Finch Therapeutics Presents Positive Data from PRISM3 Clinical Trial of CP101 for Recurrent C. difficile at American College of Gastroenterology Annual Scientific Meeting

October 25, 2021

- *New data from PRISM3 Phase 2 trial show CP101 demonstrated statistically significant efficacy for prevention of recurrent C. difficile infection and a favorable safety profile through 24 weeks*
- *Additional PRISM3 microbiome data show CP101 engraftment leads to an increase in intestinal microbiome diversity and sustained clinical cure*

SOMERVILLE, Mass., Oct. 25, 2021 (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 clinical data supporting CP101 for the prevention of recurrent *C. difficile* infection (CDI) at the American College of Gastroenterology (ACG) Annual Scientific Meeting being held October 22-27, 2021 in a hybrid format. Results from PRISM3, a Phase 2, randomized, placebo-controlled, multi-center clinical trial evaluating the investigational orally administered candidate CP101 for the prevention of recurrent CDI, including new 24-week safety and efficacy data, will be shared in two posters and an oral presentation at the meeting.

"We are excited to share these additional data supporting CP101, the first orally administered microbiome candidate to demonstrate durable efficacy and a favorable safety profile in a large randomized, placebo-controlled trial that included all stages of recurrent CDI and all guideline recommended methods of CDI diagnosis at trial entry. These are important features of the PRISM3 trial that we believe position CP101 to serve a broad patient population," said Zain Kassam, MD, MPH, Chief Medical Officer at Finch Therapeutics. "We believe these robust PRISM3 data illustrate the potential for CP101 to serve as a convenient, first-line option for clinicians and patients fighting the devastating effects of recurrent CDI."

Summary of PRISM3 posters presented at the ACG meeting:

Poster Title: "Week 24 Efficacy and Safety Data from PRISM3: A Randomized, Placebo-Controlled Trial Evaluating CP101, an Investigational Orally Administered Microbiome Therapeutic for Prevention of Recurrent *C. difficile* Infection" (P0130)

- CP101 demonstrated efficacy through week 24, with 73.5% of participants in the CP101 arm (n=102) experiencing a sustained clinical cure (defined as absence of CDI recurrence) through week 24 versus 59.4% in the placebo arm (n=96) (p=0.0347).
- CP101 exhibited a favorable safety profile through week 24, with similar rates of adverse events and drug-related treatment emergent adverse events in both the CP101 and placebo arm. No drug-related serious adverse events were reported in the CP101 arm through week 24.
- As previously reported, CP101 met its primary efficacy endpoint in PRISM3, with 74.5% of participants who received a single oral administration of CP101 following standard-of-care (SOC) antibiotics achieving a sustained clinical cure through week 8, versus 61.5% of participants who received placebo following SOC antibiotics (p=0.0488), representing a 33.8% relative risk reduction for CDI recurrence.

Poster Title: "CP101 Engraftment Drives Efficacy: Results from a Randomized, Placebo-Controlled Trial Evaluating CP101, an Investigational Orally Administered Microbiome Therapeutic for Prevention of Recurrent *C. difficile* Infection" (P0129)

- Treatment with CP101 in PRISM3 resulted in significant engraftment at week 1, with engraftment defined as the presence of CP101-specific microbes that colonized the gastrointestinal tract of participants.
- CP101 engraftment was associated with sustained clinical cure in PRISM3. Among PRISM3 participants with successful engraftment at week 1 following administration of CP101, 96.0% achieved a sustained clinical cure at week 8, while unsuccessful engraftment resulted in a 54.2% sustained clinical cure rate, similar to participants who were administered placebo following CDI antibiotics (p<0.001).
- Engraftment of CP101 microbes may have been impacted by the persistence of residual broad-spectrum vancomycin, despite participants completing a minimum two-day washout period to ensure antibiotic clearance from the colon. Data suggest that a two-day washout period may be insufficient to clear residual vancomycin. Future trials, including PRISM4, a Phase 3, placebo-controlled trial of CP101 for recurrent CDI, will deploy strategies to optimize engraftment by further minimizing the effect of residual broad-spectrum antibiotics.

In addition to the two poster presentations, Jessica R. Allegretti, MD, MPH, Associate Director, Crohn's and Colitis Center, Brigham and Women's Hospital, Assistant Professor, Harvard Medical School, will give an oral presentation on Tuesday, October 26, 2021 at 9:30 am PT entitled "CP101, an Investigational Orally Administered Microbiome Therapeutic, Increases Intestinal Microbiome Diversity and Prevents Recurrent *C. difficile* Infection: Results From a Randomized, Placebo-Controlled Trial" (oral abstract #25). The abstract was awarded ACG's prestigious Outstanding Research Award.

The presented data are available to registered attendees through the ACG Annual Scientific Meeting website and copies of the posters will be provided on the Finch website after the meeting.

About CP101

CP101 is an investigational microbiome therapeutic that delivers a complete 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, which contributes to colonization resistance. CP101 is manufactured under a rigorous, standardized process. CP101 is in late-stage clinical development for the prevention of recurrent CDI.

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 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 therapeutics that restore the microbiome following SOC antibiotics and 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. 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. In June 2020, Finch announced that CP101 met its primary efficacy endpoint in PRISM3, the first of two pivotal trials to support the development of CP101 for the prevention of recurrent CDI. PRISM4, a Phase 3 trial, is designed to serve as the second pivotal trial of CP101 for recurrent CDI. Finch is also developing CP101 for the treatment of chronic hepatitis B virus, and FIN-211 for the treatment of the gastrointestinal and behavioral symptoms of autism spectrum disorder. Finch has a partnership with Takeda focused on the development of targeted microbiome therapeutics for inflammatory bowel disease.

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

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 advance its platform of microbiome therapeutics, including Finch's ability to position CP101 to serve a broad patient population; and the therapeutic value and commercial potential of CP101. 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: 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; anticipated regulatory approvals may be delayed or refused; 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 in anticipation of commencement of 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 August 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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