

Bardoxolone Methyl (RTA 402) Designated for the Treatment of Diabetic Kidney Disease under the Priority Review and Designation System by the Ministry of Health, Labour and Welfare

Tokyo, Japan, March 28, 2018 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and COO: Masashi Miyamoto, “Kyowa Hakko Kirin”) announced today that on March 27, 2018 bardoxolone methyl*¹ (RTA 402) was designated for the treatment of diabetic kidney disease*² (DKD) under the Priority Review and Designation (SAKIGAKE Designation) System established by the Ministry of Health, Labour and Welfare (MHLW). Bardoxolone methyl is a small-molecule compound in-licensed from Reata Pharmaceuticals, Inc. (Irving, Texas, USA, CEO and President: Warren Huff, “Reata”).

The Priority Review and Designation System was established in Japan to accelerate the development of innovative new medical products by making them available to patients as early as possible. Designated products are offered such advantages as prioritized consultation services and premarket pharmaceutical affairs review by the regulatory authority. Under the Priority Review and Designation System, the designation is in principle granted to a drug that is expected to demonstrate extremely high effectiveness due to a different mechanism of action from drugs already approved.

“We are delighted to receive this SAKIGAKE Designation for bardoxolone methyl in DKD,” said Mitsuo Satoh, Ph.D., Executive Officer, Vice President Head of Research and Development Division of Kyowa Hakko Kirin. “We believe bardoxolone methyl has the potential to become an important drug for DKD patients who at present have limited treatment options.”

Kyowa Hakko Kirin signed a license agreement with Reata for the exclusive rights to develop and commercialize bardoxolone methyl in renal disease and certain other indications in Japan, China, Taiwan, South Korea, and Southeast Asia on December 24, 2009. Kyowa Hakko Kirin plans to initiate a phase 3 clinical study in Japan during 2018 to validate the efficacy and safety of bardoxolone methyl among a larger number of patients with DKD.

The Kyowa Hakko 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 bardoxolone methyl (RTA 402)

Bardoxolone methyl is a low-molecular compound that activates nuclear factor erythroid 2-related factor 2 (Nrf2), a transcription factor that has a key role in the body’s protective response to stress.

A wide range of anti-oxidative stress and anti-inflammatory effects of this compound could improve renal function. In the phase 2 clinical study conducted in Japan (the TSUBAKI study), administration of bardoxolone methyl resulted in a clear improvement in glomerular filtration rate (kidney function) measured using the inulin clearance method.

About diabetic kidney disease (DKD)

Diabetic kidney disease (DKD) is a chronic kidney disease (CKD) caused by diabetes, the most common reason for patients initiating hemodialysis. CKD, if left untreated, results in end-stage renal disease with a decrease in renal function and ultimately requires hemodialysis or renal transplantation. Reduced renal function in CKD is known to involve excessive oxidative stress and inflammation.