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Rebiotix Announces First Patient Enrolled in Phase 3 Clinical Trial of RBX2660 for the Prevention of Recurrent *Clostridium difficile* Infection

Phase 3 Initiation Advances Development of Lead Microbiome-based Drug, RBX2660, Following Completion of Three Separate Phase 2 Trials

ROSEVILLE, Minn. – August 7, 2017 – Rebiotix Inc., a clinical-stage microbiome company focused on harnessing the power of the human microbiome to treat challenging diseases, announced today that it has enrolled the first patient in a Phase 3 clinical trial of RBX2660 for the prevention of recurrent *Clostridium difficile* (*C. diff*) infection. RBX2660 is Rebiotix's most clinically advanced drug product developed from the company's Microbiota Restoration Therapy™ (MRT) platform. MRT is a standardized, stabilized drug technology that is designed to deliver a broad consortium of spore and non-spore forming microbes into a patient's intestinal tract to restore a dysbiotic gut to a healthier state.

The randomized, double-blind, placebo-controlled Phase 3 clinical trial will evaluate the efficacy and safety of RBX2660 for the prevention of recurrent *Clostridium difficile* (*C. diff*) infection. The primary endpoint of the trial compares the proportion of subjects with treatment success following a blinded treatment with RBX2660 compared to the blinded placebo arm. Treatment success is defined as preventing recurrent *C. diff* infection for eight weeks. The multicenter Phase 3 clinical trial of RBX2660 will be conducted in the United States and Canada and is designed to support a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA).

"Patients with debilitating, recurrent *C. diff* need solutions. We plan to continue our strong momentum generated by our Phase 2 results in this Phase 3 trial as we seek to advance RBX2660 toward registration and potential approval so patients have an option for this unmet medical need," said Ms. Lee Jones, President and CEO of Rebiotix. "Initiating the Phase 3 clinical study of RBX2660 is a significant milestone for Rebiotix and showcases the potential of our Microbiota Restoration Therapy™ (MRT) platform to enable the development of microbiome-directed drug products."

"It's exciting to see RBX2660 begin a Phase 3 trial for recurrent *C. diff* infection," said Dale Gerding, MD, MACP, FIDSA, Professor of Medicine at Loyola University Chicago and Chief Medical Officer of Rebiotix. "This disease is especially challenging to treat and having this microbial therapy available to

physicians could dramatically change how we manage the vexing problem of recurrences of this leading healthcare-associated infection."

RBX2660 is the first drug product in clinical study from the Microbiota Restoration Therapy (MRT) platform The initiation of the Phase 3 clinical trial follows a Phase 2 program that evaluated the safety and efficacy of RBX2660 for the prevention of recurrent *C. diff* infection. The Phase 2 program consisted of three separate Phase 2 studies, including a randomized, double-blind, placebo controlled Phase 2b trial. The drug has been tested in approximately 300 patients with many followed to 24 months post treatment. Rebiotix is also advancing RBX7455, a lyophilized, room-temperature stable, oral capsule formulation of its MRT technology in an investigator sponsored Phase 1 study.

About *Clostridium difficile* Infection

Clostridium difficile (C. diff.) infection is a serious and potentially fatal gastrointestinal disease, characterized by severe diarrhea, fever, and loss of appetite. It is a leading healthcare-associated infection (HAI), and in the U.S. alone, there are about 500,000 people infected and over 29,000 deaths annually from the disease. Currently, 20-30% of patients with *C. diff*. go on to experience more than one episode of the disease, which is known as recurrent *C. diff*. infection. Recurrent *C. diff*. infection is especially challenging to treat as, to date, there are no approved microbial-based drugs to treat patients with two or more recurrences.

About Rebiotix Inc.

Rebiotix Inc. is a clinical-stage microbiome company focused on harnessing the power of the human microbiome to revolutionize the treatment of challenging diseases. Rebiotix possesses a deep and diverse clinical pipeline, with its lead drug candidate, RBX2660, in Phase 3 clinical development for the prevention of recurrent *Clostridium difficile* (*C. diff*) infection. RBX2660 has been granted Fast Track status and Breakthrough Therapy designation from the FDA for its potential to prevent recurrent *C. diff*. infection. Rebiotix's clinical pipeline also features RBX7455, a room temperature stable, oral capsule formulation, which is currently the subject of an investigator-sponsored Phase 1 trial for the prevention of recurrent *C. diff.* infection. In addition, Rebiotix is targeting several other disease states with drug products built on 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 consortium 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 http://www.rebiotix.com/.