Finch Therapeutics Presents PRISM-EXT Biomarker Data at ACG 2022 and Proceeds with Patient Dosing in Phase 3 Trial of CP101 in Recurrent C. Difficile Infection

October 24, 2022

SOMERVILLE, Mass., Oct. 24, 2022 (GLOBE NEWSWIRE) -- Finch Therapeutics Group, Inc. (“Finch” or “Finch Therapeutics”) (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 the presentation of biomarker data from PRISM-EXT, a Phase 2 open-label trial of CP101 in recurrent *C. difficile* infection (CDI), at the American College of Gastroenterology (ACG) 2022 Annual Scientific Meeting, being held October 21-26, 2022 in Charlotte, NC. Finch also announced today that the company has proceeded with patient dosing in PRISM4, a Phase 3 trial of CP101 for the prevention of recurrent CDI.

“This is an exciting time for Finch and the overall microbiome field, with hope and new potential therapeutic options on the horizon for patients fighting recurrent CDI,” said Howard Franklin, MD, MBA, Chief Medical Officer of Finch Therapeutics. “At ACG’s annual meeting, we are pleased to be presenting biomarker data from our PRISM-EXT trial showing that higher engraftment of CP101 microbes and an increase in intestinal microbiome diversity were both associated with prevention of recurrent CDI. These results further our understanding of the pharmacokinetics and pharmacodynamics of CP101 and support our efforts to optimize engraftment of CP101 microbes.”

Dr. Franklin continued, “We are also very pleased to be back in the clinic with CP101 and are deeply grateful to our PRISM4 study sites and study participants for their dedication to supporting the development of CP101. We will continue to work with urgency to advance CP101, an investigational microbiome therapeutic that we believe holds the promise of fulfilling the need for a convenient, one-time oral therapy that can break the cycle of CDI recurrence.”

The PRISM-EXT poster details are as follows:

Poster Title: Evaluation of Engraftment and Diversity Following Open Label Administration of CP101, an Investigational Oral Microbiome Therapeutic for the Prevention of Recurrent *C. Difficile* Infection, in the PRISM-EXT Trial (E0096)
Presenting Author: Jessica R. Allegretti, MD, MPH, Brigham and Women's Hospital, Boston, MA and Harvard Medical School, Boston MA
Presentation Date and Time: Tuesday, October 25, 2022 at 3:00 pm ET

- Following open-label administration of CP101 after standard-of-care (SOC) CDI antibiotics, there was a significant increase in microbiome diversity from baseline through week 8 and week 24 in PRISM-EXT participants.
- Higher engraftment of CP101-associated taxa and improvement in diversity were both associated with prevention of CDI recurrence through week 8.
- As previously reported, 80.3% and 78.8% of participants who received CP101 following SOC antibiotics in PRISM-EXT were without CDI recurrence through week 8 and week 24, respectively (n=132). The CP101 safety results from PRISM-EXT were consistent with previously reported results, with no treatment-related serious adverse events or deaths. The most frequent treatment-related adverse events were gastrointestinal symptoms of mild-moderate severity.

PRISM-EXT was a Phase 2, multi-center, open-label trial of CP101 for the prevention of recurrent CDI in adults with one or more CDI recurrences. The primary endpoints were safety and the proportion of participants without CDI recurrence through week 8. Participants were followed through week 24 for safety and CDI recurrence. Exploratory microbiome endpoints were measured at baseline following SOC antibiotics, week 8 and week 24 using 16S rRNA gene amplicon sequencing. A copy of the PRISM-EXT poster presented at ACG will be available on the ‘ Publications’ page of the Finch website after the meeting.

About CP101

CP101 is an investigational microbiome therapeutic designed to deliver a diverse microbial community in a one-time oral administration, without the need for bowel preparation. CP101 is designed to enable prevention of recurrent *C. difficile* infection (CDI) by restoring a diverse microbial community and key physiological pathways that are believed to contribute to colonization resistance.

About the PRISM4 Phase 3 Trial

PRISM4 is a randomized, double-blind, placebo-controlled, multi-center Phase 3 trial evaluating the efficacy and safety of a one-time oral administration of CP101 for the prevention of recurrent *C. difficile* infection (CDI). After completing standard-of-care CDI antibiotics for their most recent CDI recurrence, eligible participants will be randomized in a 2:1 ratio to receive either CP101 or placebo. Participants will be evaluated for CDI recurrence and safety through week 8, the primary endpoint, as well as through week 24. Participants who qualify may enroll in the optional open label arm and receive CP101 if they experience a CDI recurrence through week 8 of the trial. To learn more about the trial, visit clinicaltrials.gov (Identifier: NCT05153499) or the study website at https://prism4trial.com/.

About Recurrent *C. difficile* Infection

Clostridioides difficile infection (CDI), one of the most common healthcare-associated infections, is a debilitating and sometimes life-threatening disease that is characterized by severe diarrhea and abdominal pain. Recurrent CDI is common following the use of standard-of-care (SOC) antibiotics to treat active CDI. SOC antibiotics can lead to significant disruption of the intestinal microbiome, which impairs colonization resistance, or

the ability of a healthy microbiome to inhibit the colonization and expansion of pathogens, which can put patients at risk for recurrent CDI. There is a significant unmet need for FDA-approved, orally administered therapeutics that restore the microbiome following SOC antibiotics and that may enable early intervention to prevent recurrent CDI.

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. Finch's lead candidate, CP101, is in late-stage clinical development for the prevention of recurrent *C. difficile* infection and has received Breakthrough Therapy and Fast Track designations from the U.S. Food and Drug Administration. Finch is exploring strategic options to potentially advance the development of its pre-clinical candidates FIN-524 for ulcerative colitis and FIN-525 for Crohn's disease and its pre-clinical program in autism spectrum disorder. Finch routinely posts information that may be important to its investors on its website at www.finchtherapeutics.com. Finch encourages investors to consult the "Investors & News" section of its website regularly.

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

Forward-Looking Statements

This press release includes "forward-looking statements." Words such as "will," "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: the therapeutic potential of options on the horizon for treatment of recurrent CDI, including Finch's product candidate, CP101; Finch's efforts to optimize engraftment of CP101 microbes and its plans to work with urgency to advance development of CP101; performance of Finch's PRISM4 trial; and Finch's ability to develop a novel class of orally administered biological drugs. 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, those related to: 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, including PRISM4; 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; results of clinical trials may not be sufficient to satisfy regulatory authorities to approve Finch's product candidates in their targeted or other indications (or such authorities may request additional trials or additional information); Finch's ability to comply with regulatory requirements; ongoing regulatory obligations and continued regulatory review may result in significant additional expense to Finch and Finch could 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; 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 Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 31, 2022, as supplemented by Finch's Quarterly Reports on Form 10-Q filed with the SEC on May 16, 2022 and August 11, 2022, 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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