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

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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 episodes or at least 2 severe episodes resulting in hospitalization; 1 case of pneumonia; 1 pelvic fracture; 1 abdominal pain; 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.