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April 8, 2021

Listing Department  
**BSE LIMITED**  
P J Towers, Dalal Street, Fort,  
Mumbai – 400 001

**Code: 532 321**

Listing Department  
**NATIONAL STOCK EXCHANGE OF INDIA LIMITED**  
Exchange Plaza, Bandra Kurla Complex,  
Bandra (E),  
Mumbai – 400 051

**Code: CADILAHC**

**Re.:** Press Release

Dear Sir/Madam,

Please find enclosed a copy of press release dated April 8, 2021 titled **“Zydus Cadila announces final USFDA approval for Macitentan Tablets, 10 mg and gets eligibility for 180-day shared exclusivity”**.

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, **CADILA HEALTHCARE LIMITED**

  
**DHAVAL N. SONI**  
**COMPANY SECRETARY**

**Encl.:** As above

## **Zydus Cadila announces final USFDA approval for Macitentan Tablets, 10 mg and gets eligibility for 180-day shared exclusivity**

*Ahmedabad, 08 April, 2021*

Zydus Cadila has received final approval from the USFDA to market Macitentan Tablets, 10 mg (US RLD: Opsumit Tablets). Macitentan is used to manage the symptoms of pulmonary arterial hypertension. Macitentan is in a class of medications called endothelin receptor antagonists. It works by stopping the action of endothelin, a natural substance that causes blood vessels to narrow and prevents normal blood flow in people who have Pulmonary Arterial Hypertension.

According to the USFDA letter, Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Macitentan Tablets, 10 mg. Therefore, with this approval, Zydus is eligible for 180 days of shared generic drug exclusivity for Macitentan Tablets, 10 mg.

The group now has 314 approvals and has so far filed over 400 ANDAs since the commencement of the filing process in FY 2003-04.

### **About Zydus**

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs nearly 25000 people worldwide and is dedicated to creating healthier communities globally.

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

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