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Study Shows Rebiotix Microbiota-based Drug Candidate Targeted at Recurrent *C. difficile* Infection is Highly Effective

Results for groundbreaking multi-center study of lead drug candidate RBX2660 (microbiota suspension) presented at IDWeek™ 2014

PHILADELPHIA (October 9, 2014) — Rebiotix Inc. announced today that results of the Phase 2 PUNCH™ CD Study found that the overall efficacy of RBX2660 in the treatment of recurrent *Clostridium difficile* infection was 87.1%. The study also found that administration of RBX2660 was well-tolerated and demonstrated satisfactory safety in the 60-day interim analysis.

The results of a 60-day interim analysis of the PUNCH CD study, the first prospective multi-center study of a next generation, standardized, commercially prepared microbiota restoration therapy for recurrent CDI were presented at IDWeek 2014.

Clostridium difficile infection, characterized by severe diarrhea, is a leading healthcare acquired infection and is linked to 14,000 deaths in the U.S. annually. The U.S. Centers for Disease Control recently termed CDI an urgent public health threat. Recurrent CDI is especially challenging to treat, and there are no indicated drugs for the condition.

The primary objective of the PUNCH CD study was product-related adverse events (AEs). A secondary objective was CDI resolution. A total of 40 patients at 11 centers in the U.S. were enrolled in the study. All of the patients had multi-recurrent CDI and had failed standard therapy. The PUNCH CD patient population was primarily elderly and female with multiple co-morbidities, thus reflecting the real-world population of patients with recurrent CDI who present with unmet medical needs.

A total of 34 patients received at least one dose of RBX2660 administered via enema. A second dose was permitted if CDI recurred < 8 weeks after the first dose. Overall efficacy of RBX2660, defined as the absence of CDI symptoms at 8 weeks after the last dose, was 87.1%.



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Adverse events were predominantly mild to moderate flatulence, belching, and constipation which were self-limiting. There were no serious adverse events linked to RBX2660 or its administration.

“Years of experience indicate microbiota therapy is a highly efficacious for treatment of recurrent CDI, however adequate data have been lacking on safety,” said Erik R. Dubberke, MD, MSPH, a PUNCH CD investigator and Director, Section of Transplant Infectious Diseases Washington University School of Medicine, St. Louis, MO. “The phase 2 study indicates RBX2660 efficacy is consistent with past studies, and it is safe and easy to administer.” The study represents a significant step forward in Rebiotix’s efforts to develop a durable cure for recurrent CDI that is debilitating to patients. RBX2660 will undergo further study in a Phase 2B randomized controlled trial scheduled to begin later this fall.

About Rebiotix Inc.

Rebiotix Inc. is a results-oriented biotechnology company revolutionizing the treatment of challenging gastrointestinal diseases by harnessing the power of the human microbiome. The Roseville, Minn. based company is pioneering Microbiota Restoration Therapy to restore healthy gut flora through the transplantation of live microorganisms. For more information, visit www.rebiotix.com.

Rebiotix is the only company that has a microbiota therapy with FDA orphan-drug designation for treatment of recurrent C. diff. infection. Orphan drugs are those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and/or disorders that affect fewer than 200,000 people in the US. The FDA has also designated RBX2660 as a Fast Track product for the treatment of recurrent C. diff. infection. This designation underscores the urgent need for a new therapy to treat patients who have this debilitating and potentially life-threatening disease and means that FDA will act to expedite the development and review of the application for the product, as appropriate.

About IDWeek

IDWeek 2014 is an annual meeting of the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA) and the Pediatric Infectious Diseases Society (PIDS). With the theme “Advancing Science, Improving Care,” IDWeek features the latest science and bench-to-bedside approaches in prevention, diagnosis, treatment, and epidemiology of infectious diseases, including HIV, across the lifespan.



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IDWeek 2014 takes place October 8-12 at the Pennsylvania Convention Center in Philadelphia, Pennsylvania. The full name of the meeting is IDWeek 2014™. For more information, visit www.idweek.org.