Zydus dedicated to life

Cadila Healthcare Limited

February 5, 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 February 5, 2021 titled "Zydus completes large scale enrolment for two Phase III trials of Desidustat."

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

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Press Release

Zydus completes large scale enrolment for two Phase III trials of Desidustat

- *Desidustat is a novel, oral, small molecule hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor under development as a potential treatment for anaemia in patients suffering from Chronic Kidney Disease (CKD).*

Ahmedabad, India, February 5, 2021

Zydus Cadila, an innovation-driven, global pharmaceutical company, today announced that it has completed patient enrolment in DREAM-ND and DREAM-D Phase III trials of Desidustat, an oral small molecule hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor for treatment of anaemia in patients with Chronic Kidney Disease (CKD).

The DREAM-ND Phase III trial has now enrolled 588 CKD patients not-on-dialysis [ClinicalTrials.gov Identifier: NCT04012957]. This Phase III study is a multicentre (68 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.

The DREAM-D Phase III trial is being conducted in 392 CKD patients on Dialysis [ClinicalTrials.gov Identifier: NCT04215120]. The primary end-point in Phase III DREAM-D multicentre study (44 sites) will be the efficacy of Desidustat tablet versus Epoetin alfa injection based on the change of hemoglobin (Hb) levels. The secondary end-points will include number of hemoglobin (Hb) responders, time to achieve target range Hb level, percentage of time spent in target Hb range, serum hepcidin levels, serum potassium (K+) levels, vascular endothelial growth factor (VEGF) levels, lipid profile and lipoproteins.

“The completion of patient enrolment into the DREAM-D and DREAM-ND Phase III trials is a major milestone in the development program of Desidustat, and we are thankful to all the patients and investigators who have persisted in this scientific research in the midst of this COVID-19 pandemic to develop novel therapies for patients with Chronic Kidney Disease.”, said, Pankaj R. Patel, Chairman, Zydus Group. “Desidustat has the potential to bring about a paradigm shift in the management of CKD patients with anaemia as it could provide an oral, safer alternative to currently available injectable erythropoietin-stimulating agents (ESAs), by additionally reducing hepcidin, reducing triglycerides, reducing inflammation, and better iron mobilisation.”

For further information please contact :
The Corporate Communications Department

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CIN : L24230GJ1995PLC025878

Desidustat had previously met its primary endpoints in the Phase II clinical studies and showed good safety profile, endogenous production of erythropoietin, downregulation of hepcidin, improved iron mobilization and reduced triglycerides in CKD patients. The Phase I trials were earlier completed in Australia. Zydus has recently reported that Desidustat in Phase 2(b) POC study conducted in Mexico showed the potential to help prevent acute respiratory distress syndrome (ARDS) in COVID-19 patients and also reduced anti-inflammatory markers including CRP and IL-6. [ClinicalTrials.gov Identifier: NCT04463602]. Desidustat is also under clinical trials for Cancer Chemotherapy Induced Anemia (CIA) [ClinicalTrials.gov Identifier: NCT04667533].

Publications on Desidustat (ZYAN1):

1. Outcomes of Desidustat Treatment in People with Anemia and Chronic Kidney Disease: A Phase 2 Study. *Am J Nephrol*. 2019;49:470–478.
2. 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.
3. Pharmacological Characterization of ZYAN1, a Novel Prolyl Hydroxylase Inhibitor for the Treatment of Anemia. *Drug Res (Stuttg).* 2016 Feb; 66(2):107-12.
4. 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.
5. 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.
6. 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.
7. Prolyl Hydroxylase Inhibitors: A Breakthrough in the Therapy of Anemia Associated with Chronic Diseases. *J Med Chem.* 2018 Aug 23; 61(16):6964-6982.
8. Prolyl hydroxylase inhibitor desidustat protects against acute and chronic kidney injury by reducing inflammatory cytokines and oxidative stress. *Drug Dev Res.* 2021; 1–9.

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 nearly 25,000 people worldwide, including 1,400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com

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