



Dedicated To Life

August 31, 2023

**BSE Limited**

P J Towers,  
Dalal Street,  
Mumbai-400001

**Code: 532321**

**National Stock Exchange of India Limited**

Exchange Plaza,  
C/1, Block G,  
Bandra-Kurla Complex, Bandra (East),  
Mumbai-400051

**Code: Zyduslife**

**Re.:** Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated August 31, 2023 titled **“Zydus receives final approval from the USFDA for Isotretinoin Capsules USP, 10 mg, 20 mg 30 mg and 40 mg”**.

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 the USFDA for Isotretinoin Capsules USP, 10 mg, 20 mg 30 mg and 40 mg**

*Ahmedabad, India, 31 August, 2023*

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as “Zydus”) has received final approval from the United States Food and Drug Administration (USFDA) for Isotretinoin Capsules USP, 10 mg, 20 mg 30 mg and 40 mg (RLD: Accutane® Capsules, 10 mg, 20 mg and 40 mg: RS: Claravis 10 mg, 20 mg, 30 mg and 40 mg).

Isotretinoin Capsules is used to treat severe cystic acne (also known as nodular acne) that has not responded to other treatment (such as benzoyl peroxide or clindamycin applied to the skin or tetracycline or minocycline taken by mouth). The drug will be manufactured at the group’s formulation manufacturing facility in Moraiya, Ahmedabad (India).

Section 505-1 of the FD&C Act authorizes FDA to require the submission of a Risk Evaluation and Mitigation Strategy (REMS) for this product. Zydus’ proposed REMS has also been approved by FDA. The Isotretinoin iPLEDGE REMS consists of Elements to Assure Safe Use (ETASU) and an implementation system.

Isotretinoin Capsules USP, 10 mg, 20 mg 30 mg and 40 mg had annual sales of USD 165 mn in the United States (IQVIA MAT July 2023).

The group now has 378 approvals and has so far filed over 444\* ANDAs since the commencement of the filing process in FY 2003-04.

(\*as of 30<sup>th</sup> June 2023)

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**PRESS  
RELEASE**

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

**Zydus Lifesciences Limited**  
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