VE303

VE303 is an orally-administered investigational live biotherapeutic product (LBP). It is produced from pure, clonal bacterial cell banks, which yield a standardized drug product in powdered form and bypasses the need to rely on direct sourcing of fecal donor material of inconsistent composition. VE303 consists of a defined consortium of live bacteria designed to restore colonization resistance against gut pathogens, including C. *difficile*. In 2017, Vedanta Biosciences received a $5.4 million research grant from CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator) to support clinical studies of VE303. VE303 was granted Orphan Drug Designation in 2017 by the United States Food and Drug Administration (FDA) for the prevention of recurrent C. *difficile* infection (rCDI).

Phase 1a/1b clinical study in healthy volunteers for its lead, orally-administered live biotherapeutic product (LBP) candidate for recurrent Clostridium difficile infection (rCDI), VE303. With these Phase 1 data to support dosage selection, Vedanta Biosciences expects to begin a Phase 2 study before the end of the year to evaluate the safety and efficacy of VE303 in patients with rCDI. Additional exploration of VE303 in healthy volunteers to inform dose selection in other indications is ongoing.

This study was designed to evaluate safety and tolerability of a range of doses of VE303 in healthy adult volunteers. The study also evaluated pharmacokinetics of intestinal colonization by the VE303 strains and pharmacodynamics of recovery of the gut microbiota after administration of antibiotics followed by a course of VE303.