



REATA.

Date: 10 May 2023

Subject: Termination of bardoxolone methyl and chronic kidney disease research

Dear Alport Syndrome Foundation,

This communication is being sent to inform you of the early termination of both the ongoing FALCON and EAGLE clinical trials with bardoxolone methyl, effective immediately as of May 10, 2023.

In May 2023, Reata's strategic collaborator, Kyowa Kirin Co., Ltd. (Kyowa Kirin) announced results from AYAME, a Phase 3, multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of bardoxolone for patients with diabetic kidney disease. The study enrolled 1,013 patients who were treated with 5 to 15 mg of bardoxolone or placebo for 3 to 4 years.

The primary endpoint of the study was time to onset of a $\geq 30\%$ decrease in estimated Glomerular Filtration Rate (eGFR) from baseline or onset of end-stage kidney disease (ESKD). The key secondary endpoint was time to onset of a $\geq 40\%$ decrease in eGFR from baseline or onset of ESKD. The AYAME study met the primary endpoint and key secondary endpoint, however, there was no separation in the occurrence of ESKD events between the two groups.

In the AYAME study, there was no imbalance in adverse events and no significant safety issues were identified in patients receiving bardoxolone. Similarly, in ongoing FALCON and EAGLE trials, no safety issues were identified by the Data Monitoring Committee (DMC) as of February 2023. Based on the AYAME results and lack of separation in the occurrence of ESKD events between placebo and bardoxolone-treated groups, Reata and Kyowa Kirin have decided to discontinue the clinical development of bardoxolone.

On behalf of Reata Pharmaceuticals, we want to thank all the investigators, clinical site staff, patients and families, and patient advocacy organizations for their tremendous efforts and participation in Reata's clinical trial development, and for their contribution towards the advancement of chronic kidney disease research. Please convey this information to the CKD community as needed.

Sincerely,

Seemi Khan, MD
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