Reata Pharmaceuticals Initiates Rolling Submission of New Drug Application with U.S. FDA for Omaveloxolone for the Treatment of Patients with Friedreich’s Ataxia

Plans to Complete Submission by the End of the First Quarter of 2022

If approved, Omaveloxolone would become the first therapy indicated for the treatment of patients with Friedreich’s Ataxia

Plano, Texas—January 31, 2022 (Business Wire)—Reata Pharmaceuticals, Inc. (Nasdaq: RETA), (“Reata,” the “Company,” “our,” “us,” or “we”), a clinical-stage biopharmaceutical company, today announced that the company has initiated a rolling submission of a New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for omaveloxolone for the treatment of patients with Friedreich’s ataxia. The rolling submission allows Reata to submit portions of the regulatory application to the FDA for review on an ongoing basis. The company reiterates that it expects to complete the submission of the NDA by the end of the first quarter of 2022.

“Today’s announcement marks an important milestone in our efforts to advance the first therapy for patients with Friedreich’s ataxia, a serious and devastating disease,” said Warren Huff, Reata’s President and Chief Executive Officer. “I want to thank all the patients, families, and investigators who participated in the MOXiLe trial and the extension phase of the study. We appreciate the FDA’s recognition of the potential of omaveloxolone for patients with Friedreich’s ataxia through its Fast Track Designation and guidance on the contents of the NDA.”

About Friedreich’s Ataxia

Friedreich’s ataxia is a rare, genetic, life-shortening, debilitating, and degenerative neuromuscular disorder, which is normally diagnosed during adolescence. Friedreich’s ataxia is caused by a trinucleotide repeat expansion in the first intron of the frataxin gene, which encodes the mitochondrial protein frataxin. Pathogenic repeat expansions can lead to impaired transcription and reduced frataxin expression, which can result in mitochondrial iron overload and poor cellular iron regulation, increased sensitivity to oxidative stress, and impaired mitochondrial ATP production. Patients with Friedreich’s ataxia experience symptoms in childhood, including progressive loss of coordination, muscle weakness, and fatigue that commonly results in motor incapacitation with patients requiring a wheelchair in their teens or early 20s. Patients with Friedreich’s ataxia may also experience visual impairment, hearing loss, diabetes, and cardiomyopathy. Based on literature and proprietary research, we believe Friedreich’s ataxia affects approximately 5,000 children and adults in the United States and 22,000 individuals globally. There are currently no approved therapies for the treatment of patients with Friedreich’s ataxia.
About Omaveloxolone

Omaveloxolone 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 and Fast Track Designations to omaveloxolone 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.

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, 2020, 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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