Finch Therapeutics Provides an Update on its Phase 3 Trial of CP101 in Recurrent C. difficile Infection

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SOMERVILLE, Mass., March 01, 2022 (GLOBE NEWSWIRE) -- Finch Therapeutics Group, Inc. (“Finch” or “Finch Therapeutics” or “Company”) (Nasdaq: FNCH), a clinical-stage microbiome therapeutics company leveraging its *Human-First Discovery*® platform to develop a novel class of orally administered biological drugs, today announced that it has paused enrollment in PRISM4, its Phase 3 clinical trial of CP101 in recurrent *C. difficile* infection (CDI) following receipt of a clinical hold letter from the U.S. Food and Drug Administration (FDA) on February 24, 2022, requesting additional information about Finch’s SARS-CoV-2 donor screening protocols.

At the outset of the COVID-19 pandemic in March 2020, the FDA issued a public safety alert regarding the potential risk of transmission of SARS-CoV-2 virus through the use of donor-derived investigational microbiome therapies and the need for additional safety precautions. At that time, the FDA placed Finch’s investigational new drug application (IND) for CP101 and the IND of its then-contract manufacturer, OpenBiome, on partial clinical hold, requiring the implementation of SARS-CoV-2 testing protocols for any microbiota material donated on or after December 1, 2019. Notwithstanding the partial clinical hold notices, Finch was able to continue dosing patients in its then-ongoing PRISM-EXT Phase 2 open-label trial of CP101 in recurrent CDI as all of the CP101 lots used for PRISM-EXT were manufactured from material donated prior to December 1, 2019.

In January 2021, Finch’s then-contract manufacturer, OpenBiome, was released from clinical hold after implementing a direct testing method for SARS-CoV-2 provided by a third-party vendor. In March 2021, Finch acquired certain manufacturing assets from OpenBiome, and in November 2021, began dosing participants in PRISM4 with CP101 lots that had been screened for SARS-CoV-2 using the same test method and vendor used by OpenBiome.

Following communications with FDA in January 2022, on February 24, 2022, the FDA sent a letter stating that it needs additional information about Finch’s SARS-CoV-2 screening protocols and that a clinical hold remains in effect until the FDA’s requests have been satisfactorily addressed. Finch has informed the FDA that participants were dosed in PRISM4 while the clinical hold was in effect and Finch is conducting a review of the matter.

In their letter the FDA requested, among other things, additional detail on how samples are shipped to the vendor performing the SARS-CoV-2 testing and how inconclusive test results will be handled. The letter did not reference any adverse clinical outcome experienced in any of Finch’s clinical trials. Finch expects to expeditiously provide the requested information and intends to work closely with the FDA to resolve the clinical hold as soon as possible. Finch is evaluating what impact, if any, the clinical hold may have on the timing of the expected readout of topline data from the PRISM4 trial.

About Finch Therapeutics

Finch Therapeutics is a clinical-stage microbiome therapeutics company leveraging its *Human-First Discovery*® platform to develop a novel class of orally administered biological drugs. With the capabilities to develop both complete and targeted microbiome therapeutics, Finch is advancing a rich pipeline of candidates designed to address a wide range of unmet medical needs. Finch’s lead candidate, CP101, is in late-stage clinical development for the prevention of recurrent *C. difficile* infection (CDI), and has received Breakthrough Therapy and Fast Track designations from the U.S. Food and Drug Administration.

Human-First Discovery® is a registered trademark of Finch Therapeutics Group, Inc.

Cautionary Note Regarding Forward-Looking Statements:

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as “anticipates,” “believes,” “expects,” “intends,” “plans,” “potential,” "projects," “would” and "future" or similar expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding Finch’s ability to resolve the clinical hold including the likelihood that the clinical hold will be lifted and timing of any such resolution; Finch’s communication plans with the FDA related to the clinical hold and the timing for receiving written correspondence from the FDA; and Finch’s plans and expectations for discussions with the FDA and the outcomes from the discussions. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: the risk that the written questions that Finch received from the FDA may require Finch to collect additional data or information beyond what it currently expects; the risk that Finch may not be able to address the FDA’s concerns regarding SARS-CoV-2 testing protocols quickly or at all; uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that FDA may not remove the clinical hold; Finch’s limited operating history and historical losses; Finch’s ability to raise additional funding to complete the development and any commercialization of its product candidates; Finch’s dependence on the success of its lead product candidate, CP101; the possibility that Finch may be delayed in initiating, enrolling or completing any clinical trials; results of clinical trials may not be indicative of final or future results from later stage or larger clinical trials (or in broader patient populations once the product is approved for use by regulatory agencies) or may not be favorable or may not support further development; Finch’s product candidates may not generate the benefits to patients that are anticipated; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; the ability of Finch to comply with regulatory requirements or experience unanticipated problems with any of its product candidates; ongoing regulatory obligations and continued regulatory review may result in significant additional expense to Finch and Finch may be subject to penalties for failure to comply; competition from third parties that are developing products for similar uses; Finch’s ability to maintain patent and other intellectual property protection and the possibility that Finch’s intellectual property rights may be infringed, invalid or unenforceable or will be threatened by third parties; Finch’s ability to qualify and scale its manufacturing capabilities to support multiple global clinical trials; Finch’s lack of experience in selling, marketing and distributing its product candidates; Finch’s dependence on third parties in connection with manufacturing, clinical trials and preclinical studies; and risks relating to the impact and duration of the COVID-19 pandemic on Finch’s business. These and other risks are described more fully in

Finch's filings with the Securities and Exchange Commission ("SEC"), including the section titled "Risk Factors" in Finch's Quarterly Report on Form 10-Q filed with the SEC on November 10, 2021, as well as discussions of potential risks, uncertainties, and other important factors in Finch's other filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Finch undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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