Zydus receives approval from USFDA to initiate clinical trials of Desidustat in cancer patients receiving chemotherapy

- *Approximately 1.3 million cancer patients are estimated to be undergoing chemotherapy every year in the US and ~ 30% to 90% of cancer patients receiving chemotherapy, develop anemia*
- *Desidustat, is currently undergoing Phase III clinical development for treating Anemia in CKD patients; and Phase II(b) studies for management of COVID-19 patients*

Ahmedabad, India, July 23, 2020

Zydus, a leading discovery based, global pharmaceutical company today announced that it has received approval from the USFDA, to initiate clinical trials of Desidustat in Chemotherapy Induced Anemia (CIA).

Cancer Patients undergoing chemotherapy develop anemia. CIA results in fatigue, impaired quality of life, discontinuation of chemotherapy and also exposes these cancer patients to red-blood cell transfusions. Desidustat is expected to increase the red blood cell count and restore the erythropoietin levels to the normal levels in the cancer patients with CIA. Estimates suggest approximately 1.3 million cancer patients undergo chemotherapy every year in the United States and 30% to 90% of cancer patients receiving chemotherapy develop anemia

Speaking on the development, Pankaj R. Patel, Chairman, Zydus Cadila said, "Chemotherapy-Induced Anemia or CIA is a serious unmet medical need and there is a need for novel therapies to address this condition. Desidustat has been specifically designed to improve haemoglobin, reduce hepcidin and thereby treat anemia. We are committed to develop Desidustat and support cancer patients battling Chemotherapy Induced Anemia."

Desidustat is a novel, oral, hypoxia inducible factor prolyl hydroxylase inhibitor, currently undergoing Phase 3 trials for treating anemia in Chronic Kidney Disease Patients. Zydus had initiated two Phase III trials of Desidustat. The DREAM-ND Phase III trial is being conducted in 588 CKD patients not-on-dialysis [ClinicalTrials.gov Identifier: NCT04012957]. The DREAM-D Phase III trial is being conducted in 392 CKD patients on Dialysis [ClinicalTrials.gov Identifier: NCT04215120]. Desidustat had previously met its primary endpoints in the Phase II clinical studies and showed good safety profile. The Phase I trials were earlier completed in Australia.

Zydus has also initiated a Phase II(b) trial of Desidustat in Mexico for the management of patients with COVID-19. [ClinicalTrials.gov Identifier: NCT04463602].

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