Finch Therapeutics Regains Full Rights to FIN-524 and FIN-525 Targeted Microbiome Product Candidates in Development for IBD

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SOMERVILLE, Mass., Aug. 25, 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 it will regain full development and commercial rights to FIN-524 (previously known as TAK-524) and FIN-525 from Takeda Pharmaceutical Company Limited (“Takeda”). Following a review of its pipeline, Takeda informed Finch of its decision to terminate its collaboration with Finch, effective November 17, 2022, resulting in the return to Finch of worldwide rights to develop and commercialize FIN-524, FIN-525, and any other microbiome product candidates for inflammatory bowel disease (IBD). FIN-524 and FIN-525 are investigational, orally administered targeted microbiome product candidates composed of bacterial strains selected for their potential immuno-modulatory properties.

“We are grateful for Takeda’s substantial investment in the FIN-524 and FIN-525 programs and want to thank our dedicated colleagues at Takeda who have worked alongside us to develop these innovative product candidates. We look forward to exploring collaboration opportunities to continue the advancement of these assets, which we believe hold the potential to fulfill the need for a disease-modifying, orally delivered, well-tolerated therapy for IBD patients who are not well served by existing options,” said Mark Smith, PhD, Chief Executive Officer of Finch Therapeutics. “We are currently conducting a review of our portfolio and assessing the financial and strategic impact of the discontinuation of our collaboration with Takeda.”

Finch has received more than $44 million from Takeda during the course of the collaboration, including an upfront payment of $10 million, $4 million in milestone payments, and more than $30 million in reimbursement of research and development expenses. Upon termination, Finch will receive a royalty-free license to all data and intellectual property generated during the collaboration, including full rights to a large library of characterized bacterial isolates, data from multiple *ex vivo* and *in vivo* studies, a suite of pharmacokinetic and pharmacodynamic assays, and a significant body of chemistry, manufacturing, and controls (CMC) data generated during the investigational new drug (IND)-enabling phase of development.

About FIN-524 & FIN-525 for Inflammatory Bowel Disease

FIN-524 and FIN-525 are investigational, orally administered targeted consortia product candidates composed of both spore-forming and non-spore-forming bacterial strains selected for the treatment of ulcerative colitis and Crohn’s disease, respectively. The product candidates are designed to include strains that target multiple mechanisms of action combined with donor strains linked to remission following microbiota transplantation in patients with inflammatory bowel disease (IBD). The design of FIN-524 and FIN-525 leverage Finch’s machine-learning based platform and data from microbiota transplantation studies in patients with IBD. The manufacture of FIN-524 and FIN-525 is donor independent, with the strains grown from master cell banks.

About Inflammatory Bowel Disease

Ulcerative colitis and Crohn’s disease are the two most common types of inflammatory bowel disease (IBD), an autoimmune condition that causes inflammation of the gastrointestinal (GI) tract. Approximately 10 million people are affected by IBD worldwide, including approximately three million people in the U.S. Symptoms of IBD include severe, chronic abdominal pain, diarrhea, GI bleeding, weight loss, and fatigue. Current treatment options are ineffective for many people living with IBD.

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 has 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 and has received Breakthrough Therapy and Fast Track designations from the U.S. Food and Drug Administration. Finch’s pipeline also includes FIN-211 for children with autism spectrum disorder and significant gastrointestinal symptoms, FIN-524 for the treatment of ulcerative colitis, and FIN-525 for the treatment of Crohn’s disease. Finch routinely posts information that may be important to its investors on its website at www.finchtherapeutics.com. Finch encourages investors to consult the “Investors & News” section of its website regularly.

Human-First Discovery® is a registered trademark of Finch Therapeutics Group, Inc.

Forward-Looking Statements

This press release includes “forward-looking statements.” Words such as “will,” "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: the potential and future development of the FIN-524 and FIN-525 programs and the Company’s other product candidates, the potential for collaboration opportunities to continue the advancement of these programs; the financial and strategic impact of termination of Finch’s collaboration with Takeda; and Finch’s ability to develop a novel class of orally administered biological drugs. 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, those related to: 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 and the potential impact of termination of Finch's collaboration with Takeda on such funding requirements and Finch's ability to obtain funding; 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; results of clinical trials may not be sufficient to satisfy regulatory authorities to approve Finch's product candidates in their targeted or other indications (or such authorities may request additional trials or additional information); Finch's ability to comply with regulatory requirements; ongoing regulatory obligations and continued regulatory review may result in significant additional expense to Finch and Finch may be subject to penalties for failure to comply; 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 in anticipation of commencement of 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 Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 31, 2022, as supplemented by Finch's Quarterly Reports on Form 10-Q filed with the SEC on May 16, 2022 and August 11, 2022, 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.

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