

Zydus to launch Oxemia™ (Desidustat) a breakthrough treatment for Anemia in patients suffering from Chronic Kidney Disease (CKD)

- *Oxemia™ (Desidustat) is a breakthrough treatment for Anemia associated with Chronic Kidney Disease (CKD) in Patients either on Dialysis or Not on Dialysis*
- *Oxemia™ (Desidustat) is an oral tablet formulation which is the first-in-India alternative to injectable erythropoietin-stimulating agents (ESAs)*
- *Oxemia™ is the 2nd NCE to be exclusively developed in India from lab to market after Saroglitazar Mg, also a Zydus innovation*
- *Discovered at Zydus Research Centre, Oxemia™ (Desidustat) is a differentiated best-in-class HIF-PH Inhibitor*

Ahmedabad, India, March 07, 2022

Zydus Lifesciences Ltd. (formerly known as Cadila Healthcare Ltd.), a discovery-driven, global lifesciences company announced that it has received approval for its New Drug Application (NDA) from the Drug Controller General of India for **Oxemia™ (Desidustat)**, a first-of-its-kind oral treatment in India for anemia associated with Chronic Kidney Disease (CKD).

Oxemia™ is an oral, small molecule hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor. Desidustat met its primary endpoints for haemoglobin improvement in the DREAM-D and DREAM-ND Phase III clinical trials and showed good safety profile, downregulation of hepcidin, improved iron mobilization and LDL-C reduction in CKD patients. The clinical development programme of Desidustat was one of the largest trials of its kind in India for Anemia in CKD patients, conducted in over 1200 subjects. Desidustat provides CKD patients with an oral convenient therapeutic option for the treatment of anemia.

Speaking on the development, Pankaj R. Patel, Chairman, Zydus Lifesciences Ltd., said, “Our life changing discoveries are guided by the need to help patients lead a better life and empower them with therapies that enable them to live healthier and more fulfilled lives. There was a potential for an oral, safer alternative to currently available injectable erythropoietin-stimulating agents (ESAs). After more than a decade of research and development into the science of HIF-PH inhibitors, results have demonstrated that Oxemia™ (Desidustat) addresses this unmet need and additionally reduces hepcidin, inflammation and enables better iron mobilisation. This advancement offers ease of convenience for the patient and will also reduce



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the disease burden by providing treatment at an affordable cost, thereby improving the quality of life for patients suffering from Chronic Kidney Disease.”

Zydus is amongst the top players in the Nephrology segment with a super-speciality portfolio with brands like Zyrop, Grafalon, Tacromus and Mycomune. With Oxemia™, the group posts a new milestone in its innovation journey which has seen the commercialisation of several novel therapies.

Chronic kidney disease (CKD) is a serious progressive medical condition characterized by a gradual loss of kidney function, usually accompanied by other comorbidities including anemia, cardiovascular diseases (hypertension, heart failure and stroke), diabetes mellitus, eventually leading to kidney failure. CKD patients are often on multiple medications and are at safety risks of drug-drug interactions.

It has been reported that 115.1 million people in India, 132 million in China, 38 million in the United States, 21 million in Japan and 41 million people in Western Europe are estimated to be living with Chronic Kidney Disease (Lancet 2020; 395: 709–33). CKD is predicted to become one of the most common causes of premature death by 2040 globally. (http://www.healthdata.org/sites/default/files/files/policy_report/2019/GBD_2017_Booklet.pdf).

Results of multiple studies of Oxemia™ (Desidustat) have been published in various international peer-reviewed scientific journals of repute such as American Journal of Nephrology, Clinical Pharmacokinetics, European Journal of Pharmacology, Journal of Medicinal Chemistry, Drug Development Research, Drug Research (Stuttg) and Xenobiotica.

Publications on Oxemia™ (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.



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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 HIF-PH inhibitor

Discoveries of how cells sense and adapt to oxygen availability had won the 2019 “**Nobel Prize in Medicine**”. Desidustat has been designed to inhibit Prolyl Hydroxylase (PHD) activity and stabilize Hypoxia Inducible Factor (HIF) levels in the body. Increased HIF stimulates Erythropoietin (EPO) production and release in the body. Increased HIF decreases hepcidin and improves iron mobilisation. Increased EPO and Iron improves haemoglobin and red blood cells in the body. Oxemia™ (Desidustat) is a Prescription Drug approved in India and can be taken only under the advice and guidance of a Nephrologist or an internal medicine specialist.

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 23000 people worldwide and is driven by its mission to unlock new possibilities in life-sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. For more details visit www.zyduslife.com.



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