Rebiotix™
Microbiota Restoration Therapy

Powerful therapy, delivered.

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Contact: Brian Bellmont, Bellmont Partners Public Relations
(952) 440-6161, brian@bellmontpartners.com

FDA Grants Fast Track Designation to Rebiotix for its Microbiota Product for Recurrent *Clostridium difficile* Infection

ROSEVILLE, Minn. (June 24, 2013) — Rebiotix Inc. announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the investigation of RBX2660 (microbiota suspension), intended for the treatment of recurrent *Clostridium difficile* infection (CDI). The FDA's Fast Track program is designed 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.

CDI, which is characterized by watery diarrhea and abdominal pain, has been linked to over 14,000 deaths annually in the U.S. and has become the most common healthcare-associated infection in some parts of the country, surpassing methicillin-resistant *Staphylococcus aureus* (MRSA) infections. Currently, there are few evidence-based approaches to the treatment of multiply-recurrent CDI.

"We're pleased to have received the Fast Track designation and look forward to working closely with the FDA as RBX2660 is developed," said Rebiotix CEO Lee Jones. "This designation reinforces the urgent need for a new therapy for recurrent CDI to treat patients who have this debilitating and potentially life-threatening disease." Patients with recurrent CDI often have to endure months of illness and only feel better when they are taking antibiotics. Once the antibiotic therapy stops, the disease process often begins again, disrupting their lives.

About RBX2660
Studies have shown that most cases of CDI occur after the normal microorganisms that reside in the gut have been disrupted by antibiotic use. Restoring the balance of "good" and "bad" microbes is thought to be key to breaking the cycle of recurrence. RBX2660, an intestinal preparation containing live microbes, will be investigated to assess its safety and efficacy in the treatment of recurrent *Clostridium difficile*-associated diarrhea.

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 processes involved including expensive and time-consuming donor screening and unappealing sample preparation made the therapy unattractive to physicians. The Rebiotix product is designed to solve these problems and, if clinically successful, is anticipated to be physician-friendly, ready-to- use, and available for order as needed.

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.