Finch Therapeutics Further Strengthens Patent Portfolio with Two New U.S. Patents Granted for FIN-211, an Investigational Microbiome Therapeutic in Development for Autism Spectrum Disorder

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SOMERVILLE, Mass., Jan. 06, 2022 (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 that the U.S. Patent and Trademark Office has issued two new patents covering the company’s FIN-211 enriched consortia microbiome product candidate in development for children with autism spectrum disorder (ASD) and significant gastrointestinal (GI) symptoms. The company’s intellectual property portfolio now includes 59 issued U.S. and foreign patents with more than 130 patent applications pending.

The first patent (U.S. Patent No. 11,202,808) covers key technologies involved in addressing ASD and GI symptoms associated with ASD by orally administering a donor-derived microbial community enriched with bacterial isolates from a genus with potential therapeutic applications in ASD. This patent is jointly owned with, and exclusively licensed from, the Arizona Board of Regents on behalf of Arizona State University and the Regents of the University of Minnesota. The second patent (U.S. Patent No. 11,207,356), solely owned by Finch, covers encapsulated compositions containing donor-derived microbiota enriched with one or more cultured bacterial strains, and methods of manufacturing such compositions. The first and second patents have expiration dates in 2036 and 2031, respectively.

“The granting of these two new patents further strengthens our growing patent portfolio and helps establish a firm foundation for the advancement of FIN-211, our first microbiome product candidate that leverages our ability to deliver a diverse microbial community that is enriched with key microbes,” said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. “We believe FIN-211 has the potential to promote the broad functions of a diverse gut microbiome while also targeting specific mechanisms that may be important in ASD. We look forward to initiating our Phase 1b trial of FIN-211 in children with ASD and constipation in the first half of 2022, research that we believe will add to the growing body of evidence supporting the potential for a microbiome-based therapeutic option for children with ASD and significant GI symptoms.”

About FIN-211 for Autism Spectrum Disorder (ASD)

FIN-211 is an investigational, orally administered microbiome therapeutic in development for children with ASD and significant gastrointestinal (GI) symptoms. FIN-211, an enriched consortia product candidate, is designed to deliver a diverse microbial community that is enriched with select bacteria grown in pure culture. FIN-211 is designed to address both the GI and core symptoms that can affect children with ASD.

Finch plans to initiate the Phase 1b AUSPIRE trial of FIN-211 in the first half of 2022, an open-label trial which is expected to enroll approximately 40 children with ASD and constipation. Multiple FIN-211 dosing regimens will be evaluated in the AUSPIRE trial, with safety and tolerability as the primary endpoints. Secondary endpoints include measures of pharmacokinetics, such as engraftment, and exploratory endpoints include assessments of behavioral scores and GI symptoms. The FIN-211 development program builds on multiple lines of evidence indicating a link between the microbiome and ASD, including several investigator-sponsored, proof-of-concept clinical (in-human) studies suggesting improvements in both GI and behavioral assessments following microbiota transplantation.[1, 2]

About Autism Spectrum Disorder (ASD)

The CDC estimates that approximately one in 44 children in the U.S. have been identified with ASD.[3] ASD can cause challenges in social interaction, communication, and behavior. A subset of individuals with ASD experience significant GI symptoms, such as constipation.[4] There are no FDA-approved therapeutics for the core symptoms of ASD and there is a significant unmet need for treatments that effectively address the GI symptoms that some children with ASD experience.

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 children with autism spectrum disorder and significant gastrointestinal symptoms. 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 leverage its platform to develop a novel class of orally administered biological drugs; the

therapeutic potential of FIN-211; and the timing, enrollment and results of Finch's Phase 1b trial of FIN-211. 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 to support 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 November 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.

1. Kang Sci Rep 2019 (https://pubmed.ncbi.nlm.nih.gov/30967657/)
2. Li Front Cell Infect Microbiol 2021 (https://pubmed.ncbi.nlm.nih.gov/34737978/)
3. Maenner MMWR Surveillance Summaries 2021 (https://www.cdc.gov/mmwr/volumes/70/ss/ss7011a1.htm)
4. Holingue Autism Res 2018 (https://pubmed.ncbi.nlm.nih.gov/28856868/)

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