November 18, 2021

BSE Limited **Code: 532321**
1st Floor,
P J Towers,
Dalal Street,
Mumbai-400001

National Stock Exchange of India Limited **Code: Cadilac**
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra-Kurla Complex, Bandra (East)
Mumbai-400051

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated November 18, 2021, titled **"Zydus Cadila gets 180-day exclusivity for Nelarabine injection, announces final approval from USFDA".**

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 gets 180-day exclusivity for Nelarabine injection, announces final approval from USFDA

November 18, 2021, Ahmedabad, India

Zydus Cadila has received final approval from the USFDA to market Nelarabine Injection 250MG/50ML in the United States (US RLD: *Arranon*®). Zydus Pharmaceuticals USA Inc (Zydus) was granted a Competitive Generic Therapy (CGT) designation for Nelarabine Injection, 250 mg/50 mL (5 mg/mL), Single-Dose Vial. Zydus is the "first approved applicant" for Nelarabine Injection, 250 mg/50 mL (5 mg/mL), Single-Dose Vial, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Zydus is eligible for 180 days of CGT exclusivity for Nelarabine Injection, 250 mg/50 mL (5 mg/mL), Single-Dose Vial, under section 505(j)(5)(B)(v) of the FD&C Act.

Nelarabine Injection had annual sales of approximately $34.5 million in the United States according to IQVIA data (September 2021). The drug is manufactured at the group's injection manufacturing facility, Alidac plant in Ahmedabad and shall be launched commercially within the US market immediately.

This medication is a chemotherapy drug and used to treat certain types of leukemia and lymphoma by slowing or stopping the growth of cancer cells. Nelarabine is in a class of medications called antimetabolites.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Cadila Healthcare Ltd., said, "This FDA approval of Nelarabine Injection underlines our long-term commitment to patients of providing them access to affordable generics. This approval builds on our proven track-record of successfully commercializing and gaining meaningful market share in complex generics products. We have created a diversified portfolio of more than 50 filed complex ANDAs and will continue to focus on complex generic products as we continue to explore opportunities to grow our US business."

Zydus, in addition to their complex injectable products, has created an industry leading portfolio of difficult to develop oral solids, drug device combinations, topicals, and transdermal patch products. The group now has 325 approvals and has so far filed over 400 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 including small molecule drugs, biologic therapeutics, and vaccines. The group employs 23,000 people worldwide and is dedicated to creating healthier communities globally. For more information, please visit www.zyduscadila.com

For further information please contact :
The Corporate Communications Department

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