Reata Announces Publication of Results From Pivotal Moxie Trial of Omaveloxolone in Patients with Friedreich’s Ataxia

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MOXIe was a randomized, double-blind, placebo-controlled study, and patients with genetically confirmed FA and baseline modified Friedreich’s Ataxia Rating Scale (mFARS) scores between 20 and 80 were randomized 1:1 to receive placebo or 150 mg of omaveloxolone daily. The primary endpoint was change from baseline in mFARS score at 48 weeks. Patients treated with omaveloxolone experienced a statistically significant, placebo-corrected mean improvement in mFARS of 2.40 points after 48 weeks of treatment (p=0.014). Omaveloxolone was generally reported to be well tolerated in this study.

The publication entitled “Safety and Efficacy of Omaveloxolone in Friedreich’s Ataxia (MOXIe Study)” can be accessed online at https://doi.org/10.1002/ana.25934.

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 U.S. Food and Drug Administration (“FDA”) for FA.

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 and the European Commission have granted orphan drug designation to omaveloxolone for the treatment of FA.

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 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.

Contact:
Reata Pharmaceuticals, Inc.
(972) 865-2219
https://www.reatapharma.com/contact-us/

Investor Relations:
Vinny Jindal
Vice President, Investor Relations and Corporate Communications
(469) 374-8721
ir@reatapharma.com
https://www.reatapharma.com/