REATA ANNOUNCES FDA ACCEPTED FOR FILING THE NDA FOR BARDOXOLONE FOR THE TREATMENT OF PATIENTS WITH CHRONIC KIDNEY DISEASE CAUSED BY ALPORT SYNDROME

APPROXIMATELY 30,000-60,000 PATIENTS IN THE UNITED STATES ARE AFFECTED WITH ALPORT SYNDROME, A LIFE-THREATENING DISEASE WITH NO APPROVED THERAPIES

APPLICATION ASSIGNED A PDUFA DATE OF FEBRUARY 25, 2022

IF APPROVED, BARDOXOLONE WOULD BECOME THE FIRST APPROVED THERAPY FOR ALPORT SYNDROME IN THE UNITED STATES

PLANO, Texas—April 26, 2021 (GLOBE NEWSWIRE)—Reata Pharmaceuticals, Inc. (Nasdaq: RETA) ("Reata," the "Company," or "we"), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration ("FDA") accepted for filing the New Drug Application ("NDA") for bardoxolone methyl ("bardoxolone") for the treatment of patients with chronic kidney disease ("CKD") caused by Alport syndrome.

This NDA submission is based on the efficacy and safety data from the CARDINAL Phase 3 clinical trial. The FDA will review the application under a Standard Review timeline. The Prescription Drug User Fee Act ("PDUFA") date, the FDA action date for the application, is scheduled for February 25, 2022. The FDA also advised the Company that it is currently planning to hold an Advisory Committee meeting to discuss the application.

"We are pleased with the FDA's decision to accept for filing our NDA for bardoxolone and look forward to continuing to work with the Division during the review process," said Warren Huff, Reata's President and Chief Executive Officer. "Alport syndrome is one of the most rapidly progressive forms of CKD and a truly devastating disease to those patients and the families who are affected by it. If approved, bardoxolone may be the first therapy to slow the progression of kidney disease in patients with this serious and debilitating disease."

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 approved therapies to treat CKD caused by Alport syndrome.

About the CARDINAL Phase 3 Clinical Study

The CARDINAL Phase 3 study was a double-blind, placebo-controlled, randomized trial that enrolled 157 patients with CKD caused by Alport syndrome at approximately 50 study sites in the United States, Europe, Japan, and Australia. Patients were randomized 1:1 to once-daily, oral bardoxolone or placebo. The primary endpoint for Year 2 of the study was the change from baseline in eGFR after 100 weeks of treatment. The key secondary endpoint for Year 2 of the study was the change from baseline in eGFR at Week 104 (four weeks after the last dose in the second year of treatment). Results from CARDINAL demonstrated that patients treated with bardoxolone experienced a statistically significant improvement in kidney function as measured by eGFR at Week 100 and Week 104, compared to patients treated with placebo. Bardoxolone was generally reported to be well tolerated in this study, and the safety profile was similar to that observed in prior trials. The reported adverse events ("AE") were generally mild to moderate in intensity, and the most common AEs observed more frequently in patients treated with bardoxolone compared to patients treated with placebo were muscle spasms and increases in aminotransferases.

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 has granted Orphan Drug designation to bardoxolone for the treatment of Alport syndrome and autosomal dominant polycystic kidney disease ("ADPKD"). The European Commission has granted Orphan Drug designation in Europe to bardoxolone for the treatment of Alport syndrome.

In addition to the CARDINAL Phase 3 study, bardoxolone is currently being studied in FALCON, a Phase 3 study for the treatment of ADPKD, MERLIN, a Phase 2 study for the treatment of patients with CKD at risk of rapid progression, and AYAME, a Phase 3 study for the treatment of diabetic kidney disease that is being conducted by our licensee, Kyowa Kirin Co., Ltd., in Japan. Bardoxolone treatment has produced positive results in Phase 2 studies in patients with CKD caused by ADPKD, IgA nephropathy, focal segmental glomerulosclerosis, and type 1 diabetes.

About Reata Pharmaceuticals, Inc.

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, bardoxolone and omaveloxolone, target the important transcription factor Nrf2 that promotes the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling. We possess exclusive, worldwide rights to develop, manufacture, and commercialize bardoxolone, omaveloxolone, and our next-generation Nrf2 activators, excluding certain Asian markets for bardoxolone in certain indications, which are licensed to Kyowa Kirin Co., Ltd. (KKC).

Bardoxolone and omaveloxolone 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, 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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