



REATA PHARMACEUTICALS PLANS NDA SUBMISSION FOR OMAVELOXOLONE IN FIRST QUARTER OF 2022 FOLLOWING COMPLETION OF PRE-NDA MEETING WITH FDA

APPROXIMATELY 5,000 CHILDREN AND ADULTS IN THE UNITED STATES AND 22,000 GLOBALLY ARE AFFECTED WITH FRIEDREICH'S ATAXIA, A LIFE-THREATENING DISEASE WITH NO APPROVED THERAPIES

PLANO, Texas—September 30, 2021 (BUSINESS WIRE)—[Reata Pharmaceuticals, Inc.](https://www.reata.com) (Nasdaq: RETA) (“Reata,” the “Company,” or “we”), a clinical-stage biopharmaceutical company, today announced that it has completed its pre-New Drug Application (“NDA”) meeting with the United States Food and Drug Administration (“FDA”) for omarveloxolone for the treatment of patients with Friedreich’s ataxia and reaffirmed its plan to submit an NDA in the first quarter of 2022.

The purpose of the pre-NDA meeting was to discuss the content of Reata’s planned NDA submission. We plan to submit the NDA seeking standard approval for omarveloxolone for the treatment of Friedreich’s ataxia. We are not planning to conduct a second pre-approval clinical study prior to the submission. The FDA indicated that the appropriate approval pathway would be a matter of review after submission of the NDA. In response to our questions about the contents of the filing and because of the seriousness of the indication, the FDA exercised its discretion subject to review to permit us to submit the results of certain nonclinical and clinical studies after approval.

“We are pleased with the outcome of our recent pre-NDA meeting and that we have a path to submit our NDA in the first quarter of 2022,” said Warren Huff, Reata’s President and Chief Executive Officer. “Friedreich’s ataxia is a severe, ultra-rare disease that affects approximately 5,000 patients in the United States. We remain committed to our goal of working with the FDA to secure regulatory approval for omarveloxolone as quickly as possible for patients with this devastating disease.”

“Omarveloxolone could be the first drug approved for the treatment of Friedreich’s ataxia—actually the first drug approved for any ataxia,” said Dr. Susan Perlman, MD, Professor, Department of Neurology, David Geffen School of Medicine, University of California, Los Angeles, CA. “The MOXIe Part 2 study with omarveloxolone is the first to demonstrate a significant improvement in neurological function in patients with Friedreich’s ataxia. While not a cure, if approved, Friedreich’s ataxia would finally become a treatable disease, something the Friedreich’s ataxia community has been working towards for a long time.”

About Friedreich's Ataxia

Friedreich’s ataxia is a rare, inherited, 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 resulting in motor incapacitation with patients requiring a wheelchair by 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 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. We possess exclusive, worldwide rights to develop, manufacture, and commercialize bardoxolone, omaveloxolone, and our next-generation Nrf2 activators, excluding certain Asian markets for bardoxolone in certain indications, which are licensed to Kyowa Kirin Co., Ltd. ("KKC"). **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/>

Investor Relations & Media:

Manmeet Soni
Andres Lorente
ir@reatapharma.com
media@reatapharma.com
<https://www.reatapharma.com/contact-us/>