



## Reata Provides Program Update on Phase 2 Rare Renal Clinical Trials

February 27, 2018

**First patient enrolled for all cohorts of PHOENIX**

**First data from PHOENIX expected 2H18**

**Retained benefit analysis from Phase 2 portion of CARDINAL expected 3Q18**

IRVING, Texas, Feb. 27, 2018 (GLOBE NEWSWIRE) -- Reata Pharmaceuticals, Inc. (Nasdaq:RETA) (Reata or Company), a clinical-stage biopharmaceutical company, today provided guidance on the timing of data announcements from the ongoing Phase 2 PHOENIX and CARDINAL trials of bardoxolone methyl ("bardoxolone") in rare forms of chronic kidney disease ("CKD").

The Phase 2 PHOENIX program is studying bardoxolone in patients with autosomal dominant polycystic kidney disease ("ADPKD"), IgA nephropathy, focal segmental glomerulosclerosis ("FSGS"), and CKD associated with type 1 diabetes. Approximately 25 patients per cohort will receive bardoxolone open-label, orally, once-daily for 12 weeks. The purpose of this study is to determine the safety and efficacy of bardoxolone, and the primary efficacy endpoint is change from baseline in eGFR after 12 weeks of treatment. Each cohort of patients is being independently enrolled and analyzed, and each has now enrolled at least one patient. The Company anticipates that initial data from one or more PHOENIX cohorts will be released during the second half of 2018.

CARDINAL is a Phase 2/3 study of bardoxolone in patients with CKD caused by Alport syndrome. The Phase 2 portion of CARDINAL enrolled a total of 30 patients to assess the safety and efficacy of once-daily, oral administration of bardoxolone, and its primary efficacy endpoint was change from baseline in estimated glomerular filtration rate (eGFR) at week 12. Full primary endpoint results from the study were reported in November 2017 after all patients had reached week 12. Patients remain in the study for up to two years, and eGFR will be measured at 52 weeks following 48 weeks of treatment and 4 weeks of drug withdrawal ("retained benefit"). The Company expects to report the week 52 retained benefit analysis from this study in the third quarter of this year.

Results from the 52-week retained benefit analysis are relevant to the ongoing Phase 3 portion of CARDINAL, a double-blind, placebo-controlled trial enrolling up to 150 patients worldwide. This Phase 3 study can support accelerated approval by the FDA based upon an improvement in eGFR following 48 weeks of once-daily treatment and 4 weeks of drug withdrawal. After this retained benefit analysis, patients will continue on their original study treatment for another 48 weeks, and full approval can be supported by a retained benefit at 104 weeks following a second 4-week drug withdrawal. Prior trials in patients with other forms of CKD have demonstrated that improvements in eGFR are durable for up to two years, and the change in eGFR after 12 weeks correlates with changes at one year on-treatment and post-withdrawal.

"Diverse forms of CKD are driven by a common final set of inflammatory pathways that bardoxolone targets," said Colin Meyer, M.D., Chief Medical Officer of Reata. "Treatment with bardoxolone has resulted in clinically meaningful increases in kidney function in patients with Alport syndrome, CKD caused by type 2 diabetes, and CKD associated with pulmonary hypertension, and we hope to demonstrate similar efficacy in these additional types of CKD being studied in PHOENIX. We anticipate that bardoxolone may complement commonly used therapies that modestly affect progression in these diseases, which have no FDA-approved treatments."

### **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. In addition to CARDINAL and PHOENIX, bardoxolone methyl is currently being studied in CATALYST, a Phase 3 study for the treatment of connective tissue disease associated pulmonary arterial hypertension. The FDA has granted orphan designation to bardoxolone methyl for the treatment of Alport syndrome and pulmonary arterial hypertension.

### **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 methyl 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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