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Rebiotix Appoints Edward S. Burd, Ph.D., to Head of Regulatory Affairs

Dr. Burd to Spearhead Rebiotix's Regulatory Affairs Strategy as Company Advances RBX2660 Through Phase 3 and Towards a Potential Biologics License Application

ROSEVILLE, Minn. – September 6, 2017 – Rebiotix Inc., a late-stage clinical microbiome company focused on harnessing the power of the human microbiome to treat challenging diseases, today announced the appointment of Edward S. Burd, Ph.D., to Head of Regulatory Affairs. Dr. Burd brings more than 25 years of regulatory affairs experience to Rebiotix, having previously worked in government with the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) and in industry with several global and emerging pharmaceutical companies.

As Head of Regulatory Affairs, Dr. Burd will be responsible for leading Rebiotix's regulatory strategy in addition to strategic input for the clinical programs involving the company's clinical pipeline. Notably, Dr. Burd will serve as a primary liaison with CBER as Rebiotix advances its lead microbiome product candidate, RBX2660, which is currently the subject of a randomized, double-blind, placebo-controlled Phase 3 clinical trial for the prevention of recurrent *Clostridium difficile* (*C. diff*) infection. The Phase 3 trial is intended to support a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA). Rebiotix's microbiome drug pipeline also includes RBX7455, a lyophilized, non-frozen, oral capsule formulation, which is being evaluated in an investigator sponsored Phase 1 study for the prevention of recurrent *C. diff*.

"The appointment of Dr. Burd as Head of Regulatory Affairs is an important addition to Rebiotix's leadership team as we continue to enhance our regulatory expertise and begin preparing for a potential BLA submission for RBX2660 following the recent initiation of our Phase 3 clinical trial," said Ms. Lee Jones, President and CEO of Rebiotix. "Dr. Burd possesses extensive knowledge of FDA and CBER processes, having worked both on the inside reviewing applications and at small and large biotech companies preparing application packages for review. His experience will be key as we advance RBX2660, and subsequently RBX7455, toward registration and potential approval."

Prior to joining Rebiotix, Dr. Burd served as Global Regulatory Leader (GRL) for Allergan in dermatology, facial aesthetics, and neurology. Before that, he served as Director of Global Product

Strategy and Regulatory Affairs for AbbVie, where he served as GRL for the biologics and new chemical entities for investigational treatments of multiple sclerosis, neuropathic pain, rheumatoid arthritis, cystic fibrosis, Crohn's disease, and celiac disease. Dr. Burd's career is further highlighted by senior regulatory affairs positions at Amgen, Bayer Healthcare Pharmaceuticals and Maxygen.

Prior to his career in the biotech industry, Dr. Burd was Senior Staff Fellow at the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. Here he spent seven years as a CMC reviewer for Gene Therapy products and authored more than 20 publications. Dr. Burd received his undergraduate degree in biology from California State College, earned a Ph.D. in microbiology from Virginia Polytechnic Institute and State University, and performed post-doctoral research at Harvard Medical School, MIT, and the National Institutes of Health. He is a past fellow of the National Research Council.

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.