Finch Therapeutics' Investigational Drug CP101 Granted Breakthrough Therapy Designation from FDA for Recurrent C. Difficile Infection

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Designation to accelerate Finch's efforts to provide an effective therapy for patients fighting recurrent C. difficile infection.

SOMERVILLE, Mass.–(BUSINESS WIRE)–Finch Therapeutics Group, Inc., a clinical-stage microbiome therapeutics company, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to investigational drug CP101 for the treatment of patients with recurrent *Clostridium difficile (C. difficile)* infection. Breakthrough Therapy Designation is intended to expedite the development and review of investigational therapeutics for serious or life-threatening conditions where preliminary clinical evidence indicates that the product may demonstrate a substantial improvement over existing therapies on one or more clinically significant endpoints.

Finch's lead therapeutic candidate CP101 is designed to prevent recurrent *C. difficile*, a bacterial infection affecting over 500,000 patients each year and leading to an estimated 29,000 annual deaths. Recurrent *C. difficile* has been named an urgent public health threat by the Centers for Disease Control (CDC) and, with a high percentage of patients failing standard-of-care antibiotic treatment, presents a clear and urgent unmet medical need.

"We are thrilled that CP101 has been designated as a Breakthrough Therapy for recurrent *C. difficile*," said Mark Smith, CEO of Finch. "CP101 is designed to break the cycles of infection by restoring the balance of the gut microbiome, an approach supported by numerous clinical studies and Finch's extensive experience providing microbial treatments to patients suffering from *C. difficile*. This designation will accelerate our efforts to provide an effective therapy for patients living with this devastating infection, and we look forward to working closely with the FDA to advance that mission."

Finch is actively enrolling patients with recurrent *C. difficile* in PRISM3, a randomized, placebo-controlled Phase II clinical study to assess the safety and efficacy of CP101. The study drug is an oral capsule that is administered in a single dose. For more information about this trial, please visit www.prism3trial.com.

CP101 is not approved in any country. The FDA's Breakthrough Therapy Designation does not constitute or guarantee a future approval and does not alter the standards for approval.

About Finch Therapeutics Group, Inc.

Finch Therapeutics Group, Inc. (Finch) is developing novel microbial therapies to serve patients with serious unmet medical needs. Built on 30 years of translational research at OpenBiome, MIT, University of Minnesota and the Center for Digestive Diseases, Finch uses *Human-First Discovery* to develop therapies from microbes that have demonstrated clinically significant impacts on patient outcomes. Finch is unique in having both a donor-derived *Full-Spectrum Microbiota* (*FSM*) product platform and a *Rationally Selected Microbiota* (*RSM*) product platform based on microbes grown in pure culture. Finch's lead program, CP101, is an investigational *FSM* product for prevention of recurrent *C. difficile* infections. Finch's *RSM* platform employs machine-learning algorithms to mine Finch's unique clinical datasets, reverse engineering successful clinical experience to identify the key microbes driving patient outcomes. Finch has a strategic partnership with Takeda to develop FIN-524, an investigational *RSM* product for inflammatory bowel disease. Finch is using a rich foundation of clinical data to advance its pipeline, leveraging proof-of-principle results to evaluate target indications and inform the design of this new therapeutic class.

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