Infectious Diseases and Therapy

PEER-REVIEWED FEATURE

Final Results from a Phase 2b Randomized, Placebo-Controlled Clinical Trial of RBX2660: A Microbiota-Based Drug for the Prevention of Recurrent *Clostridioides difficile* Infection

Phase 2b Trial

Enrollment and Randomization (1:1:1)

- Group A (2x RBX2660)
- Group B (2x Placebo)
- Group C (1x RBX2660, 1x Placebo)

All participants were treated with 2 doses 7 ± 2 days apart.

Blinded Treatment Follow-up

Weekly follow-ups were done during in-person visits or by telephone.

Treatment success (no CDI) Measured at 8 weeks

Non-responders (CDI before 8 weeks) could elect open-label RBX2660

Non-responders were eligible to receive up to two doses of RBX2660 administered 7 ± 2 days apart in the open-label portion of the study. Participants remained blinded to the original dosing regimen.

Long-term Follow-up

24 months

Blinded treatment

Open-label RBX2660

Cross-over to the open-label portion of the study reset the 8-week efficacy evaluation, resulting in approximately two additional months of overall follow-up.

Recurrent ***Clostridioides difficile*** infection (CDI) is a major health problem worldwide, and effective treatments are urgently needed.

RBX2660 is a microbiota-based live biotherapeutic designed to reduce CDI recurrence following standard-of-care antibiotic treatment in individuals with rCDI.

Preliminary Data

Preliminary data (first reported in Dubberke et al. *CID*, 2018, 67:1198-1204) reported the primary endpoint of treatment success at 8 weeks between Groups A and B

Treatment Success	
Interim ITT (N=127)	
Group A	61% (25/41) p= 0.152
Group B	45.5% (20/44)
Group C	66.7% (28/42) p= 0.048

Final Data

Final results report 24-month safety follow-up and updated efficacy that reflects refinements to analysis population definitions.

Treatment Success*	Final ITT (N=133)	Final mITT (N=121)	Final PP (N=83)
A	55.6% (25/45) p= 0.243	62.5% (25/40) p = 0.095	75% (21/28) p = 0.170
B	43.2% (19/44)	44.2% (19/43)	58.1% (18/31)
C	56.8% (25/44) p= 0.201	65.8% (25/38) p = 0.051	87.5% (21/24) p = 0.017

**p value from chi-square test for the difference between group A or group C vs group B with respect to % of treatment successes*

- ITT population: all participants who were randomized, including those who were not treated, as well as participants with an "indeterminate" treatment outcome, who were also conservatively categorized as treatment failures
- mITT population: participants who received treatment, excluding participants who discontinued prior to outcome evaluation or had eligibility deviations
- PP population: all randomized participants who successfully received both treatment doses and were evaluable for outcome, excluding participants for predefined reasons

Overall, the cumulative efficacy and safety data for RBX2660 to date show meaningful outcomes for reduction of CDI recurrence in adults.

Abbreviations: CDI: *Clostridioides difficile* infection; ITT: intention-to-treat; mITT: modified intention-to-treat; PP: per protocol