Finch Therapeutics Receives Fast Track Designation for the Investigation of Full-Spectrum Microbiota as a Treatment for Children with Autism Spectrum Disorder

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SOMERVILLE, Mass.–(BUSINESS WIRE)–Finch Therapeutics Group, Inc., a clinical-stage microbiome therapeutics company, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its *Full-Spectrum Microbiota*® (*FSM*®) therapy for the treatment of children with Autism Spectrum Disorder (ASD). Fast Track designation is intended to facilitate development and expedite review of therapies designed to treat serious conditions and fill an unmet medical need.

Studies have shown that individuals with ASD commonly suffer from GI symptoms, such as constipation, diarrhea, and abdominal pain. Research characterizing the gut microbiome of individuals with ASD has revealed an abnormal gut microbiome compared to healthy controls. Previously, Adams and Krajmalnik-Brown, Finch's collaborators at Arizona State University treated 18 children affected by ASD with *Full-Spectrum Microbiota* in an open-label study. They found the treatment was well-tolerated and led to a 77% reduction of GI symptoms and a 24% reduction of core ASD symptoms at eight weeks post-treatment. A recently published study that followed these 18 children for two years after initial treatment reports sustained improvements in GI symptoms and core behavioral ASD symptoms.

"With an estimated 1 in 59 children diagnosed with ASD and no FDA-approved medications indicated for the core symptoms of ASD, there is clearly a strong need to provide children and families impacted by ASD with an effective therapy," said Mark Smith, CEO of Finch. "We are very encouraged by the preliminary clinical data in this field and look forward to conducting the randomized, controlled clinical trials necessary to fully assess the safety and efficacy of *Full-Spectrum Microbiota* therapy for the treatment of children with ASD."

Finch is supporting an actively enrolling Phase II investigator-initiated clinical study evaluating the safety and efficacy of its *Full-Spectrum Microbiota* therapy in adults with ASD (NCT03408886). Finch also plans to conduct a randomized, placebo-controlled, Phase II clinical study in children with ASD (NCT03829878). In both studies, the study drug is an oral capsule designed to contain a diverse community of microbiota capable of restoring an unbalanced microbiome. Finch's *FSM* therapy is also being evaluated in PRISM3, an actively enrolling Phase II study in patients with recurrent *C. difficile* infections (NCT03110133).

Full-Spectrum Microbiota therapy is not approved in any country. The FDA's Fast Track 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 also developing an *FSM* product for the treatment of children with Autism Spectrum Disorder and associated GI symptoms. 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.

Full-Spectrum Microbiota, *FSM*, *Rationally-Selected Microbiota*, *RSM*, and *Human-First Discovery* are trademarks of Finch Therapeutics Group, Inc.

Contact:

Gabriella Linville-Engler
media@finchtherapeutics.com