Fulcrum Therapeutics Appoints Pamela Strode, Seasoned Industry Executive, to Lead Regulatory Affairs Team

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Strode brings experience leading regulatory affairs and quality assurance across multiple therapeutic areas, including rare diseases with high unmet need

CAMBRIDGE, Mass., Sept. 04, 2019 (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 the appointment of Pamela Strode as senior vice president, regulatory affairs and quality assurance. Strode will leverage deep experience in regulatory affairs and quality assurance to help to ensure safety and compliance for Fulcrum's development programs, including its lead product candidate losmapimod, currently in a Phase 2b trial to investigate its potential use in facioscapulohumeral muscular dystrophy (FSHD).

"Pam has a strong track record of successfully guiding the development and ultimate approval of multiple drug candidates," said Robert Gould, Ph.D., Fulcrum's president and chief executive officer. "Her regulatory acumen and experience working on programs for underserved diseases will make her a wonderful asset to the Fulcrum team as we advance our clinical programs to improve the lives of people affected by genetic diseases, beginning with FSHD."

Strode comes to Fulcrum from Epizyme, Inc., where she served as senior vice president, regulatory affairs and quality assurance, and played a critical role in establishing the team's regulatory affairs and quality assurance departments. At Epizyme, Strode directed multiple U.S. Fast Track and U.S./E.U. Orphan Drug Designations and also led the regulatory strategy and operations for several clinical trial applications and a New Drug Application (NDA). Strode brings more than 30 years of regulatory leadership for investigational and marketed products across multiple therapeutic areas, with increasing levels of responsibility at Bristol-Myers Squibb, Boehringer Ingelheim Pharmaceuticals, Inc. and Cerulean Pharma.

"Fulcrum's recent entry into clinical development is a testament to the company's strong team, clear mission and patient-focused strategy," said Strode. "I am thrilled to bring my development experience in rare disease and other indications to help lead the Fulcrum team and contribute to addressing the underlying causes of severe diseases."

About Fulcrum Therapeutics

Fulcrum Therapeutics is a clinical-stage biopharmaceutical company focused on improving the lives of patients with genetically defined diseases in areas of high unmet medical need, with an initial focus on rare diseases. Fulcrum's proprietary product engine identifies drug targets which can modulate gene expression to treat the known root cause of gene mis-expression. 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. 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 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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