



Dedicated To Life

October 6, 2022

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 a copy of press release dated October 6, 2022, titled "**Zydus receives final approval from USFDA and 180 days shared exclusivity for Brivaracetam 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](http://www.zyduslife.com) | CIN : L24230GJ1995PLC025878



## **Zydus receives final approval from USFDA and 180 days shared exclusivity for Brivaracetam Tablets**

*Ahmedabad, India, 06 October, 2022*

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) U.S. subsidiary Zydus Pharmaceuticals (USA) Inc. has received final approval from the United States Food and Drug Administration (USFDA) to market Brivaracetam Tablets USP 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg. (USRLD: Briviact®).

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Brivaracetam Tablets USP 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg. It is therefore eligible for 180 days of shared generic drug exclusivity for Brivaracetam Tablets USP 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg.

Brivaracetam is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Brivaracetam Tablets USP 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg had annual sales of USD 412 mn in the United States according to IQVIA data (IQVIA MAT August 2022).

The group now has 326 approvals and has so far filed over 428\* ANDAs since the commencement of the filing process in FY 2003-04.

*(\*as of 30<sup>th</sup> June 2022)*

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**PRESS  
RELEASE**

For further information please contact :  
**The Corporate Communications Department**

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