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## **Rebiotix Reports Positive Top Line Data from Open-Label Phase 2 Trial of RBX2660 in Recurrent *Clostridium difficile***

*Results Demonstrate 78.8% Treatment Success Versus 51.8% Historical Control (p<0.0001)*

**ROSEVILLE, MN – April 11, 2017** – [Rebiotix Inc.](#), a clinical-stage microbiome company focused on harnessing the power of the human microbiome to treat challenging diseases, today announced top line results from a controlled open-label Phase 2 trial of RBX2660 (PUNCH™ Open Label) for the prevention of recurrent *Clostridium difficile* (*C. diff.*) infection. Data indicated that RBX2660 was well-tolerated and achieved the primary efficacy endpoint of preventing *C. diff.* recurrence; patients treated with RBX2660 exhibited a treatment success rate of 78.8% compared with a historical control of 51.8% (p<0.0001). RBX2660 is a broad-spectrum microbiota suspension that is designed to rehabilitate the human microbiome by delivering live microbes into a patient's intestinal tract to treat disease.

Lee Jones, president and CEO of Rebiotix, stated, “The 78.8% treatment success achieved in this open-label Phase 2 trial demonstrates the potential of RBX2660, a broad spectrum microbiota drug product, to rehabilitate the gut microbiome and break the cycle of *C. diff.* recurrence. These results, coupled with the safety and efficacy data observed in our prior Phase 2b and Phase 2 clinical trials, position Rebiotix to advance RBX2660 into Phase 3 clinical development, solidifying our standing as the most clinically advanced microbiome company in the industry.”

PUNCH™ Open Label was designed as a prospective, multicenter, open-label, controlled Phase 2 study to assess the efficacy and safety of RBX2660 for the prevention of recurrent *C. diff.* The primary efficacy endpoint involved a comparison of patients treated with RBX2660 to a closely matched set of antibiotic only treated historical controls through 56 days. There were 31 active treatment sites and four control sites in the US and Canada. 132 RBX2660 and 110 historical control subjects were included in this topline analysis.

Actively treated patients, after determining eligibility, were administered two doses of RBX2660; the first at day one and the second at day seven. Patients were then monitored for eight weeks to determine



whether there was a recurrence of *C. diff*. Top line results from the trial, which examined responses from 132 patients versus a historical control of 110 patients, indicated a treatment success rate of 78.8% as compared to a historical control of 51.8% ( $p < 0.0001$ ). Overall, RBX2660 was generally well-tolerated with the most commonly reported adverse events being gastrointestinal, including diarrhea, abdominal pain, flatulence, constipation and distension.

#### **About Rebiotix Inc.**

Rebiotix Inc. is a clinical-stage microbiome company focused on harnessing the power of the human microbiome to revolutionize the treatment of challenging diseases. Rebiotix is the most clinically advanced microbiome company in the industry, with its lead drug candidate, RBX2660, expected to enter Phase 3 clinical development for the prevention of recurrent *Clostridium difficile* (*C. diff.*) infection. Previously, RBX2660 was the subject of three Phase 2 trials in recurrent *C. diff.*, including a Phase 2b randomized, double-blind, placebo-controlled trial (PUNCH™ CD2), with data indicating the drug was well-tolerated and demonstrated statistically significant treatment efficacy. RBX2660 has been granted Orphan Drug status, Fast Track status and Breakthrough Therapy Designation from the FDA for its potential to prevent recurrent *C. diff.* infection. Rebiotix's development pipeline includes multiple formulations targeting several disease indications and is built around its pioneering Microbiota Restoration Therapy (MRT) platform. MRT is a standardized, stabilized drug technology that is designed to rehabilitate the human microbiome by delivering a broad spectrum of live microbes into a patient's intestinal tract via a ready-to-use and easy-to-administer format. For more information on Rebiotix and its pipeline of human microbiome-directed therapies, visit [www.rebiotix.com](http://www.rebiotix.com).