Fulcrum Therapeutics Strengthens Leadership Team with the Appointments of Isabel Kalofonos as Chief Commercial Officer and Heather Faulds as Chief Regulatory Affairs & Quality Assurance Officer

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CAMBRIDGE, Mass., Aug. 19, 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 Isabel Kalofonos as chief commercial officer and Heather Faulds as chief regulatory affairs & quality assurance officer. Together, Ms. Kalofonos and Ms. Faulds will be instrumental in advancing losmapimod towards a New Drug Application (NDA) submission and preparing for commercial launch.

“I am excited to welcome Isabel to our leadership team as we continue to advance towards the potential approval and launch of losmapimod for the treatment of FSHD,” said Alex C. Sapir, Fulcrum’s president and chief executive officer. “Isabel has a proven track record of highly successful rare disease drug launches including the launch of ELAHERE® and TAKHZYRO®. With her leadership and experience, we are well positioned to transform Fulcrum Therapeutics into a commercial-stage biotechnology company.”

Mr. Sapir continued, “We are equally excited to have Heather join our leadership team. Heather brings deep knowledge of the neuromuscular landscape and experience in designing and implementing innovative regulatory strategies. During her tenure at Biogen, Heather led the global filing for SPINRAZA® for the treatment of spinal muscular atrophy, which was approved by the FDA under priority review designation in 90 days. Heather’s expertise will be invaluable as we continue to prepare for the NDA filing and potential approval of losmapimod.”

Isabel Kalofonos, Chief Commercial Officer

Ms. Kalofonos joins Fulcrum from ImmunoGen where she served as Senior Vice President and Chief Commercial Officer. While at ImmunoGen, Ms. Kalofonos led commercial efforts globally for the launch of ELAHERE (mirvetuximab soravtansine-gynx) for the treatment of adult patients with FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. Prior to ImmunoGen, she served as Senior Vice President and Global Head of the Prescription Business Unit at Galderma. During her tenure, she led the launch preparation for NEMLUVIO® (nemolizumab), a monoclonal antibody for the treatment of atopic dermatitis and prurigo nodularis, which included marketing, global market access, pricing, and health economics / outcomes research. Ms. Kalofonos also led all commercial franchises of prescription products. Prior to Galderma, Ms. Kalofonos held roles of increasing responsibility at Takeda Pharmaceuticals (formerly Shire), most recently serving as Vice President and Head of the Hereditary Angioedema (HAE) franchise. In this role, she oversaw the global blockbuster launch of TAKHZYRO (lanadelumab-flyo). Prior to the Takeda acquisition, Ms. Kalofonos held roles of increasing responsibility at Shire within corporate strategy, new product planning, and commercial, and gained experience across multiple therapeutic areas including immunology, oncology, neurology, transplant, and gene therapy. Before Shire, she worked in commercial, business strategy, and product launch positions at Forest Labs, Bionevia Pharmaceuticals, and Sunovion Pharmaceuticals.

"Losmapimod is positioned to be a potential first-to-market oral therapy for the treatment of FSHD, a progressive and debilitating disease for which there are no approved treatments,” said Isabel Kalofonos. “This is a pivotal moment, and I am thrilled to join as the company prepares to transition to a commercial-stage organization. With a strong commitment to delivering innovative therapies to patients who currently have no treatment options, I look forward to building on the team’s exceptional work and driving the successful launch of losmapimod.”

Heather Faulds, Chief Regulatory Affairs and Quality Assurance Officer

Ms. Faulds brings over 20 years of experience leading global regulatory strategies across all phases of development, as well as multiple therapeutic areas and modalities. Most recently, Ms. Faulds served as SVP, Regulatory Affairs at Alkermes, where she led the team that achieved FDA approval for LYBALVI® (olanzapine and samidorphan) for the treatment of schizophrenia and bipolar disease. Previously, Heather served as SVP, Regulatory Affairs at Scholar Rock where she led multiple functions spanning regulatory affairs, GxP compliance, pharmacovigilance, and medical writing, and was responsible for regulatory strategies across clinical programs for rare diseases and immuno-oncology. Prior to joining Scholar Rock, Heather spent 12 years at Biogen in roles of increasing responsibility across CMC regulatory and global regulatory strategy. While there, her leadership paved the way for several novel health authority approvals including SPINRAZA (nusinersen), the first treatment for spinal muscular atrophy, which was approved by FDA in 90 days from NDA submission. Ms. Faulds also led regulatory activities for programs in alzheimer’s disease and multiple sclerosis.

“I have been fortunate to work on significant advances for the treatment of neurodegenerative and neuromuscular diseases to address the high unmet needs for patients, including SPINRAZA for the treatment of spinal muscular atrophy, and I am eager to bring my regulatory expertise and passion to Fulcrum,” said Heather Faulds. “With an opportunity to build on a strong foundation of scientific innovation and clinical execution, I look forward to working closely with the team as we prepare for the next stage of growth. Together, we’ll strive to deliver potentially transformative therapies to patients as expeditiously as possible.”

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.

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 slower 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 FDA Fast Track designation and Orphan Drug Designation for the treatment of FSHD. Losmapimod is currently being evaluated in a Phase 3 multi-center randomized, double-blind, placebo-controlled, 48-week parallel-group study in people with FSHD (NCT05397470).

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 30,000 in the United States alone.

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, approval and commercial launch; the timeline for reporting topline data in the Phase 3 REACH trial of losmapimod in FSHD Fulcrum’s ability to deliver an FDA-approved therapy for FSHD patients; and losmapimod’s potential as a first-to-market oral therapy; 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 new employees; 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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