Rebiotix Media Contact:
Jason Rando
Tiberend Strategic Advisors
212-375-2665
jrando@tiberend.com

Presentations at ID Week™ 2017 Highlight Clinical Results and Microbiome Analysis of Patients Treated in Rebiotix's RBX2660 Phase 2 Studies

Positive Topline Data from Open-Label Phase 2 Trial of RBX2660 in Recurrent Clostridium difficile to be Presented for First Time

ROSEVILLE, MN – OCTOBER 4, 2017 – Rebiotix Inc., a clinical-stage microbiome company focused on harnessing the power of the human microbiome to treat challenging diseases, today announced that three posters highlighting RBX2660 clinical and microbiome data will be featured at ID Week™ 2017 in San Diego, Oct. 4th to the 8th. The posters describe clinical findings that highlight the key changes to the human microbiome profiles of patients who received RBX2660, Rebotix's Phase 3 drug candidate. For the first time, researchers will discuss findings from the open-label Phase 2 trial of RBX2660 for the prevention of recurrent *Clostridium difficile* (*C. diff.*) infection. Data indicated that RBX2660 was well-tolerated and achieved the primary efficacy endpoint of preventing *C. diff.* recurrence; patients treated with RBX2660 exhibited a treatment success rate of 78.8% compared with a historical control of 51.8% ($p<0.0001$, N=242). These results demonstrate a 55% reduction in recurrence for those patients treated with RBX2660 compared to the historical controls reflecting standard-of-care antibiotics today. RBX2660 is currently being evaluated in a multinational Phase 3 clinical trial for the prevention of recurrent *C. diff*.

Researchers will also be presenting two posters on the microbiome analyses of the Phase 2B randomized, placebo-controlled, double-blind clinical trial of RBX2660. The analyses, utilizing leading edge genomic sequencing technology to measure the patient's microbiome, provide measurable evidence of RBX2660's rehabilitative effect on human microbiome profiles of patients who were successfully treated with Rebiotix's microbiota drug technology.

"The clinical potential of RBX2660 has been highlighted in multiple trials, including our recently completed open-label Phase 2 study, and the data being presented at ID Week enables us to more fully understand RBX2660's ability to rehabilitate a dysbiotic intestinal microbiome," commented Lee Jones, president and CEO of Rebiotix. "These findings are important in that not only can we observe the clinical

effect of RBX2660, such as in the open-label Phase 2 study, but by analyzing the microbiota of RBX2660-treated patients, we can see how the microbiome changes in response to RBX2660 treatment and how those changes correlate to treatment success and to the microbiomes of healthy individuals."

The first poster (#1863; to be presented Friday, Oct. 6th), titled *RBX2660 is Safe, Superior to Antibiotic-Treated Controls for Preventing Recurrent Clostridium difficile, and May Rehabilitate Patient Microbiomes: Open Label Trial Results*, reported data from an open-label Phase 2 study of RBX2660 that included 242 subjects. Data from the study indicated that RBX2660's efficacy in preventing recurrent *Clostridium difficile* infection (rCDI) was higher (78.8%) than CDI-free rates in the Historical Control Group (51.8%, $p<0.0001$). The reduction in recurrence of *C. diff* between these two arms is approximately 55%. Moreover, the safety profile of RBX2660 was consistent with results from previous clinical trials, and microbiota analysis suggested that RBX2660 may rehabilitate patient microbiota as RBX2660-treated subjects' microbiomes were significantly altered compared to baseline and more closely resembled the RBX2660 microbiome profile than at baseline ($p<0.05$ by Dirichlet multinomial Wald-type pairwise hypothesis test).

The second poster (#1267; to be presented Saturday, Oct, 7th), titled *Successful Response to Microbiota-Based Drug RBX2660 in Patients with Recurrent Clostridium Difficile Infection is Associated with More Pronounced Alterations in Microbiome Profile,* involved an analysis of 58 patients whose stool samples were collected in the randomized Phase 2B clinical trial to determine the effect of RBX2660 on rCDI patient microbiomes. 16s RNA sequencing analyses of patients' microbiomes indicated that RBX2660 treatment shifted the relative microbiome densities, with taxa-specific increase in Bacteroidia, Clostridia, and decrease in Gamma-proteobacteria abundance. Importantly, a larger shift from baseline microbiome was seen in responders to RBX2600 compared to non-responders, and RBX2660 treatment appears to increase microbiome diversity.

The third poster (#1870; to be presented Saturday, Oct. 7th), titled *Microbiome Profile is Distinct in Patients with Successful Response to Microbiota-Based Drug RBX2660 Relative to Placebo Responders* involved a sub-analysis of 57 patients who participated in the randomized Phase 2B clinical trial of RBX2660. 16s rRNA sequencing analysis was used to compare the microbiome changes from baseline of patients classified as responders to RBX2660 vs placebo. Investigators determined that RBX2660 treatment for rCDI is associated with greater changes in patient microbiomes than placebo treatment. Notably, at 7, 30 and 60 days, microbiomes from RBX2660-treated patients had high Kullback-Leibler divergence from baseline and significantly different means from baseline ($p<0.001$). Further, active responders trended toward higher Bacteroides and lower Gamma-proteobacteria and Bacilli after treatment, both of which are characteristic of a healthier microbiome. According to the

researchers, these changes are consistent with the hypothesis that RBX2660 can restore a healthier microbiome in rCDI patients.

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.