# REATA ANNOUNCES THAT THE FDA HAS ASKED THE COMPANY TO REQUEST A PRE-NDA MEETING FOR OMAVELOXOLONE FOR THE TREATMENT OF FRIEDREICH'S ATAXIA

**PLANO, Texas—May 19, 2021 (GLOBE NEWSWIRE)—**Reata Pharmaceuticals, Inc. (Nasdaq: RETA) ("Reata," the "Company," or "we"), a clinical-stage biopharmaceutical company, today announced that it received a communication from the Division of Neurology Products 1 ("Division") of the U.S. Food and Drug Administration ("FDA") stating that, after a preliminary review of briefing materials for an upcoming Type C meeting, a pre-NDA meeting is the most appropriate format for a discussion of the development program for omaveloxolone in Friedreich's ataxia ("FA"). The Division suggested that the Company withdraw the current meeting request for a Type C meeting and instead request a pre-NDA meeting, which the Division will grant upon receipt. The Division asked the Company to focus the new briefing package on questions, issues, and needs applicable to a pre-NDA meeting. As requested by the FDA, the Company plans to withdraw the current request for a Type C meeting and submit a request for a pre-NDA meeting as soon as practicable.

"We welcome the opportunity to have a pre-NDA meeting regarding our omaveloxolone development program for the treatment of patients with FA," said Warren Huff, Reata's President and Chief Executive Officer. "We look forward to working with the FDA on our goal of securing the regulatory review and approval necessary to make omaveloxolone available to patients with FA."

**About Friedreich's Ataxia**

FA is a rare, inherited, life-shortening, debilitating, and degenerative neuromuscular disorder, which is normally diagnosed during adolescence. FA is typically 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 lead to mitochondrial iron overload and poor cellular iron regulation, increased sensitivity to oxidative stress, and impaired mitochondrial ATP production. Patients with FA experience initial symptoms in childhood, including progressive loss of coordination, muscle weakness, and fatigue, commonly resulting in motor incapacitation, with patients requiring a wheelchair by their teens or early 20s. FA patients may also experience visual impairment, hearing loss, diabetes, and cardiomyopathy. Based on literature and proprietary research, we believe FA 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 FA.

**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 designation 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 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. Reata possesses exclusive, worldwide rights to develop, manufacture, and commercialize omaveloxolone, and our other next-generation Nrf2 activators. **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 the detailed factors discussed under the caption "Risk Factors." in its Annual Report on Form 10-K for the fiscal year ended December 31, 2020. 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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