Fulcrum Therapeutics Provides Business Update on Impact of COVID-19

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CAMBRIDGE, Mass., April 02, 2020 (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 provided a business update in the context of the developing situation with the COVID-19 (coronavirus) pandemic.

“During the unprecedented challenges we all face with the SARS-CoV-2 pandemic, we have recently implemented plans to protect the safety, health and well-being of the patients, families and healthcare professionals involved in our clinical development programs, as well as our employees,” said Robert J. Gould, Ph.D., Fulcrum’s president and chief executive officer. “A number of our clinical trial sites are temporarily postponing trial-related activities in the wake of COVID-19. While we are fully focused on moving our clinical programs forward, Fulcrum supports this temporary reallocation of resources to ensure hospitals and healthcare workers can focus on meeting the needs of patients with COVID-19. I am confident in Fulcrum’s ability to face this challenge with tenacity, humility, and spirit. FSHD is an area of tremendous unmet need, we remain as eager as ever to continue to advance a therapy that may impact patients.”

Losmapimod for Facioscapulohumeral Muscular Dystrophy (FSHD) Program Update

- The Company’s ReDUX4 trial is fully enrolled. As a result of the suspension of clinical-trial activity by a number of the Company’s clinical trial sites stemming from the pandemic, the Company is currently assessing the impact to the ReDUX4 clinical trial, including whether it will have topline data for the primary endpoint by the end of the third quarter of 2020 as previously disclosed. Fulcrum plans to provide a further update when it has more clarity. ReDUX4 is an international, multicenter, randomized, Phase 2b double-blind, placebo-controlled, 24-week trial of losmapimod in 80 patients with genetically confirmed facioscapulohumeral muscular dystrophy (FSHD).

Employee Safety

- Fulcrum has instituted a mandatory work-from-home policy for the majority of its employees. The duration of this remote working arrangement will be guided by the direction of the Commonwealth of Massachusetts and actions and guidelines issued by the U.S. federal government, including the Centers for Disease Control and Prevention.
- Due to the nature of Fulcrum’s work, essential-work exemptions continue to permit critical research and development and laboratory activities for limited personnel. Those exemptions enable some continued discovery research and activities. For these employees, Fulcrum has established a set of safety guidelines to reduce close interactions, including limiting the number of people on-site.

About FSHD
FSHD is characterized by progressive skeletal muscle loss that initially causes weakness in muscles in the face, shoulders, arms and trunk, and progresses to weakness throughout the lower body. Skeletal muscle weakness results in significant physical limitations, including an inability to smile and difficulty using arms for activities, with many patients ultimately becoming dependent upon the use of a wheelchair for daily mobility.

FSHD is caused by mis-expression of DUX4 in skeletal muscle, resulting in the presence of DUX4 proteins that are toxic to muscle tissue. Normally, DUX4-driven gene expression is limited to early embryonic development, after which time the DUX4 gene is silenced. In people with FSHD, the DUX4 gene is turned “on” as a result of a genetic mutation. The result is death of muscle and its replacement by fat, leading to skeletal muscle weakness and progressive disability. There are no approved therapies for FSHD, one of the most common forms of muscular dystrophy, with an estimated patient population of 16,000 to 38,000 in the United States alone.

About Losmapimod
Losmapimod is a selective p38α/β mitogen activated protein kinase (MAPK) inhibitor that was exclusively in-licensed from GSK by Fulcrum Therapeutics following Fulcrum’s discovery of the role of p38α/β inhibitors in the reduction of DUX4 expression and an extensive review of known compounds. Utilizing its internal product engine, Fulcrum discovered that inhibition of p38α/β reduced expression of the DUX4 gene in muscle cells derived from patients with FSHD. Although losmapimod has never previously been explored in muscular dystrophies, it has been evaluated in more than 3,500 subjects in clinical trials across multiple other indications, including in several Phase 2 trials and a Phase 3 trial. No safety signals were attributed to losmapimod in any of these trials. Fulcrum is currently conducting Phase 2 trials investigating the safety, tolerability, and efficacy of losmapimod to treat the root cause of FSHD.

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 proprietary product engine identifies drug targets which can modulate gene expression to treat the known root cause of gene mis-expression. The company has advanced losmapimod to Phase 2 clinical development for the treatment of facioscapulohumeral muscular dystrophy (FSHD) and has completed extensive pre-clinical research for FTX-6058 for the treatment of sickle cell disease and beta-thalassemia.

Please visit www.fulcrumtx.com.

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, including statements regarding the development status of the Company’s product candidates and the timing of availability of clinical trial data. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company’s strategy, future operations, future financial position, prospects, plans and objectives of management, are forward-looking statements. 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 relating to the COVID-19 pandemic; risks associated with Fulcrum’s ability to obtain and maintain necessary approvals from the FDA and other regulatory authorities; continue to advance its product candidates in clinical trials; replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of losmapimod and its other product candidates; advance the development of its product candidates under the timelines it anticipates in current and future clinical trials; obtain, maintain or protect intellectual property rights related to its product candidates; manage expenses; and raise the substantial additional capital needed to achieve its business objectives. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company’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 the Company’s most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company’s views as of the date hereof and should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

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