BACKGROUND

• Effective treatment options for recurrent C. difficile infection (CDI) are limited
• High recurrence rates are associated with current standard of care
• Microbiota-based therapies are being developed and evaluated in clinical trials
• Here we collectively present results from two Phase 2 controlled trials to evaluate the safety and efficacy of RBX2660

RBX2660 Microbiota-based drug manufactured from live human-derived microbes using standardized processes and controls.

METHODS (common to both trials)

• Inclusion criteria: >18 years of age with documentation of either ≥2 episodes of severe CDI resulting in hospitalization; a positive stool sample or history of radiographic or endoscopic findings; evidence of active CDI; known exposure to antibiotics within 6 months after study enrollment; compromised immune system (white blood cell count <1000 cells/μL)
• Exclusion criteria: History of irritable bowel disease (ulcerative colitis, Crohn’s disease or microscopic colitis); irritable bowel syndrome; chronic diarrhea; collagen disease; colostomy; evidence of active colitis; mean duration of CDI episode ≥103 days (n=110) with ≤226 days (n=136) following completion of the last treatment. Patients were classified as a treatment failure if all four of the following criteria were met: recurrence of diarrhea less than 8 weeks after administration of the last assigned study entity, a positive laboratory diagnosis of C. difficile as conducted and reported by the study investigator, a need for reintervention for CDI, and no other cause for diarrhea.

THE MICROBIOTA-BASED DRUG RBX2660 IS EFFICACIOUS AND SAFE IN PATIENTS WITH RECURRENT CLOSTRIDIUM DIFFICILE INFECTIONS: RESULTS FROM 2 CONTROLLED TRIALS

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