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Microbiota Restoration Therapy

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Rebiotix Presents Additional Results of PUNCH™ CD Study of Microbiota-based Drug Candidate for Recurrent *C. difficile* Infection at ACG 2014

Safety, delivery method and impact on psychological well-being of patients evaluated

PHILADELPHIA , PA. (October 20, 2014) - Rebiotix Inc. announced today that a 60-day interim analysis of the Phase 2 PUNCH CD study found that RBX2660 (microbiota suspension) had a satisfactory safety profile and that enema administration of the drug was well-tolerated, among other findings.

The PUNCH CD study enrolled 40 patients at 11 centers in the US. A total of 34 patients with recurrent *Clostridium difficile* infection (CDI), a leading healthcare acquired infection characterized by severe diarrhea, received 1 or 2 doses of RBX2260, a next-generation version of fecal transplant, in the study.

While fecal transplant is increasingly recognized as an effective treatment for recurrent CDI, it has not been well researched and there are many unknowns regarding patient selection, administration and safety. The PUNCH CD study was the first time that adverse events were aggressively solicited and systematically recorded in the context of a multi-center study of a microbiota-based drug containing live human-derived microbes.

Adverse events were reported by 29 patients in the study and were primarily mild-to-moderate self-limiting gastrointestinal symptoms. There were 9 serious adverse events, none of which was determined related to RBX2660 or its administration. RBX2660 demonstrated overall 87.1% efficacy, in a previously released finding.

In other study findings:

Enema administration was found safe and well-tolerated. This route was chosen for RBX2660 administration because of simplicity, convenience and safety compared with colonoscopic or nasoenteral administration which may add risk, especially in patients with recurrent CDI who are typically elderly with multiple comorbidities. Additionally, RBX2660 was administered without a bowel

cleansing procedure as is required with colonoscopic administration. The enema could be delivered by a nurse or other healthcare provider in regular clinical setting – sedation was not necessary.

The psychological well-being of patients enrolled in the study improved 17.7% compared with baseline using the Short Form 36, a standardized tool for measuring health–related quality of life. This finding suggests that the psychological impact of the disease, which is chronic in nature, may be underappreciated and should be considered in patient care.

About RBX2660

RBX is the first in a new category of drugs using live human-derived microbes. The drug is prepared using standardized processes and was available to physicians participating in the PUNCH CD study a ready-to-use enema format.

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.