



## **REATA PHARMACEUTICALS ANNOUNCES THREE MONTH EXTENSION OF THE REVIEW PERIOD FOR NEW DRUG APPLICATION FOR OMAVELOXOLONE FOR THE TREATMENT OF FRIEDREICH'S ATAXIA**

***REATA SUBMITTED NEW DATA AND ANALYSES TO ADDRESS FDA QUESTIONS DURING MID-CYCLE MEETING***

***FDA EXTENDED PDUFA DATE TO PROVIDE TIME FOR FULL REVIEW OF NEW SUBMISSIONS***

***PDUFA DATE EXTENDED TO FEBRUARY 28, 2023***

**PLANO, Texas—August 9, 2022 (BUSINESS WIRE)—**[Reata Pharmaceuticals, Inc.](https://www.reatapharma.com) (Nasdaq: RETA) ("Reata," the "Company," "our," "us," or "we"), a clinical-stage biopharmaceutical company, announced that on August 8, 2022, after the U.S. financial markets closed, we received a communication from the U.S. Food and Drug Administration ("FDA") informing us that they have extended the review timeline for the New Drug Application ("NDA") for omarveloxolone for the treatment of Friedreich's ataxia by three months.

We recently submitted an updated Delayed-Start Analysis of the MOXIe Extension study using a March 2022 data cut-off, a new Propensity-Matched Analysis of MOXIe Extension data using patient data from the Clinical Outcome Measures in Friedreich's Ataxia Study ("FA-COMS") as controls, and an analysis of the relevance of Nrf2, the target of omarveloxolone, to the pathophysiology of Friedreich's Ataxia. These submissions were provided as confirmatory evidence of the results of the MOXIe Part 2 study in response to concerns raised by the FDA during the mid-cycle communication meeting. FDA determined that these submissions were a major amendment to our NDA and extended the Prescription Drug User Fee Act ("PDUFA") date to provide time for a full review of the new data and analyses. The updated PDUFA date for the application is February 28, 2023. The FDA put the planned advisory committee meeting on hold pending review of the new NDA amendments.

"We are pleased with the FDA's decision to review the new information we recently provided to the Division," said Warren Huff, Reata's Chief Executive Officer. "We remain committed to our goal of working with the FDA to secure regulatory approval for omarveloxolone as quickly as possible for patients with this severe disease that has no approved therapies."

### **About Omarveloxolone**

Omarveloxolone is an investigational, 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 Drug, Fast Track, and Rare Pediatric Disease Designations to omarveloxolone for the treatment of Friedreich's ataxia. The European Commission has granted



Orphan Drug designation in Europe to omaveloxolone for the treatment of Friedreich's ataxia. An NDA for omaveloxolone for the treatment of Friedreich's ataxia is currently under review by the FDA.

#### **About Reata**

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, omaveloxolone and bardoxolone methyl ("bardoxolone"), target the important transcription factor Nrf2 that promotes the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling. **Omaveloxolone and bardoxolone 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 for the fiscal year ended December 31, 2021, 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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