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Japan's Kyowa Hakko Kirin Co Ltd has announced the results of an interim efficacy analysis of a phase II clinical study (TSUBAKI study) in Japan of bardoxolone methyl (RTA 402), which is a small-molecule compound in-licensed from US-based Reata Pharmaceuticals Inc.

The clinical study is a randomized, double-blind, parallel group, placebo-controlled study in patients with chronic kidney disease (CKD) and type II diabetes, and has been evaluating the safety and efficacy of once-daily administration of RTA 402 for 16 weeks.

Insulin clearance method as the gold standard for measuring glomerular filtration rate (GFR) was used in the efficacy evaluation to make a precise assessment of GFR, which is an indicator reflecting kidney function. Data from interim analysis were assessed by an Independent Data Monitoring Committee and demonstrated that a significant improvement in GFR was seen in the RTA 402 compared with the placebo group. This is the world's first result showing improvement in renal function by inulin clearance. There are no safety concerns with RTA 402. Kyowa Hakko Kirin will continue to evaluate RTA 402 toward the completion of the study.

Kyowa Hakko Kirin signed a license agreement with Reata for exclusive right to develop and commercialize RTA 402 in Japan, China, Taiwan, Korea and Southeast Asia on Dec 24, 2009.

Reata has been conducting a phase II clinical study on RTA 402 in pulmonary hypertension in the US, and its initial positive data were presented at the annual meeting of the 2015 American College of Chest Physicians (CHEST). Reata is proceeding

into a global Phase III clinical study on RTA 402 including Japan in connective tissue disease associated pulmonary arterial hypertension.