



## **REATA ANNOUNCES POSITIVE PHASE 2 DATA FOR BARDOXOLONE METHYL IN PATIENTS WITH FOCAL SEGMENTAL GLOMERULOSCLEROSIS AND IN PATIENTS FROM ALL FOUR COHORTS OF PHOENIX**

***STATISTICALLY SIGNIFICANT IMPROVEMENT IN KIDNEY FUNCTION OBSERVED IN PATIENTS WITH FOCAL SEGMENTAL GLOMERULOSCLEROSIS AFTER 12 WEEKS OF TREATMENT***

***BARDOXOLONE METHYL SIGNIFICANTLY IMPROVED KIDNEY FUNCTION IN PATIENTS FROM ALL FOUR COHORTS OF PHOENIX***

***BARDOXOLONE METHYL SIGNIFICANTLY REDUCED BLOOD PRESSURE AND WAS WELL-TOLERATED IN PATIENTS FROM ALL FOUR COHORTS OF PHOENIX***

***CONFERENCE CALL WITH MANAGEMENT SCHEDULED FOR TODAY, FEBRUARY 20, 2019***

**IRVING, Texas—February 20, 2019**—Reata Pharmaceuticals, Inc. (Nasdaq: RETA), a clinical-stage biopharmaceutical company, today announced positive, final results from the focal segmental glomerulosclerosis (FSGS) cohort of PHOENIX, a Phase 2 study of bardoxolone methyl (bardoxolone) in patients with rare forms of chronic kidney disease (CKD). Compared to baseline, bardoxolone significantly improved kidney function as measured by patients' estimated glomerular filtration rate (eGFR) at Week 12, which was the primary endpoint of the PHOENIX study.

Patients treated with bardoxolone experienced a significant increase in eGFR of 7.8 mL/min/1.73 m<sup>2</sup> (n=18; p=0.003) at Week 12 compared to baseline. Reata collected historical eGFR data for 17 of the 18 patients, which demonstrated that these patients' kidney function was declining at an average annual rate of 2.6 mL/min/1.73 m<sup>2</sup> prior to study entry. The observed 7.8 mL/min/1.73 m<sup>2</sup> improvement after 12 weeks of treatment with bardoxolone represents a recovery of three years of average eGFR loss. With respect to safety, no treatment-related serious adverse events were reported, and the reported adverse events were generally mild to moderate in intensity.

Overall, the PHOENIX trial studied 103 patients who had one of four rare forms of CKD, including autosomal dominant polycystic kidney disease (ADPKD) (n=31), IgA nephropathy (n=26), type 1 diabetic CKD (n=28), and FSGS (n=18). Historical eGFR data collected from 91 of the 103 patients demonstrated that these patients' kidney function was declining at an average annual rate of 2.8 mL/min/1.73 m<sup>2</sup> prior to study entry. After 12 weeks of once-daily, oral administration of bardoxolone, the mean change in eGFR from baseline across all four cohorts was 7.8 mL/min/1.73 m<sup>2</sup> (n=103; p<0.00001). Notably, 88% of patients who reached Week 12 demonstrated an improvement in eGFR. Bardoxolone significantly reduced mean systolic blood pressure by 3.8 mmHg (n=103; p=0.002) and mean diastolic blood pressure by 2.8 mmHg (n=103; p=0.0009). Urinary albumin excretion was low upon study entry and remained unchanged by bardoxolone treatment (n=103; p=0.6). Bardoxolone was well-tolerated, with 89% of patients in PHOENIX completing treatment through Week 12, and no treatment-related serious adverse events were reported.

“In studies to date, bardoxolone has significantly improved kidney function in a high proportion of patients across six distinct forms of CKD. This supports the hypothesis that bardoxolone addresses a final common pathway of CKD progression,” said Colin Meyer, M.D., Reata’s Chief Medical Officer. “Additionally, in PHOENIX, bardoxolone treatment was well tolerated, did not increase proteinuria, and significantly reduced blood pressure. In three prior longer-term trials, bardoxolone treatment produced eGFR improvements that were maintained for at least one year and were associated with a retained eGFR benefit after drug withdrawal. We believe that these clinical data suggest that bardoxolone treatment may prevent or delay kidney failure and the need for dialysis or a kidney transplant in many forms of CKD.”

Reata management will host a conference call and webcast to discuss these results on Wednesday, February 20, 2019, at 8:00 a.m. ET at the following:

#### **CONFERENCE CALL INFORMATION**

Date:	Wednesday, February 20, 2019
Time:	8:00 a.m. ET
Audience Dial-in (toll-free):	(844) 348-3946
Audience Dial-in (international):	(213) 358-0892
Conference ID:	6555059
Webcast Link:	<a href="https://edge.media-server.com/m6/p/pcxmgtgj">https://edge.media-server.com/m6/p/pcxmgtgj</a>

#### **About the PHOENIX Study**

The Phase 2 PHOENIX program studied bardoxolone in patients with ADPKD, IgA nephropathy, FSGS, and type 1 diabetic CKD. Patients received bardoxolone open-label, orally, once daily for 12 weeks, and the primary efficacy endpoint was change from baseline in eGFR after 12 weeks of treatment. Endpoints were assessed for each cohort separately. PHOENIX is complete, and results from all four cohorts have now been released.

#### **About Focal Segmental Glomerulosclerosis**

FSGS is a rare form of CKD that is characterized by progressive scarring of kidney glomeruli in a focal and segmental pattern, such that not all glomeruli (focal) and only a part of the glomerular tuft (segmental) are affected. Abnormal leakage of proteins through the glomerular basement membrane (GBM) and excessive reabsorption of protein in the proximal tubules of the kidney induce oxidative stress, chronic inflammation, fibrosis, and loss of kidney function. FSGS is one of the most common primary glomerular disorders causing end-stage renal disease and affects approximately 40,000 people in the United States. There are currently no U.S. Food and Drug Administration (FDA)-approved therapies for FSGS.

### **About Bardoxolone Methyl**

Bardoxolone 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 and pulmonary arterial hypertension. 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, CATALYST, a Phase 3 study for the treatment of connective tissue disease-associated pulmonary arterial hypertension, and AYAME, a Phase 3 study for the treatment of diabetic kidney disease in Japan. AYAME is being conducted by our licensee Kyowa Hakko Kirin Co., Ltd.

### **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.

### **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, 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," 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) 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 (iv) 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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