

New Drug Application of Zydus' innovative drug Desidustat tablets by China Medical System Holdings Limited accepted in China

- *China Medical System Holdings Limited which obtained an exclusive license for the Desidustat from Zydus had filed New Drug Application for the drug in China.*
- *China Phase III trial of the Product has demonstrated positive results. The primary endpoint has indicated that Desidustat is more effective than placebo in increasing Hb level.*
- *Discovered and developed by Zydus, Desidustat is being marketed by the group in India under the brand name Oxemia™.*

Ahmedabad, April 23, 2024

Zydus Lifesciences Limited (including its subsidiaries/affiliates hereafter referred to as “Zydus”) a discovery-driven, global lifesciences company announced that the New Drug Application (NDA) of Desidustat Tablets (“Desidustat Tablets” or the “Product”) has been accepted by the National Medical Products Administration of China (NMPA). CMS International Development and Management Limited, a wholly-owned subsidiary of China Medical System Holdings Limited (“CMS”) obtained an exclusive license for the Product from Zydus in 2020.

Desidustat, administered orally is a novel, oral Hypoxia-Inducible Factor-Prolyl Hydroxylase Inhibitor (HIF-PHI) for treating anaemia in Chronic Kidney Disease (CKD) patients. CKD involves the gradual loss of functioning of kidneys and eventually leads to kidney failure. Healthy kidneys naturally secrete a hormone called Erythropoietin (EPO), which stimulates red blood cell production also known as erythropoiesis. When kidneys are impaired as in patients suffering from Chronic Kidney Disease, EPO production is impaired, leading to development of anaemia. HIF-PHI promotes erythropoiesis through increasing endogenous erythropoietin, reducing hepcidin thereby improves iron availability.

Speaking on the development, Managing Director of Zydus Lifesciences, Dr. Sharvil Patel said, “We are excited about the NDA acceptance of Desidustat in China by NMPA. Our life-

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changing discoveries are guided by the need to help patients and empower them with therapies that enable them to live healthier and more fulfilled lives. We believe this collaboration with CMS will accelerate the development and commercialization process of Desidustat in Greater China”.

Discovered and developed by Zydus, Desidustat is being marketed by the group in India under the brand name Oxemia™. China Medical System Holdings Limited through its wholly-owned subsidiary gained a royalty bearing, exclusive, sub-licensable license under the licensed technology and Zydus data to develop, register and to manufacture, use and commercialise the Product in Greater China (including Mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan).

It is estimated that more than 120 million people are living with CKD in China^[1]. Anaemia is one of the frequent complications of CKD. A survey in China showed that the prevalence of anaemia in patients at CKD stage 1 to 5 were 22.0%, 37.0%, 45.4%, 85.1%, and 98.2%, respectively^[2]. The target-achieving rate (the haemoglobin (Hb) level reaching the target value (110~120g / L)) was only 8.2% for anaemia patients in non-dialysis CKD and 35.2% for haemodialysis CKD, showing a large unmet healthcare need^[3].

China Phase III trial of the Product has demonstrated positive results. The primary endpoint of the Hb mean change from baseline to the period of Week 7-9 has indicated that, Desidustat is more effective than placebo in increasing Hb level. The least squares mean and 95% CI of Hb change from baseline to the period of Week 7-9, using covariance model analysis, has shown an increase of 16.38 g/l [95%CI: 14.50, 18.26] in the Desidustat group and a decrease of 1.13 g/l [95%CI: -3.68, 1.41] in the placebo group, for a between-group difference of 17.52 g/l [95%CI:14.353, 20.681], with the lower limit of 95% CI above 0.

The Product is administrated orally, thus expecting to improve the treatment compliance of patients and to meet the unmet treatment needs in the field of CKD anaemia, including both dialysis and non-dialysis patients.

Reference:

1. ZhangL, WangF, WangL, et al. Prevalence of chronic kidney disease in China: a cross-sectional survey[J]. *Lancet*, 2012, 379(9818):815-822. DOI: 10.1016/S0140-6736(12)60033-6
2. *Chinese expert consensus on diagnosis and therapy of renal anaemia (the 2014 revised edition)*, Chinese

A decorative graphic in the bottom left corner consisting of overlapping, wavy shapes in shades of purple and teal.

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- Journal of Nephrology*, 2014;30:712-716
3. *Chinese expert consensus on diagnosis and therapy of renal anaemia (the 2018 revised edition)*, *Chinese Journal of Nephrology*, 2018, 34(11): 860-866

About Zydus

Zydus Lifesciences Ltd. 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 26,000 people worldwide, including 1,400 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. Over the last decade, Zydus has introduced several innovative, first-in-class products in the market for treating unmet healthcare needs with vaccines, therapeutics, biologicals and New Chemical Entities. For more details visit www.zyduslife.com



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