Table: Summary of culture and CFU log reduction among infected prosthetics

| Species of culture | PLG 0260D Dose | CFU Uncertred | CFU Treated | Log Reduction |
|-------------------|---------------|-------------|-----------|---------------|
| 1                  |               |             |           |               |
| S. epidermidis     | 1.00E-07      | 0           | 7.0       |               |
| 2                  |               |             |           |               |
| S. epidermidis     | 1.00E-07      | 0           | 7.0       |               |
| 3                  |               |             |           |               |
| S. aureus (MSSA)   | No isolate*   | N/A         |           |               |
| 4                  |               |             |           |               |
| S. aureus (MRSA)   | 0.12          | 60          | 1.8       |               |
| 5                  |               |             |           |               |
| S. hemolyticus     | 7.3E+02       | 2.9         |           |               |
| 6                  |               |             |           |               |
| Entertococcus      | 1.4E+00       | 80          | 4.1       |               |
| 7                  |               |             |           |               |
| S. epidermidis     | 1.00E-04      | 9.2         |           |               |
| 8                  |               |             |           |               |
| H. parainfluenzae  | 1.00E-07      | 0           | 7.0       |               |
| 9                  |               |             |           |               |
| H. parainfluenzae  | 1.00E-07      | 0           | 7.0       |               |
| 10                 |               |             |           |               |
| S. aureus (MRSA)   | 1.10E-04      | 4.0         |           |               |

* CFU 10E-07 is an estimate of uninfected sonic lye derived from micro lab measurements.

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1042. Safety of Investigational Microbiota-Based Live Biotherapeutic RBX2660 in Individuals with Recurrent Clostridioioides difficile Infection: Data from Five Prospective Clinical Studies

Session: P-59. New Drug Development

Background. RBX2660 is an investigational oral biotherapeutic剂 for reducing relapse of recurrent Clostridium difficile infection (rCDI). RBX2660 is a live biotherapeutic—oral preparation of human microbiota. RBX2660 is a registered investigational product in the USA with consistent investigational product safety data. A phase 2d clinical study demonstrated efficacy of RBX2660 in reducing rCDI recurrence compared with placebo. RBX2660’s safety profile is consistent with that of other probiotics. There are no reported infections for which the causative pathogen was RBX2660. There were no reported infections for which the causative pathogen was RBX2660.

Methods. Methods included three phase 2, phase 2d, and two phase 3 trials (PUNCH CD1, PUNCH CD2, PUNCH CD3 OLS ad hoc analysis). In the two phase 3 trials, participants were ≥18 years old with documented rCDI who completed standard-of-care oral antibiotic therapy prior to treatment with RBX2660. Participants were randomized to RBX2660 or placebo and were treated for 1 week and followed for 8 weeks. Safety was assessed by treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs). Results. Across five clinical studies with consistent investigational product, RBX2660 was well-tolerated in CDI participants in aggregate. Data provides compelling and consistent safety data for RBX2660.

Disclosures. Tricia Braun, PharmD, Rebiotix, a Ferring Company (Employee); Beth Guthmuller, AS, Rebiotix Inc, A Ferring Company (Employee); Adam J. Harvey, PhD, Rebiotix, A Ferring Company (Employee).

1043. Activity of Mecillinam Against Enterobacteriaceae Isolates Collected From Patients With Urinary Tract Infections (UTIs) in the USA During 2019

Session: P-59. New Drug Development

Background. Mecillinam is a β-lactam antibiotic, or a β-lactamase inhibitor. Mecillinam is in development for the treatment of complicated UTIs in the hospital setting and as a step-down therapy transitioning from IV to oral mecillinam. Most toxic effects were observed in patients with UTI in the USA, collected during 2019.

Methods. This study evaluated the activity of mecillinam and other antimicrobial agents against 1075 selected Enterobacteriaceae isolates collected from patients with UTI in the USA during 2019. Antibiotic activity (minimum inhibitory concentration [MIC]) was determined by the US Naval Medical Research Unit 6 Laboratory Standards Institute (CLSI) agar dilution methodology, and susceptibility was interpreted according to CLSI guidelines.

Results. The selected 1075 isolates, producers of extended-spectrum beta-lactamase (ESBL) represented 96.9% of Escherichia coli and 50% of Klebsiella pneumoniae. Ninety-five percent of the isolates tested were susceptible to mecillinam (Table 1). The MIC<sub>50</sub> and MIC<sub>90</sub> values for mecillinam were 0.25 and 2 µg/mL, respectively. Fosfomycin MIC<sub>50</sub> and MIC<sub>90</sub> were 1 and 32 µg/mL, respectively (97.6% of isolates susceptible).