Reata Enrolls First Patient in the MOXIe Study, a Phase 2/3 Study Examining RTA 408 in Friedreich's Ataxia Patients

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IRVING, Texas, January 29, 2015 – Reata announces enrollment of the first patient in a Phase 2 dose-ranging study examining the safety, tolerability, and efficacy of RTA 408 Oral Capsules versus placebo for the treatment of patients with Friedreich's ataxia.

MOXIe (A two-part, randomized, placebo-controlled Phase 2/3 Study of the Safety, Efficacy, and Pharmacodynamics of RTA 408 in the Treatment of Friedreich's Ataxia) is a multi-center study in approximately 52 patients and is designed to support a potential NDA submission. Part 1 of the study is a randomized, placebo-controlled, double-blind, dose-escalation study to evaluate the safety of RTA 408 at 2.5 mg, 5 mg, and 10 mg in patients with Friedreich's ataxia. Part 2 of the study is a randomized, placebo-controlled, double-blind, parallel-group study to evaluate the safety, efficacy, and pharmacodynamics of up to 2 dose levels of RTA 408. The study is designed to evaluate a variety of clinical, and biochemical endpoints, including exercise capacity and quality of life measures.

Friedreich's ataxia (FA) is an inherited disorder caused by defects in the gene for frataxin, a protein that regulates iron levels in the mitochondria. Defects in frataxin result in mitochondrial iron overload, causing impaired metabolism, oxidative stress, and damage to mitochondrial DNA. Patients with FA suffer progressive degeneration of the central and peripheral nervous systems, impaired motion and gait, and eventually may develop cardiomyopathy and diabetes. FA patients have substantially lowered quality of life, with most becoming wheelchair bound by their mid-20s and surviving only into their 30s. Approximately 20,000 people in the US and Europe have FA. There are currently no approved therapies for FA.

"Our large body of preclinical and clinical data with RTA 408 and related molecules provides strong support for the hypothesis being tested in MOXIe that RTA 408 may be beneficial in patients suffering from Friedreich's ataxia", noted Dr. Colin Meyer, Reata's Chief Medical Officer. "We have been productively collaborating with key FA clinicians and patient advocacy, and we look forward to evaluating the results of MOXIe as they become available".

For more information on this study, visit: https://clinicaltrial.gov/ct2/show/NCT02255435.

About RTA 408 and Bioenergetic Effects

In preclinical studies, RTA 408 and analogs have been shown to improve cellular bioenergetics. Mouse models have demonstrated that frataxin deficiency is correlated to lower expressions of the transcription factor Nrf2 and lower mitochondrial function (http://www.ncbi.nlm.nih.gov/pubmed/23350650). RTA 408 directly activates the body's anti-oxidative pathways through Nrf2 and may be able to improve mitochondrial function. In mouse models, RTA 408 and analogs demonstrated the ability to increase glucose uptake, fatty oxidation, and oxygen consumption – direct signs of healthier cellular metabolism (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3003357).

About Reata Pharmaceuticals, Inc.

Reata Pharmaceuticals, Inc. is a privately held company aiming to translate innovative research into breakthrough medicines for difficult diseases that have significant unmet needs. Reata is the leader in developing a novel class of drugs with potent transcription-regulating activity, called antioxidant inflammation modulators (AIMs). AIMs activate Nrf2, promoting the production of numerous antioxidant, detoxification, and anti-inflammatory genes, and inhibit NF-κB, a gene that regulates many pro-inflammatory proteins. The pharmacology of the AIMs mimics that of endogenous prostaglandin metabolites that are responsible for the orchestrated resolution of inflammation. The anti-inflammatory, cytoprotective and energy metabolism effects of AIM pharmacology have been documented in more than 250 scientific papers and are potentially relevant to a wide range of diseases.

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