# REATA ANNOUNCES POSITIVE TOPLINE RESULTS FROM THE MOXIE REGISTRATIONAL TRIAL OF OMAVELOXOLONE IN PATIENTS WITH FRIEDREICH'S ATAXIA

***ACHIEVED PRIMARY ENDPOINT OF STATISTICALLY SIGNIFICANT IMPROVEMENT IN MFARS COMPARED TO PLACEBO AFTER 48 WEEKS OF TREATMENT***

***CONFERENCE CALL WITH MANAGEMENT SCHEDULED FOR OCTOBER 15, 2019, AT 8:00 AM ET***

**IRVING, Texas—October 14, 2019**—Reata Pharmaceuticals, Inc. (Nasdaq: RETA), a clinical-stage biopharmaceutical company, announced today that the registrational Part 2 portion of the MOXIe Phase 2 trial of omaveloxolone in patients with Friedreich's ataxia (FA) met its primary endpoint of change in the modified Friedreich's Ataxia Rating Scale (mFARS) relative to placebo after 48 weeks of treatment. Patients treated with omaveloxolone (150 mg/day) demonstrated a statistically significant, placebo-corrected 2.40 point improvement in mFARS after 48 weeks of treatment (p=0.014). Omaveloxolone treatment was generally reported to be well-tolerated. Based on these positive results, and subject to discussions with regulatory authorities, the company plans to proceed with the submission of regulatory filings for marketing approval in the United States and internationally.

"The results of MOXIe represent a truly historic moment for the patients, families, and caregivers that comprise the Friedreich's ataxia community," said Ronald Bartek, President of the Friedreich's Ataxia Research Alliance (FARA). "Based on the results reported today for omaveloxolone, we are hopeful that our community will finally have its first approved therapy that can slow this relentlessly progressive disease. We are extremely proud of, and grateful for, the FA community including all those who have participated in this clinical trial and in the natural history study important in designing the trial. We are also grateful to the clinical teams who conducted the trial and to our Reata colleagues. We look forward to continuing the Reata-FARA partnership as we work in pursuit of approval of the first FA therapy."

"Patients living with Friedreich's ataxia experience a devastating and progressive loss of neurological function. The MOXIe trial with omaveloxolone is the first study to demonstrate a significant improvement in neurological function in patients with FA. We believe that the MOXIe findings announced today bring us closer to our goal of providing an urgently needed therapy to patients with FA," said Warren Huff, President and Chief Executive Officer of Reata. "On behalf of everyone at Reata, I would like to express my sincere appreciation to all of the patients, families, and investigators who participated in the MOXIe study."

Full MOXIe study results will be presented at a future medical meeting.

**Trial Overview and Results**

Part 2 of MOXIe, an international, multi-center, double-blind, placebo-controlled, randomized registrational Phase 2 trial, enrolled 103 patients with FA at 11 study sites in the United States, Europe, and Australia and is the largest global, interventional study ever conducted in FA. Patients were randomized 1:1 to 150 mg of omaveloxolone or placebo. The primary analysis population included patients without *pes cavus* (n=82), a musculoskeletal foot deformity that may interfere with the patient's ability to perform some components of the mFARS exam. Safety analyses were evaluated in the all randomized population (n=103).

The primary endpoint for the study was change in the mFARS score relative to placebo after 48 weeks of treatment. The mFARS is a physician-assessed neurological rating scale used to measure FA disease progression. It includes four sections that measure the patient's performance of activities such as speaking and swallowing, upper limb coordination, lower limb coordination, and standing and walking. The United States Food and Drug Administration (FDA) has indicated that mFARS is an acceptable primary endpoint to evaluate the effect of omaveloxolone for the treatment of patients with FA.

Omaveloxolone treatment met the primary endpoint of the study producing a statistically significant, placebo-corrected 2.40 point improvement (decrease) in mFARS (n=82; p=0.014). Patients treated with omaveloxolone experienced a mean improvement in mFARS of -1.55 points from baseline, while patients treated with placebo experienced a mean worsening in mFARS of +0.85 points from baseline. The observed placebo-corrected improvements in mFARS were time-dependent, increasing over the course of treatment with the largest improvement observed after 48 weeks of treatment.

Omaveloxolone treatment also improved the mFARS scores of patients with *pes cavus*. When the *pes cavus* patients are included in the analysis of the mFARS scores at Week 48 (the all randomized population), omaveloxolone treatment produced a mean statistically significant, placebo-corrected 1.93 point improvement in mFARS (n=103; p=0.034). Omaveloxolone treatment also improved several secondary endpoints included in the study.

Omaveloxolone was generally reported to be well tolerated in this study. Four (8%) omaveloxolone patients and two (4%) placebo patients discontinued study drug due to an adverse event (AE). The reported AEs were generally mild to moderate in intensity, and the most common AEs (> 20%) observed more frequently compared to placebo were headache, nausea, increased aminotransferases, fatigue, and abdominal pain. Increases in aminotransferases are a pharmacological effect of omaveloxolone, which increases production of aminotransferases *in vitro*, and we believe are related to restoration of mitochondrial function. In MOXIe, the aminotransferase increases were associated with improvements (reductions) in total bilirubin and were not associated with liver injury. The overall rate of serious adverse events (SAEs) was low, with three patients in each group reporting SAEs while receiving study drug. Two additional omaveloxolone-treated patients reported SAEs approximately two weeks after receiving their final dose.

Reata management will host a call to discuss these results tomorrow, October, 15, 2019 at 8:00 a.m. ET.

**CONFERENCE CALL INFORMATION**

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| Date: | 10/15/2019 |
| Time: | 08:00 Eastern Time |
| Audience Dial-in (toll-free): | (844) 348-3946 |
| Audience Dial-in (international): | (213) 358-0892 |
| Conference ID: | 8653916 |
| Webcast Link: | https://edge.media-server.com/mmc/p/r87cj2nt |

This press release and the management slide presentation for the call will be available on Reata's website shortly before the call at http://reatapharma.com/investors/ and will be available for 12 months after the call. The audio recording and webcast of the call will be accessible for at least 90 days after the call at http://reatapharma.com/investors/.

**About Friedreich's Ataxia**

FA is an inherited, debilitating, and degenerative neuromuscular disorder that is typically diagnosed during adolescence and can ultimately lead to premature death. Patients with FA experience progressive loss of coordination, muscle weakness, and fatigue, which commonly progresses to motor incapacitation and wheelchair reliance. Symptoms generally occur in children, with patients requiring a wheelchair by their teens or early '20s. FA affects approximately 5,000 children and adults in the United States and 22,000 globally. Currently, there are no treatments approved by the FDA for FA.

**About Omaveloxolone**

Omaveloxolone is an experimental, oral, once-daily activator of Nrf2, a transcription factor that induces molecular pathways that promote restoration of mitochondrial function, reduction of oxidative stress, and inhibition of pro-inflammatory signaling. The FDA and the European Commission have granted orphan drug 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 (bardoxolone) and omaveloxolone, target the important transcription factor Nrf2 that promotes restoration of mitochondrial function, reduction of oxidative stress, and inhibition of 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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