KYOWA KIRIN

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GSK and Kyowa Hakko Kirin sign strategic commercialisation deal in Japan for daprodustat, a potential new oral treatment for anaemia associated with chronic kidney disease

GSK and Kyowa Hakko Kirin Co., Ltd., today announced a strategic collaboration for the future commercialisation of daprodustat in Japan. Daprodustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor currently in phase 3 development by GSK for the treatment of anaemia associated with chronic kidney disease (CKD).

This agreement recognises the importance of bringing this potential new medicine to patients in Japan and its joint nature brings together the global development and commercial expertise of GSK with the detailed CKD expertise of Kyowa Hakko Kirin. Under the terms of the agreement, GSK will be responsible for completion of the ongoing phase 3 clinical programme and regulatory submissions for marketing authorisation in Japan. Distribution of daprodustat will be exclusively conducted by Kyowa Hakko Kirin in the Japan market. Launch activities, including engagement of healthcare professionals and commercial activities, are expected to be conducted jointly by Kyowa Hakko Kirin and GSK. The financial details of the deal are not being disclosed.

Dr Hal Barron, Chief Scientific Officer and President R&D, GSK, said, “We anticipate making a regulatory submission to the Japanese Ministry of Health, Labour and Welfare in 2019 and if approved, we believe daprodustat would be an important new oral treatment option for Japanese patients with anaemia associated with CKD. We look forward to working with Kyowa Hakko Kirin, given their extensive experience in this area, to successfully launch and commercialise daprodustat in Japan.”

Wataru Murata, Executive Officer, Director of Corporate Strategy & Planning Department of Kyowa Hakko Kirin, said, “With this collaboration, we look to expand our existing product portfolio in Nephrology and meet medical needs by providing more treatment options for patients suffering with anaemia associated with CKD.”

Ongoing development for daprodustat in Japan
Positive results from two phase 3 studies in dialysis dependent Japanese patients were recently announced. Results from the final Japanese phase 3 study in non-dialysis dependent patients are anticipated in 1H2019, with filing anticipated in 2H2019.

Global development programme for daprodustat
In addition to the Japanese development programme, GSK has an ongoing global phase 3 registration programme, including:

- ASCEND-D (Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Dialysis) will enrol approximately 3,000 dialysis dependent patients with anaemia associated with CKD switching from an erythropoietin-stimulating agent (ESA). Recruitment has completed, and results are anticipated in 2020
- ASCEND-ND (Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Non-Dialysis) will enrol approximately 4,500 non-dialysis dependent patients with anaemia associated with CKD, and will include patients either switching from or naive to an ESA. Recruitment remains ongoing and results are anticipated in 2020.

For both studies, the co-primary endpoints are time to first occurrence of major adverse cardiovascular events (MACE) and mean change in haemoglobin between the baseline and efficacy period (mean over Weeks 28-52). The studies will assess whether daprodustat is non-inferior to recombinant human erythropoietin and its analogues on these endpoints as the primary analysis. If non-inferiority of the primary analysis is met, superiority will be assessed for the MACE endpoint.

About daprodustat
Daprodustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor. Inhibition of oxygen-sensing prolyl hydroxylase enzymes stabilises hypoxia-inducible factors, which can lead to transcription of erythropoietin and other genes involved in the production of red blood cells and iron metabolism, similar to the physiological effects that occur in the body at high altitude. Daprodustat is not approved as a treatment for anaemia associated with CKD or any other indication anywhere in the world.

About anaemia associated with chronic kidney disease (anaemia associated with CKD)
Anaemia is the term used to describe a decrease of red blood cells or haemoglobin concentration which carry oxygen to the body, and in general, haemoglobin is used for diagnosis of anaemia. Kidneys produce hormones including erythropoietin, which stimulates red blood cell production. Anaemia commonly arises in patients with kidney impairment because the kidneys no longer produce sufficient amount of erythropoietin. Patients with anaemia associated with CKD have symptoms such as palpitation, breath shortness, dizziness and fatigue.

About GSK
GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com.

About Kyowa Hakko Kirin

Kyowa Hakko 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 Hakko 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.kyowa-kirin.com.