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

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Purpose: The purpose of the PUNCH CD study was to assess the safety of RBX2660 (microbiota suspension) for recurrent *Clostridium difficile* infection (CDI). RBX2660 is a biologic drug consisting of a suspension of live human-derived intestinal microbes. A secondary objective of the study was CDI resolution at 8 weeks**.**

Methods: Patients with recurrent CDI (at least 2 recurrences after a primary episode) who completed at least 2 rounds of standard antibiotic therapy or have had 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 (defined as passage of 3 or more unformed stools in ≤ 24 hours for at least 2 consecutive days) in < 8 weeks. Adverse events (AEs) were aggressively solicited. Follow-up was at 7, 30 and 60 days and 3 and 6 months after the last treatment. We report on an interim 60-day analysis.

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 with RBX2660. Six patients were enrolled but not treated due to screen failure. A total of 31 patients were included in a 60-day interim analysis (2 patients dropped out after the first dose and 1 died of respiratory failure). AEs were reported in 29 patients: predominantly mild to moderate; primarily flatulence, abdominal pain/cramping, constipation, and diarrhea. There were 9 serious AEs reported in 6 patients (including 3 recurrent CDI ≤ 8 weeks post-treatment, all of which required hospitalization). None of the serious AEs was determined definitely or probably related to RBX2660 or its administration. Efficacy of RBX2660 defined as the absence of CDI at 8 weeks after the last treatment was 87.1% (n=31).

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

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