RBX2660, a standardized, stabilized microbiota restoration drug has been shown to prevent recurrent Clostridioides difficile infections (rCDI).

A preliminary analysis demonstrated decolonization of multidrug-resistant organisms (MDRO) in association with clinical response.

In parallel, we are developing a Microbiome Health Index (MHI™) to monitor dysbiosis and microbiota restoration.

Given the public health challenges related with MDROs, we evaluated MHI as a potential sentinel of MDRO colonization among rCDI patients who responded to RBX2660 in a Phase 2 clinical trial.

METHODS

**Background**

- The PUNCH CD2 Phase 2 trial (NCT02299570) compared RBX2660, a microbiota-based investigational drug for treatment of rCDI, to placebo.
- 127 participants were enrolled, randomized, and treated in three cohorts: Group A: two doses of RBX2660; Group B: two placebo doses; Group C, one dose of RBX2660 and one dose of placebo.
- Samples were collected prior to treatment (BL) and 7, 30 & 60 days after treatment.
- This analysis is based on samples from 55 patients who responded to RBX2660 in a Phase 2 clinical trial.

**Microbiome Health Index (MHI) Analysis**

MHI can distinguish between baseline “unhealthy” and “healthier” microbiome.

**Microbiome Composition Shifts Post-RBX2660**

Taxa levels from PUNCH CD2 participants with successful response to RBX2660 approach product profile levels over time.

**Microbiome Health Index (MHI)**

- MHI inversely correlates with AMR gene abundance in a cohort of rCDI patients who had successful response to RBX2660.
- These results suggest MHI as a potential sentinel of MDRO colonization, and this role will be evaluated in future cohorts outside of the rCDI patient population.

**Conclusion**

- MHI can effectively distinguish patients with dysbiosis from healthier patients, as defined by the RBX2660 product profile and the Human Microbiome Project.

- MHI inversely correlates with AMR gene abundance in a cohort of rCDI patients who had successful response to RBX2660.

- These results suggest MHI as a potential sentinel of MDRO colonization, and this role will be evaluated in future cohorts outside of the rCDI patient population.