

VE303 for Prevention of Recurrent Clostridioides Difficile Infection

NCT06237452

Status	RECRUITING
Phase	Phase 3
Sponsor	Vedanta Biosciences, Inc.
Enrollment	852 participants

Key Eligibility Criteria

Inclusion (19)

- Age ≥ 12 years where permitted, and ≥ 18 years in other locations, with a laboratory-confirmed qualifying episode of CDI and at least 1 prior occurrence within the last 6 months
 - Age ≥ 75 years with a laboratory-confirmed qualifying episode of CDI
 - OR age ≥ 12 years where permitted, and ≥ 18 years in other locations, with least two of the following risk factors:
 - Age ≥ 65 years
 - Kidney dysfunction, defined as estimated creatinine clearance $< 60 \text{ mL/min/1.73 m}^2$ at the time of the qualifying CDI episode
- ... and 14 more (see full listing online)

Exclusion (8)

- History of chronic diarrhea (defined as ≥ 3 loose stools per day lasting for at least 4 weeks) within 3 months prior to randomization that is not related to CDI
 - Known or suspected toxic megacolon or small bowel ileus at the time of randomization
 - History of confirmed celiac disease, inflammatory bowel disease, microscopic colitis, short gut, GI tract fistulas, or a recent episode (within 6 months of screening) of intestinal ischemia or ischemic colitis
 - Receipt of bezlotoxumab during the course of SoC antibiotic treatment for the qualifying CDI episode
 - Use of antidiarrheal drugs (eg, loperamide, diphenoxylate) within 3 days prior to the planned first dose of study drug
- ... and 3 more (see full listing online)

Locations (214 total)

Advanced Gastroenterology, P.C., Chandler, Arizona, United States
Mayo Clinic Hospital, Phoenix, Arizona, United States
GI Alliance, Sun City, Arizona, United States
... and 211 more locations