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Kyowa Hakko Kirin Announces the Development Status of Bardoxolone Methyl (RTA 402) in Patients with Chronic Kidney Disease and Type 2 Diabetes in Japan

Tokyo, Japan, November 11, 2013 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo; 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today the discontinuation of its Phase 2 clinical studies evaluating a small molecule compound, bardoxolone methyl (RTA 402) *[1] licensed from Reata Pharmaceuticals, Inc. (Irving, Texas, USA; CEO and President: Warren Huff, “Reata”), in chronic kidney disease (CKD) patients with type 2 diabetes in Japan. In the mean time, Kyowa Hakko Kirin has been considering a new development program of bardoxolone methyl (RTA 402) in CKD patients with type 2 diabetes.

Reata discontinued the Phase 3 clinical study, known as BEACON, designed to evaluate bardoxolone methyl in CKD patients with type 2 diabetes in the US, Europe, Canada, Australia, and Central America in October 2012. The decision was made based on a recommendation of the Independent Data Monitoring Committee (IDMC) *[2] to stop the study "for safety concerns due to excess serious adverse events and mortality in the bardoxolone methyl arm." The results of the BEACON study were presented at the American Society of Nephrology’s 2013 Annual Meeting (November 7-10, in Atlanta, Georgia, USA) and published in The New England Journal of Medicine.

The results of the BEACON study showed no statistically significant difference between bardoxolone methyl and placebo groups in all-cause mortality but significantly higher incidence of heart failure events (heart failure hospitalization and deaths due to heart failure). The primary composite outcome (end-stage renal disease or cardiovascular death) did not demonstrate statistical significance and estimated GFR*[3] increased significantly in bardoxolone methyl group.

In view of the fact that bardoxolone methyl increased cardiovascular event risk, especially heart failure, in the BEACON study, Kyowa Hakko Kirin decided to discontinue the Phase 2 clinical studies that were suspended in October 2012. Kyowa Hakko Kirin is now looking at the data in greater detail to analyze the risk factors that caused the adverse events. After careful

consideration, Kyowa Hakko Kirin will make a decision on a future development program for bardoxolone methyl.

Kyowa Hakko Kirin signed a license agreement with Reata for the exclusive rights to develop and commercialize bardoxolone methyl in Japan, China, Taiwan, Korea, and Southeast Asia on December 24, 2009.

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*1 Bardoxolone methyl (RTA 402)

Bardoxolone methyl activates the Nrf2, which controls the production of over 250 antioxidant and detoxification proteins. Activation of Nrf2 protects tissues by increasing cellular antioxidant content and suppressing inflammatory signaling pathways. It is known that chronic inflammation promotes type 2 diabetes and its complications, including cardiovascular disease and CKD.

*2 Independent Data Monitoring Committee (IDMC)

IDMC is established by the sponsor to assess periodically the progress of this clinical study, safety data and critical efficacy variables. The committee recommends to the sponsor whether to continue, modify, or discontinue the study.

*3 Estimated GFR (eGFR)

The eGFR (estimated glomerular filtration rate) is the flow rate of filtered fluid through the kidney and calculated from serum creatinine level, age, gender, and race. The eGFR is a marker of renal function and decreases in patients with kidney disease.