

June 17, 2019

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 June 17, 2019 titled "Zydus Announces Completion of Enrolment in EVIDENCES IV Phase 2 Clinical Trial of Saroglitazar Magnesium in NASH".

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 Announces Completion of Enrolment in EVIDENCES IV Phase 2 Clinical Trial of Saroglitazar Magnesium in NASH**

*Ahmedabad, India, 17 June 2019*

Zydus Cadila, an innovation-driven, global pharmaceutical company, announced that it has completed enrolment of 104 patients with Non-Alcoholic Fatty Liver Disease (NAFLD), including Non-Alcoholic SteatoHepatitis (NASH) across 20 clinical sites in the United States of America.

The trial will evaluate the percentage change from baseline in serum ALT levels in patients treated with Saroglitazar Magnesium as compared to placebo as the primary endpoint. The change in liver fat content as measured by magnetic resonance imaging will also be compared, along with several other secondary endpoints. This study is one of several EVIDENCES trials conducted to assess the effect of Saroglitazar Magnesium in various populations with NAFLD, including patients with NASH.

Speaking on the development, Mr. Pankaj R. Patel, Chairman, Zydus group said, “This is a major milestone in our innovation journey and we hope to report the top line results of this trial by the end of the year. In keeping with our mission of creating healthier, happier communities, we are committed towards developing this drug for millions of patients suffering from NASH, an unmet healthcare need.”

### **About EVIDENCES IV trial (ClinicalTrials.gov Identifier: NCT03061721)**

This is a randomized, double-blind, placebo-controlled study in up to 104 patients with a diagnosis of NAFLD and/or NASH. The study will be conducted over a period of up to 22 weeks. Patients have been randomly assigned in a ratio of 1:1:1:1 to receive Saroglitazar Magnesium 1 mg or 2 mg or 4 mg or matching placebo once daily for 16 Weeks. The primary endpoint of the study is the percentage change from baseline in serum ALT levels at Week-16 in the Saroglitazar Magnesium groups as compared to the placebo group.

### **About NASH**

NASH is a significant unmet medical need, with an estimated 6.5 million adults in the United States and five major European countries having advanced NASH. NASH is a progressive disease of the liver. Starting with fat accumulation in liver, this condition can progress to cirrhosis and liver failure. NASH ranks as one of the major causes of cirrhosis in America, behind hepatitis C and

alcoholic liver disease. Liver transplantation is the only option for managing advanced cirrhosis with liver failure. There are currently no treatments approved by the U.S. Food and Drug Administration (USFDA) for the treatment of NASH.

#### **About Saroglitazar Magnesium**

Saroglitazar Magnesium is an investigational molecule in USA, undergoing clinical evaluation for the treatment of liver diseases like Nonalcoholic Steatohepatitis (NASH) and Primary Biliary Cholangitis (PBC). Nonclinical studies have demonstrated that Saroglitazar Mg, because of its unique mechanism of engaging PPAR alpha and PPAR gamma, favorably affects all components of NASH including steatosis, ballooning, inflammation and fibrosis.

#### **About Zydus**

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. For more information, visit [www.zyduscadila.com](http://www.zyduscadila.com)

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