Bardoxolone Methyl Improved Kidney Function in Patients With Autosomal Dominant Polycystic Kidney Disease and IgA Nephropathy in the Ongoing Phase 2 Phoenix Study

May 25, 2018

Interim Data Demonstrate Significant Improvement in Kidney Function in Both Diseases

Conference Call With Management Scheduled Today, May 25, 2018 at 8:00am ET

IRVING, Texas, May 25, 2018 (GLOBE NEWSWIRE) -- Reata Pharmaceuticals, Inc. (NASDAQ:RETA), a clinical-stage biopharmaceutical company, today announced that positive interim data from the autosomal dominant polycystic kidney disease (ADPKD) and IgA nephropathy cohorts of the ongoing, open-label, Phase 2 PHOENIX trial are being presented by Pablo E. Pergola, M.D., Ph.D., Research Director, Renal Associates, PA, San Antonio, at the European Renal Association and European Dialysis and Transplant Association (ERA-EDTA) meeting in Copenhagen.

The ADPKD cohort of PHOENIX enrolled 31 patients, and available data demonstrate that bardoxolone methyl (bardoxolone) significantly improved kidney function in ADPKD patients as measured by their estimated glomerular filtration rate (eGFR). Bardoxolone-treated patients showed a mean improvement of 6.6 mL/min/1.73 m^2 at Week 4 (n=31; p<0.0001), increasing to 12.0 mL/min/1.73 m^2 at Week 12 (n=8; p<0.0001) from a mean baseline eGFR of 47.7 mL/min/1.73 m^2. The IgA nephropathy cohort enrolled 26 patients, and data were reported through Week 8. Bardoxolone-treated patients showed a mean improvement of 8.4 mL/min/1.73 m^2 at Week 8 (n=9; p<0.0001) from a mean baseline eGFR of 46.2 mL/min/1.73 m^2. No drug-related serious adverse events have been reported, and reported adverse events have generally been mild to moderate in intensity. Full data for the primary endpoint of change in eGFR at Week 12 for the ADPKD, IgA nephropathy, and type 1 diabetic chronic kidney disease (CKD) cohorts of PHOENIX will be available in the third quarter of 2018.

“Bardoxolone has now produced large improvements in kidney function in a high percentage of patients spanning 11 trials and five different forms of chronic kidney disease,” said Dr. Pergola. “These observations suggest that bardoxolone is addressing pathogenic pathways of inflammation and fibrosis that contribute to the loss of kidney function in patients with chronic kidney disease.”

Additionally, Dr. Christoph Wanner, M.D., Chief of the Division of Nephrology and Hypertension at the University Hospital of Würzburg, Germany, gave an oral presentation at ERA-EDTA entitled “Bardoxolone Methyl Prevents eGFR Decline in Patients with Chronic Kidney Disease Stage 4 and Type 2 Diabetes — Post-hoc Analyses from BEACON.” The analysis demonstrated that patients randomized to bardoxolone were more than 50 percent less likely than patients receiving placebo to experience events that predict kidney failure. The authors of the abstract concluded that bardoxolone preserves kidney function and may delay the onset of kidney failure in patients with type 2 diabetes and stage 4 CKD. The abstract was named a Ten Best Abstract by the Paper Selection Committee of ERA-EDTA.

“Bardoxolone’s improvements in kidney function in patients with ADPKD and IgA nephropathy are consistent with improvements observed in other forms of CKD, which have been durable and predictive of retained eGFR benefit after withdrawal of drug in prior trials,” said Colin Meyer, M.D., Reata’s Chief Medical Officer. “Additionally, selection of the BEACON outcomes analysis for oral presentation at one the world’s top nephrology meetings, six years after BEACON concluded, reinforces the importance of the study’s results. The durable increases in eGFR associated with a 50 percent reduction in outcomes inspire optimism for bardoxolone’s potential to delay or prevent dialysis in CKD.”

Reata management will host a call at 8:00 a.m. ET today to review these data and the development program for bardoxolone in chronic kidney disease.

CONFERENCE CALL INFORMATION

Date:	Friday, May 25, 2018
Time:	8:00 a.m. ET
Audience Dial-in (toll-free):	(844) 348-3946
Audience Dial-in (international):	(213) 358-0892
Passcode:	1475149
Webcast Link:	https://edge.media-server.com/m6/p/fgq55vqo

About Autosomal Dominant Polycystic Kidney Disease

ADPKD is a genetic form of CKD caused by mutations in *PKD1* and *PKD2* genes leading to inflammation that stimulates the formation of fluid-filled cysts in the kidneys that cause pain and progressive loss of kidney function. ADPKD is the leading inheritable cause of kidney failure with an estimated 116,000 diagnosed patients in the United States.

About IgA Nephropathy

IgA nephropathy, also known as Berger’s Disease, is a rare form of CKD that is characterized by deposits of IgA immune complexes in the glomeruli leading to persistent inflammation, oxidative stress, and loss of kidney function. IgA nephropathy is one of the most prevalent primary chronic glomerular diseases with an estimated 120,000 patients in the United States. There are currently no FDA-approved therapies for IgA nephropathy.

About the PHOENIX Study

The Phase 2 PHOENIX program is studying bardoxolone in patients with ADPKD, IgA nephropathy, focal segmental glomerulosclerosis, and CKD associated with type 1 diabetes. Patients receive bardoxolone open-label, orally, once-daily for 12 weeks, and the primary efficacy endpoint is change

from baseline in eGFR after 12 weeks of treatment. Endpoints will be assessed for each cohort separately.

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 designation to bardoxolone for the treatment of Alport syndrome and for the treatment of connective tissue disease associated 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 which 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.

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

Investor:
Vinny Jindal
Vice President, Strategy
(855) 55-REATA
ir@reatapharma.com

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

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