

## Media Release

# Rebiotix, a Ferring Company, Completes Enrollment for First-Ever, Pivotal Phase 3 Clinical Trial of Microbiota-based RBX2660

- *Enrollment completion for the first Phase 3 clinical trial in microbiome industry*
- *Largest randomized, double-blinded study, with over 300 patients enrolled aimed to demonstrate the potential benefit of RBX2660 in reducing rates of recurrent *Clostridioides difficile* (C. diff) infection*
- *Rebiotix intends to use the results from the Phase 3 trial to serve as the basis for licensure application to the US Food and Drug Admin (FDA)*

**Saint-Prex, Switzerland – February 4, 2020** – Rebiotix, a Ferring company, announced today that it has completed enrollment of the pivotal Phase 3 clinical trial for RBX2660, an investigational therapy aimed at breaking the cycle of recurrent *Clostridioides difficile* (C. diff) infection, which is responsible for the deaths of thousands of people in the US alone. The Centers for Disease Control and Prevention (CDC) has classified C. diff as an urgent public health threat, with limited options for treatment.

RBX2660 was developed under Rebiotix’s investigational microbiota-based MRT™ drug platform with the goal of delivering standardized, stabilized formulations to meet unmet medical needs. Conducted in the US and Canada, this is the first Phase 3 trial of its kind to be completed using a broad consortia microbiota-based formulation.

*“Rebiotix was founded to harness the power of the human microbiome to treat debilitating diseases,”* said Lee Jones, Rebiotix Founder and CEO. *“Microbiota-based therapies have shown tremendous potential as an innovative, non-antibiotic therapy, starting with C. diff. The completion of enrollment of this trial is a critical next step in making microbiota-based products accessible to patients - we are excited about this important milestone and look forward to sharing results later this year.”*

The Phase 3 trial builds on the company’s extensive history with the formulation, including several hundred participants previously enrolled in multiple Phase 2 clinical trials. The robust data collected over the course of the company’s multi-year clinical development program will be eventually presented to the US FDA as part of a Biological License Application (BLA).

Ferring Pharmaceuticals, also with a rich and vast history of microbiome research of its own, led the industry by becoming the first major pharmaceutical company to acquire a microbiome therapeutics company in April 2018. Headquartered in Saint-Prex, Switzerland, Ferring is expected to have the first regulatory approved microbiota-based therapeutic in the world through the potential approval of the RBX2660 in the US.

### **About *Clostridioides difficile* Infection**

*Clostridioides difficile* (also known as C. diff) is a bacterium that causes diarrhea and colitis (an inflammation of the colon). C. diff, impacts nearly a half a million people each year in the United States; of those impacted, up to one in five patients will experience a recurrent episode.<sup>1</sup> In 2019, the U.S. Centers for Disease Control listed C. diff as an urgent threat to public health.<sup>2</sup>

### **About RBX2660**

RBX2660 is currently in Phase 3 clinical development for the reduction of recurrent *Clostridioides difficile* (C. diff) infection. RBX2660 has been granted Fast Track, Orphan, and Breakthrough Therapy Status designations from the US FDA. For more information about the RBX2660 Phase 3 study, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03244644).

### **About Rebiotix**

Rebiotix Inc., part of the Ferring Pharmaceuticals Group, 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).

### **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. 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](#).

### **References:**

<sup>1</sup>Centers for Disease Control and Prevention. What Is C. Diff?, 17 Dec. 2018. Available at: <https://www.cdc.gov/cdiff/what-is.html>.

<sup>2</sup>Centers for Disease Control and Prevention. Biggest Threats and Data, 14 Nov. 2019. Available at: <https://www.cdc.gov/drugresistance/biggest-threats.html>.

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