



Dedicated To Life

April 24, 2023

**BSE Limited**

1<sup>st</sup> Floor,  
P J Towers,  
Dalal Street,  
Mumbai-400001

**Code: 532321**

**National Stock Exchange of India Limited**

Exchange Plaza, 5<sup>th</sup> 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 April 24, 2023 titled **"Zydus receives final approval from the USFDA for Icosapent Ethyl Capsules, 0.5 g and 1 g"**.

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 from the USFDA for Icosapent Ethyl Capsules, 0.5 g and 1 g**

*Ahmedabad, India, 24 April, 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 Icosapent Ethyl Capsules, 0.5 g and 1 g (USRLD: Vascepa® Capsules, 0.5 g and 1 g).

Icosapent Ethyl Capsules are indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.

Zydus’s Icosapent Ethyl Capsules are not approved for the indication as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels ( $\geq 150$  mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

Limitations of Use: The effect of Icosapent Ethyl Capsules on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Icosapent Ethyl Capsules, 0.5 g and 1 g had annual sales of USD 1,316 mn in the United States (IQVIA MAT Feb. 2023).

The group now has 365 approvals and has so far filed over 440\* ANDAs since the commencement of the filing process in FY 2003-04.

(\*as of 31<sup>st</sup> December 2022)

\*\*\*



**PRESS  
RELEASE**

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

**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