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Rebiotix Completes Enrollment in Phase 2 Trial of a Microbiota Restoration Therapy (MRT) for the Treatment of Recurrent *Clostridium difficile* Infection

ROSEVILLE, MN (November 18, 2015) – Rebiotix Inc. announces the completion of enrollment for its PUNCH CD 2 study, a Phase 2B multi-center, randomized, double-blind, placebo-controlled trial to evaluate RBX2660 for the treatment of multi-recurrent *Clostridium difficile* (*C. diff.*) infection. A total of 117 patients recruited at more than 20 sites in the U.S. and Canada were enrolled in the study, which is the largest randomized controlled study of a Microbiota Restoration Therapy (MRT) for recurrent *C. diff.* to date.

Studies have shown that most cases of *C. diff.* infection occur after the normal microorganisms that reside in the gut have been disrupted by antibiotic use. Restoring the balance of microbes is thought to be key to breaking the cycle of recurrence. MRT is the Rebiotix drug platform for delivering live microbes into a sick patient’s intestinal tract to treat disease.

“There is significant promise in MRT and this milestone exemplifies Rebiotix’s leadership position in realizing the potential in this therapy,” said Rebiotix CEO Lee Jones. “The completed enrollment of this trial keeps Rebiotix at the forefront of microbiome research and eventual product commercialization. We continue to drive our key milestones with the goal of helping treat patients with recurrent *C. diff.*”

Patients enrolled in the study were randomized into three groups to enable the assessment of safety and efficacy of RBX2660 compared to placebo.

About the PUNCH CD Program

PUNCH CD is the name of Rebiotix’s clinical program to assess the safety and effectiveness of RBX2660 for the treatment of recurrent *C. diff.* infection. The program is being conducted with oversight from the U.S. Food and Drug Administration (FDA) with the goal of obtaining Biologics License Application (BLA) approval to commercialize the microbiota-based drug.



About *Clostridium difficile* Infection

Clostridium difficile (*C. diff.*) infection is a serious and potentially fatal gastrointestinal disease, characterized by severe diarrhea, fever, and loss of appetite. It is a leading healthcare acquired infection, and in the U.S. alone, there are over 29,000 deaths annually from the disease.¹ Currently, 20-30% of patients with *C. diff.* go on to experience more than one episode of the disease, which is known as recurrent *C. diff.* infection.² Recurrent *C. diff.* infection is especially challenging to treat as, to date, there are no approved drugs to treat patients with two or more recurrences.

About Rebiotix Inc.

Rebiotix Inc. is a results-oriented biotechnology company revolutionizing the treatment of challenging diseases by harnessing the power of the human microbiome. The Roseville, Minn. based company is pioneering Microbiota Restoration Therapy (MRT) for delivering live microbes into a sick patient's intestinal tract to treat disease. Rebiotix's lead candidate RBX2660 was granted Orphan Drug status, Fast Track status and Breakthrough Therapy Designation from the FDA. For more information, visit www.rebiotix.com.

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¹ Lessa FC et al. Burden of *Clostridium difficile* Infection in the United States. *NEJM*. 2015. 372:825-834.

² Cornely OA, Miller MA, Louie TJ, Crook DW, Gorbach SL. Treatment of first recurrence of *Clostridium difficile* infection: fidaxomicin versus vancomycin. *CID* 2012;55 (Suppl 2):S154-S161.