



## **REATA RECEIVES ORPHAN DRUG DESIGNATION FROM THE EUROPEAN COMMISSION FOR OMAVELOXOLONE FOR THE TREATMENT OF FRIEDREICH'S ATAXIA**

**IRVING, Texas—July 10, 2018**—Reata Pharmaceuticals, Inc. (Nasdaq:RETA), a clinical-stage biopharmaceutical company, today announced that the European Commission has granted orphan drug designation for omaveloxolone for the treatment of Friedreich's ataxia (FA), based on the positive opinion from the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA).

FA is an inherited, debilitating, and degenerative neuromuscular disorder that is typically diagnosed during adolescence and can ultimately lead to early death. Patients with FA experience progressive loss of coordination, muscle weakness, and fatigue that commonly progresses to motor incapacitation and wheelchair reliance. FA affects approximately 6,000 children and adults in the United States and 22,000 globally. Currently, there are no drugs approved for the treatment of FA.

Last year, Reata reported results from part 1 of MOXle, a two-part, international, multi-center, randomized, double-blind, placebo-controlled Phase 2 trial studying the safety and efficacy of omaveloxolone in patients with FA. Treatment of FA patients with omaveloxolone produced dose- and time-dependent improvements in their modified Friedreich's Ataxia Rating Scale (mFARS) scores, which are a measure of the neurologic function of FA patients. Reata is currently enrolling approximately 100 FA patients in the registrational part 2 portion of MOXle and expects to have results in the second half of 2019.

"Orphan drug designation from the EMA is an important recognition of the potential for omaveloxolone to become the first approved therapy for patients affected by this devastating disease," said Warren Huff, Reata's President and Chief Executive Officer.

In Europe, orphan drug designation is granted to therapies intended for the treatment of life-threatening or chronically debilitating diseases that affect no more than five in 10,000 people in the European Union and for which no satisfactory treatments are available, or where the new therapy has the potential to be a significant benefit to those affected by the disease. Orphan designation provides specific financial and regulatory incentives, including reduced fees, protocol assistance, access to the centralized authorization procedure, and ten years of market exclusivity once the drug is approved.

### **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 United States Food and Drug Administration has granted orphan 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 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.

## **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, 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," 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) 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 (iv) 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  
[info@reatapharma.com](mailto:info@reatapharma.com)  
<http://news.reatapharma.com>

### **Investor Relations:**

Vinny Jindal  
Vice President, Strategy  
(469) 374-8721  
[ir@reatapharma.com](mailto:ir@reatapharma.com)

### **Media:**

Matt Middleman, M.D.  
LifeSci Public Relations  
(646) 627-8384  
[matt.middleman@lifescipublicrelations.com](mailto:matt.middleman@lifescipublicrelations.com)