Reata Pharmaceuticals Announces the Activation of an Investigational New Drug Application for Bardoxolone Methyl and Commencement of Clinical Program in Pulmonary Arterial Hypertension

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IRVING, Texas, November 26, 2013 – Reata Pharmaceuticals, Inc., announced today the activation of an Investigational New Drug application (IND) filed with the U.S. Food and Drug Administration (FDA) Division of Cardiovascular and Renal Products for the study of bardoxolone methyl in patients with pulmonary arterial hypertension (PAH).

Preclinical data demonstrate that bardoxolone methyl and related analogs reduce vascular inflammation, promote a vasodilatory phenotype, and reduce vascular remodeling through anti-proliferative and anti-fibrotic mechanisms. In addition, activation of the Nrf2 pathway has been shown to increase the efficient use of fuel (fatty acids and glucose) by mitochondria and increase energy production. In addition to its positive effects on metabolic efficiency, Nrf2 activation has also been shown to promote muscle repair and recovery and reduce markers of oxidative stress and muscle injury. Finally, analyses from the BEACON trial with bardoxolone methyl in late stage chronic kidney disease patients determined risk factors that were predictors of heart failure and fluid overload. These analyses were discussed with the FDA prior to submission of the IND, and patients with these specific risk factors will be excluded from future trials of bardoxolone methyl.

Reata plans to initiate a dose ranging Phase 2 study in PAH patients in Spring of 2014 to test the safety and efficacy of bardoxolone methyl in this patient population.

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 transcription factor 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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