Fulcrum Announces Completion of Enrollment in the Phase 3 REACH Clinical Trial of Losmapimod in Facioscapulohumeral Muscular Dystrophy (FSHD)

September 7, 2023 at 8:01 AM EDT

Enrolled 260 patients; topline data expected in the fourth quarter of 2024

CAMBRIDGE, Mass., Sept. 07, 2023 (GLOBE NEWSWIRE) -- Fulcrum Therapeutics, Inc.® (Nasdaq: FULC), a clinical-stage biopharmaceutical company focused on improving the lives of patients with genetically defined rare diseases, today announced that it has completed enrollment in REACH, a Phase 3 clinical trial evaluating losmapimod in patients with FSHD at sites in the United States, Canada, and Europe.

"We are very pleased to have enrolled 260 patients in REACH, our global Phase 3 pivotal clinical trial for patients with FSHD," said Alex C. Sapir, Fulcrum's president and chief executive officer. "The rapid pace of enrollment is a testament to the high unmet need for a treatment option with potential to slow progression of this rare disease, for which there are currently no approved treatments. We expect to report topline data from REACH in the fourth quarter of 2024, bringing us one step closer to potentially delivering the first FDA-approved therapy for FSHD."

REACH is a Phase 3 multi-center, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of losmapimod for the treatment of FSHD. The trial enrolled 260 patients who were randomized 1:1 to receive either losmapimod, administered orally as a 15 mg tablet twice a day, or placebo, and will be evaluated over a 48-week treatment period. The primary endpoint of the study is the absolute change from baseline in Reachable Workspace (RWS). Secondary endpoints include muscle fat infiltration (MFI), Patient Global Impression of Change (PGIC), and Quality of Life in Neurological Disorders of the Upper Extremity (Neuro QoL UE). REACH also includes patient-centered assessments of healthcare utilization. More information about the study is available at ClinicalTrials.gov (NCT Number: NCT05397470).

About Losmapimod
Losmapimod is a selective p38α/β mitogen activated protein kinase (MAPK) inhibitor. Fulcrum exclusively in-licensed losmapimod from GSK following Fulcrum's discovery of the role of p38α/β inhibitors in the reduction of DUX4 expression and an extensive review of known compounds. Results reported from the Phase 2b ReDUX4 trial demonstrated slowed disease progression and improved function, including positive impacts on upper extremity strength and functional measures supporting losmapimod's potential to be a transformative therapy for the treatment of FSHD. Although losmapimod had never previously been explored in muscular dystrophies, it had been evaluated in more than 3,600 subjects in clinical trials across multiple other indications with no safety signals attributed to losmapimod. Losmapimod has been granted U.S. Food and Drug Administration (FDA) Fast Track designation and Orphan Drug Designation for the treatment of FSHD.

About FSHD
FSHD is a serious, rare, progressive and debilitating disease for which there are no approved treatments. It is characterized by fat infiltration of skeletal muscle leading to muscular atrophy involving primarily the face, scapula and shoulders, upper arms, and abdomen. Impact on patients includes relentless and accumulating muscle and functional loss impacting their ability to perform activities of daily living, loss of upper limb function, loss of mobility and independence, and chronic pain. FSHD is one of the most common forms of muscular dystrophy and has an estimated patient population of 16,000 to 38,000 in the United States alone.

About Fulcrum Therapeutics
Fulcrum Therapeutics is a clinical-stage biopharmaceutical company focused on improving the lives of patients with genetically defined rare diseases in areas of high unmet medical need. Fulcrum's two lead programs in clinical development are losmapimod, a small molecule for the treatment of facioscapulohumeral muscular dystrophy (FSHD), and pociredir, formerly FTX-6058, a small molecule designed to increase expression of fetal hemoglobin for the treatment of sickle cell disease (SCD) and other hemoglobinopathies. Fulcrum's proprietary product engine, FulcrumSeek™, identifies drug targets that can modulate gene expression to treat the known root cause of gene mis-expression. For more information, visit www.fulcrumtx.com and follow us on Twitter **@FulcrumTx** and **LinkedIn**.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, including express or implied statements regarding timing of REACH topline data; losmapimod's potential to slow progression of FSHD; the losmapimod clinical program and potential for FDA approval as a therapy for FSHD; among others. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with Fulcrum's ability to continue to advance its product candidates in clinical trials; initiating, enrolling and reporting data from clinical trials on the timeline expected or at all; obtaining and maintaining necessary approvals from the FDA and other regulatory authorities; replicating in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials; obtaining, maintaining or protecting intellectual property rights related to its product candidates; managing expenses; managing executive and employee turnover, including integrating a new CEO and CFO; and raising the substantial additional capital needed to achieve its business objectives, among others. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Fulcrum's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties, and other important factors, in Fulcrum's most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Fulcrum's views as of the date hereof and should not be relied upon as representing Fulcrum's views as of any date subsequent to the date hereof. Fulcrum anticipates that subsequent events and developments will cause Fulcrum's views to change. However, while Fulcrum may elect to update these forward-looking statements at some point in the future, Fulcrum specifically disclaims any obligation to do so.

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