

# Ferring to Present Award-Winning, Landmark Research for Investigational Microbiota-Based Live Biotherapeutic RBX2660 at IDWeek 2021

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## Microbiome Therapeutics Development

PARSIPPANY, N.J.--(BUSINESS WIRE)--Ferring Pharmaceuticals and Rebiotix, a Ferring Company, today announced they will present data from the clinical development program for RBX2660, an investigational microbiota-based live biotherapeutic for reduction of recurrent *Clostridioides difficile* (*C. difficile*) infection, as part of IDWeek 2021. The congress will take place virtually from September 29 – October 3, 2021.

“Our data presentations at IDWeek will not only add to the growing body of clinical evidence supporting RBX2660, but they bring together nearly a decade of research that show exciting advancements in how RBX2660 clinical outcomes relate to microbiome composition”

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Notably, the data include the first-time presentation of an analysis from five prospective clinical studies, which represent the totality of this comprehensive body of clinical evidence for a microbiota-based live biotherapeutic. IDWeek acknowledged this presentation and its author, Lindy L. Bancke, PharmD, Head of Clinical Development at Rebiotix, as one of only four recipients of the 2021 Program Committee Choice award, based on outstanding scientific research.

Additionally, the company will present data demonstrating the association of RBX2660 in gut microbiome restoration and the impact of the decolonization of deadly multi-drug resistant organisms.

“Our data presentations at IDWeek will not only add to the growing body of clinical evidence supporting RBX2660, but they bring together nearly a decade of research that show exciting advancements in how RBX2660 clinical outcomes relate to microbiome composition,” said James P Tursi, M.D., Chief Scientific Officer, Ferring Pharmaceuticals U.S.

The clinical development program for RBX2660 is the largest and most robust ever conducted in the field of microbiome-based therapeutics for recurrent *C. diff* infection, enrolling more than 1,000 patients to date and including two studies that followed patients for 24 months.

The details of the five abstracts being presented are as follows:

**Presentation Title:** Efficacy of Investigational Microbiota-Based Live Biotherapeutic RBX2660 in Individuals with Recurrent *Clostridioides difficile* Infection: Data from Five Prospective Clinical Studies

**Presenting Author:** Lindy Bancke, PharmD, Head of Clinical Development, Rebiotix

**EMBARGOED UNTIL:** Wednesday, September 29 at 8:00 AM EDT

**Presentation Title:** Antimicrobial Resistance Genes were Reduced Following Administration of Investigational Live Biotherapeutic RBX2660 to Individuals with Recurrent *Clostridioides difficile* Infection

**Presenting Author:** Heidi Hau, PhD, Director of Translational Biology, Rebiotix

**EMBARGOED UNTIL:** Wednesday, September 29 at 8:00 AM EDT

**Presentation Title:** Treatment Success in Reducing Recurrent *Clostridioides difficile* Infection with Investigational Live Biotherapeutic RBX2660 is Associated with Microbiota Restoration: Consistent Evidence from a Phase 3 Clinical Trial

**Presenting Author:** Ken Blount, PhD, Chief Scientific Officer, Rebiotix and VP Microbiome Research, Ferring Pharmaceuticals

**EMBARGOED UNTIL:** Wednesday, September 29 at 8:00 AM EDT

**Presentation Title:** Safety of Investigational Microbiota-Based Live Biotherapeutic RBX2660 in Individuals with Recurrent *Clostridioides difficile* Infection: Data From Five Prospective Clinical Studies

**Presenting Author:** Tricia Braun, PharmD, Associate Director of Clinical Research, Rebiotix

**EMBARGOED UNTIL:** Wednesday, September 29 at 8:00 AM EDT

**Presentation Title:** Rapid Restoration of Bile Acid Compositions After Treatment with RBX2660 for Recurrent *Clostridioides difficile* Infection-Results from the PUNCH CD3 Phase 3 Trial

**Presenting Author:** Romeo Papazyan, PhD, Scientist, Ferring Research Institute

**EMBARGOED UNTIL:** Wednesday, September 29 at 8:00 AM EDT

IDWeek has made abstracts available on their website.

### **About the gut microbiome and *C. difficile* infection**

*C. difficile* infection (CDI) is a serious and potentially deadly disease that impacts people across the globe. The *C. difficile* bacterium causes debilitating symptoms such as severe diarrhea, fever, stomach tenderness or pain, loss of appetite, nausea and colitis (an inflammation of the colon).<sup>1</sup> Declared a public health threat by the U.S. Centers for Disease Control and Prevention (CDC) requiring urgent and immediate action, CDI causes an estimated half a million illnesses and tens of thousands of deaths in the U.S. alone each year.<sup>1,2,3</sup>

*C. difficile* infection often is the start of a vicious cycle of recurrence, causing a significant burden for patients and the healthcare system.<sup>4,5</sup> Up to 35% of CDI cases recur after initial diagnosis<sup>6,7</sup> and people who have had a recurrence are at significantly higher risk of further infections.<sup>8,9,10,11</sup> After the first recurrence, it has been estimated that up to 60% of patients may develop a subsequent recurrence.<sup>12</sup>

Recurrent *C. difficile* infection (rCDI) is associated with disruptions to the gut microbiome, or “dysbiosis”. The gut microbiome is a highly-diverse microbial community that plays an essential role in human health. There is a growing body of evidence that shows when there is a disruption of the composition and/or diversity of the gut microbiome, there may be an associated risk for serious illnesses, including CDI. The current standard of care treatment for rCDI is antibiotics, which does not address the underlying dysbiosis or restore the gut microbiome.<sup>13</sup> The use of antibiotics has been shown to disrupt the ecology of the gut microbiome and are a predominant risk factor for rCDI.<sup>6,7,13</sup>

Restoring the gut microbiome is increasingly accepted as a promising treatment option for recurrent *C. difficile* infection.<sup>14</sup>

### **About RBX2660**

RBX2660 is a potential first-in-class microbiota-based live biotherapeutic being studied to deliver a broad consortium of diverse microbes to the gut to reduce recurrent *C. difficile* infection. RBX2660 has been granted Fast Track, Orphan, and Breakthrough Therapy designations from the U.S. Food and Drug Administration (FDA). The pivotal Phase 3 program builds on nearly a decade of research with robust clinical and microbiome data collected over six controlled clinical trials with more than 1,000 participants.

## 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 maternal 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 approximately 6,500 people worldwide, has its own operating subsidiaries in nearly 60 countries and markets its products in 110 countries. Learn more at [www.ferring.com](http://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. difficile* infection. With the 2018 acquisition of Rebiotix and several other alliances, Ferring is a world leader in microbiome research, developing novel microbiome-based therapeutics to address significant unmet needs and help people live better lives. The Ferring Research Institute Inc. (FRI), based in San Diego, USA, is part of the Global Drug Discovery & External Innovation unit, which is the research and ideas engine of Ferring Pharmaceuticals. FRI is an integral part of Ferring's R&D organization, focusing on early drug discovery and development. Connect with us on our dedicated microbiome therapeutics development channels on Twitter and LinkedIn.

## About Rebiotix

Rebiotix Inc, a Ferring Company, is a late-stage clinical microbiome company focused on harnessing the power of the human microbiome to revolutionize the treatment of challenging diseases. Rebiotix has a diverse pipeline of investigational drug products built on its pioneering microbiota-based MRT™ drug platform. The platform consists of investigational drug technologies designed to potentially rehabilitate the human microbiome by delivering a broad consortium of live microbes into a patient's intestinal tract. For more information on Rebiotix and its pipeline of human microbiome-directed therapies for diverse disease states, visit [www.rebiotix.com](http://www.rebiotix.com), or connect with us on Twitter, Facebook, LinkedIn and YouTube.

## About IDWeek

IDWeek is the joint annual meeting of the Infectious Diseases Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA), the HIV Medical Association (HIVMA), the Pediatric Infectious Diseases Society (PIDS), and the Society of Infectious Diseases Pharmacists (SIDP). More information can be found at [www.idweek.org](http://www.idweek.org).

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