THE MICROBIOTA-BASED DRUG RBX2660 IS EFFICACIOUS AND SAFE IN PATIENTS WITH RECURRENT *CLOSTRIDIUM DIFFICILE* INFECTIONS: RESULTS FROM 2 CONTROLLED CLINICAL TRIALS

Poster P0369

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BACKGROUND

- Effective treatment options for recurrent *C. difficile* infection (rCDI) are limited
- High recurrence rates are associated with current standard of care
- Microbiota-based therapies are being developed and evaluated in clinical trials
- Here we collectively present results from two Phase 2 controlled trials to evaluate the safety and efficacy of RBX2660

RBX2660
Microbiota-based drug manufactured from live human-derived microbes using standardized processes and controls.

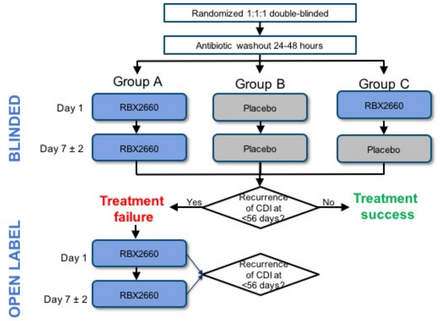
METHODS (common to both trials)

- Inclusion criteria: >18 years old with documentation of either 2 recurrences after a primary episode and has completed at least two rounds of standard-of-care oral antibiotic therapy, or at least 2 episodes of severe CDI resulting in hospitalization; a positive stool test for the presence of toxigenic *C. difficile* within 60 days prior to enrollment
- Exclusion criteria: History of irritable bowel disease (ulcerative colitis, Crohn's disease or microscopic colitis); irritable bowel syndrome; chronic diarrhea; celiac disease; colostomy; evidence of active colitis; known exposure to antibiotics within 6 months after study enrollment; compromised immune system (white blood cell count <1000 cells/μL)
- Antibiotics were discontinued 24-48 hours prior to the first enema
- Safety was assessed in clinic at 1, 4, and 8 weeks and via telephone at 2, 3, between 5-7 weeks, and at 3, 6, 12 and 24 months.
- Success was defined as the absence of CDI at 8 weeks following completion of the last treatment. Patients were classified as a treatment failure if all four (4) of the following criteria were met: recurrence of diarrhea less than 8 weeks after administration of the last assigned study enema, a positive laboratory diagnosis of C. difficile as conducted and reported by the study investigator, a need for retreatment for CDI, and no other cause for diarrhea

RBX2660 IS EFFICACIOUS & SAFE relative to placebo controls

A Phase 2B randomized, double-blind placebo controlled trial (NCT02299570)

TRIAL DESIGN



DEMOGRAPHICS

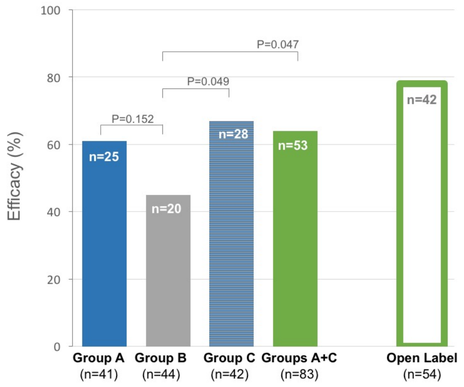
CHARACTERISTIC	GROUP A 2 Doses RBX2660	GROUP B 2 Doses Placebo	GROUP C 1 Dose RBX2660+1 Dose Placebo
n	41	44	42
Mean age–years (range)	62.8 (24-89)	58.8 (19-92)	61.5 (18-88)
Female sex- n (%)	25 (61)	30 (68)	24 (57)
Race-White – n (%)	39 (95)	42 (96)	40 (95)
Antibiotic used at screening – n(%)			
Vancomycin	38 (93)	40 (91)	37 (88)
Fidaxomicin	1 (2)	2 (5)	2 (5)
Metronidazole	2 (5)	2 (5)	2 (5)
None			1 (2)
Mean number of CDI episodes (range)	3.9 (3-8)	3.7 (2-11)	3.8 (2-12)
Mean duration of qualifying CDI episode, days (range)	17.1 (2-64)	21.1 (2-78)	18.3 (2-70)

SAFETY

(24-month follow-up in progress)

Key Safety Events	Group A	Group B	Group C
	Total Events/# Subjects (% Total Subjects)		
Adverse Events	169/25 (61.0)	105/26 (59.1)	105/31 (72.1)
Serious Adverse Events (SAEs)	19/13 (31.7)	8/6 (13.6)	18/7 (16.3)
SAEs possibly related to product	3 (7.3)	0 (0)	-

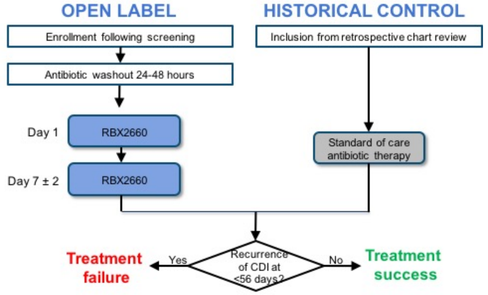
EFFICACY



RBX2660 IS EFFICACIOUS & SAFE relative to historical controls

A Phase 2 open-label trial (NCT02589847)

TRIAL DESIGN



DEMOGRAPHICS

CHARACTERISTIC	2 doses RBX2660	Historical Control
n	136	110
Mean age – years (range)	65.8 [19-103]	67.8 [21-97]
Female sex - n (%)	88 (65)	76 (69)
Race-White – n (%)	124 (91)	40 (36)
Treatment for CDI Episodes – n (%)		
Vancomycin	428 (59)	322 (55)
Fidaxomicin	58 (8)	40 (7)
Metronidazole	196 (27)	166 (28)
Other	29 (4)	54 (9)
Mean number of CDI episodes (range)	4.8 [2-25]	5.4 [2-11]
Mean duration of CDI episode, days	22.6	36.9

SAFETY

(24-month follow-up in progress)

Key Safety Events	RBX2660	Historical Control
	Total Events/# Subjects (% Total Subjects)	
Adverse Events	385 / 94 (69.1)	691 / 69 (62.7)
Serious Adverse Events (SAEs)	80 / 23 (16.9)	80/31 (28.2)
SAEs possibly related to product	3 (2.2)	-

EFFICACY