



## **REATA ANNOUNCES TOP-LINE DATA FROM THE DOSE-ESCALATION COHORTS OF THE PHASE 2 MOTOR STUDY OF OMAVELOXOLONE IN PATIENTS WITH MITOCHONDRIAL MYOPATHIES**

**IRVING, Texas—March 1<sup>st</sup>, 2018**—Reata Pharmaceuticals, Inc. (Nasdaq:RETA) (Reata or Company), a clinical-stage biopharmaceutical company, today announced top-line data from the dose-escalation cohorts of the Phase 2 MOTOR trial of omaveloxolone for the treatment of patients with mitochondrial myopathies. This 12-week, exploratory, dose-ranging trial enrolled 53 patients across six dose levels. The purpose of the first-in-patient MOTOR trial was to evaluate initial safety, efficacy, pharmacokinetics, and pharmacodynamics of omaveloxolone in this patient population.

The sample size of six to ten patients randomized to omaveloxolone and two to three randomized to placebo for safety controls at each dose level was based upon a traditional dose-escalation design. The small number of patients at each dose was not expected to fully characterize safety, efficacy, or pharmacodynamics, but rather to inform the data safety monitoring board and Reata of the appropriate dose to select for future study. The optimal dose of omaveloxolone associated with robust Nrf2 induction and improvement in markers of mitochondrial function was determined to be 160 mg. At this dose, significant, placebo-corrected improvements were noted in Nrf2 biomarkers.

Clinical activity was assessed under maximal and submaximal conditions. The maximal exercise and 6-minute walk tests were used to determine peak workload and 6-minute walk distance, which reflect exercise capacity during maximal exertion. The submaximal exercise test measured mitochondrial function under submaximal conditions that reflect exertion levels during normal activities of daily living. Heart rate and blood lactate levels increase as mitochondrial function and aerobic capacity are depleted, and these were the two key parameters that were assessed during the submaximal exercise test.

Clinical activity was observed during submaximal but not maximal exercise testing. Omaveloxolone did not improve peak work or 6-minute walk distance versus placebo, which were the primary and secondary endpoints of the trial. However, in the submaximal exercise test, which is a more sensitive assessment of mitochondrial function, a significant lowering of heart rate and blood lactate levels versus placebo was observed. At Week 12, patients treated with 160 mg of omaveloxolone demonstrated a placebo-corrected reduction in heart rate of 12.0 beats per minute ( $p=0.01$ ) and blood lactate of 1.3 mM ( $p=0.04$ ) at the end of the test (omaveloxolone,  $n=10$ ; placebo,  $n=13$ ). The decrease in heart rate and lactate levels produced by omaveloxolone are indicative of improved mitochondrial function.

The trial was overseen by an independent data safety monitoring board, which identified no safety concerns.

“In patients with mitochondrial disease, an important goal of interventional therapy is lowering perceived effort during every day activities of daily living,” said Professor John Vissing, M.D., DMSci, Director, Neuromuscular Clinic and Research Unit at the University of Copenhagen. “By improving oxidative capacity, omaveloxolone lowered heart rate during submaximal exercise, which is a major achievement towards this goal. Likewise, lowering lactate production



with omaveloxolone treatment reflects better mitochondrial function, which supports further investigation of omaveloxolone for treatment of patients with mitochondrial diseases.”

### **About Omaveloxolone**

Omaveloxolone 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 omaveloxolone for the treatment of Friedreich’s ataxia.

### **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 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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