Reata Pharmaceuticals' bardoxolone methyl receives FDA Orphan Drug Designation in Pulmonary Arterial Hypertension

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IRVING, TX – April 10, 2015– Reata Pharmaceuticals, Inc., a biopharmaceutical company dedicated to the development of breakthrough medicines for difficult-to-treat diseases, today announced that the FDA Office of Orphan Products Development (OOPD) has granted orphan drug designation for bardoxolone methyl for the treatment of pulmonary arterial hypertension. **Pulmonary arterial hypertension** (PAH) is a life-threatening disease involving endothelial dysfunction, pulmonary vasoconstriction, vascular remodeling, pulmonary fibrosis, and right ventricular hypertrophy. Additionally, PAH involves skeletal muscle dysfunction that contributes to the exercise intolerance observed in PAH patients. In preclinical studies, bardoxolone methyl has demonstrated potent antioxidant, anti-inflammatory, and bioenergetic properties, which may lead to improved exercise tolerance in patients.

"Pulmonary arterial hypertension is a devastating disease for patients and significantly decreases their quality of life and lifespan. The FDA's decision to grant orphan designation is an important step in the development of bardoxolone methyl to potentially treat this population with high unmet need," said Colin Meyer, MD, Chief Medical Officer of Reata. "We believe the novel mechanism of activating Nrf2 has profound bioenergetic effects which have the potential to meaningfully impact the course of disease."

Bardoxolone methyl is currently being evaluated in the LARIAT study, a Phase 2 dose-ranging study examining the safety, tolerability and efficacy of bardoxolone methyl in patients with PAH. LARIAT is a multi-center, double-blind, randomized, dose-ranging, placebo-controlled study. The primary efficacy endpoint is a six minute walk test. For more information on this study, visit: http://clinicaltrials.gov/show/NCT02036970.

The Orphan Drug Designation program provides orphan status to novel drugs or biologics that are intended to treat a rare disease or condition affecting fewer than 200,000 patients in the US. There are several benefits of the orphan designation, including seven years of market exclusivity, tax credits for clinical research costs, and waiver or partial payment of application fees. Orphan Drug Designation does not alter the standard regulatory requirements for obtaining marketing approval.

About Reata Pharmaceuticals

Reata Pharmaceuticals, Inc. translates innovative research into breakthrough medicines to create options for patients with rare and difficult to treat diseases. Reata's lead drugs are called antioxidant inflammation modulators (AIMs). AIMs are potent activators of the transcription factor Nrf2 and potent inhibitors of the transcription factor NF-κB. Through this pharmacology, AIMs have cytoprotective and anti-inflammatory effects, and they promote increased cellular energy production by restoring mitochondrial function.

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