



Dedicated To Life

October 17, 2022

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 Releases

Dear Sir / Madam,

Please find enclosed copy of two press releases both dated October 17, 2022, with titles as under:

1. **Zydus receives tentative approval from the USFDA for Valbenazine Capsules and**
2. **Zydus receives tentative approval from the USFDA for Roflumilast 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 Valbenazine Capsules

Ahmedabad, India, 17 October, 2022

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) subsidiary Zydus Worldwide DMCC has received tentative approval from the United States Food and Drug Administration (USFDA) to market Valbenazine Capsules USP 40 mg, 60 mg, and 80 mg (USRLD: Ingrezza[®]).

Valbenazine Capsules are indicated for the treatment of adults with tardive dyskinesia (movements in the face, tongue, or other body parts that cannot be controlled). The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Valbenazine Capsules had annual sales of USD 781mn in the United States according to IQVIA data (IQVIA MAT Aug 2022).

The group now has 327 approvals and has so far filed over 428* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th June 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 Roflumilast Tablets

Ahmedabad, India, 17 October, 2022

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) U.S. subsidiary Zydus Pharmaceuticals (USA) Inc. has received tentative approval from the United States Food and Drug Administration (USFDA) to market Roflumilast Tablets USP, 250 mcg (USRLD: Daliresp[®]).

Roflumilast Tablets are indicated as a treatment to reduce the risk of Chronic Obstructive Pulmonary Disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Roflumilast Tablets had annual sales of USD 248mn in the United States according to IQVIA data (IQVIA MAT Aug 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 30th June 2022)*



**PRESS
RELEASE**

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