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## **Rebiotix Receives FDA IND Approval to Begin Phase 2 Trial of Pioneering Microbiota Restoration Therapy**

**Microbiota suspension designed for patients with recurrent *Clostridium difficile* infection**

ROSEVILLE, Minn. (July 29, 2013) — Rebiotix Inc. announced today that the U.S. Food and Drug Administration has approved the company's Investigational New Drug (IND) application to begin the Phase 2 clinical study of RBX2660 for the treatment of recurrent *Clostridium difficile* infection (CDI). If successful, RBX2660, a preparation containing live microbes designed to rebuild a healthy intestinal microbiome, has the potential to become the first FDA-approved drug based on the human microbiome.

CDI has become one of the most common health-care associated infections in the U.S., affecting more than 500,000 patients annually. The infection is characterized by profuse watery diarrhea and abdominal pain. Approximately 20 to 30 percent of patients with CDI who are treated with commonly used first-line antibiotics experience a recurrence. The risk of recurrence increases with each relapse or reinfection.

Currently, the only treatments available for patients with recurrent disease are more antibiotics or surgery, both of which have serious limitations.

In a new investigational approach to the treatment of recurrent CDI, Rebiotix leveraged the growing body of research about the human microbiome that indicates that patients with recurrent CDI may have an imbalance in their intestinal flora that facilitates the disease process. Microbiota restoration therapy may restore this balance and halt the symptoms of disease.

Emerging research on the human microbiome suggests that similar imbalances may be present in patients experiencing other challenging gastrointestinal diseases such as ulcerative colitis.

Recognizing the urgent need for a new therapy for recurrent CDI, the FDA previously granted Fast Track status to the RBX2660 clinical program. 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.

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“IND approval represents a significant milestone for Rebiotix, and continues our progress toward developing and commercializing a new therapy to treat patients with this debilitating and potentially life-threatening disease,” said Rebiotix CEO Lee Jones. “We are working quickly to get the clinical trial running and to recruit patients.” Jones also noted that Rebiotix is committed to conducting a full program of clinical trials to expand treatment options for recurrent CDI and to explore additional indications for its microbiota restoration therapy.

#### **About RBX2660**

RBX2660 (microbiota suspension) is a preparation containing live microbes designed to rebuild a healthy intestinal microbiome.

Fecal transplant, the predecessor to microbiota restoration therapy, has demonstrated high rates of success in curing recurrent CDI in clinical studies. However, the non-standardized and unappealing processes involved in sample preparation, in addition to expensive and time-consuming donor screening, are limiting factors for patients and physicians. RBX2660 is designed to solve these problems and, if clinically successful, is anticipated to be physician friendly, ready to use, and available on demand.

#### **About the Planned Clinical Study**

The PUNCH™ CD study is designed to assess the safety of RBX2660 (microbiota suspension) for the treatment of recurrent *Clostridium difficile*-associated diarrhea (CDAD). Secondary objectives of the multi-center, open-label study include gathering efficacy information, data to assess patient quality of life, and cost-effectiveness of the therapy.

#### **Rebiotix Development Program**

Rebiotix is actively pursuing a research program to develop microbiota restoration therapy for other challenging GI disorders such as ulcerative colitis. This pioneering effort is based on new knowledge about the human microbiome pointing to the important role of the microbes that live inside and on the human body in the genesis and modulation of human disease.

#### **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](http://www.Rebiotix.com).