



Date: 20 December 2022

Subject: Alport syndrome EMA Application Withdrawal

Dear Alport Syndrome Foundation,

This letter is to inform you that on November 9, 2022, Reata withdrew its application with the European Medicines Agency (EMA) for marketing authorization of bardoxolone for the treatment of chronic kidney disease (CKD) caused by Alport syndrome. Reata withdrew its application because the Agency indicated that they would not be able to make a positive benefit risk analysis at the present time based on the submitted data.

The withdrawal of the application does not affect current or future clinical trials of bardoxolone in chronic kidney disease. Specifically, it does not affect patients with Alport syndrome currently enrolled in the EAGLE extension trial. Likewise, the withdrawal of the application does not affect other ongoing bardoxolone clinical trials.

We remain committed to collecting long-term safety and efficacy data from patients with Alport syndrome enrolled in our EAGLE extension trial. Reata has reserved the right to file additional submissions with regulatory agencies in the future of CKD caused by Alport syndrome, or other therapeutic indications. Data from long-term exposure to bardoxolone in patients with Alport syndrome will be critical in this effort.

Thank you for your continued support of Reata clinical development programs. If you have any questions, don't hesitate to contact me. Please convey this information to the Alport syndrome community as needed.

Sincerely,

Payal Shah, PharmD

Associate Director, Patient Advocacy

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