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Zydus develops new treatment for patients suffering from Chronic Kidney Disease (CKD), submits first New Drug Application (NDA) to DCGI

Desidustat is an oral alternative to injectable erythropoietin-stimulating agents (ESAs) for the Treatment of Anemia Due to Chronic Kidney Disease in Patients on Dialysis and Not on Dialysis

Ahmedabad, India, November 23, 2021

Zydus Cadila, an innovation-driven, global pharmaceutical company, today announced that it has submitted the New Drug Application (NDA) to the Drug Controller General of India for Desidustat, an oral small molecule hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor for treatment of anaemia in patients with Chronic Kidney Disease (CKD) who are on Dialysis and Not on Dialysis.

Chronic Kidney Disease is a serious progressive medical condition which is a global unmet healthcare need involving gradual loss of functioning of kidneys eventually leading to kidney failure. It has been reported that 114 million people in India, 132 million people in China, 38 million people in the United States, 21 million patients in Japan and 41 million people in Western Europe are estimated to be living with Chronic Kidney Disease (Lancet 2020; 395: 709–33).

The NDA for Desidustat is based on positive data from the DREAM-ND and DREAM-D Phase 3 trials in patients with Chronic Kidney Disease (CKD) Not on Dialysis and on Dialysis.

- The DREAM-ND Phase III trial of 588 CKD patients not-on-dialysis compared Desidustat versus Darbepoietin alpha injection [ClinicalTrials.gov Identifier: NCT04012957]. In the Desidustat group, mean Hb increased and reached the predefined target of 10.0–12.0 g/dl in patients and was maintained within the target range for 24 weeks. The study demonstrated the noninferiority of Desidustat compared to Darbepoetin in the treatment of anemia in patients with CKD who were not on dialysis.
- The DREAM-D Phase III trial of 392 CKD patients on Dialysis compared Desidustat tablet versus Epoetin alfa injection [ClinicalTrials.gov Identifier: NCT04215120]. In the Desidustat group, mean Hb increased and reached the predefined target of 10.0–12.0 g/dl in patients and was maintained within the target range for 24 weeks. The study demonstrated the noninferiority of Desidustat compared to Epoetin in the treatment of anemia in patients with CKD who were on dialysis.

Desidustat met its primary efficacy endpoint in both Phase 3 trials, DREAM-ND and DREAM-D, conducted in Chronic Kidney Disease (CKD) patients on Dialysis and Not on Dialysis. The data will be presented at upcoming scientific meetings and published in peer-reviewed scientific journals.

“We are excited by this important milestone and thankful to all the patients, investigators, regulators and scientists, who led the discovery and development of Desidustat over the last decade. Desidustat has the potential to provide an oral, safer alternative to currently available injectable erythropoietin-stimulating agents (ESAs), by additionally reducing hepcidin, reducing inflammation, and better iron mobilisation. With patient-centricity at the core of all that we do, we have been looking at innovative

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approaches to improving the quality of life of patients and bridging unmet needs and with Desidustat we have taken yet another step in this direction. ” said, Mr. Pankaj R. Patel, Chairman, Cadila Healthcare Ltd.

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 in CKD patients. The Phase I trials were earlier completed in Australia. Desidustat is also under clinical trials for Cancer Chemotherapy Induced Anemia (CIA) [ClinicalTrials.gov Identifier: NCT04667533].

The data of Desidustat (ZYAN1) has so far been published in various peer-reviewed scientific journals of repute such as American Journal of Nephrology, Clin Pharmacokinet, European Journal of Pharmacology, Journal of Medicinal Chemistry , Drug Dev Res, Drug Res (Stuttg) and Xenobiotica.

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 23,000 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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