



REATA ANNOUNCES CLINICAL TRIAL DESIGN FOR FALCON, A PHASE 3 TRIAL OF BARDOXOLONE METHYL FOR THE TREATMENT OF AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE

IRVING, Texas—January 3, 2019—Reata Pharmaceuticals, Inc. (Nasdaq: RETA), a clinical-stage biopharmaceutical company, today announced that it has completed a successful end-of-Phase 2 meeting with the United States Food and Drug Administration (FDA) regarding the design of a Phase 3 clinical trial of bardoxolone methyl (bardoxolone) in patients with autosomal dominant polycystic kidney disease (ADPKD).

The trial, named FALCON, will be an international, double-blind, placebo-controlled, parallel group, Phase 3 trial. The Company plans to enroll approximately 300 ADPKD patients randomized 1:1 to oral, once-daily bardoxolone or placebo. The trial will include ADPKD patients from 18 to 70 years old with an estimated glomerular filtration rate (eGFR) between 30 to 90 mL/min/1.73 m². The primary efficacy endpoint is the change from baseline in eGFR compared to placebo after 48 weeks of treatment followed by a 4-week drug withdrawal period, the retained eGFR benefit.

FALCON is statistically powered to detect a placebo-corrected, retained eGFR benefit of 1.6 mL/min/1.73 m². Based upon guidance from the FDA, the 52-week retained eGFR benefit data may support accelerated approval under subpart H. After Week 52, patients will be restarted on study drug with their original treatment assignments and will continue on study for a second year. The second-year retained eGFR benefit will be measured at Week 104 after withdrawal of drug for four weeks. Based upon guidance from the FDA, the year-two retained eGFR benefit data may support full approval.

The Company expects to initiate enrollment in the FALCON trial during mid-2019.

“The meaningful improvements in kidney function and quality of life observed in the ADPKD cohort of the Phase 2 PHOENIX trial give us confidence that bardoxolone may become an important treatment option for patients with ADPKD,” said Colin Meyer, M.D., Reata’s Chief Medical Officer. “FALCON closely mirrors the design of CARDINAL, our ongoing Phase 3 study of bardoxolone in Alport syndrome patients. This should allow us to leverage our operational expertise and investigator network to efficiently enroll and execute the trial. Additionally, the acceptance of retained eGFR benefit after a 4-week withdrawal period for a second bardoxolone chronic kidney disease (CKD) trial further validates it as the appropriate approval endpoint for bardoxolone in pivotal trials for rare forms of CKD.”

Reata management will host a conference call and webcast to discuss the FALCON clinical trial design on Thursday, January 3, 2019, at 4:30 p.m. ET at the following:



CONFERENCE CALL INFORMATION

Date: Thursday, January 3, 2019
Time: 4:30 p.m. ET
Audience Dial-in (toll-free): (844) 348-3946
Audience Dial-in (international): (213) 358-0892
Conference ID: 8078409
Webcast Link: <https://edge.media-server.com/m6/p/23y2d7it>

About Autosomal Dominant Polycystic Kidney Disease

ADPKD is a genetic form of CKD caused by mutations in *PKD1* and *PKD2* genes leading to the formation of fluid-filled cysts in the kidneys and other organs. The cysts continue to grow and can cause the kidneys to expand up to five to seven times their normal volume leading to pain and progressive loss of kidney function. As in other forms of CKD, decreased mitochondrial function and chronic inflammation are key drivers of disease progression.

ADPKD affects both men and women of all racial and ethnic groups and is the leading inheritable cause of kidney failure with an estimated diagnosed population of 116,000 patients in the United States. As an autosomal dominant disease, an affected parent has a 50% chance of passing ADPKD on to their children. An estimated 50% of ADPKD patients progress to end-stage kidney disease and require dialysis or a kidney transplant by 60 years of age despite current standard of care treatment.

About Bardoxolone

Bardoxolone is an experimental, oral, once-daily activator of Nrf2, a transcription factor that promotes the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling. The FDA has granted Orphan Drug designation in the United States 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. In addition to FALCON, bardoxolone is currently being studied in CARDINAL, a Phase 3 study for the treatment of CKD caused by Alport syndrome, CATALYST, a Phase 3 study for the treatment of connective tissue disease associated pulmonary arterial hypertension, AYAME, a Phase 3 study for the treatment of diabetic kidney disease being conducted in Japan by Reata's licensee, Kyowa Hakko Kirin Co. Ltd., and PHOENIX, a Phase 2 study of bardoxolone for the treatment of ADPKD, 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 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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