



Dedicated To Life

January 12, 2023

BSE Limited

1st Floor,
P J Towers,
Dalal Street,
Mumbai-400001

Code: 532321

National Stock Exchange of India Limited

Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Code: Zyduslife

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated January 12, 2023 titled **“Zydus receives final approval and 180 days shared exclusivity from the USFDA for Brexpiprazole Tablets”**.

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, **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 final approval and 180 days shared exclusivity from the USFDA for Brexpiprazole Tablets

Ahmedabad, India, 12 January, 2023

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) subsidiary Zydus Worldwide DMCC (Zydus) has received final approval from the United States Food and Drug Administration (USFDA) to market Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg (USRLD: REXULTI® tablets).

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg and therefore is eligible for 180 days of shared generic drug exclusivity for Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg.

Brexpiprazole is an atypical antipsychotic indicated for use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults. It is also indicated for the treatment of schizophrenia in adults and pediatric patients ages 13 years and older. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Brexpiprazole tablets had annual sales of USD 1,548 million in the United States according to IQVIA data (IQVIA MAT Sept. 2022).

The group now has 340 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)*



**PRESS
RELEASE**

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)

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