



## **REATA ANNOUNCES IMPROVEMENTS IN KIDNEY FUNCTION WITH BARDOXOLONE METHYL MAINTAINED FOR TWO YEARS IN PAH PATIENTS FROM LARIAT TRIAL**

***PROGRESSIVE LOSS OF KIDNEY FUNCTION IS A VALIDATED INDEPENDENT PREDICTOR OF DEATH AND HOSPITALIZATION IN PAH PATIENTS***

***INCREASES IN EGFR FROM BARDOXOLONE METHYL TREATMENT WERE MAINTAINED FOR TWO YEARS***

***LONGEST DURATION OF TREATMENT IN ANY PATIENT POPULATION STUDIED***

***CONFERENCE CALL TO UPDATE BARDOXOLONE RARE CKD PROGRAM ON FEBRUARY 13, 2018, AT 8:30AM ET***

**IRVING, Texas—February 12<sup>th</sup>, 2018**—Reata Pharmaceuticals, Inc. (Nasdaq:RETA) (Reata or Company), a clinical-stage biopharmaceutical company, today announced results from the long-term follow up portion of the LARIAT study demonstrating that pulmonary arterial hypertension (PAH) patients treated with bardoxolone methyl (bardoxolone) experienced kidney function improvements that were durable for two years and not associated with adverse outcomes. The two-year duration of sustained eGFR improvement in LARIAT is twice as long as Reata has previously reported for bardoxolone and supports the rationale for Reata’s ongoing CARDINAL and PHOENIX programs in rare forms of chronic kidney disease (CKD).

Progressive loss of kidney function is a prevalent and critical complication for patients with PAH and is a validated, independent predictor of mortality and all-cause hospitalization in this population. PAH patients experience an annualized loss of kidney function of approximately 8 to 13 mL/min/1.73 m<sup>2</sup>. Patients in the placebo-controlled, double-blind phase of LARIAT had impaired kidney function upon study entry with an eGFR averaging 75.6 mL/min/1.73 m<sup>2</sup>. Patients who received treatment with bardoxolone (n=71) had significantly increased eGFR compared to placebo (n=30) by 10.6 mL/min/1.73 m<sup>2</sup> (p<0.0001) after 16 weeks of treatment.

After patients in LARIAT completed 16 weeks of treatment, all patients were eligible to receive bardoxolone in an open-label extension study. At the time of the analysis, 55 patients had received at least 56 weeks of bardoxolone treatment, and 26 of these patients had received bardoxolone treatment for at least 104 weeks. After 56 weeks of treatment, patients experienced a significant, mean increase in eGFR of 10.7 mL/min/1.73 m<sup>2</sup> from baseline (p<0.0001), and after 104 weeks of treatment, patients experienced a significant, mean increase in eGFR of 11.3 mL/min/1.73 m<sup>2</sup> from baseline (p<0.0001). Notably, 88% of patients on bardoxolone maintained increases in eGFR above baseline after two years of treatment. The large proportion of responders and overall magnitude of improvement that is durable for two years contrasts with the chronic loss of kidney function in this patient population.



The LARIAT PAH patients experienced a lower rate of hospitalization when compared to recent registrational and observational PAH studies, and there were no deaths among these LARIAT PAH patients. Upon study entry, the LARIAT PAH patients had a median time since diagnosis of 3.3 years (n=101; 66 weeks median duration of treatment). For patients with PAH, the median survival from time of diagnosis is 4 to 7 years.

“Loss of kidney function is common in PAH patients and associated with an increased risk of adverse outcomes and death. Treatments for PAH improve symptoms but often worsen kidney function, placing patients at greater risk,” said Daniel W. Coyne, M.D., Nephrologist and Professor of Medicine at Washington University in St. Louis, Missouri. “The two-year trial data are the longest available with bardoxolone and suggest raising kidney function with bardoxolone is not harmful and is likely to be beneficial in PAH patients and other disease states.”

The two-year eGFR data from LARIAT extend earlier observations that bardoxolone treatment is associated with preservation of kidney function. Recently published data from Reata’s diabetic CKD trials (BEAM and BEACON) demonstrated that eGFR improvements from bardoxolone treatment were durable for at least one year and associated with a more than 50% reduced likelihood of adverse renal events validated to predict kidney failure. Most important, these data demonstrated that patients treated with bardoxolone for at least one year had a persisting improvement in kidney function versus placebo even after the drug was withdrawn for one month. This persisting increase after withdrawal suggests that the drug is improving, not harming, the structure of the kidney in humans as it does in multiple animal models of CKD.

“Through these analyses of long-term clinical data, we have been able to differentiate the improvements in kidney function with bardoxolone from agents that may modestly, transiently, and adversely increase kidney function by increasing blood pressure in the kidney,” said Colin Meyer, M.D., Reata’s Chief Medical Officer. “The longer term data in PAH patients, who are extremely sensitive to any adverse perturbations of renal or cardiac function, provides further evidence that bardoxolone may be beneficial, and not harmful, to the kidney.”

#### **CONFERENCE CALL INFORMATION**

Date:	Tuesday, February 13, 2018
Time:	8:30AM ET
Audience Dial-in (toll-free):	(844) 348-3946
Audience Dial-in (international):	(213) 358-0892
Conference ID:	8850769
Webcast Link:	<a href="https://edge.media-server.com/m6/p/zgexpb9f">https://edge.media-server.com/m6/p/zgexpb9f</a>

#### **About Kidney Function and PAH**

The role of kidney dysfunction and outcomes in PAH has recently been characterized in an analysis of data from the REVEAL registry, the largest US cohort of patients with PAH (Chakinala et al., 2017). The analysis showed that, in



PAH patients, a decline in renal function was associated with a nearly two-fold increase in mortality (HR=1.90;  $p<0.001$ ). Furthermore, a 10% decrease in eGFR was an independent predictor of mortality for patients with PAH (HR=1.66;  $p<0.0001$ ) and also associated with increased risk for the composite of mortality and all-cause hospitalization (HR=1.33;  $p=0.0019$ ). Notably, the relationship between declining eGFR and survival persisted even when adjusting for key factors like baseline eGFR, REVEAL risk score, 6MWD change, and WHO functional class changes.

#### **About LARIAT**

LARIAT is a two-part study of the efficacy and safety of bardoxolone in patients with pulmonary hypertension. Part 1 was a double-blind, randomized, placebo-controlled treatment period, and Part 2 was an open-label extension period. The study enrolled primarily WHO Group I PAH patients classified as WHO/NYHA Functional Class II and III, including those with CTD-PAH. Patients receiving one or two disease-specific PAH therapies, including endothelin receptor antagonists, riociguat, phosphodiesterase5 (PDE5) inhibitors, or prostacyclins (subcutaneous, oral, or inhaled), were eligible for enrollment. Patients from Part 1 who completed the 16-week treatment period as planned were eligible to continue directly into the extension period (Part 2) to evaluate the intermediate and long-term safety and efficacy of bardoxolone.

#### **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. Bardoxolone is currently being studied in the Phase 3 portion of the CARDINAL trial in patients with CKD caused by Alport syndrome as well as the Phase 2 PHOENIX trial in patients with autosomal dominant polycystic kidney disease, IgA nephropathy, type 1 diabetic CKD, and focal segmental glomerulosclerosis. In addition to the CARDINAL and PHOENIX trials, bardoxolone 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 for the treatment of Alport syndrome and the treatment of 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 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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