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Zydus receives approval from Mexico to study Desidustat for COVID-19 management

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Novel mechanism of targeting 'hypoxia' through HIF-PH inhibitor will be studied for the first time in Covid-19

Ahmedabad based Zydus, a leading discovery based global pharmaceutical company has announced that it has received approval from the regulatory authority of Mexico, COFEPRIS, for its one of its lead research candidate Desidustat to be tested in the management of COVID-19.

COFEPRIS is a decentralized and autonomous body run by a commissioner appointed by the Mexican president .

Clinical and regulatory development of Desidustat in COVID-19 is being executed in Mexico by Avant Santé Research Center S.A. de C.V., a leading Contract Research Organization (CRO) headquartered in Monterrey, Mexico.

The company will be conducting a Phase 2b, Multicenter, Open-label, Randomized, Comparator- Controlled Study to Evaluate the Efficacy and Safety of Desidustat Tablet for the Management of COVID-19 patients. As a part of the study 100 mg tablets of Desidustat will be administered for a period of 14 days along with recommended standard care during the trial.

Patients infected with COVID-19 have been reported to display signs of 'Hypoxia' leading to organ failure and death despite the use of antivirals, anti-inflammatory drugs or ventilators. The attack with the novel coronavirus pneumonia (COVID-19) will cause less and less haemoglobin that can carry oxygen and carbon dioxide.

The lung cells have been reported to develop extremely intense poisoning and inflammation due to the inability to exchange carbon dioxide and oxygen frequently, which eventually results in ground-glass-like lung images.

Desidustat (a hypoxia inducible factor prolyl hydroxylase inhibitor, currently undergoing Phase 3 trials) mimics the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxiainducible factor, and this can lead to increased red blood cell production and improved oxygen delivery to tissues.

Speaking on the development, Pankaj R. Patel, Chairman, Zydus Cadila said, "At Zydus, we have been stepping up our efforts to fight the Covid-19 pandemic through therapeutic drugs, diagnostics and vaccines. With Desidustat we will study a novel approach for management of Covid-19." 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*. The DREAM-D Phase III trial is being conducted in 392 CKD patients on Dialysis# . 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.