Kyowa Hakko Kirin Announces Suspension of Early Phase 2 Clinical Study of Bardoxolone methyl (RTA 402) in Patients with Chronic Kidney Disease and Type 2 Diabetes in Japan

Tokyo, Japan, October 19, 2012--- Kyowa Hakko Kirin Co., Ltd., ("Kyowa Hakko Kirin") announced the suspension of an early Phase 2 clinical study evaluating a small molecule compound, bardoxolone methyl (RTA 402) licensed from Reata Pharmaceuticals, Inc. (Reata) based in Irving, Texas, USA, in patients with chronic kidney disease and type 2 diabetes in Japan

Reata informed Kyowa Hakko Kirin that it is discontinuing the Phase 3 clinical study, known as BEACON, designed to evaluate bardoxolone methyl in patients with advanced (stage 4) chronic kidney disease (CKD) and type 2 diabetes in the US, Europe, Canada, Australia and Central America. The discontinuation is based on a recommendation from the study's Independent Data Monitoring Committee (IDMC) regarding safety concerns due to "excess serious adverse events and mortality in the bardoxolone methyl arm."

Base on the information from Reata, Kyowa Hakko Kirin decided to suspend the early Phase 2 clinical study currently conducted in Japan from the standpoint of securing the safety of patients.

From now on, Kyowa Hakko Kirin will make further investigation of BEACON and the study conducted in Japan to find out possibility to resume the study in Japan.

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 Asian markets on December 24th, 2009.