Zydus
dedicated to life

Cadila
Healthcare Limited

April 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 April 17, 2019 titled "Zydus Announces Phase 3 Trial of Desidustat in Non-Dialysis Dependent Chronic Kidney Disease (CKD) Patients with Anemia".

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

CADILA HEALTHCARE LIMITED
AHMEDABAD

Encl.: As above

Zydus Announces Phase 3 Trial of Desidustat in Non-Dialysis Dependent Chronic Kidney Disease (CKD) Patients with Anemia

Ahmedabad, India, April 17, 2019

Zydus Cadila, an innovation-driven, global pharmaceutical company, announced the Phase III trials of Desidustat, an Investigational New Drug targeted at treating anemia in non-dialysis dependent chronic kidney disease (NDD-CKD) patients. This Phase III study will be a multicenter (50- 60 sites), randomized, active-controlled clinical trial to evaluate the efficacy and safety of Desidustat versus Darbepoetin for the treatment of anaemia in patients with chronic kidney disease (CKD) who are not on dialysis.

Speaking on the development, Mr. Pankaj R. Patel, Chairman, Zydus Group said, "This innovation has the potential to bring about a paradigm shift in the management of CKD patients with anemia. An HIF-PH inhibitor could provide an oral, safer alternative to currently available erythropoietin-stimulating agents (ESAs), which are associated with increased risk of cardiovascular events and have to be given via injections and a cold chain has to be maintained. This is a significant milestone in our research journey."

Earlier, Desidustat had met its primary endpoints in the Phase II clinical study of Non-dialysis dependent Chronic Kidney Disease (NDD-CKD) patients suffering from anemia. The Phase II NDD-CKD study was a randomized, double-blind, placebo-controlled study of the efficacy and safety of Desidustat for the treatment of anemia in CKD patients not on dialysis. Desidustat demonstrated superiority in efficacy versus placebo in terms of hemoglobin (Hb) response rate at all doses tested when compared to placebo over six weeks. This result was supported by the efficacy demonstrated across multiple secondary endpoints. The Phase I trials were earlier completed in Australia. Detailed data from this NDD-CKD Phase II study will be published in the peer-reviewed scientific journal 'American Journal of Nephrology'.

About Chronic Kidney Disease (CKD) Anemia

Chronic Kidney Disease is a serious medical condition involving gradual loss of functioning of kidneys eventually leading to kidney failure. More than 200 million people worldwide are estimated to be living with CKD. In a Chronic Kidney Disease condition, the kidneys fail to produce EPO and this leads to low levels of hemoglobin (Hb) in the blood or anemia.

For further information please contact :
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About Desidustat

Desidustat is a novel, oral, HIF-PH inhibitor being developed for treating anemia in Chronic Kidney Disease patients. In Phase I studies Desidustat was well tolerated at doses from 10 to 300 mg. About 27-42% of Desidustat was eliminated by renal route in healthy volunteers. In Phase II studies in non-dialysis dependent CKD patients, Desidustat was found to be safe and well tolerated at 100 mg, 150 mg and 200 mg alternate-day dosing regimen. No serious AEs were observed. In Phase II pre-dialysis CKD subjects there was an increase in Cmax and AUC as compared to healthy volunteers. However, no accumulation was observed on repeated dosing. Higher exposure observed in non-dialysis dependent CKD patients as compared to healthy individuals may have led to greater erythropoietic response even at the lower doses.

Publications on Desidustat (ZYAN1):

1. Phase I Clinical Study of ZYAN1, A Novel Prolyl-Hydroxylase (PHD) Inhibitor to Evaluate the Safety, Tolerability, and Pharmacokinetics Following Oral Administration in Healthy Volunteers. Clin Pharmacokinet. 2018 Jan; 57(1):87-102.
2. Pharmacological Characterization of ZYAN1, a Novel Prolyl Hydroxylase Inhibitor for the Treatment of Anemia. Drug Res (Stuttg). 2016 Feb; 66(2):107-12.
3. Influence of acute and chronic kidney failure in rats on the disposition and pharmacokinetics of ZYAN1, a novel prolyl hydroxylase inhibitor, for the treatment of chronic kidney disease-induced anemia. Xenobiotica. 2018 Jan; 48(1):37-44.
4. A sensitive assay for ZYAN1 in human whole blood and urine utilizing positive LC-MS/MS electrospray ionization. Bioanalysis. 2017 May; 9(9):719-732.
5. Pharmacological inhibition of prolyl hydroxylase protects against inflammation-induced anemia via efficient erythropoiesis and hepcidin downregulation. Eur J Pharmacol. 2019 Jan 15; 843:113-120.
6. Prolyl Hydroxylase Inhibitors: A Breakthrough in the Therapy of Anemia Associated with Chronic Diseases. J Med Chem. 2018 Aug 23; 61(16):6964-6982.

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. The group employs over 23,000 people worldwide, including 1400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com