Fulcrum Therapeutics Appoints Patrick Horn M.D., Ph.D., as Chief Medical Officer

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—Industry veteran with late-stage clinical development, medical affairs, and regulatory experience; well-positioned to advance losmapimod towards a potential regulatory submission and approval —

— Interim Chief Medical Officer, Iain Fraser, MBChB, DPhil, will continue to serve on Fulcrum's executive leadership team as senior vice president (SVP) of early development —

CAMBRIDGE, Mass., March 18, 2024 (GLOBE NEWSWIRE) -- Fulcrum Therapeutics, Inc.® (Fulcrum) (Nasdaq: FULC), a clinical-stage biopharmaceutical company focused on developing small molecules to improve the lives of patients with genetically defined rare diseases, today announced the appointment of Patrick Horn, M.D., Ph.D., as chief medical officer, effective immediately. Dr. Horn is a seasoned executive with over 20 years of end-to-end drug development experience spanning multiple therapeutic areas, with an emphasis on rare diseases, across both large pharmaceutical and biotech companies. Interim chief medical officer, Iain Fraser, MBChB, DPhil, will continue to serve on Fulcrum's executive leadership team as SVP of early development. Together, Drs. Horn and Fraser will be responsible for leading clinical development and overseeing regulatory strategy and execution.

"I am very pleased to enrich our leadership team with Pat, an accomplished industry veteran who has successfully guided multiple therapies —including rare disease programs lacking existing regulatory pathways—through late clinical development, regulatory approval, and commercial launch," said Alex C. Sapir, Fulcrum's president and chief executive officer. "This is a key moment for Fulcrum as we continue to advance our Phase 3 REACH trial of losmapimod for patients with facioscapulohumeral muscular dystrophy and reinitiate our Phase 1b PIONEER trial of pociredir in sickle cell disease. We believe both Pat and Iain's complementary expertise will be invaluable as we near several pivotal milestones for our two key clinical programs and advance our early-stage pipeline."

Dr. Horn added, "Joining Fulcrum is an exciting opportunity to bring potentially transformative therapies to patients especially as we advance towards near-term inflection points for losmapimod, a late-stage clinical program with first-to-market potential, and pociredir, a highly differentiated oral treatment option that may shift the current standard of care. Building on the encouraging clinical data generated to date, I, alongside Iain, look forward to working with the management team to deliver on the promise of Fulcrum's differentiated pipeline of rare disease programs."

Dr. Patrick Horn is a distinguished professional with over 20 years of experience in the field of rare disease drug development, encompassing all stages from initial research to regulatory approval and commercial launch. His most recent role was as the Chief Medical Officer at HemoShear Therapeutics, specializing in rare metabolic diseases. Previously, he held the position of Chief Medical Officer at Albireo Pharma where he led the team that achieved marketing approvals in the US and Europe for Bylvay™ in progressive familial intrahepatic cholestasis (PFIC). Before his tenure at Albireo, he served as the Senior Vice President of Medical and Clinical Development at Orphan Technologies, directing the advancement of novel treatments for homocystinuria. Prior to this, he was the Chief Medical Officer at Tetraphase Pharmaceuticals, where he oversaw the clinical development of antibiotic candidates, including the program leading to the New Drug Application for eravacycline. Before Tetraphase, Dr. Horn led the clinical program at Dyax Corp. that resulted in the approval of Kalbitor® for the treatment of hereditary angioedema. Dr. Horn received his M.D., and Ph.D., from the University of Chicago and completed his pediatric residency at Boston Children's Hospital. Prior to transitioning to industry, Dr. Horn was a practicing pediatrician at major academic institutions in Chicago.

About Fulcrum Therapeutics
Fulcrum Therapeutics is a clinical-stage biopharmaceutical company focused on developing small molecules to improve 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 in development for the treatment of facioscapulohumeral muscular dystrophy (FSHD), and pociredir (formerly known as FTX-6058), a small molecule designed to increase expression of fetal hemoglobin and in development for the treatment of sickle cell disease (SCD). Fulcrum uses proprietary technology to identify 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/X (@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 advancement of losmapimod towards regulatory submission and approval;; reinitiation of the Phase 1b trial; advancement of Fulcrum's early-stage pipeline; Fulcrum's ability to deliver an FDA-approved therapy for FSHD patients; and the potential for pociredir to shift the standard of care;; 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 and enrolling 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 of losmapimod, pociredir and any other product candidates; obtaining, maintaining or protecting intellectual property rights related to its product candidates; managing expenses; managing executive and employee turnover, including integrating a new CMO; 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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