



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

ACHIEVED PRIMARY ENDPOINT OF STATISTICALLY SIGNIFICANT IMPROVEMENT IN EGFR COMPARED TO PLACEBO AFTER 48 WEEKS OF TREATMENT

ACHIEVED KEY SECONDARY ENDPOINT OF STATISTICALLY SIGNIFICANT IMPROVEMENT IN RETAINED EGFR COMPARED TO PLACEBO AFTER 48 WEEKS OF TREATMENT AND WITHDRAWAL OF DRUG FOR 4 WEEKS

CONFERENCE CALL WITH MANAGEMENT SCHEDULED FOR NOVEMBER 12, 2019 AT 8:00 AM ET

PLANO, Texas—November 11, 2019—Reata Pharmaceuticals, Inc. (Nasdaq:RETA) (“Reata” or the “Company”), a clinical-stage biopharmaceutical company, announced today that the Phase 3 portion of the CARDINAL study of bardoxolone methyl (bardoxolone) in patients with chronic kidney disease (CKD) caused by Alport syndrome met its primary and key secondary endpoints. After 48 weeks of treatment, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean estimated glomerular filtration rate (eGFR) of 9.50 mL/min/1.73 m² (p<0.0001). After 48 weeks of treatment and a four-week withdrawal period, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m² (p=0.0012). Bardoxolone treatment was generally reported to be well-tolerated and showed a similar safety profile to the Phase 2 portion of the CARDINAL study. Based on these positive results, and subject to discussions with regulatory authorities, the Company plans to proceed with the submission of regulatory filings for marketing approval in the United States and internationally.

“The first year results from the CARDINAL study are very promising. This provides hope to the entire Alport syndrome community that we could finally have the first therapy to treat this rare, genetic kidney disease,” said Lisa Bonebrake, Executive Director of the Alport Syndrome Foundation. “The Alport Syndrome Foundation is grateful to the patients who participated in the study. Their willingness to contribute to our understanding of bardoxolone is a gift to all patients facing the devastating impact that Alport syndrome can have on their lives, others with the disease in their family, and those who care about them. We also extend our deepest gratitude to the clinicians and their institutions for conducting this study and caring for these patients through the process, and to Reata Pharmaceuticals for investing their scientific expertise in the search to find a therapy for Alport syndrome.”

“Patients living with Alport syndrome experience a severe and progressive loss of kidney function that can lead to the need for chronic dialysis treatment or a kidney transplant in the prime of their lives. The CARDINAL trial of bardoxolone is the first study in which a therapy halted the progression of chronic kidney disease in patients with Alport syndrome,” said Warren Huff, Reata’s President and Chief Executive Officer. “On behalf of everyone at Reata, I would like to



express my sincere appreciation to all of the patients, families, and investigators who are participating in the ongoing CARDINAL study.”

Trial Overview and Results

The Phase 3 portion of CARDINAL is an international, multi-center, double-blind, placebo-controlled, randomized registrational trial that enrolled 157 patients with Alport syndrome at approximately 50 study sites in the United States, Europe, Japan, and Australia. Pediatric patients represented approximately 15% of enrolled patients. Patients were randomized 1:1 to bardoxolone or placebo. The primary endpoint for the study was the change in eGFR, an important measure of the ability of the kidney to filter waste products out of the blood, after 48 weeks of treatment. The key secondary endpoint for the study was the change in the retained eGFR after 48 weeks of treatment and four weeks of drug withdrawal. After 52 weeks, patients who completed the first 48 weeks of treatment are restarted on study drug with their original treatment assignments and continue on study drug for a second year. The second-year on-treatment eGFR will be measured after 100 weeks of treatment and the retained eGFR will be measured at Week 104 after withdrawal of drug for four weeks. The FDA has provided the Company with written guidance that, in patients with CKD caused by Alport syndrome, an analysis of retained eGFR demonstrating an improvement versus placebo after one year of bardoxolone treatment may support accelerated approval and an improvement versus placebo after two years of treatment may support full approval.

After 48 weeks of treatment, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean eGFR of 9.50 mL/min/1.73 m² (p<0.0001). Patients treated with bardoxolone experienced a statistically significant increase from baseline in mean eGFR of 4.72 mL/min/1.73 m², while patients treated with placebo experienced a statistically significant decline from baseline in mean eGFR of -4.78 mL/min/1.73 m². Patients' retained eGFR was also assessed at Week 52, after 48 weeks of treatment and four weeks of drug withdrawal. At Week 52, patients treated with bardoxolone had a statistically significant improvement compared to placebo in mean retained eGFR of 5.14 mL/min/1.73 m² (p=0.0012). Patients treated with bardoxolone experienced a nonsignificant decline from baseline in mean retained eGFR of -0.96 mL/min/1.73 m², while patients treated with placebo experienced a statistically significant decline from baseline in mean retained eGFR of -6.11 mL/min/1.73 m². Similar efficacy at Week 48 and Week 52 was observed across multiple subgroups, including among pediatric patients.

Bardoxolone was generally reported to be well tolerated in this study and showed a similar safety profile to the Phase 2 portion of the CARDINAL study. Seventy-five patients (97%) receiving bardoxolone and 73 patients (91%) receiving placebo experienced an adverse event (AE). Nine patients (12%) 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.



Four patients (5%) receiving bardoxolone and 10 patients (13%) receiving placebo experienced a treatment-emergent serious adverse event (SAE). No fluid overload or major adverse cardiac events were reported in patients treated with bardoxolone. Blood pressure was reduced relative to baseline in the bardoxolone group, and the between group difference was not significant. 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 increases in aminotransferases and muscle spasms. Increases in aminotransferases are a pharmacological effect of bardoxolone, which increases production of aminotransferases *in vitro*. The aminotransferase increases observed in CARDINAL were associated with improvements (reductions) in total bilirubin and were not associated with liver injury, and we believe they are related to restoration of mitochondrial function. Laboratory markers associated with pharmacodynamic activity, including urinary albumin to creatinine ratio and aminotransferases, were unchanged relative to placebo at Week 52 following withdrawal of drug for four weeks.

Reata management will host a call to discuss these results as well as the financial results for the third quarter of 2019 tomorrow, November 12, 2019 at 8:00 a.m. ET.

CONFERENCE CALL INFORMATION

Date:	November 12, 2019
Time:	8:00 a.m. ET
Audience Dial-in (toll-free):	(844) 348-3946
Audience Dial-in (international):	(213) 358-0892
Conference ID:	4159656
Webcast Link:	https://edge.media-server.com/mmc/p/ofwujzi9

About the Retained eGFR Analysis

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.

The FDA has accepted for approval in rare forms of CKD the placebo-corrected “retained eGFR” after withdrawal of drug. Withdrawal of drug after long-term treatment provides evidence whether a drug either protected or harmed the kidney during treatment. If retained eGFR is higher than placebo, this is evidence that the drug protected the kidney during treatment, and, if retained eGFR is lower than placebo, this is evidence that the drug harmed the kidney during treatment. A positive retained eGFR benefit 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. Alport syndrome patients experience a progressive loss in the kidney's capacity to filter waste products out of the blood that can lead to end stage kidney failure (ESKD) and the need for chronic dialysis treatment or a kidney transplant. A majority of patients with Alport syndrome develop ESKD, and approximately 50% of patients with the most severe form of the disease require dialysis or a kidney transplant by the age of 25. 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 Alport syndrome.

About Bardoxolone Methyl

Bardoxolone methyl is an experimental, 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.

Bardoxolone is currently being studied in CARDINAL, a Phase 3 study for the treatment of Alport syndrome, 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 CATALYST, a Phase 3 study for the treatment of connective tissue disease associated with pulmonary arterial hypertension. 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 restoration of mitochondrial function, reduction of oxidative stress, and inhibition of pro-inflammatory signaling. **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.

Contact:

Reata Pharmaceuticals, Inc.
(972) 865-2219
info@reatapharma.com
<http://news.reatapharma.com>

Investor Relations:

Vinny Jindal
Vice President, Strategy
(469) 374-8721
ir@reatapharma.com

Media:

Matt Middleman, M.D.
LifeSci Public Relations
(646) 627-8384
matt.middleman@lifescipublicrelations.com