

News release

Kyowa Kirin Announces Daprodustat Submission in Japan by GSK for Patients with Anemia due to Chronic Kidney Disease

Tokyo, Japan, August 21, 2019 – Kyowa Kirin Co., Ltd., (Kyowa Kirin, TYO: 4151) today announced that GSK, its strategic collaboration partner of daprodustat, has submitted a New Drug Application (NDA) to the Ministry of Health, Labour and Welfare seeking marketing approval for daprodustat, an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the treatment of patients with renal anemia due to chronic kidney disease.

“This is a key milestone for both GSK and Kyowa Kirin in efforts to provide more treatment options for patients suffering from renal anemia due to chronic kidney disease.” said Takeyoshi Yamashita, Ph.D., Executive Officer, Director of Corporate Strategy & Planning Department of Kyowa Kirin. “If approved, we are confident to maximize the value of daprodustat with our long-year experience in this disease area.”

Further information can be found in [the press release issued by GSK](#) on 21 August 2019.

Daprodustat has been developed to provide an orally-convenient treatment option which avoids the administration challenges and cold storage requirements of injectable erythropoiesis-stimulating agents /recombinant human erythropoietin (rhEPO). If daprodustat is approved, Kyowa Kirin will be exclusively responsible for the product distribution in Japan, following the strategic commercialization deal with GSK in Japan in 2018. Launch activities including engagement of healthcare professionals and commercial activities, are expected to be conducted jointly by Kyowa Kirin and GSK.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

About renal anemia

Anemia is the term used to describe a decrease of red blood cells or hemoglobin concentration which carry oxygen to the body, and in general, hemoglobin is used for diagnosis of anemia. Kidneys produce hormones including erythropoietin, which stimulates red blood cell production. Renal anemia commonly arises in

patients with kidney impairment because the kidneys no longer produce sufficient amount of erythropoietin, a hormone involved in prompting the production of red blood cells.¹ The incidence of renal anemia increases as kidney function declines. It is estimated that 10.9 million patients in Japan have stages 3-5 CKD and of these, 32% have anaemia.^{2, 3}

About Kyowa Kirin

Kyowa Kirin Co., Ltd. is a research-based life sciences company, with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology and immunology/allergy, Kyowa Kirin leverages leading-edge biotechnologies centered on antibody technologies, to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, the company is working to realise its vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and wellbeing of people around the world.

You can learn more about the business at www.kyowakirin.com

References

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2. Akizawa T. et al. Burden of Anemia in Chronic Kidney Disease Patients in Japan: A Literature Review. *Ther Apher Dial.* 2018;22(5):444-56. <https://doi.org/10.1111/1744-9987.12712>
3. Imai E. et al. Prevalence of chronic kidney disease in the Japanese general population. *Clin Exp Nephrol.* 2009 Dec;13(6):621-30. <https://doi.org/10.1007/s10157-009-0199-x>