Fulcrum Therapeutics Signs Exclusive Global License Agreement in Rare Hematology

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CAMP4 Therapeutics grants exclusive rights to advance novel therapies for Diamond-Blackfan Anemia

CAMBRIDGE, Mass., July 10, 2023 (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 that it has entered into a worldwide, exclusive license agreement with CAMP4 Therapeutics Corp., whereby Fulcrum will advance the discovery, development, and commercialization of novel therapeutic agents against an undisclosed target for the potential treatment of Diamond-Blackfan Anemia (DBA).

DBA is a congenital, rare blood disorder that affects an estimated 5,000 individuals worldwide. DBA is caused by genetic mutations in ribosomal subunits that halt red blood cell maturation and lead to anemia. Patients are usually diagnosed in infancy with the presentation of severe anemia and potential developmental abnormalities. Patients with DBA require lifelong management with corticosteroids and blood transfusions that are known for their toxicities and long-term complications.

“We are deeply committed to bringing hope and new options to patients suffering from rare hematologic diseases and are excited to expand on the work of CAMP4’s pre-clinical DBA program,” said Jeff Jacobs, Chief Scientific Officer, Fulcrum Therapeutics. “This agreement further strengthens our discovery pipeline and reinforces our strategy of addressing rare genetic conditions through small molecules.”

Under the terms of the agreement, Fulcrum has been granted an exclusive, worldwide license to intellectual property arising from CAMP4’s DBA program, including the right to research, develop, manufacture, and commercialize investigational compounds against an undisclosed target. In exchange, CAMP4 Therapeutics will receive an undisclosed upfront payment and up to $70 million in additional payments, upon the achievement of certain development, regulatory, and commercial milestones. Fulcrum will assume sole responsibility for research, development, manufacturing and commercialization costs and activities, and will pay tiered royalties on future commercial sales.

“Our mission is to harness the power of the cell’s transcriptional regulators to unlock new options for people living with genetic diseases like DBA,” said Josh Mandel-Brehm, Chief Executive Officer, CAMP4 Therapeutics. “By uniting our scientific insights with Fulcrum’s deep expertise in hematology and small molecule development, this agreement will help accelerate the discovery and delivery of ground-breaking therapies for this underserved community.”

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 two lead programs in clinical development are losmapimod, a small molecule for the treatment of facioscapulohumeral muscular dystrophy (FSHD), and FTX-6058, a small molecule designed to increase expression of fetal hemoglobin for the treatment of sickle cell disease (SCD) and other hemoglobinopathies, which is currently under a full clinical hold issued by the U.S. Food and Drug Administration. The company’s proprietary product engine, FulcrumSeek™, identifies drug targets that can modulate gene expression to treat the known root cause or consequences of gene mis-expression. For more information, 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. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, including express or implied statements regarding Fulcrum’s exclusive license agreement with CAMP4 Therapeutics, and the milestone and royalty payments thereunder; Fulcrum’s ability to develop a therapy for DBA; and the potential effect of this agreement on Fulcrum’s discovery pipeline; 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 biopharmaceutical development, Fulcrum’s ability to continue to advance its product candidates into and through clinical trials; initiate and enroll clinical trials on the timeline expected or at all; obtain and maintain necessary approvals from the FDA and other regulatory authorities; replicate in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials; obtain, maintain or protect intellectual property rights related to its product candidates; manage expenses; realize the anticipated benefits of the strategic realignment; manage executive and employee turnover; and raise 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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