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Rebiotix and Washington University Treat First Patient with Urinary Tract Infection Utilizing Investigational RBX2660 to Potentially Reverse Multidrug Resistant Organisms

Pioneering study of fecal microbiota transplantation (FMT) in patients with a history of Multi Drug Resistant Organism (MDRO) infections

ROSEVILLE, MN and ST. LOUIS, MO (January 11, 2016) – Rebiotix Inc. announces the first patient with recurrent urinary tract infections has been treated in a clinical study to evaluate the ability of RBX2660, a microbiota-based drug candidate, to suppress or reverse colonization with multidrug resistant organisms (MDROs). The patient was treated at Washington University School of Medicine in St. Louis.

While antibiotics have revolutionized medicine in the twentieth century, bacterial resistance to these life-saving medications has now outpaced the development of new antibiotics. Some bacteria are now resistant to most, if not all, current antibiotics.[1] A major concern is that once a patient is colonized with MDROs, he or she is at risk for recurrent infection and can also serve as a reservoir for spread of the bacteria to others for a long period of time.[2]

"A new approach is needed to address infections caused by MDRO other than more antibiotics," said Dr. Erik Dubberke, associate professor of medicine in the Division of Infectious Diseases at

Washington University School of Medicine, St. Louis, MO and lead investigator of the trial. "What we found is that many of the MDRO infections are related to bacteria that normally colonize in the colon. Fecal microbiota transplantation (FMT) could potentially repopulate the intestines with normal, diverse microbiota that could compete with MDRO and possibly reduce MDRO colonization. This in turn might prevent future MDRO infections, such as in recurrent urinary tract infections."

"We are watching the growing impact of MDRO infections globally and agree that a solution other than antibiotic treatment is needed. For this reason, we are very excited to be taking part in this innovative study assessing MDRO clearance with our MRT drug development platform, said Rebiotix CEO Lee Jones. "Patients with MDRO infections who have few therapeutic options may benefit from treatment with RBX2660. Rebiotix continues to focus on utilizing microbiota therapy to treat challenging diseases."

About the Study

The prospective, single-center, open-label study will evaluate the potential of RBX2660 to prevent relapse of infections due to MDRO in patients with a history of recurrent MDRO infections. Patients will receive RBX2660 by enema and will be monitored to assess efficacy and potential adverse events for 12 months.

About Rebiotix Inc.

Rebiotix Inc. is a results-oriented biotechnology company revolutionizing the treatment of challenging diseases by harnessing the power of the human microbiome. The Roseville, Minn. based company is pioneering Microbiota Restoration Therapy (MRT) for delivering live microbes into a sick patient's intestinal tract to treat disease. Rebiotix's lead candidate RBX2660 was granted Orphan Drug status, Fast Track status and Breakthrough Therapy Designation from the FDA for its potential that it may treat recurrent *C. diff*. infection. For more information, visit www.rebiotix.com.

About Washington University School of Medicine in St. Louis

Washington University School of Medicine's 2,100 employed and volunteer faculty physicians also are the medical staff of Barnes-Jewish and St. Louis Children's hospitals. The School of Medicine is one of the leading medical research, teaching and patient-care institutions in the nation, currently ranked sixth in the nation by U.S. News & World Report. Through its affiliations with Barnes-Jewish and St. Louis Children's hospitals, the School of Medicine is linked to BJC HealthCare.

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1. Spellberg B, Blaser M, Guidos RJ, et al. Combating antimicrobial resistance: Policy recommendations to save lives. *Clin Infect Dis.* 2011;52 (Suppl5):S397-S428.
2. Sommer MO, Dantas G. Antibiotics and the resistant microbiome. *Curr Opin Microbiol.* 2011;14:556-63.