Zydus announces second Phase 3 trial of Desidustat

Ahmedabad, India, November 18, 2019

- DREAM-D is the second Phase 3 Trial of Desidustat, and will recruit 392 dialysis dependent chronic kidney disease (CKD) patients with anemia.
- Zydus had earlier initiated recruitment in DREAM-ND trial in CKD patients not-on-dialysis. The DREAM-ND trial will recruit 588 patients [ClinicalTrials.gov Identifier: NCT04012957]

Zydus Cadila, an innovation-driven, global pharmaceutical company, announced the second Phase III DREAM-D trials of Desidustat, an Investigational New Drug (IND) targeted at treating anemia in dialysis dependent CKD patients.

Chronic kidney disease is a serious medical condition which is an unmet healthcare need involving gradual loss of functioning of kidneys eventually leading to kidney failure. More than 200 million people worldwide are estimated to be living with chronic kidney disease. In a chronic kidney disease condition, the kidneys fail to produce EPO and this leads to anemia.

Desidustat is a novel, oral, HIF-PH inhibitor being developed for treating anemia in CKD patients. This Phase III DREAM-D study will be a multicenter (50- 60 sites in India), randomized, active-controlled clinical trial to evaluate the efficacy and safety of Desidustat versus Epoetin for the treatment of anemia in patients with CKD who are on dialysis.

Speaking on the development, Mr. Pankaj R. Patel, Chairman, Zydus Group said, “Based on the positive proof-of-concept established in the Phase 2 clinical trials, we are committed to developing this novel drug, Desidustat that can benefit millions of CKD patients. We believe that Desidustat has the potential to provide an oral, safer alternative to the currently available therapy which is in an injectable form.”

The primary end-point in Phase III DREAM-D study will be the efficacy of Desidustat tablet versus Epoetin alfa injection based on the change of hemoglobin (Hb) levels at 24 weeks. 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.

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.

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 24,000 people worldwide, including 1400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com