FERRING PHARMACEUTICALS

Microbiome Therapeutics Development

For Media Use Only

Ferring Pharmaceuticals and the Future of Microbiome Therapeutics

Ferring Pharmaceuticals aims to deliver innovative therapeutics to help people live better lives. With the 2018 acquisition of Rebiotix, along with several other alliances, Ferring is a leader in microbiome research, committed to shedding light on the link between disease and the microbiome – beginning with disruptions in the gut – and restoring hope to patients.

Ferring is pioneering a new category of scientifically-validated, microbiome-based therapeutics that are standardized for quality and safety, starting with the treatment of recurrent *Clostridioides difficile (C. difficile)* infection.

About the Gut Microbiome and *C. difficile* Infection:

When there is a disruption of the composition and/or diversity of the gut microbiome, there is an associated risk for serious illnesses, such as *C. difficile* infection.

C. difficile infection is named as a major and urgent public health threat by the U.S. Centers for Disease Control and Prevention (CDC) that requires immediate and urgent action, affecting nearly half a million people every year.[1,2] *C. difficile* infection recurs in up to 35% of cases after initial CDI diagnosis[2,3] and people who have had a recurrence are at a higher risk of further infections.[4,5,6,7]

Restoring a healthy gut microbiome is increasingly recognized as a promising treatment option for recurrent *C. difficile* infection (rCDI),[8,9] although there are currently no microbiome-based therapeutics approved by the U.S. Food and Drug Administration (FDA) or any other regulatory agency outside of the U.S.

About RBX2660:

RBX2660, which has completed Phase 3 development, is a potential first-in-class microbiota-based live biotherapeutic that is being studied to deliver a broad consortium of diverse microbes to reduce rCDI.

RBX2660 has Fast Track, Orphan, and Breakthrough Therapy designations from the U.S. FDA.

In the field of microbiome-based therapeutics, the clinical development program for RBX2660 is the largest and most robust in the world, with the highest number of patients enrolled in prospective clinical trials. The program includes 6 clinical trails enrolling more than 1,000 patients, including two randomized, double-blind, placebo-controlled clinical trials.

About Ferring's Dedication to Microbiome-based Scientific Leadership and Pipeline Research:

Our microbiome-based R&D pipeline includes a robust development program utilizing the MRT™ drug platform to research the application of microbiota-based live biotherapeutics – starting with rCDI. Additionally, we are exploring therapeutic applications in chronic gastrointestinal diseases, liver dysfunction, antimicrobial resistance, oncology, reproductive medicine, and urology, as well as other therapeutic areas of high unmet needs.

In addition to the acquisition of Rebiotix, Ferring is:

- Collaborating with the Karolinksa Institutet and the Science for Life Laboratory on the Centre for Translational Microbiome Research (CTMR) on exploring the microbiome and developing novel therapeutics in reproductive medicine, neonatology and gastroenterology.
- Partnering in a multi-year strategic collaboration with MyBiotics Pharma Ltd. to develop live microbiota-based biotherapeutics to address vaginosis.
- Developing bacteriophage treatments for microbiome-associated conditions with Intralytix, Institut Pasteur, DigestScience and the Lille Inflammation Research International Center (LIRIC).
- Researching microbiome-based treatments related to intrahepatic cholestasis of pregnancy (ICP) with Metabogen.
- Evaluating the role of the microbiome in patients with inflammatory bowel disease (IBD) with Nordsjaellands Hospital in Denmark.

Ferring is also committed to connecting clinical and microbiome data. Rebiotix and Ferring developed the Microbiome Health Index™ (MHI™) to provide the microbiome research community with a standardized metric to quantify microbiome restoration.

1 Centers for Disease Control and Prevention. 2019 Antibiotic Resistance Threats Report: Clostridioides Difficile. https://www.cdc.gov/drugresistance/pdf/threats-report/clostridioides-difficile-508.pdf.
2 Lessa FC, Mu Y, Bamberg WM, et al. Burden of Clostridium difficile infection in the United States. N Engl J Med. 2015;372(9):825-834
3 Cornely OA, et al. Treatment of First Recurrence of Clostridium difficile Infection: Fidaxomicin Versus Vancomycin. Clinical Infectious Diseases. 2012;55(S2):S154–61.
4 Riddle DJ, Dubberke ER. Clostridium difficile infection in the intensive care unit. Infect Dis Clin North Am. 2009;23(3):727-743.
5 Nelson WW, et al. Health care resource utilization and costs of recurrent Clostridioides difficile infection in the elderly: a real-world claims. J Manag Care Spec Pharm. Published online March 11, 2021.
6 Kelly, CP. Can we identify patients at high risk of recurrent Clostridium difficile infection? Clin Microbiol Infect. 2012; 18 (Suppl. 6): 21–27
7 Smits WK, et al. Clostridium difficile infection. Nat Rev Dis Primers. 2016;2:16020. doi: 10.1038/nrdp.2016.20.
8 van Nood E, Vrieze A, Nieuwdorp M, et al. Duodenal infusion of donor feces for recurrent Clostridium difficile. N Engl J Med. 2013;368(5):407-415.
9 Gough E, Shaikh H, Manges AR. Systematic review of intestinal microbiota transplantation (fecal bacteriotherapy) for recurrent Clostridium difficile infection. Clin Infect Dis. 2011;53(10):942-1002.