



March 10, 2022

Statement from Reata Pharmaceuticals to Alport Syndrome Foundation and the larger community of Alport syndrome patients and families:

On February 25, 2022, Reata Pharmaceuticals, Inc received a complete response letter from the FDA with respect to its review of bardoxolone in the treatment of patients with chronic kidney disease (“CKD”) caused by Alport syndrome. The letter confirms that the FDA denied the approval of bardoxolone for the treatment of Alport syndrome patients with CKD. The FDA’s conclusion was based on efficacy and safety concerns outlined in the FDA’s briefing book and discussed at the Cardiovascular and Renal Drugs Advisory Committee meeting held on December 8, 2021.

Reata will continue to seek FDA advice regarding the path forward for bardoxolone in Alport syndrome as well as on FALCON, the Phase 3 study of bardoxolone in patients with autosomal dominant polycystic kidney disease (ADPKD). In response to feedback already received, we recently submitted a major amendment to the FALCON protocol.

As was communicated to investigators, coordinators, and study partners at clinical sites, Reata will continue to enroll patients in FALCON and continue to dose patients with Alport syndrome and ADPKD in EAGLE (the extended access study).

We are highly appreciative of the support from patients and their families toward the studies of bardoxolone.

Sincerely,
Seemi Khan, Chief Medical Officer, Reata Pharmaceuticals, Inc