Finch Therapeutics Presents Data from its Positive PRISM3 Trial of CP101 in Recurrent C. difficile Infection at Two Leading Medical Conferences

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PRISM3 data presented at the annual meetings of the United European Gastroenterology and the American College of Gastroenterology

SOMERVILLE, Mass.–(BUSINESS WIRE)–Finch Therapeutics Group, Inc. (Finch), a clinical-stage microbiome drug development company, reported today the presentation of results from the positive PRISM3 trial of CP101 for the prevention of recurrent *C. difficile* infection (CDI) at the United European Gastroenterology Week (UEGW) and the American College of Gastroenterology (ACG) Annual Scientific Meeting, two leading gastroenterology conferences held virtually this month. The data presented expand on the positive topline results previously reported from PRISM3, a randomized, placebo-controlled, multi-center, Phase 2 trial, which demonstrated that CP101 met the primary efficacy endpoint with a statistically significant improvement in the prevention of recurrent CDI compared to placebo.

“The presented PRISM3 results show that CP101 resulted in a statistically significant and clinically meaningful improvement in the prevention of recurrent CDI when evaluated in a broad patient population, including participants enrolled after their first recurrence and participants enrolled with any guideline-approved CDI diagnostic method,” said Colleen Kelly, MD, Associate Professor of Medicine at Warren Alpert Medical School of Brown University and a Principal Investigator in the PRISM3 trial at the Lifespan Physician Group Gastroenterology. “Demonstrating positive results in this broad population is exciting because it provides compelling evidence to support the potential use of CP101 early in the disease cycle and increases the generalizability of the results to real-world clinical practice.”

Highlights of the PRISM3 results shared at UEGW and ACG virtual conferences include:

- PRISM3 enrolled a broad patient population, with 28.8% of participants having one CDI recurrence prior to study entry and 61.1% of participants qualifying for participation with PCR-based CDI testing at study entry.
- As previously reported, following standard-of-care antibiotics, the proportion of participants with sustained clinical cure, defined as absence of CDI recurrence through week 8 following dosing, was significantly higher with CP101 than placebo (relative risk reduction (RRR) 21%; 74.5% [76/102] vs 61.5% [59/96], $p<0.05$).
- An analysis of the population that adhered to the study protocol (determined prior to unblinding), showed that the proportion of participants with sustained clinical cure in the per-protocol population was also significantly higher with CP101 than placebo (RRR 33%; 73.5% [61/83] vs 55.4% [46/83], $p=0.0150$).
- Time-to-event analysis showed CP101 had a significantly lower probability of CDI recurrence over time than placebo ($p=0.0139$).
- As previously reported, CP101 was well-tolerated with no treatment-related serious adverse events.

“We are enthusiastic that the PRISM3 results demonstrate that CP101 has the potential to fulfill the need for an oral drug that breaks the cycle of CDI recurrence early and prevents the debilitating effects of recurrent CDI on patients’ lives,” said Zain Kassam, MD, MPH, Chief Medical Officer at Finch. “Leveraging CP101’s Breakthrough Therapy designation, we look forward to continuing to engage with the FDA on the next steps necessary to bring CP101 to patients suffering from recurrent CDI.”

About CP101

CP101 is an investigational, orally administered microbiome drug that Finch is developing for conditions linked to microbiome dysfunction. With 42 billion doses of antibiotics administered globally each year, resulting in widespread damage to the microbiome, research suggests that microbiome dysfunction is associated with the pathogenesis of a wide range of serious medical conditions. CP101 is designed to deliver complete microbiome communities in orally administered, enteric release capsules. CP101 is rigorously tested and manufactured under Good Manufacturing Practice conditions. CP101 is in late-stage clinical development for the prevention of recurrent *C. difficile* infection. Finch plans to deploy CP101 to other conditions linked to microbiome disruption, starting with the evaluation of CP101 as a treatment for chronic hepatitis B.

About Finch Therapeutics

Finch Therapeutics is developing novel microbiome drugs to serve patients with serious unmet medical needs. Finch’s *Human-First Discovery*® platform enables reverse translation from clinical data to engineer the composition of the microbiome based on disease-modifying mechanisms. Finch’s platform uniquely enables development of both complete microbiome communities and rationally selected consortia to restore microbiome functionality and resolve conditions driven by dysbiosis, or disruption of the microbiome. Finch’s lead candidate CP101 is an investigational, orally administered microbiome drug with Fast Track and Breakthrough Therapy designation from the US Food and Drug Administration for the prevention of recurrent *C. difficile* infection. Finch is also developing FIN-211 for the treatment of children with autism spectrum disorder and CP101 for the treatment of chronic hepatitis B. Finch has a strategic partnership with Takeda Pharmaceuticals focused on the development of microbiome drugs for inflammatory bowel diseases.

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