Rebiotix Media Contact:
Amy Wheeler
Tiberend Strategic Advisors, Inc.
646-362-5750
awheeler@tiberend.com

Rebiotix Treats First Patient in Phase 1 Study of RBX7455, an Orally Delivered Broad-Spectrum Non-Frozen Microbiota Capsule for Recurrent *Clostridium difficile* Infection

RBX7455 is an oral capsule formulation of Rebiotix's Microbiota Restoration Therapy (MRT)

ROSEVILLE, Minn. (January 4, 2017) – Rebiotix Inc., a clinical-stage biotechnology company focused on harnessing the power of the human microbiome to treat challenging diseases, announced today that the first patient has been treated in a Phase 1 study of RBX7455 for the prevention of recurrent *Clostridium difficile* (*C. diff.*) infection. RBX7455 is a lyophilized non-frozen oral capsule formulation of Rebiotix's Microbiota Restoration Therapy (MRT), a standardized, stabilized drug technology that is designed to rehabilitate the human microbiome by delivering a broad spectrum of live microbes into a patient's intestinal tract via a ready-to-use and easy-to-administer format. RBX7455 lyophilized capsules remove the need for patients to keep the product frozen or refrigerated.

This prospective, single center, two-arm Phase 1 study is a proof of concept dosing study of RBX7455 for the prevention of recurrent *C. diff.* infection, an increasingly difficult-to-resolve intestinal infection that causes approximately 29,000 deaths in the U.S. each year.[1] It is also the first clinical study of an oral microbiota therapy that allows the patient to take the medication at home. RBX7455 requires no special handling or storage needs for patients. The study will enroll approximately 20 patients at a single U.S. site and is being conducted by the Mayo Clinic, a nonprofit worldwide leader in medical care, research and education.

"New therapies are urgently needed to prevent recurrent *C. diff.*, a debilitating, costly and potentially life-threatening infection," said Dr. Sahil Khanna, Assistant Professor of Medicine, Department of Gastroenterology and Hepatology, Mayo Clinic, who is leading the study. "RBX7455 not only provides standardized and stabilized human microbes orally, but may provide several advantages in terms of patient dosing and therapy accessibility since no freezing or refrigeration is needed when the patient takes the product home."

The initiation of the Phase 1 study of RBX7455 enhances Rebiotix's clinical pipeline of human microbiome-directed drug candidates. The Company's lead drug candidate, RBX2660, recently completed a Phase 2b randomized, double-blind placebo-controlled trial examining the efficacy and safety of the microbiota restoration therapeutic as a prevention for recurrent *C. diff.* infection after a standard of care course of antibiotics (PUNCH™ CD2).

"Dosing the first patient in the Phase 1 study of RBX7455 is a significant milestone for Rebiotix as it solidifies our position as the most clinically advanced microbiome company in the industry, while showcasing the potential of our MRT platform to create new solutions for challenging diseases through standardized microbiota-based drug development," stated Lee Jones, president and CEO of Rebiotix. "RBX7455 is a potentially ground-breaking product for Rebiotix and the entire microbiome industry in that the lyophilized oral capsules do not need to be kept frozen and thus can be stocked in a pharmacy with no special handling or storage needs. As such, RBX7455 offers the unique opportunity to introduce live microbial therapy as a potential treatment for numerous diseases where chronic or repeat dosing is required."

About *Clostridium difficile* Infection

Clostridium difficile infection is a serious and potentially fatal disease, characterized by severe diarrhea, fever, and loss of appetite. It is a leading healthcare acquired infection. Some 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 the standard of care therapy may lead to recurrence.

About Rebiotix Inc.

Rebiotix Inc. is a clinical-stage biotechnology company focused on harnessing the power of the human microbiome to revolutionize the treatment of challenging diseases. Rebiotix is the most clinically advanced microbiome company in the industry, with its Phase 3-ready drug candidate, RBX2660, having recently completed a Phase 2b randomized, double-blind, placebo-controlled trial as a possible prevention of recurrent *Clostridium difficile* (*C. diff.*) infection after a standard of care course of antibiotics (PUNCH™ CD2). RBX2660 has been granted Orphan Drug status, Fast Track status and Breakthrough Therapy Designation from the FDA for its potential to prevent recurrent *C. diff*. infection. Rebiotix's development pipeline includes multiple formulations targeting several disease indications and is built around its pioneering Microbiota Restoration Therapy (MRT) platform. MRT is a standardized, stabilized drug technology that is designed to rehabilitate the human microbiome by delivering a broad spectrum of live microbes into a patient's intestinal tract via a ready-to-use and easy-to-administer format. For more information on Rebiotix and its pipeline of human microbiome-directed therapies, visit www.rebiotix.com.

About Mayo Clinic

Mayo Clinic is a nonprofit organization committed to medical research and education, and providing expert, whole-person care to everyone who needs healing. For more information, visit www.mayoclinic.org/about-mayo-clinic or newsnetwork.mayoclinic.org.

[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.

###