Clearance of Vancomycin-Resistant Enterococcus Concomitant with Administration of a Microbiota-Based Drug Targeted at Recurrent Closstridium difficile Infection

Erik Dubberke, MD, MSPH, Washington University School of Medicine, St. Louis, MO; Courtney Jones, BS, Rebiotix Inc., Roseville, MN

Background:
- Vancomycin-resistant Enterococcus (VRE) is a major nosocomial pathogen and is a well-known complication among transplantation and immune compromised patients.
- VRE colonization and Closstridium difficile infection (CDI) share similar risk factors; antibiotic-induced perturbation of the gut microbiota may contribute to both.
- VRE carriers are at increased risk for infection and a source of transmissions to others.
- Controlling transmission in a healthcare setting can be challenging.
- Fecal microbiota transplantation (FMT) may be effective in clearing VRE and restoring colonization resistance.

Methods:
- A total of 34 patients with recurrent CDI enrolled at 11 sites in the U.S. received 1 or 2 doses of RBX2660, a next-generation FMT drug, between August 2013 and January 2014 as part of the PUNCH CD study.
- Patients were requested to voluntarily submit stool samples at baseline and at 7, 30 and 60 days after the last administration of RBX2660.

Results:
- During the study period, 30 patients with recurrent CDI had at least 1 stool sample available for VRE testing. All submitted samples were deemed acceptable by the independent laboratory used for testing.
- All stool samples for patients treated with RBX2660 were VRE negative at the first test (baseline or 7-day follow-up).
- Of the patients who tested VRE positive at least once, 72.7% (n=21) converted to negative as of the last available follow-up.

PBX2660 (microbiota suspension)
- Designed to mimic FMT
- Raw material human stool
- Donors rigorously screened
- Contains a minimum guaranteed quantity of microbes

VRE TESTING PROTOCOL
- Test type: Bile esculin agar seeded with 10^6 colony forming units/mL Enterococcus (Remel, Lenexa, KS, USA)
- Manufactured using standardised, quality controlled processes
- Supplied in a ready-to-use enema format, 50g/150 mL dose

VRE STATUS AFTER RBX2660 ADMINISTRATION
- VRE Positive Patients by Time Since Last Dose

BASELINE CHARACTERISTICS
- Parameter
  - Total
  - VRE positive
  - VRE positive by 20 days

Follow-up:
- 7 days; 30 days; 60 days; 3 months; 6 months

References: