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Rebiotix Announces Expansion of Phase 1 Trial of the Company's Oral Capsule Microbiota Product, RBX7455, Following Successful Completion of Initial Study Arms

Additional cohorts to examine potential of reduced dosing regimens of RBX7455 for the prevention of recurrent Clostridium difficile infection

ROSEVILLE, MN – NOVEMBER 29, 2017 – Rebiotix Inc., a clinical-stage microbiome company focused on harnessing the power of the human microbiome to treat challenging diseases, announced today an expansion of the [investigator sponsored Phase 1 study of RBX7455 for the prevention of recurrent Clostridium difficile \(C. diff.\) infection](#). The expansion follows the successful completion of the study's two initial cohorts and is intended to explore reduced dosing regimens of RBX7455 in two new treatment arms. [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.

“Expansion of the Phase 1 study is a key advancement in the development of RBX7455 as it provides an opportunity to explore the potential efficacy of reduced dosing regimens of our oral capsule product in the prevention of recurrent *C. diff.* infection,” stated Lee Jones, president and CEO of Rebiotix. “RBX7455 is a ground-breaking product in that its oral capsule design is the first in the microbiome industry not requiring storage in frozen conditions. As such, patients are able to administer RBX7455 at home as they would a typical oral capsule medication, which potentially makes RBX7455 ideally suited for diseases where chronic or repeat dosing is required.”

The Phase 1 study of RBX7455 is an investigator sponsored, prospective, single center, proof of concept dosing study of RBX7455 for the prevention of recurrent *C. diff.* infection. The first two arms enrolled 10 patients per arm (20 total). The expansion of the Phase 1 study adds two additional arms, which will enroll approximately 10 patients per arm (20 total) with reduced dosing regimens from the



first two arms. Rebiotix expects data from the first two cohorts of the Phase 1 study of RBX7455 to be released publicly by mid-2018.

In addition to the expanded Phase 1 study of RBX7455, Rebiotix's [clinical development pipeline](#) is highlighted by the company's [ongoing Phase 3 clinical trial of RBX2660 for the prevention of recurrent *C. diff.* infection](#). RBX2660 is the first and only microbiome drug to be tested in three separate Phase 2 trials, with more than 300 subjects having been treated with the microbial therapy. Recently, Rebiotix announced the presentation of [research from the RBX2660 Phase 2 program demonstrating measurable evidence](#) of the drug's rehabilitative effect on the human microbiome and the potential advantages of its broad consortia design.

Ms. Jones continued, "We look forward to the continued progress of the RBX7455 Phase 1 study as well as our Phase 3 study of RBX2660, our lead microbiome drug candidate. Importantly, since both drugs were developed with our MRT platform, we can leverage knowledge from the extensive RBX2660 clinical program, as well as research into the drug's rehabilitative impact on the gut microbiome, to inform and expedite the development of RBX7455."

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 late-stage clinical 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](#), Orphan Drug and [Breakthrough Therapy designation from the FDA](#) for its potential to prevent recurrent *C. diff.* infection. Rebiotix's clinical pipeline also features RBX7455, a lyophilized non-frozen, 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 www.rebiotix.com.