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Vedanta Biosciences Initiates Phase 2 Study for VE303

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Clinical Stage company, Vedanta Biosciences developing a new category of therapies for immune-mediated diseases based on rationally-defined consortia of human microbiome-derived bacteria has announced that it has initiated a Phase 2 study of its lead, orally-administered live biotherapeutic product (LBP) candidate, VE303, for recurrent Clostridium difficile infection (rCDI).

Vedanta Biosciences' pipeline of microbiome-derived product candidates also includes the recently announced Phase 1 study of VE202 with Janssen Biotech, Inc. for inflammatory bowel disease (IBD), and the Company expects to initiate a Phase 1/2 study of VE416 in food allergy in Q1 2019 in addition to a Phase 1/2 study of VE800 and Opdivo (nivolumab) in advanced or metastatic cancers in mid-2019.

The Phase 2, multi-center, randomized, double-blind, placebo-controlled CONSORTIUM study is designed to evaluate the safety and efficacy of two doses of VE303 compared to placebo in patients with rCDI.

The study is expected to enroll up to 146 patients with a recent diagnosis of rCDI, confirmed using a Clostridium difficile toxin assay, and who have completed a course of antibiotics but remain at risk for recurrence. The primary endpoint will be prevention of infection recurrence at eight weeks.

Ciaran P. Kelly, Professor of Medicine, Harvard Medical School said, "The results of the VE303 Phase 1a/1b are very promising, and I look forward to the continued progression of this – and Vedanta's other product candidates – through the clinic. Vedanta's approach yields product candidates with a defined and uniform composition, potentially mitigating the safety and variability challenges associated with approaches based on fecal transplants or fecal fractions."

Dose selection for this study was based on the results of a recently concluded Phase 1a/1b study of VE303 in healthy volunteers. That study found that all doses of VE303 were safe and well-tolerated and that treatment with VE303 resulted in rapid, durable, and dose-dependent colonization of VE303 strains. The Phase 1 study also found that VE303 treatment accelerated the restoration of gut microbiota after a course of antibiotics.

Bernat Olle, Co-founder and Chief Executive Officer of Vedanta Biosciences said, "This is the first Phase 2 study, to our knowledge, of a rationally-defined bacterial consortium candidate in any indication, so it represents a major milestone for Vedanta Biosciences and the field. Our Phase 1a/1b study helped de-risk key questions for our modality, in particular

whether robust, durable colonization – superior to what has been reported for probiotics in the past – can be obtained with a defined consortium and whether the right consortium can rapidly restore the gut microbiota after antibiotics."

Unlike single strain or microbiome-derived metabolite approaches to microbiome modulation, Vedanta Biosciences is developing consortia of bacterial strains designed to effect robust and durable therapeutic changes in a patient's gut microbiota. In contrast to fecal transplants or administration of fecal fractions, Vedanta Biosciences' consortia are defined compositions of bacteria manufactured from pure, clonal cell banks, bypassing the need to rely on direct sourcing of fecal donor material of inconsistent composition.

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).