



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

Rebiotix Develops Microbiome Health Index™ to Identify Indicators for Microbiome Restoration

Initial research indicates that Microbiome Health Index can effectively distinguish patients with dysbiosis from healthier patients

ROSEVILLE, MN – February 12, 2018 – [Rebiotix Inc.](#), a clinical-stage microbiome company focused on harnessing the power of the human microbiome to treat debilitating diseases, announced today the development of the Microbiome Health Index™ (MHI™) to provide the microbiome research community with a standardized metric to quantify the rehabilitation of the human microbiome. MHI was established in partnership with data analytics firm, [BioRankings®](#), to enable a non-biased comparison of the efficacy of microbiome-based therapeutics. New MHI data will be presented at the 28th European Congress of Clinical Microbiology and Infectious Diseases ([ECCMID 2018](#)) in April.

“In developing the Microbiome Health Index, our aim is to provide an objective, universal tool to measure the restoration of a dysbiotic microbiome across different trial designs, sequencing methods and across multiple drug technologies,” stated Ken F. Blount, Ph.D., Chief Scientific Officer of Rebiotix. “Initial analyses using MHI in *Clostridium difficile* (*C. diff*) infections have demonstrated its significant potential to quantify and differentiate dysbiotic from healthier microbiomes. [As presented at ACG2017](#), MHI was able to quantify the relationship between four key bacterial classes into a single metric that can distinguish patients with dysbiosis resulting from *C. diff*. From this, we were able to gain valuable insight into the mechanism of action by which [Rebiotix’s Phase 3 microbiota drug, RBX2660](#), is able to rehabilitate a dysbiotic microbiome to a healthier state.”

Blount continued, “MHI is now being employed to analyze microbiome profile data gathered in the ongoing [Phase 1 clinical trial of RBX7455](#), Rebiotix’s lyophilized, non-frozen oral capsule formulation. The intent with this research is to further strengthen and refine MHI and confirm the RBX2660 analysis. Additionally, we will look to utilize MHI in new diseases states being studied.”



Bill Shannon, Ph.D., MBA, Co-Founder and Managing Partner of Analytics at BioRankings said, “The human microbiome is a new frontier where very little analytical methodology or rigorous statistical methods have been developed specifically for this type of data. Analytical tools such as MHI will be critical to advance translational clinical microbiome research, and we are emboldened by the MHI data that have been reported and continuing to be collected. Our vision is for MHI to become a standard measure for microbiome research, potentially serving as a validated endpoint for clinical trials and providing both a predictive measure and actionable data.”

MHI provides a unidimensional expression of changes in four taxonomic classes known to have relevance to microbiome health and colonization resistance – Bacteroidia, Clostridia, Gammaproteobacteria and Bacilli. Utilizing microbiome profiles of patients from the PUNCH CD2 Phase 2b trial of RBX2660, researchers determined that MHI can effectively distinguish patients with dysbiosis from healthier patients, as defined by the RBX2660 product profile and the [Human Microbiome Project](#). Notably following RBX2660 treatment, MHI significantly increased as early as seven days in responders compared to baseline and continued to increase at day 30 and day 60.

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 BioRankings®

BioRankings is a contract analytics firm that works with clients to extract actionable results from their data. Their business philosophy centers on providing clients and partners with the methods, software, and support they need to make full use of their data and design accurate, cost-efficient experiments. For more information on BioRankings, please visit <http://www.biorankings.com/>.

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 debilitating 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 <http://www.rebiotix.com/>.