Reata Pharmaceuticals, Inc. Announces Interim Data From Extension Phase 2 LARIAT Study in Pulmonary Arterial Hypertension

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IRVING, Texas, June 23, 2016 (GLOBE NEWSWIRE) -- Reata Pharmaceuticals, Inc. (Nasdaq:RETA) (“Reata”), a clinical-stage biopharmaceutical company, today announced interim data from the extension Phase 2 LARIAT trial of bardoxolone methyl for the treatment of pulmonary arterial hypertension (“PAH”).

The increase in six minute walk distance (“6MWD”) through 16 weeks of treatment that was previously reported was sustained through 32 weeks of treatment and was not significantly different from that at week 16 in the same set of patients. Bardoxolone methyl-treated patients with connective tissue disease (“CTD”)-associated PAH had similar sustained increases in 6MWD through week 32. Bardoxolone methyl was well-tolerated, and fewer adverse events were reported during the extension study than during the first 16 weeks of treatment.

"We are pleased that the interim data demonstrate that the clinically meaningful improvements in 6MWD noted through 16 weeks of treatment are sustained through 32 weeks of treatment," said Colin Meyer, M.D., Reata's Chief Medical Officer. "We are planning to submit the data to a scientific meeting and believe the available efficacy and safety data support the continued development of bardoxolone methyl in pulmonary hypertension.”

About Bardoxolone Methyl

Bardoxolone methyl is an experimental, oral once-daily antioxidant inflammation modulator (“AIM”) that has received orphan drug designation for the treatment of PAH by the U.S. Food and Drug Administration. Bardoxolone methyl targets the Nrf2 pathway, which controls the transcription of genes that increase cellular antioxidant content and anti-inflammatory mediators. Preclinical data suggest that activation of the Nrf2 pathway also regulates multiple genes that promote the production of cellular energy within the mitochondria and facilitates mitochondrial homeostasis and efficiency. Unlike therapies that primarily promote vasodilation, preclinical data suggest that bardoxolone methyl may directly target inflammation as well as mitochondrial dysfunction in PAH. Bardoxolone methyl and analogs have demonstrated activity in preclinical models of lupus and scleroderma, and these autoimmune conditions contribute to the second most common subtype of PAH, known as connective tissue disease-associated PAH. The available preclinical data suggest that bardoxolone methyl has the potential to impact multiple aspects of PAH pathology not significantly attenuated by current therapies.

About the LARIAT Study

LARIAT (A Dose-Ranging Study of the Efficacy and Safety of Bardoxolone Methyl in Patients with Pulmonary Hypertension) is a Phase 2 dose-ranging study examining the safety, tolerability, and efficacy of bardoxolone methyl in patients with PAH on stable background therapy. To determine if bardoxolone methyl could complement approved PAH therapies, the Phase 2 study was designed to assess efficacy through exercise capacity.

Patients were randomized 1:3 to receive once-daily placebo or bardoxolone methyl for 16 weeks. Patients were required to be stable on at least one approved PAH therapy. The primary efficacy variable, 6MWD, was collected at baseline and at every 4 weeks. Patients who completed the 16 week treatment period were allowed to enter an open-label, long-term extension phase of the study.

About Pulmonary Arterial Hypertension

Pulmonary arterial hypertension (“PAH”) is a life-threatening disease involving chronic fatigue, endothelial dysfunction, vasoconstriction in small pulmonary arteries, dysregulated proliferation of certain vascular cells, and dysregulated pro-inflammatory signaling leading to vascular remodeling, pulmonary fibrosis, and right ventricular hypertrophy. PAH affects an estimated 15,000-20,000 people in the United States, predominantly middle-aged women. Available treatments for PAH can provide symptomatic improvement, primarily by relieving vasoconstriction. However, even with existing treatments the disease continues to progress, and PAH has a high mortality rate with 60 to 80 percent of patients dying within five years of diagnosis. Consequently, there is a very high unmet clinical need for new therapies.

About Reata Pharmaceuticals, Inc.

Reata Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on identifying, developing, and commercializing product candidates that modulate the activity of key regulatory proteins involved in the biology of mitochondrial function, oxidative stress, and inflammation to address the unmet medical needs of patients with a variety of serious or life-threatening diseases. Reata focuses on drugs with novel mechanisms of action that modulate important regulatory proteins, called transcription factors, that coordinate the cellular response to stressors by activating or suppressing the activity of many target proteins.

Forward-Looking Statements

This press release includes certain disclosures which 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 are set forth in Reata’s filings with the SEC, including its registration statement on Form S-1, as amended from time to time, under the caption “Risk Factors.”

Contact:
Reata Pharmaceuticals, Inc.
(972) 865-2219
info@reatapharma.com
http://news.reatapharma.com

Investor Relations:
The Trout Group
Lee M. Stern, CFA
(646) 378-2922
IR@reatapharma.com

Reata Pharmaceuticals, Inc.