Finch Therapeutics Announces Positive Topline Results from Randomized Controlled Trial of CP101, an Oral Microbiome Drug, for the Prevention of Recurrent C. difficile Infection

June 19, 2020

- *CP101 met the primary efficacy endpoint with statistically significant improvement in the prevention of recurrent C. difficile infection over standard of care alone in a 206-patient trial*
- *CP101 was well-tolerated with no treatment-related serious adverse events*
- *CP101 is the first oral microbiome drug to meet its primary endpoint in a pivotal trial*
- *Finch announces the initiation of a program to evaluate CP101 in the treatment of chronic hepatitis B*

SOMERVILLE, Mass.–(BUSINESS WIRE)–Finch Therapeutics Group, Inc. (“Finch”), a clinical-stage microbiome drug development company, announced today positive topline results from PRISM3, its multi-center, randomized, double-blind, placebo-controlled Phase 2 trial of CP101, an investigational oral microbiome drug, for the prevention of recurrent *C. difficile* infection (CDI).

In the PRISM3 trial, CP101 met the primary efficacy endpoint, with 74.5% of recurrent CDI patients who received a single administration of CP101 achieving a sustained clinical cure through week eight, a statistically significant improvement in comparison to 61.5% of patients in the control group who received standard-of-care antibiotic therapy alone ($p < 0.05$). CP101 was well-tolerated in the study at eight weeks post treatment, with no treatment-related serious adverse events. PRISM3 randomized 206 patients with recurrent CDI at 51 sites across the U.S. and Canada, representing the largest placebo-controlled trial to date of an oral microbiome drug. CP101 is the first oral microbiome drug to meet its primary endpoint in a pivotal trial.

“These results are very encouraging and show that CP101 has the potential to fulfill the need for an oral drug that breaks the cycle of CDI recurrence, preventing the devastating effects of recurrent *C. difficile* infections on patients’ lives,” said Jessica Allegretti, MD, MPH, Principal Investigator in the PRISM3 clinical trial at Brigham and Women’s Hospital in Boston. “This validates the approach of microbiome restoration and is a critical milestone for the field, opening the potential to develop this class of therapy for many other conditions arising from disruption of the microbiome.”

CP101 is an investigational, potentially first-in-class oral microbiome drug that has been granted Fast Track designation and Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for the prevention of recurrent CDI. Breakthrough Therapy designation provides expedited review and access to collaborate with the FDA on rapid development of CP101. PRISM3 is expected to provide pivotal data to support the approval of CP101 for the prevention of recurrent CDI.

PRISM3 Trial and CP101 Oral Administration Advance the Microbiome Field

PRISM3 participants received a one-time oral administration of CP101 or placebo, following a course of standard-of-care CDI antibiotic therapy, which all patients received. Participants in the trial included patients experiencing their first recurrence of CDI, enabling the evaluation of CP101 as an early intervention in the course of this debilitating and life-threatening disease, enhancing the clinical relevance of the trial. The study included patients diagnosed with CDI by polymerase chain reaction (PCR) or toxin enzyme immunoassay (EIA) laboratory testing, reflecting real-world clinical practices for detecting CDI. The primary endpoint of the trial is defined as the absence of CDI through eight weeks following treatment. After the eight-week period evaluating the primary efficacy endpoint, patients in the trial are being followed for an additional 16 weeks for additional safety and efficacy endpoints. Finch plans to present the full results of the study at an upcoming medical conference.

“Recurrent CDI has a life-changing impact on patients, robbing them of their health and well-being. Intervening early in the cycle of the disease is crucial to preventing the debilitating effects of recurrent CDI, which is why we made it a priority to include patients experiencing their first recurrence of CDI in PRISM3,” said Zain Kassam, MD, MPH, Chief Medical Officer at Finch. “We are excited by the topline results and look forward to engaging with FDA on the next steps to bring CP101 through the regulatory process.”

CP101 builds on the significant body of evidence that microbiome restoration via microbiota transplantation procedures can prevent recurrent CDI. Unlike antibiotics, which inhibit *C. difficile* growth but do not restore the function of the microbiome, CP101 is designed to prevent recurrent CDI by restoring colonization resistance, or the ability of a healthy microbiome to prevent colonization of potential pathogens. As an oral microbiome drug with rigorous testing that is manufactured under Good Manufacturing Practices (GMP) conditions, CP101 is designed to achieve an improved safety profile, while delivering the full diversity of a healthy microbiome and improving the patient experience.

New CP101 Development Program for the Treatment of Chronic Hepatitis B

Finch also announced today the initiation of a program to evaluate CP101 for the treatment of chronic hepatitis B. This program builds on clinical evidence demonstrating hepatitis B virus e-antigen clearance following microbiome restoration, even among patients that have failed to achieve clearance following long-term antiviral therapy [1,2]. Finch intends to study if CP101 may restore the microbiome and support activation of an immune response in chronic hepatitis B patients. Research suggests that the microbiome can modulate the immune system, a mechanism targeted by approved therapies for hepatitis B such as pegylated interferon.

“The positive results from PRISM3 mark a pivotal moment for patients, Finch, and the entire microbiome field, as they demonstrate the ability to drive clinically meaningful outcomes with a microbiome drug. We plan to apply the same principles we used in CDI against the many other conditions linked to microbiome dysfunction,” said Mark Smith, PhD, Chief Executive Officer of Finch. “As an important next step towards this vision, we are announcing

today a new development program for CP101 in the treatment of chronic hepatitis B."

All of Finch's investigational drugs are composed of microbial communities designed to restore the composition and function of the gut microbiome, the community of microbes that inhabit the gastrointestinal tract. While dysbiosis, or disruption, of this microbial community has been implicated in a wide range of diseases and numerous clinical studies have demonstrated promising clinical outcomes from investigational microbiota transplantation procedures, there are currently no FDA-approved drugs designed to restore the microbiome [3,4].

About CP101

CP101 is an investigational, oral 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 [5]. CP101 is designed to deliver complete microbiome communities in orally administered, enteric release capsules. CP101 is rigorously tested and manufactured under Good Manufacturing Practices (GMP) conditions. CP101 is in late-stage clinical development for the prevention of recurrent *C. difficile* infection and will be evaluated as an investigational drug for the treatment of chronic hepatitis B.

The development of CP101 as a microbiome drug reflects the 2013 FDA policy that microbiome-based treatments are regulated as drugs [6].

About *C. difficile* Infections

Clostridioides difficile infection (CDI) is one of the most urgent antibiotic-resistant bacterial threats in the U.S. and is the most common healthcare-associated infection according to the U.S. Centers for Disease Control. *C. difficile*, a gastrointestinal pathogen that causes life-threatening diarrhea, is characterized by high rates of recurrence after standard-of-care antibiotic therapy. Approximately 500,000 individuals in the U.S. suffer from CDI each year, with approximately 45% of patients experiencing another CDI recurrence following treatment of their first recurrence of CDI [7,8]. CDI contributes to more than 29,000 deaths and drives more than $6 billion in direct healthcare costs each year in the U.S. [7,9].

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 program, CP101, is an investigational microbiome drug with Fast Track and Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for the prevention of recurrent *C. difficile* infection. The company is also evaluating CP101 for the treatment of chronic hepatitis B. Finch also has Fast Track designation from the FDA for a microbiome drug program for the treatment of autism spectrum disorder with gastrointestinal symptoms in children. The company has a strategic partnership with Takeda Pharmaceuticals focused on the development of microbiome drugs for inflammatory bowel diseases.

1. Ren et al. Fecal microbiota transplantation induces hepatitis B virus e-antigen (HBeAg) clearance in patients with positive HBeAg after long-term antiviral therapy. Hepatology 2017.

2. Chauhan et al. Fecal Microbiota Transplantation in Hepatitis B e Antigen-Positive Chronic Hepatitis B Patients: A Pilot Study. Dig Dis Sci 2020.

3. Lynch et al. The Human Intestinal Microbiome in Health and Disease. N Engl J Med 2016.

4. Allegretti et al. The Evolution of the Use of Faecal Microbiota Transplantation and Emerging Therapeutic Indications. Lancet 2019.

5. Klein et al. Global increase and geographic convergence in antibiotic consumption between 2000 and 2015. PNAS 2018.

6. Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies. https://www.fda.gov/media/96562/download

7. McDonald et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis 2018.

8. Kelly C. Can We Identify Patients at High Risk of Recurrent Clostridium Difficile Infection? Clin Microbiol Infec 2012.

9. Zhang et al. Cost of Hospital Management of Clostridium Difficile Infection in United States-a Meta-Analysis and Modelling Study. BMC Infect Dis 2016.

CP101 is not approved in any country. The FDA's Fast Track and Breakthrough Therapy designations do not constitute or guarantee future approval or alter the standards for approval.

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