Rebiotix™
Microbiota Restoration Therapy

Powerful therapy, delivered.

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Rebiotix Begins Clinical Trial of Therapy for the Treatment of Recurrent *Clostridium difficile*-Associated Diarrhea

ROSEVILLE, Minn. (October 16, 2013) — Rebiotix Inc. has announced that physicians have treated the first patients as part of the PUNCH™ CD Phase 2 clinical trial of RBX2660 (microbiota suspension) for the treatment of recurrent *Clostridium difficile*-associated diarrhea (CDAD). RBX2660 represents the first drug product in the Rebiotix Microbiota Restoration Therapy (MRT) platform.

The purpose of the PUNCH™ CD study is to assess the safety of RBX2660, a drug preparation containing live human-derived microbes. Secondary objectives of the multi-center, open-label study include gathering information on the efficacy and cost-effectiveness of the therapy. Approximately 40 patients at up to 20 centers in the US and Canada will take part in the study. Patients will be followed for six months after treatment.

First use of RBX2660, a unique, non-antibiotic drug treatment for recurrent CDAD, took place at the Metropolitan Gastroenterology Group, Chevy Chase, Md. “We are pleased that we have initiated the PUNCH CD study on schedule,” said Rebiotix CEO Lee Jones. “RBX2660 has the potential to reduce dependence on antibiotics which have been shown to have limited effectiveness in treating multiply recurrent CDAD.”

The US Food and Drug Administration recognized the urgent need for a new therapy for recurrent *Clostridium difficile* infection (CDI) and granted Fast Track status to the RBX2660 clinical program earlier this summer. The Fast Track designation is meant to facilitate the development and expedite the review of new drugs or biologic products that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Rebiotix received Investigational New Drug approval from the FDA in July.

About *Clostridium difficile* Infection
CDI is a life-threatening intestinal infection that is usually hospital-acquired. It affects more than 700,000 people in the US annually, placing an estimated $3 billion burden the healthcare system. Symptoms of CDI include profuse watery diarrhea and abdominal pain. In healthy individuals, a mix of “good” and “bad” gut microbes work together to regulate human functions. In patients with CDI, the disease-causing bacteria predominate.

About Microbiota Restoration Therapy
MRT is patterned after fecal transplants, a technique that has demonstrated success in the treatment of serious gastrointestinal illnesses, including CDI, for more than 50 years. Fecal transplant therapy has failed to be widely adopted due to challenges involved in donor screening and product preparation. MRT solves these problems by making available a standardized product in a ready-to-use format. RBX2660 has the potential to treat disease by overwhelming the disease-causing bacteria and restoring a patient’s healthy gut microbial community.

Rebiotix Development Program
Rebiotix Inc. is aggressively pursuing a solution to the critical health concerns posed by CDI and has gone from concept to clinical application in less than two years. This pioneering effort is based on new knowledge about the human microbiome showing the importance of microbes that live inside the human body in the genesis and modulation of human disease.

The company believes that MRT has great potential benefits for the treatment of other GI disease, such as ulcerative colitis, and is actively pursuing a research program to develop additional MRT products.

About Rebiotix
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 reverse pathogenic processes and restore healthy gut flora through the transplantation of live microorganisms. For more information, visit www.Rebiotix.com.