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Media Release

Ferring Inc. Receives Health Canada Approval for PrREBYOTA® (fecal microbiota, live)

A Novel First-in-Class Microbiome-Restoration Therapy for the Prevention of Recurrence of *C. diff* Infection

- *Ferring's novel first-in-class REBYOTA is indicated for the prevention of recurrence of Clostridioides difficile infection (C. diff) in individuals 18 years of age and older, following antibiotic treatment for recurrent C. diff. REBYOTA is not indicated for the treatment of C. diff.*
- *The safety and efficacy of REBYOTA was studied in the largest clinical trial program in the field of microbiome-based therapeutics, including five clinical trials with more than 1,000 participants, including over 230 Canadian patients across 5 Canadian clinical trial sites.*
- *Recurrent C. diff represents a significant burden for patients, caregivers and the healthcare system.*

Toronto, ON – 6 March, 2025 – Ferring Inc. announced Health Canada has issued a Notice of Compliance, approving REBYOTA® (fecal microbiota, live), a novel first-in-class microbiome-restoration therapy indicated for the prevention of recurrence of *Clostridioides difficile* infection (*C. diff*) in individuals 18 years of age and older, following antibiotic treatment for recurrent *C. diff.*[1]

C. diff is the most common cause of infectious diarrhea in hospitalized patients in the industrialized world, including Canada.[2] Once a person has an initial infection, *C. diff* can be the start of a vicious cycle of recurrence, causing a significant burden for patients and the healthcare system.[3,4] It has been estimated that up to 35% of *C. diff* cases recur after initial diagnosis and people who have had a recurrence are at significantly higher risk of further recurrences. *"REBYOTA is a much needed new therapy that offers hope to the thousands of people who suffer from recurrent C. diff infection each year,"* said Gail Attara, Chief Executive Officer and Co-Founder, Gastrointestinal Society (www.badgut.org). *"REBYOTA has the potential to break the vicious recurrence cycle, thus having a significant effect on patients and caregivers. Its effectiveness can reduce healthcare costs by keeping patients out of the hospital."*

"Recurrent C. diff is a debilitating condition, affecting physical, psychological, social, and professional aspects of a patient's life. Until now, patients living with the devastating cycle of recurrent C. diff have had limited approved treatment options in Canada. This frequently leads to long periods of time suffering with incapacitating symptoms that prevent them from leaving their homes and even separating them from immediate family members, or a need to stay on chronic antibiotics to maintain their health," said Dr. Theodore Steiner, Head, Division of Infectious Disease, University of British Columbia, and Principal Investigator, Vancouver General Hospital/UBC. "*With the approval of REBYOTA, we finally have a regulatory approved therapy that can help prevent future C. diff. recurrence by restoring the microbiome to a healthier state."*

Health Canada's approval of REBYOTA® is based on the results from the clinical program including the randomized, double-blind, placebo-controlled Phase 3 PUNCH™ CD3 trial[5]. The results from the Canadian cohort of the Open Label Study (OLS) of PUNCH CD3 were presented this past week at the Canadian Digestive Disease Week (CDDW) conference in Quebec City. In the Canadian OLS cohort (n=117), treatment success was achieved by 75.2% (88/117) of patients who were

administered REBYOTA® after standard-of-care (SoC) antibiotics and sustained clinical response at six months was achieved by 90.9% (80/88) of Canadian participants.[6]

Across 5 studies in the clinical development program,[7] encompassing safety data of 978 trial participants through 6 months, REBYOTA® was well tolerated with primarily mild to moderate treatment-emergent adverse events (TEAEs) and most were related to preexisting conditions. Through six months, incidence of TEAEs was similar between REBYOTA recipients compared with placebo (66.4%, n=507/763, REBYOTA; 60.2%, n=50/83, placebo).

"We believe the overall results of the PUNCH-CD clinical program and particularly the results from the Canadian OLS cohort of the study, represent a major breakthrough in harnessing the power of the human microbiome to address significant unmet medical needs. This is the first Health Canada approval of a microbiome restoration therapy that prevents future C. diff recurrences, and the culmination of decades of research and clinical development," said Lee Ferreira, General Manager, Canada, Ferring Inc.

"Today's announcement is a significant milestone for people living with recurrent C. diff infection, and represents a significant step which holds promise that many other diseases might be better understood, diagnosed, and prevented using our rapidly evolving insights on the role of the microbiome in human health and disease." added Brian Clark, Vice President, Global Medical Head of Gastro-Enterology Therapeutic Area, Global Research and Medical, Ferring.

Please see important safety information below, and for full prescribing information visit Rebyota® Product Monograph .

About *C. difficile* Infection (*C. diff*)

C. diff is a serious and potentially deadly infection that impacts people across the globe. The *C. diff* bacterium causes debilitating symptoms, such as severe diarrhea, fever, stomach tenderness or pain, loss of appetite, nausea and colitis (an inflammation of the colon).[8] *C. diff* can be the start of a vicious cycle of recurrence, causing a significant burden for patients and the healthcare system.[3,4] It has been estimated that up to 35% of *C. diff* cases recur after initial diagnosis and people who have had a recurrence are at significantly higher risk of further infections.[9-12] After the first recurrence, it has been estimated that up to 65% of patients may develop a subsequent recurrence.[11,12] Antibiotics – the current standard of care for treatment of *C. diff*– treat the disease but can also be a contributing factor for a vicious cycle of recurrence, causing a significant burden for patients suffering from this debilitating and potentially deadly illness.[8,13]

ABOUT REBYOTA

REBYOTA is indicated for the prevention of recurrence of *Clostridioides difficile* infection *(C. diff)* in individuals 18 years of age and older, following antibiotic treatment for recurrent *C. diff.* REBYOTA is a pre-packaged, single-dose 150 mL microbiota suspension for rectal administration. REBYOTA is sourced from qualified donors and tested for a panel of transmissible pathogens. REBYOTA can be administered by any healthcare professional.[1]

INDICATION

REBYOTA is indicated for the prevention of recurrence of *Clostridioides difficile* (*C. diff*) infection in individuals 18 years of age and older, following antibiotic treatment for recurrent *C. diff*. REBYOTA is not indicated for the treatment of *C. diff.*[1]

IMPORTANT SAFETY INFORMATION

- You should not receive REBYOTA if you have a history of a severe allergic reaction (e.g. anaphylaxis) to REBYOTA or any of its components. Prior to treatment with REBYOTA, talk to your doctor about the possibility of a sudden allergic reaction following administration.

- You should report to your doctor any infection you think you may have acquired after administration.

- REBYOTA is manufactured from human fecal matter and may contain food allergens. Prior to treatment talk to your doctor about any known food allergies.

- Most common side effects may include stomach pain (8.9%), diarrhea (7.2%), bloating (3.9%), gas (3.3%), and nausea (3.3%).

- REBYOTA for the prevention of recurrent *C. diff* has not been studied in patients below 18 years of age.

About Ferring Pharmaceuticals
Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group committed to helping people around the world build families and live better lives. Headquartered in Saint-Prex, Switzerland, Ferring is a leader in reproductive medicine and women's health, and in specialty areas within gastroenterology and urology. Ferring has been developing treatments for mothers and babies for over 50 years and has a portfolio covering treatments from conception to birth. Founded in 1950, privately owned Ferring now employs around 6,000 people worldwide, has its own operating subsidiaries in more than 50 countries, and markets its products in 110 countries.

Learn more at www.ferring.com, or connect with us on Twitter, Facebook, Instagram, LinkedIn and YouTube.

Ferring is committed to exploring the crucial link between the microbiome and human health, beginning with the threat of recurrent *C. diff* infection. Ferring is working to develop novel microbiome-based therapeutics to address significant unmet needs and help people live better lives. Connect with us on our dedicated microbiome therapeutics development channels on Twitter and LinkedIn.

References:

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