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Zydus submits NDA to DCGI for chronic kidney disease drug

23 November 2021 | News

Desidustat is an oral alternative to injectable erythropoietin-stimulating agents (ESAs) for the treatment of anaemia due to CKD



Ahmedabad-based Zydus Cadila has submitted the New Drug Application (NDA) to the Drug Controller General of India (DCGI) for Desidustat, an oral small molecule hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor for the treatment of anaemia in patients with Chronic Kidney Disease (CKD) who are on dialysis and not 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.

"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", said said, Pankaj R. Patel, Chairman, Cadila Healthcare.