Finch Therapeutics Announces Positive Topline Results from PRISM-EXT Phase 2 Trial of CP101 for Prevention of Recurrent C. difficile Infection

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- *New data from 132-participant PRISM-EXT Phase 2 open-label trial show 80.3% sustained clinical cure rate through 8 weeks, with a similar rate maintained through 24 weeks and a safety profile consistent with previously reported data*
- *Aggregated 88.2% sustained clinical cure rate shown through 8 weeks following last dose in post-hoc analysis of participants that received up to two doses of CP101 in PRISM3 and PRISM-EXT trials*
- *Finch also announces start of enrollment in PRISM4 Phase 3 trial*

SOMERVILLE, Mass., Nov. 09, 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 positive topline results from PRISM-EXT, an open-label extension of the company's PRISM3 Phase 2 placebo-controlled trial evaluating CP101 for the prevention of recurrent *C. difficile* infection (CDI).

PRISM-EXT was a 24-week trial that evaluated the safety and efficacy of CP101 for the prevention of recurrent CDI in 132 participants who either rolled over from PRISM3 after experiencing a CDI recurrence (n=50) or directly enrolled after experiencing a CDI recurrence without previously participating in PRISM3 (n=82). In the PRISM-EXT trial, there were no treatment-related serious adverse events reported and CP101 exhibited an overall safety profile consistent with the profile observed in PRISM3. The primary efficacy endpoint was sustained clinical cure (defined as absence of CDI recurrence) through eight weeks post-treatment. Overall, 80.3% of participants who received a single oral administration of CP101 following standard-of-care (SOC) antibiotics in PRISM-EXT achieved sustained clinical cure through week 8. At week 24, 78.8% of participants had sustained clinical cure. The PRISM-EXT results are consistent with and build on the previously reported PRISM3 results, which showed that CP101 provided a statistically significant improvement in the prevention of recurrent CDI compared to placebo through 8 weeks and 24 weeks post-treatment.

"The robust PRISM-EXT topline results add to the growing body of evidence supporting the potential for CP101 to meet the need for a convenient, orally administered therapeutic that can prevent recurrent *C. difficile* infection," said Jessica R. Allegretti, MD, MPH, Principal Investigator in the PRISM-EXT and PRISM3 trials at Brigham and Women's Hospital in Boston. "I am excited to participate in the ongoing evaluation of this novel therapeutic candidate."

PRISM-EXT Trial Design and Additional Results

The PRISM-EXT trial was a multi-center, open-label extension of the PRISM3 Phase 2 randomized, placebo-controlled trial evaluating CP101 for the prevention of recurrent CDI. The primary endpoints were safety and sustained clinical cure (absence of CDI recurrence) through 8 weeks post-treatment. Participants were followed for a total of 24 weeks for safety and sustained clinical cure. PRISM-EXT enrolled adults of any age with one or more CDI recurrences. Following successful completion of SOC antibiotics, participants were treated with a single oral administration of CP101 without bowel preparation. There were two cohorts of participants; one cohort directly enrolled in the trial following a recent CDI recurrence without having previously participated in PRISM3 (n=82) and one cohort enrolled after experiencing a CDI recurrence following administration of placebo or a single dose of CP101 in PRISM3 (n=50).

Among the 102 participants who were treated with CP101 in PRISM3, 20 were enrolled in PRISM-EXT and treated with a second dose of CP101. Of the participants who received either a single dose of CP101 in PRISM3 (n=82) or a second dose by enrolling in PRISM-EXT (n=20), a post-hoc analysis shows that a total of 90 participants achieved sustained clinical cure through 8 weeks after their final dose, resulting in a cumulative efficacy of 88.2% (n=102).

In PRISM-EXT, treatment-related adverse events were of mild to moderate severity, and primarily gastrointestinal in nature, with no treatment-related serious adverse events reported through week 24. Finch plans to present additional data from PRISM-EXT at a future medical conference.

"These data provide hope to patients suffering from recurrent *C. difficile* infection," said Sahil Khanna, MBBS, Co-Investigator in the PRISM-EXT and PRISM3 trials at the Mayo Clinic in Rochester. "A proportion of patients who contract *C. difficile* become trapped in repeating cycles of infection. Standard-of-care antibiotics effectively treat the active infection, but most antibiotics disrupt the intestinal microbiome and its ability to fight off *C. difficile*, putting patients at high risk for recurrence. CP101 is a promising option for restoring the microbiome and breaking the cycle of CDI recurrence."

PRISM4 Phase 3 Trial Update

Finch also announced today the start of enrollment in PRISM4, a Phase 3, randomized, double-blind, placebo-controlled, global trial that will evaluate the efficacy and safety of a single oral administration of CP101 for the prevention of recurrent CDI.

"We look forward to continuing to advance the clinical development of CP101, with our PRISM4 Phase 3 trial now enrolling and topline data expected in 2023," said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. "We believe the encouraging CP101 data from PRISM3 and PRISM-EXT, the largest reported dataset to our knowledge for any orally administered investigational microbiome therapeutic, underscore the potential for microbiome therapeutics to transform care for recurrent CDI as well as other conditions linked to disruption of the intestinal microbiome."

Finch expects to enroll approximately 300 participants in PRISM4, with the trial designed to serve as a second pivotal trial to support the development of CP101 for the prevention of recurrent CDI.

About CP101

CP101 is an investigational microbiome therapeutic designed to deliver 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 are believed to contribute 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; the therapeutic and commercial potential of CP101; and the structure and timing of PRISM4, Finch's Phase 3 clinical trial of CP101 in recurrent CDI, including specifically the period in which topline data from PRISM4 will be available and the number of participants that will be enrolled in the trial. 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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