Deadline Reached Abstract #45151

The deadlines for abstract submissions and modifications for this program have been reached.
View Submission (no changes allowed.)

• Title: RBX2660 (microbiota suspension) for Recurrent ***C. difficile*** Infection: 60-Day Interim Analysis of the PUNCH-CD Phase 2 Safety Study

• Original Submission Date: April 21, 2014

• Last Edited Date: June 20, 2014

• Submitter's E-mail Address: HGuthertz@aol.com

• Preferred Presentation Format: Either Poster or Oral

• Subject Categories: A5. Treatment of HAIs/antimicrobial resistant infections; C1. Clinical Trials

• Keyword: CLOSTRIDIUM DIFFICILE and GASTROINTESTINAL DISEASE

Applying for:

I do not want to apply for any awards or grants. ***No changes will be allowed after the May 6 deadline.***

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Background: There is increasing recognition that fecal transplant (FT) is an effective treatment for recurrent *C. difficile* infection (CDI). However, donor screening and product preparation can be burdensome. Despite promising efficacy results, safety data are limited. We report on a 60-day interim analysis of the first prospective open-label multi-center safety study of a next generation microbiota restoration therapy that has been standardized and manufactured under controlled conditions.

Methods: Patients with recurrent CDI, defined as at least 3 CDI episodes or at least 2 severe episodes resulting in hospitalization, were enrolled. All patients received treatment with RBX2660 (microbiota suspension) administered via enema. A second treatment was permitted if CDI recurred in < 8 weeks after the first treatment. Follow-up was at 7, 30 and 60 days and 3 and 6 months after the last treatment. The primary objective was the product-related adverse events (AEs). A secondary objective was CDI resolution.

Results: Of the 40 patients enrolled at 11 centers in the US, 34 patients (mean age 66.8 years, 67.6% female) received at least one treatment. Thirty-one patients were included in a 60-day interim analysis. A total of 158 AEs were elicited in 29 patients. AEs were predominantly mild to moderate and included flatulence, belching, constipation, and occasional bouts of diarrhea. There were 9 serious AEs reported in 6 patients (3 recurrent CDI = 8 weeks days post-treatment, all of which required hospitalization; 1 case of pneumonia; 1 pelvic fracture; 1 stab wound; 1 chronic obstructive pulmonary disease; 1 pulmonary edema and 1 respiratory failure). None of the serious AEs was related to RBX2660 or its administration. Efficacy of RBX2660 defined as the absence of CDI at 8 weeks after the last dose was 87.1%.

Conclusion: RBX2660 was well-tolerated and demonstrated satisfactory safety in a 60-day interim analysis of the first prospective multi-center study of a next generation standardized, commercially prepared microbiota restoration therapy for recurrent CDI.

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Biographical Sketch: Dr. Dubberke specializes in epidemiology and infectious diseases. He is an Assistant Professor of Medicine in the Division of Infectious Diseases at Washington University School of Medicine, St. Louis, MO. His interests include transplant infectious diseases, infections in oncology patients, Clostridium difficile-associated disease and healthcare epidemiology. Dr. Dubberke's experience includes didactic and training in infectious diseases and epidemiology, conducting healthcare epidemiology-based research, collaborating with the Centers for Disease Control on study design and developing infection surveillance and prevention guidelines, and professional duties as a hospital epidemiologist. Dr. Dubberke is an active member of the Society for Healthcare Epidemiology of America (SHEA) and is working on updating the CDI portion of the SHEA Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospital. He is on the editorial board of Infection Control and Hospital Epidemiology and has functioned as an ad hoc reviewer for numerous journals, including: Clinical Infectious Diseases, Lancet ID, the Journal of the American Medical Association, and the New England Journal of Medicine.

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Biographical Sketch: Dr. Orenstein is focused on the prevention and management of healthcare-acquired infections, in particular Clostridium difficile infection (CDI). He has helped design systems for the surveillance of CDI and designed interventions to reduce its transmission in the hospital environment. In collaboration with Mayo Clinic gastroenterologists, he has also studied risks for the transmission of Clostridium difficile in the community. Additionally, he provides fecal microbiota transplants for patients with recurrent CDI. Together with his team, he has been responsible for transmitting learnings and best practices on CDI management across Mayo clinics and campuses as well as assisting other healthcare institutions.

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Biographical Sketch: Graduated from the undergraduate from the University of Miami with a degree in analytical mathematics. Completed medical school in 2000 from K. Marcinkowski School of Medical Sciences in Poznan, Poland. Pursued an Internal Medicine residency at the University of North Dakota which was completed in 2004.

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Kathleen Mullane DO, PharmD, is an expert in the diagnosis and treatment of infections in immunocompromised patients. She is active in the general infectious diseases clinic, where she treats stem cell and solid organ transplant recipients who have infections, as well as patients who have HIV infection.
A distinguished physician-scientist, Dr. Mullane's research interests include new treatments for infections in immuno-compromised hosts, as well as for resistant bacterial, viral and fungal pathogens. As the director of infectious diseases clinical trials, she is currently investigating experimental agents for treating aspergillosis, skin and soft tissue infections, HIV, cytomegalovirus, varicella zoster, Pneumocystis, osteomyelitis and *Clostridium difficile*-associated diarrhea.
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View a partial list of Dr. Mullane's publications through the National Library of Medicine's PubMed online database.

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Biographical Sketch: Mary Kay Sobcinski is the Director of Clinical Operations at Rebiotix Inc, Roseville, MN, and is spearheading the company's clinical development program, including all aspects of clinical strategy and study design, implementation, and management. Drawing on her extensive experience, including ten years as a senior-level advisor overseeing over 75 regulated human studies, her expertise in clinical research is integral to Rebiotix' efforts to pioneer an FDA-approved live microbial drug for the treatment of recurrent Clostridium difficile. She is a registered nurse and has a Master's degree in health care administration from the University of Minnesota.

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