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Rebiotix Announces First-Ever Randomized Study of a Microbiota-based Drug for Recurrent *Clostridium difficile* Infection under an FDA IND

First enrollment cements Rebiotix leadership in drive to commercialize next-generation fecal transplant product

ROSEVILLE, MN (December 16, 2014) – Rebiotix Inc. announced today the start of the PUNCH™ CD 2 study, a multi-center randomized double-blind placebo-controlled trial of Rebiotix lead candidate RBX2660 (microbiota suspension) for the treatment of recurrent *Clostridium difficile* (*C. diff.)* infection.

The study, the first of its kind conducted under a Food and Drug Administration (FDA) Investigational New Drug (IND) application, is designed to provide the highest quality clinical evidence to-date about the use of the human gut microbiota in a therapeutic application to treat disease.

The PUNCH CD 2 study follows quickly on the heels of Rebiotix's successful PUNCH CD study, a recently completed open-label IND trial of RBX2660 that demonstrated positive results for its new microbiota-based drug. Enrollment in the first study proceeded very quickly due to the high degree of investigator interest and unmet patient need.

In the PUNCH CD 2 study, RBX2660 will be investigated in approximately 120 patients with recurrent *C. diff.* at more than 20 sites in the US and Canada. Patients will be randomized into different study groups with and without the active drug product.

The first patient in the PUNCH CD 2 study was enrolled at Capital Digestive Care, Chevy Chase, MD. "I am happy to be participating in the Punch CD 2 study. There is a general belief that microbiota transplantation works well to treat patients with recurrent *C. diff.* infection.

However, this study will demonstrate the actual therapeutic potential of this new drug in those patients who have not responded to standard antibiotic therapy," said Dr. Robert Hardi, the PUNCH CD lead investigator. Dr. Hardi is a gastroenterologist and Medical Director of Chevy Chase Clinical Research, a division of Capital Digestive Care, Chevy Chase, MD.

C. diff. infection is characterized by severe diarrhea and is a leading healthcare acquired infection linked to 14,000 deaths in the U.S. annually. Recurrent *C. diff.* infection is especially challenging to treat as there are no approved drugs for the condition.

Fecal transplantation for recurrent *C. diff.* infection has been the subject of much media attention recently. However, there are many unknowns about the treatment and rigorous clinical research is lacking. Rebiotix is the leading commercial researcher in this field.

"The PUNCH CD 2 study is key to our efforts to bring this potentially lifesaving microbiota-based drug therapy to market so that it can be made widely available to those people who have failed standard therapy for their recurrent *C. diff.* infection," said Rebiotix CEO Lee Jones. "We are excited about the start of the study and look forward to furthering evidence-based knowledge about the power of the human microbiome to treat disease."

About Rebiotix Inc.

Rebiotix Inc. is a results-oriented biotechnology company revolutionizing the treatment of challenging gastrointestinal diseases by harnessing the power of the human microbiome. The Roseville, Minn. based company is pioneering Microbiota Restoration Therapy to restore healthy gut flora through the transplantation of live microorganisms. For more information, visit www.rebiotix.com.

Rebiotix is the only company that has a microbiota therapy with FDA orphan-drug designation for treatment of recurrent *C. diff.* infection. Orphan drugs are those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and/or disorders that affect fewer than 200,000 people in the US. The FDA has also designated RBX2660 as a Fast Track product for the treatment of recurrent *C. diff.* infection. This designation underscores the urgent need for a new therapy to treat patients who have this debilitating and potentially life-threatening disease and means that FDA will act to expedite the development and review of the application for the product, as appropriate.