

# Fulcrum Therapeutics Announces Multiple Presentations at the 28th Annual FSHD Society International Research Congress (IRC)

June 21, 2021 at 7:00 AM EDT

– Fulcrum to host conference call on June 24, 2021 at 8:00am ET to present results from Phase 2b ReDUX4 trial with losmapimod in facioscapulohumeral muscular dystrophy (FSHD) –

CAMBRIDGE, Mass., June 21, 2021 (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 multiple presentations at the 28<sup>th</sup> Annual FSHD Society International Research Congress (IRC).

## June 24, 2021 IRC Virtual Presentations

- **10:43 am ET** - Use of snRNA-seq to characterize the skeletal muscle microenvironment during pathogenesis in FSHD
- **1:33 pm ET** - A Phase 2, Randomized, Double-Blind, Placebo-Controlled, 48-Week, Parallel-Group Study of the Efficacy and Safety of Losmapimod in Treating Subjects with Facioscapulohumeral Muscular Dystrophy (FSHD) with Open Label Extension (OLE): ReDUX4
- **1:58 pm ET** - Fulcrum Panel Q&A
- **Poster** - Evaluating DUX4 Activity in a Phase 2, Randomized, Double-Blind, Placebo-Controlled, 48-Week Study of the Efficacy and Safety of Losmapimod in Subjects with FSHD
- **Poster** - Quantitative Muscle Analysis in FSHD Using Whole-Body MRI: Composite Muscle Measurements for Cross-Sectional Analysis

The sessions will be available to registered conference attendees. The posters and presentation will also be made available in the “Events & Presentations” section of [fulcrumtx.com](#).

Management will host a conference call on June 24, 2021 at 8:00 am ET to discuss the results of the ReDUX4 trial.

## Conference Call Details

Dial-in Number

U.S./Canada Dial-in Number: 800-527-6973

International Dial-in Number: 470-495-9162

Conference ID: 3005948

Replay Dial-in Number: 855-859-2056

Replay International Dial-in Number: 404-537-3406

Conference ID: 3005948

An audio webcast will be accessible through the Investor Relations section of the company's website <https://ir.fulcrumtx.com/events-and-presentations>. Following the live webcast, an archived replay will also be available.

## **About FSHD**

FSHD is a serious, rare, progressive and disabling disease for which there are no approved treatments. FSHD is characterized by muscle degeneration and fat infiltration, initially affecting movement of the face and eventually the arms, trunk and legs. Disease progression results in accumulation of disability, with many patients ultimately becoming dependent upon the use of a wheelchair for daily mobility. Impact on patients includes decreased ability to perform activities of daily living, maintain independence, and lost ability to function or work.

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 p38 $\alpha$ / $\beta$  mitogen activated protein kinase (MAPK) inhibitor that was exclusively in-licensed from GSK by Fulcrum Therapeutics following Fulcrum's discovery of the role of p38 $\alpha$ / $\beta$  inhibitors in the reduction of DUX4 expression and an extensive review of known compounds. Utilizing its proprietary product engine, FulcrumSeek, Fulcrum discovered that inhibition of p38 $\alpha$ / $\beta$  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 3,600 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. Losmapimod has been granted U.S. Food and Drug Administration (FDA) Fast Track designation and Orphan Drug Designation for the treatment 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, FulcrumSeek, 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). Fulcrum has also advanced FTX-6058, a small molecule designed to increase expression of fetal hemoglobin for the treatment of sickle cell disease and beta-thalassemia into Phase 1 clinical development.

Please visit [www.fulcrumtx.com](http://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. 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. 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.

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