



REATA PHARMACEUTICALS RECEIVES COMPLETE RESPONSE LETTER FROM THE FDA FOR BARDOXOLONE FOR THE TREATMENT OF PATIENTS WITH CHRONIC KIDNEY DISEASE CAUSED BY ALPORT SYNDROME

PLANO, Texas — February 25, 2022 (BUSINESS WIRE)—[Reata Pharmaceuticals, Inc.](#) (Nasdaq: RETA) (“Reata,” the “Company,” or “we”), today announced that the U.S. Food and Drug Administration (“FDA”) has issued a Complete Response Letter (“CRL”) regarding the New Drug Application (“NDA”) for bardoxolone methyl (“bardoxolone”) for the treatment of patients with chronic kidney disease (“CKD”) caused by Alport syndrome.

The CRL indicates that the FDA cannot approve the NDA in its present form. Based on its review, the FDA concluded that it does not believe the submitted data demonstrates that bardoxolone is effective in slowing the loss of kidney function in patients with Alport syndrome and reducing the risk of progression to kidney failure and has requested additional data to support the efficacy and safety of bardoxolone. Their conclusion was based on efficacy and safety concerns primarily set forth in the FDA’s briefing book and discussed at the Cardiovascular and Renal Drugs Advisory Committee meeting held on December 8, 2021.

The FDA stated that the issues could be resolved by providing evidence of effectiveness that includes evidence from an adequate and well-controlled study showing a clinically relevant effect on the rate of loss of kidney function in patients with Alport syndrome or, alternatively, an effect on a clinical outcome (i.e., an endpoint that captures how patients with Alport syndrome feel, function, or survive). In addition, the FDA stated that we would need to address whether bardoxolone has a clinically relevant effect on the QT interval and show that the demonstrated clinical benefits of bardoxolone outweigh its risks. The FDA welcomed continued discussion on the details of a path forward. We plan to work closely with the FDA to bring this important medicine to patients in the US.

“This outcome is a significant disappointment for our company, as well as the many patients, families, and investigators who have participated in our development program for bardoxolone in Alport syndrome patients. We will continue to work with the FDA to confirm our next steps on our Alport syndrome program,” said Warren Huff, Reata’s Chief Executive Officer.

About Alport Syndrome

Alport syndrome is a rare, genetic form of CKD caused by mutations in the genes encoding type IV collagen, which is a major structural component of the glomerular basement membrane in the kidney. Alport syndrome affects both children and adults. The kidneys of patients with Alport syndrome progressively lose the capacity to filter waste products out of the blood, which can lead to end-stage kidney disease and the need for chronic dialysis treatment or a kidney transplant. In patients with the most severe forms of the disease, approximately 50% progress to dialysis by



age 25, 90% by age 40, and nearly 100% by age 60. According to the Alport Syndrome Foundation, Alport syndrome affects approximately 30,000 to 60,000 people in the United States. There are currently no therapies approved to treat CKD caused by Alport syndrome.

About Bardoxolone

Bardoxolone is an investigational, once-daily, orally administered activator of Nrf2, a transcription factor that induces molecular pathways that promote the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling. The FDA and European Commission have granted Orphan Drug designation to bardoxolone for the treatment of Alport syndrome and autosomal dominant polycystic kidney disease (“ADPKD”).

We submitted a Marketing Authorization Application for bardoxolone to the European Medicines Agency for the treatment of patients with CKD caused by Alport syndrome, and the application is currently under review. Kyowa Kirin Co., Ltd. (“Kyowa Kirin”), our licensee, submitted an NDA in Japan to the Ministry of Health, Labour and Welfare for bardoxolone for improvement of renal function in patients with Alport syndrome, and the application is currently under review. Additionally, bardoxolone is currently being studied in FALCON, a Phase 3 study for the treatment of CKD caused by ADPKD, EAGLE, an open-label, extended access trial in patients with CKD caused by Alport syndrome who participated in the CARDINAL trial and patients with ADPKD who participated in the FALCON trial, and AYAME, a Phase 3 study for the treatment of diabetic kidney disease that is being conducted by Kyowa Kirin in Japan.

About Reata

Reata is a clinical-stage biopharmaceutical company that develops novel therapeutics for patients with serious or life-threatening diseases by targeting molecular pathways involved in the regulation of cellular metabolism and inflammation. Reata’s two most advanced clinical candidates, omaveloxolone and bardoxolone, target the important transcription factor Nrf2 that promotes the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling. **Omaveloxolone and bardoxolone are investigational drugs, and their safety and efficacy have not been established by any agency.**

Forward-Looking Statements

This press release includes certain disclosures that contain “forward-looking statements,” including, without limitation, statements regarding the success, cost, and timing of our product development activities and clinical trials, our plans to research, develop, and commercialize our product candidates, our plans to submit regulatory filings, and our ability to obtain and retain regulatory approval of our product candidates. You can identify forward-looking statements

because they contain words such as “believes,” “will,” “may,” “aims,” “plans,” “model,” and “expects.” Forward-looking statements are based on Reata’s current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, (i) the timing, costs, conduct, and outcome of our clinical trials and future preclinical studies and clinical trials, including the timing of the initiation and availability of data from such trials; (ii) the timing and likelihood of regulatory filings and approvals for our product candidates; (iii) whether regulatory authorities determine that additional trials or data are necessary in order to obtain approval; (iv) the potential market size and the size of the patient populations for our product candidates, if approved for commercial use, and the market opportunities for our product candidates; and (v) other factors set forth in Reata’s filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2020, under the caption “Risk Factors.” The forward-looking statements speak only as of the date made and, other than as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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