PureTech Health Affiliate Vedanta Biosciences Announces Expanded Data from Successful Phase 1a/1b Study of VE303 at Digestive Disease Week

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Expanded data on rapid, durable, and dose-dependent colonisation of VE303 strains further support optimal dosing regimen and pharmacodynamics of gut microbiota restoration

Phase 2 study of VE303 in recurrent Clostridium difficile *infection is ongoing*

PureTech Health plc (LSE:PRTC) ("PureTech Health"), an advanced biopharmaceutical company developing novel medicines for dysfunctions of the Brain-Immune-Gut (BIG) axis, is pleased to note that its affiliate Vedanta Biosciences announced the presentation of expanded data from its Phase 1a/1b study of VE303, the Company's lead, orally-administered live biotherapeutic product (LBP) candidate for recurrent *Clostridium difficile* infection (rCDI). In a milestone for the microbiome field, VE303 data demonstrated that Vedanta's product candidate, composed of a defined bacterial consortium, administered as a standardised lyophilized powder in capsule form, induced rapid, durable and dose-dependent colonisation of VE303 strains. The data were presented at Digestive Disease Week 2019, the world's largest gathering of physicians, researchers, and industry in the fields of gastroenterology, hepatology, endoscopy, and gastrointestinal surgery, held in San Diego, California.

VE303 is currently being evaluated in a Phase 2 study designed to evaluate the safety and efficacy of two different dosages in patients with rCDI. The data from the presentation support the dosing regimen selected for this study and further validate the Company's rationally-defined consortia approach.

The full text announcement from Vedanta Biosciences is as follows:

Vedanta Biosciences Presents Positive Expanded Data from Phase 1a/1b Study of VE303 at Digestive Disease Week

Expanded data on rapid, durable, and dose-dependent colonisation of VE303 strains further support optimal dosing regimen and pharmacodynamics of gut microbiota restoration

Phase 2 study of VE303 in recurrent Clostridium difficile *infection is ongoing*

CAMBRIDGE, Mass., May 20, 2019 – Vedanta Biosciences, a clinical-stage company developing a new category of therapies for immune-mediated diseases based on rationally-defined consortia of human microbiome-derived bacteria, today announced the presentation of expanded, long-term positive data from its Phase 1a/1b study of VE303, the Company's lead, orally-administered live biotherapeutic product (LBP) candidate for recurrent *Clostridium difficile* infection (rCDI). The data were presented at Digestive Disease Week 2019, held in San Diego, California, and supports the dosing employed in the ongoing Phase 2 study of VE303 and further illuminate interactions between VE303 and gut microbiota.

The expanded data build on the preliminary results of the Phase 1a/1b study previously disclosed by the Company, which found that all doses of VE303 were safe and well-tolerated and that treatment with VE303 resulted in rapid, durable, and dose-dependent colonisation of VE303 strains across a heterogenous group of 23 adults. The study also found that VE303 treatment accelerated the restoration of gut microbiota after a course of antibiotics.

"This study served as an important validation for our approach of developing rationally-defined consortia and our ability to quantify their pharmacology," said Bernat Olle, Ph.D., chief executive officer of Vedanta Biosciences. "These expanded data underscore the benign safety profile of VE303 and further demonstrate the pharmacokinetics of colonisation and its relationship to dose exposure and gut microbiota restoration after treatment with antibiotics."

In late 2018, Vedanta announced the initiation of a Phase 2, multi-centre, randomised, double-blind, placebo-controlled study ("CONSORTIUM") designed to evaluate the safety and efficacy of two doses of VE303 compared to placebo in patients with rCDI. The study is expected to enrol 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.

About VE303

VE303 is a first-in-class orally-administered investigational live biotherapeutic product (LBP) consisting of a defined bacterial consortium. It is produced under GMP conditions from pure, clonal bacterial cell banks, which yield a standardised drug product in powdered form and bypasses the need to rely on direct sourcing of faecal donor material of inconsistent composition. VE303 is designed to restore colonisation resistance against gut pathogens, including C. *difficile,* after treatment with antibiotics. 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) and is currently being evaluated in a Phase 2 clinical study for the treatment of rCDI.

About Vedanta Biosciences

Vedanta Biosciences is a clinical-stage microbiome leader developing a new category of therapies for immune-mediated diseases based on rationally-defined consortia of human microbiome-derived bacteria. Vedanta's proprietary capabilities include what is believed to be the largest collection of human-gut associated bacteria, assays and bioinformatics techniques for consortia design and optimisation, vast datasets from human interventional studies and facilities for cGMP-compliant manufacturing of rationally-defined bacterial consortia in powder form.

Vedanta Biosciences' pioneering work, in collaboration with its scientific co-founders, has led to the identification of human commensal bacteria that induce a range of immune responses – including induction of regulatory T cells, CD8+ T cells, and Th17 cells, among others. These advances have been published in leading peer-reviewed journals, including *Science* (multiple), *Nature* (2013, 2019), *Cell*, and *Nature Immunology*. Vedanta Biosciences has harnessed these biological insights and its capabilities to generate a pipeline of investigational live biotherapeutic products (LBPs) in infectious disease, autoimmune disease, allergy, and immuno-oncology. This pipeline includes 2 clinical-stage product candidates currently being evaluated for the treatment of recurrent *C. difficile* infection and inflammatory bowel disease (in collaboration with Janssen Biotech, Inc.) as well as two additional product candidates entering the clinic in 2019 in food allergy and in patients with advanced or metastatic cancers (in combination with Bristol-Myers Squibb's checkpoint inhibitor OPDIVO®).

Vedanta's IP portfolio contains 20 US patents and numerous foreign issuances with coverage extending to 2037. Earlier this year, the European Patent Office upheld Vedanta's foundational Honda Patent, which is now issued in major commercial markets, including the United States, Europe, and Japan. Vedanta Biosciences was founded by PureTech Health (LSE.PRTC). Its scientific co-founders are world-renowned experts in immunology and microbiology who have pioneered the fields of innate immunity, Th17 and regulatory T cell biology.

About PureTech Health

PureTech Health (LSE: PRTC) is an advanced biopharmaceutical company developing BIG medicines for dysfunctions of the Brain-Immune-Gut axis. The Company has gained deep insights into the connection between these systems and the resulting role in diseases that have proven resistant to established therapeutic approaches. By harnessing this emerging field of human biology, PureTech Health is developing new categories of medicines with the potential to have great impact on people with serious diseases.

PureTech Health is advancing a rich pipeline of innovative therapies with an unbiased, non-binary, and capital efficient R&D model across its affiliates and its internal labs. PureTech's affiliates include seven clinical-stage platforms, including one product that has been cleared by the US Food and Drug Administration (FDA) and a second product candidate that has been filed with the FDA for review, and several other novel preclinical programmes. The PureTech Health pipeline includes ground-breaking platforms and therapeutic candidates that were developed in collaboration with some of the world's leading experts.

PureTech's internal research and development is centred on tissue-selective immunomodulation for the treatment of oncology, autoimmune, and CNS-related disorders, with a near-term focus on targeting newly-discovered, foundational immunosuppressive mechanisms in oncology and novel approaches that harness the lymphatic infrastructure.

For more information, visit www.puretechhealth.com or connect with us on Twitter @puretechh.

Forward Looking Statement

This press release contains statements that are or may be forward-looking statements, including statements that relate to the company's future prospects, developments and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks and uncertainties that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risks and uncertainties described in the risk factors included in the regulatory filings for PureTech Health plc. These forward-looking statements are based on assumptions regarding the present and future business strategies of the company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law and regulatory requirements, neither the company nor any other party intends to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.