



REATA ANNOUNCES POSITIVE RESULTS FROM YEAR 2 OF THE PIVOTAL PHASE 3 CARDINAL STUDY OF BARDOXOLONE METHYL IN PATIENTS WITH ALPORT SYNDROME

BARDOXOLONE ACHIEVED THE YEAR 2 PRIMARY AND KEY SECONDARY ENDPOINTS WITH STATISTICALLY SIGNIFICANT IMPROVEMENTS IN EGFR AS COMPARED TO PLACEBO AT WEEK 100 AND WEEK 104

BARDOXOLONE PATIENTS WHO REMAINED ON TREATMENT HAD CONTINUED IMPROVEMENT ABOVE BASELINE IN KIDNEY FUNCTION AT WEEK 100

BARDOXOLONE'S LARGEST TREATMENT EFFECT WAS OBSERVED IN PEDIATRIC PATIENTS

IMPROVEMENT IN KIDNEY FUNCTION CONTINUED IN THIRD YEAR OF TREATMENT

NEW DRUG APPLICATION (NDA) SUBMISSION FOR FULL APPROVAL PLANNED FOR 1Q21

BARDOXOLONE HAS THE POTENTIAL TO BECOME THE FIRST APPROVED THERAPY FOR ALPORT SYNDROME, A LIFE-THREATENING DISEASE THAT AFFECTS 30,000-60,000 PATIENTS IN THE UNITED STATES

CONFERENCE CALL WITH MANAGEMENT TODAY AT 8:00 A.M. ET

PLANO, Texas—November 9, 2020 (GLOBE NEWSWIRE)— Reata Pharmaceuticals, Inc. (Nasdaq:RETA) (“Reata” or the “Company,” or “we”), a clinical-stage biopharmaceutical company, today announced that the Phase 3 CARDINAL study of bardoxolone methyl (“bardoxolone”) in patients with chronic kidney disease (“CKD”) caused by Alport syndrome met its primary and key secondary endpoints at the end of Year 2. At Week 100, in the intent-to-treat (“ITT”) population, which included estimated glomerular filtration rate (“eGFR”) values for patients who either remained on or discontinued study drug, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR of 7.7 mL/min/1.73 m² (p=0.0005). In the modified ITT (“mITT”) analysis, which assessed the effect of receiving treatment by excluding values after patients discontinued treatment, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR at Week 100 of 11.3 mL/min/1.73 m² (p<0.0001). At Week 104 (four weeks after last dose in second year of treatment), patients in the ITT population treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR of 4.3 mL/min/1.73 m² (p=0.023). Bardoxolone treatment was generally reported to be well-tolerated. In the long-term extension study (“EAGLE”), for the 14 patients who completed three years of treatment, bardoxolone treatment resulted in a mean increase from baseline in eGFR of 11.0 mL/min/1.73 m². Based on these positive results and following a recently completed pre-NDA meeting with the U.S. Food and Drug Administration (“FDA”), we plan to proceed with the submission of an NDA for full marketing approval in the United States in the first quarter of 2021. We also plan to pursue marketing approval outside of the United States and work has commenced on preparations to file for marketing approval in Europe.

“The positive results of the CARDINAL trial in the treatment of children and adults with Alport syndrome increase the potential of this novel therapeutic agent to be approved as the first specific treatment for this type of chronic kidney disease. For patients with limited treatment options and faced with a kidney disorder characterized by relentless

progression, the potential availability of an additional and long-awaited therapy is very exciting. This is particularly true for children with Alport syndrome, whose important results in CARDINAL emphasizes the benefit of early diagnosis and treatment,” said Bradley Warady, MD, Director, Division of Nephrology/ Dialysis and Transplantation at Children’s Mercy Kansas City.

“It’s an exciting time for the nephrology community. As potentially the first specific therapy for Alport syndrome, bardoxolone could bring hope to thousands of Alport syndrome patients, their caregivers and families. In addition, its novel mechanism of action suggests that it could prove effective against other kidney diseases whose unmet clinical need is just as great,” said Kerry Willis, Ph.D., Chief Scientific Officer of the National Kidney Foundation.

“Chronic kidney disease caused by Alport syndrome is a serious, progressive disease with an urgent need for new therapeutic options. The two-year CARDINAL study, now complete, represents the first time that an investigational medicine has shown a significant clinical benefit in this disease, and it marks an important step toward making a treatment available for patients with Alport syndrome. We look forward to submitting our New Drug Application for bardoxolone in the first quarter of 2021. On behalf of everyone at Reata, I would like to express my sincere appreciation to all of the patients, families, and investigators who participated in the CARDINAL study,” said Warren Huff, Reata’s President and Chief Executive Officer.

CARDINAL Trial Overview and Results

The Phase 3 CARDINAL study was an international, multi-center, double-blind, placebo-controlled, randomized clinical trial that enrolled 157 patients with Alport syndrome at approximately 50 study sites in the United States, Europe, Japan, and Australia. Patients were randomized 1:1 to bardoxolone or placebo. The primary endpoint for Year 2 of the study was the change from baseline in eGFR after 100 weeks of treatment (end-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 last dose in second year of treatment).

At Week 100, in the ITT population, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR of 7.7 mL/min/1.73 m² (p=0.0005). Patients treated with bardoxolone experienced a mean change from baseline in eGFR of -0.8 mL/min/1.73 m², while patients treated with placebo experienced a mean change from baseline in eGFR of -8.5 mL/min/1.73 m². In the mITT analysis, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean change from baseline in eGFR at Week 100 of 11.3 mL/min/1.73 m² (p<0.0001). Patients treated with bardoxolone experienced a mean increase from baseline in eGFR of 1.7 mL/min/1.73 m², while patients treated with placebo experienced a mean decline from baseline in eGFR of -9.6 mL/min/1.73 m². At Week 104 (four weeks after last dose in second year of treatment), patients in the ITT population treated with bardoxolone had a statistically significant

improvement compared to placebo in mean change from baseline in eGFR of 4.3 mL/min/1.73 m² (p=0.023). Patients treated with bardoxolone experienced a mean change from baseline in eGFR of -4.5 mL/min/1.73 m², while patients treated with placebo experienced a mean change from baseline in eGFR of -8.8 mL/min/1.73 m².

Efficacy was observed across multiple subgroups at Week 100 and Week 104, including pediatric patients and patients with different genetic subtypes of Alport syndrome. The largest treatment effect at Week 104 was observed in the pediatric subgroup where the difference between treatment groups was 14.6 mL/min/1.73 m² (p=0.004). The risk of kidney failure events (defined as end stage kidney disease, confirmed 30% eGFR decline, or confirmed eGFR < 15 mL/min/1.73 m²) was reduced by approximately 50% in bardoxolone-treated patients (9 patients versus 17 patients in placebo).

Bardoxolone was generally reported to be well tolerated in this study, and the safety profile was similar to that observed in prior trials. Seventy-five patients (97%) receiving bardoxolone and 77 patients (96%) receiving placebo experienced an adverse event ("AE"). Ten patients (13%) receiving bardoxolone and four patients (5%) receiving placebo discontinued study drug due to an AE, and no individual AE contributed to more than two discontinuations in either group. The reported AEs 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.

Eight patients (10%) receiving bardoxolone and 15 patients (19%) receiving placebo experienced a treatment-emergent serious adverse event ("SAE"). No SAEs were reported in pediatric patients treated with bardoxolone. No fluid overload or major adverse cardiac events were reported in patients treated with bardoxolone. Blood pressure was not significantly different between the two groups. The urinary albumin-to-creatinine ratio ("UACR") was not significantly different between treatment groups at Week 100 or Week 104. Non-kidney symptoms associated with Alport syndrome, including psychiatric, hearing, vestibular, and ocular AEs, occurred less frequently in bardoxolone-treated patients.

EAGLE Long Term Results

Today, we announced results from the long-term extension study, called EAGLE, that included enrollment of eligible patients with Alport syndrome who completed the CARDINAL study. Change from baseline in eGFR was assessed for 14 patients with Alport syndrome who were treated with bardoxolone for three years, with four-week off treatment periods occurring at Weeks 48 and 100. Bardoxolone produced a mean increase from baseline in eGFR of 11.5 mL/min/1.73 m² at Year 1, 13.3 mL/min/1.73 m² at Year 2, and 11.0 mL/min/1.73 m² at Year 3.

Conference Call Information

Reata management will host a call to discuss these results as well as the financial results for the third quarter of 2020 today, November 9, 2020 at 8:00 a.m. ET. The conference call will be accessible by dialing (844) 348-3946 (toll-free domestic) or (213) 358-0892 (international) using the access code: 2896858. The webcast link is <https://edge.media-server.com/mmc/p/z6fgbcwf>.

Third quarter 2020 financial results to be discussed during the call will be available on the Company's website shortly before the call at <http://reatapharma.com/investors/> and will be available for 12 months after the call. The audio recording and webcast will be accessible for at least 90 days after the event at <http://reatapharma.com/investors/>.

About the Off-Treatment eGFR Endpoint

CKD is characterized by a progressive worsening in the rate at which the kidney filters waste products from the blood called the glomerular filtration rate or GFR. When GFR falls too low, patients require dialysis or a kidney transplant to survive. Dialysis leads to a reduced quality of life and increases the likelihood of serious and life-threatening complications. The five-year survival rate for hemodialysis patients is only approximately 42%. eGFR is an estimate of GFR that nephrologists use to track the decline in kidney function and progression of CKD.

In rare forms of CKD, the FDA has accepted the off-treatment endpoint as the basis for approval. Withdrawal of drug after long-term treatment provides evidence whether a drug either protected or harmed the kidney during treatment. If off-treatment changes in eGFR are higher than placebo, this is evidence that the drug protected the kidney during treatment, and, if off-treatment changes in eGFR are lower than placebo, this is evidence that the drug harmed the kidney during treatment. An off-treatment eGFR benefit relative to placebo provides evidence that drug treatment may delay kidney failure.

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. 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. Alport syndrome affects both children and adults. 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 Bardoxolone Methyl

Bardoxolone methyl is an investigational, oral, once-daily 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. 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 autosomal dominant polycystic kidney disease, 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, and BARCONA, an investigator-sponsored Phase 2 study for the treatment in patients suffering from COVID-19 conducted by researchers at NYU Grossman School of Medicine. Bardoxolone treatment has produced positive results in Phase 2 studies in patients with IgA nephropathy, focal segmental glomerulosclerosis, and CKD associated with 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. **Bardoxolone is an investigational drug, and its safety and efficacy have not been established by any regulatory agency.**

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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 the detailed factors discussed under the caption “Risk Factors” in its Annual Report on Form 10-K for the fiscal year ended December 31, 2019. 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.