New Clinical Data and Microbiome Research from Rebiotix’s Phase 2 Program for RBX2660 Highlighted at the World Congress of Gastroenterology at ACG2017

Research Identifies Quantifiable Microbiome Indicators of Successful Treatment with RBX2660, Including Potential Criteria for Establishing a Microbiome Health Index™

ROSEVILLE, MN – OCTOBER 16, 2017 – Rebiotix Inc., a clinical-stage microbiome company focused on harnessing the power of the human microbiome to treat challenging diseases, today announced new clinical findings from the RBX2660 Phase 2 program that are being presented in three poster presentations at the World Congress of Gastroenterology at ACG2017 in Orlando, Fl. The posters include sub-group analyses of clinical outcomes and microbiome profiles of patients who were successfully treated with RBX2660 in Phase 2, as well as new Rebiotix-sponsored biomarker research aimed at developing a human Microbiome Health Index (MHI)™. RBX2660 is currently being evaluated in an international Phase 3 clinical trial for the prevention of recurrent Clostridium difficile infection (C. diff.)

“These studies add to the growing body of clinical evidence from the RBX2660 Phase 2 program that supports our ability to positively impact the human microbiome and generate a demonstrable clinical benefit, which is the basis for our entire Microbiota Restoration Therapy (MRT)™ pipeline,” said Lee Jones, president and CEO of Rebiotix. “The research being presented at ACG2017 offers several important insights into RBX2660 as a potential treatment for recurrent C. diff infection and its potential to rehabilitate a dysbiotic intestinal microbiome to a healthier state.”

The first poster (#87; presented Sunday, Oct. 15th), titled “Developing Microbiome Rehabilitation Biomarkers for Clostridium difficile Infections: Evaluation and Plan of a Prototype Microbiome Health Index™ (MHI™),” is an analysis aimed at evaluating the ability of using microbiome data to create a quantitative index representative of microbiome health. Based upon the data, MHI can effectively distinguish patients with dysbiosis from healthier patients. MHI significantly increased as early as 7 days
in responders compared to baseline, and continued to increase at 30 and 60 days post-RBX2660 treatment. Investigators will evaluate MHI prospectively in ongoing clinical trials as an exploratory endpoint.

The second poster (#932; to be presented Monday, October, 16th), titled, “There is No Association Between Patient Outcomes and Demographics in an Open Label Safety and Efficacy Study of RBX2660, a Microbiota-Based Drug for Recurrent Clostridium difficile Infection,” offers an analysis of Rebiotix’s prospective, multicenter, Phase 2 controlled open-label study of RBX2660 to determine whether the success rate of prevention of recurrent Clostridium difficile infection (rCDI) differs in relationship to age, gender, or geographic location. A total of 138 RBX2660 and 110 historical control subjects were compared. The success rates for RBX2660 in preventing rCDI are shown to be highly significant compared to the rates in the historical control group across all major sub-groups in the study including age <65 (p<0.0001), age >65 (p<0.0001), males (p<0.0001), females (p<0.0001) and region (p=0.0233).

The third poster (#1787; to be presented Tuesday, October 17th), titled “Altering the Microbiome: Patients with a Successful Outcome Following Microbiota-Based RBX2660 Treatment Trend Toward Human Microbiome Project Healthy Subjects’ Profile,” included an analysis of the Phase 2 controlled open-label trial of RBX2660, which compared rCDI patient baseline microbiome profiles pre-RBX2660 treatment to post treatment profiles and to healthy intestinal microbiome profiles as defined by the Human Microbiome Project (HMP). Results indicated microbiota from patients with recurrent CDI shifted toward the HMP profile following RBX2660 treatment including a relative increase in the abundance of Bacteroidia classes converging toward the HMP profile after successful treatment of RBX2660. Results also showed microbiota diversity increased following successful treatment of RBX2660. This data concludes that RBX2660 restores a healthier microbiome profile among patients who responded to RBX2660 open-label treatment.

Rebiotix, Inc. funded all three studies.

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 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](http://www.rebiotix.com).