



## **REATA PHARMACEUTICALS PROVIDES UPDATE ON THE IMPACT OF THE COVID-19 PANDEMIC ON ITS CLINICAL STUDIES AND BUSINESS OPERATIONS**

***ONGOING TRIALS IN PATIENTS WITH PULMONARY ARTERIAL HYPERTENSION STOPPED DUE TO HIGH RISK OF COVID-19 TO THESE PATIENTS***

***SECOND YEAR OF PHASE 3 CARDINAL TRIAL CONTINUING AS PLANNED***

***ENROLLMENT OF NEW PATIENTS IN FALCON TRIAL TEMPORARILY PAUSED***

**PLANO, Texas—March 30, 2020**—Reata Pharmaceuticals, Inc. (Nasdaq: RETA), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of severe, life-threatening diseases, today provided an update on the impact of the COVID-19 pandemic on its clinical programs, drug supply chain, and business operations. The Company announced measures it is taking to protect the health and safety of patients and health care workers involved in ongoing clinical studies of its investigational medicines, as well as its employees and collaborators.

### **Clinical Programs**

Reata conducts clinical studies in many countries around the world that are being impacted by the COVID-19 pandemic. Regulatory agencies, governments, and health care providers have implemented restrictive measures designed to reduce potential exposure to the virus, particularly for patients at increased risk of severe illness. For each clinical development program, Reata is working with health care providers to implement changes that mitigate risk to patients; comply with regulatory, institutional, and government guidance; and maintain the integrity of our ongoing clinical studies.

- In consideration of the risk of severe, adverse outcomes associated with COVID-19 among patients with respiratory and autoimmune diseases, and after consultation with the study's Data Safety Monitoring Board (DSMB), the Company has decided to stop the Phase 3 CATALYST study of bardoxolone methyl (bardoxolone) in patients with connective tissue disease-associated pulmonary arterial hypertension (CTD-PAH). Patients with CTD-PAH have compromised cardiopulmonary function, are often receiving immunosuppressants, and are at an inherently high risk of adverse outcomes in the event of infection. The Company concluded that continued exposure of these high-risk patients to clinic or in-person visits presented an unacceptable risk. The study is not being stopped as a result of any bardoxolone-related safety concern, and the DSMB has not reported any treatment-related safety concern. An initial review of CATALYST safety data provided by the DSMB suggests that bardoxolone was well-tolerated, with fewer patients discontinuing in the bardoxolone arm compared to the placebo arm. There were no deaths in the bardoxolone arm, and fewer patients reported serious adverse events in the bardoxolone arm compared to the placebo arm. While no futility analyses have been performed, an initial review of available efficacy data provided by the DSMB

suggests that the study is unlikely to meet the primary endpoint of improvement in six-minute walk distance compared to placebo at Week 24. After the data are formally analyzed, the Company will provide safety and efficacy data for CATALYST at a future medical meeting. Concomitant with the close of CATALYST, the Company is also closing RANGER, the open-label extension study of bardoxolone in patients with PAH.

- The Phase 3 CARDINAL trial of bardoxolone in patients with CKD caused by Alport syndrome is fully enrolled and ongoing. During the fourth calendar quarter of last year, the Company reported significant improvements in on- and off-treatment estimated glomerular filtration rate (eGFR) after one year of treatment, which are the primary and key secondary endpoints of the study. After one year of treatment, patients were restarted on the study drug and are continuing for a second year. The Company has implemented the use of at-home visits to collect blood draws and to assess safety as an alternative to in-clinic visits when necessary. The Company has also made arrangements for home delivery of the study drug to patients. At this time, the Company does not believe that the COVID-19 pandemic will have a significant impact on its ability to complete the study or execute on its planned NDA submission for CARDINAL. Patients who participated in the CARDINAL study are eligible to enroll in an open-label extension study known as EAGLE. The Company is implementing procedures for the conduct of EAGLE that are similar to those being using in CARDINAL to ensure continued access to bardoxolone and appropriate safety monitoring.
- The Company has temporarily paused enrollment of new patients in the Phase 3 FALCON trial of bardoxolone in patients with autosomal dominant polycystic kidney disease (ADPKD). Patients already enrolled in FALCON will continue in the study. The Company is implementing procedures for the conduct of FALCON that are similar to those being used in CARDINAL to ensure continued access to study drug and appropriate safety monitoring. The Company plans to resume patient screening and enrollment as soon as the situation permits.
- The MOXle Part 2 trial of omaveloxolone in patients with Friedreich's ataxia (FA) was completed prior to the onset of the COVID-19 threat. At this time, the Company does not believe that the COVID-19 pandemic will have a significant impact on its ability to execute on its planned NDA submission for omaveloxolone in FA. Patients who participated in MOXle Part 1 or 2 were eligible to enroll in an open-label extension portion of the study. The Company is implementing procedures for the conduct of the MOXIE extension that are similar to those being used in our other ongoing studies to ensure continued access to omaveloxolone and appropriate safety monitoring.



## **Drug Supply Chain**

Reata's current inventory of investigational product is adequate to support its ongoing clinical trials. Based on current evaluations, the Company believes that its supply chains are adequate to meet its 2020 clinical, nonclinical, and chemistry, manufacturing and control supply demands across all programs. The Company is alert to the potential for disruptions that could arise from COVID-19 and remains in close contact with suppliers.

## **Business Operations**

In accordance with recommendations from local, state, and national health authorities, Reata has implemented work-from-home measures and additional safety protocols to protect employees and the broader community and to ensure business continuity. The Company has restricted on-site staff to only those required to execute their job responsibilities and limited the number of staff working in its research and development laboratory. The Company has suspended all in-person meetings and international travel, and it has sharply limited travel within the United States. Reata has also suspended attendance at medical congresses, conferences, and other large events. The Company continues to monitor this dynamic situation closely, and it will take additional measures as required to preserve the safety of its employees and broader community.

"The COVID-19 pandemic presents an unprecedented threat to public health," said Warren Huff, Reata's Chief Executive Officer and President. "The adjustments we have made to our studies reflect our foremost concern for the safety and well-being of study participants, clinical investigators and their site staffs, our employees and communities as we face this challenging and unpredictable operating environment. We will continue to monitor and make adjustments, if needed, as we navigate this highly fluid landscape."

## **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. **Bardoxolone and omaveloxolone are investigational drugs, and their safety and efficacy have not been established by any agency.**

## **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, our plans to submit regulatory filings, 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,” “model,” 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) whether regulatory authorities determine that additional trials or data are necessary in order to obtain approval; (iv) 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 (v) 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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