Waldenstrom's macroglobulinemia.

According to the USFDA letter, Zydus was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Ibrutinib Capsules, 70 mg. Therefore, with this approval, Zydus is eligible for 180 days of generic drug exclusivity for Ibrutinib Capsules, 70 mg. For Ibrutinib Capsules, 140 mg, the company will have 180-days of shared generic drug exclusivity. The 70 mg capsule has brand sales of USD 32.5 mn, while the 140 mg dose has brand sales of USD 745.9 mn. Zydus is the first company to receive approval for generic Ibrutinib 70 mg capsules.

Managing Director, Zydus Group, Dr. Sharvil Patel commented, "This FDA approval of Ibrutinib Capsules reinforces our long-term commitment to provide patients and caregivers access to affordable therapies. We have been investing significantly in building a portfolio of complex generic products and leveraging capabilities that will help us successfully commercialize and gain meaningful market share in the complex generic products and difficult-to-manufacture generic products. We have created a diversified portfolio of over 50 filed complex ANDAs seeking USFDA approval and we will continue to expand this as we explore opportunities to grow our US business in 2021 and beyond."

The drug will be manufactured at the group's formulation manufacturing facility at the SEZ, Ahmedabad. The group now has 313 approvals and has so far filed over 400 ANDAs since the commencement of the filing process in FY 2003-04.

**About Zydus**

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**

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