



PureTech Founded Entity Vedanta Biosciences Announces Additional Pharmacokinetics Data from Phase 1 Study of VE202 for Inflammatory Bowel Disease to be Presented at United European Gastroenterology Week 2020

October 12, 2020

Data to be presented showing VE202 microbiome-derived bacterial strains rapidly, abundantly and durably colonise the gut of healthy volunteers

[PureTech Health plc](#) (LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to discovering, developing and commercialising highly

differentiated medicines for devastating diseases, is pleased to note that its Founded Entity, Vedanta Biosciences, today announced that additional pharmacokinetics data from a Phase 1 clinical study of VE202 in healthy volunteers will be presented by Janssen Research & Development, LLC, at United European Gastroenterology (UEG) Week 2020, held virtually from October 11-13.

Topline data from placebo-controlled Phase 1 studies were announced in June, which reported that VE202 was generally well-tolerated at all doses studied. The new UEG Week data presentation focuses on the kinetics and durability of colonisation from an 11-strain consortium of VE202 under various dosing and pre-treatment regimens.

Bharatt Chowrira, JD, PhD, PureTech's president and chief of business and strategy, said: "These additional Phase 1 data are important, as sustained and durable colonisation of the healthy human gut suggests that VE202 is having the desired effect. The findings further validate Vedanta's unique and differentiated approach to developing microbiome-based products and support the potential of VE202 as a novel treatment for inflammatory bowel disease (IBD). We're pleased that Vedanta will continue to progress the programme into a Phase 2 study in patients with IBD."

The full text of the announcement from Vedanta Biosciences is as follows:

Vedanta Biosciences Announces Additional Pharmacokinetics Data from Phase 1 Study of VE202 for Inflammatory Bowel Disease to be Presented at United European Gastroenterology Week 2020

Phase 1 development partner Janssen to present data showing VE202 microbiome-derived bacterial strains rapidly, abundantly and durably colonise the gut of healthy volunteers

CAMBRIDGE, Mass., October 12, 2020 – [Vedanta Biosciences](#), a leading 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 that additional pharmacokinetics data from a Phase 1 clinical study of VE202 in healthy volunteers will be presented by Janssen Research & Development, LLC, at United European Gastroenterology (UEG) Week 2020, held virtually from October 11-13.

Topline data from placebo-controlled Phase 1 studies were announced in June, which reported that VE202 was generally well-tolerated at all doses studied. The new UEG Week data presentation focuses on the kinetics and durability of colonisation from an 11-strain consortium of VE202 under various dosing and pre-treatment regimens.

"People living with inflammatory bowel disease often struggle to find lasting relief with currently available medications. Our defined bacterial consortia are designed to reshape the ecosystem of the gut microbiome, an aspect of inflammatory bowel disease (IBD) that has not been addressed by biologics and other existing drug classes," said Bernat Olle, PhD, co-founder and chief executive officer of Vedanta Biosciences. "We are encouraged by these results and look forward to further advancing VE202 to patient studies."

Vedanta plans to take the VE202 programme forward into a Phase 2 study in inflammatory bowel disease in 2021.

The data presented at UEG Week focus on 74 healthy volunteers treated with an 11-strain consortium of VE202 or a placebo. Results include:

- The consortium colonised the gut abundantly and above background strains detected by qPCR. Colonisation was most effective with vancomycin pre-treatment followed by multiple doses of the consortium. In multiple-day dosing cohorts, vancomycin pre-treatment reduced microbial density and was required for sustained detection of VE202 compared to non-vancomycin pre-treated cohorts. In these cohorts, VE202 strains were detected up to six months post-treatment.
- Vedanta is currently conducting metagenomic and metabolomic profiling to further characterise the mechanisms by which VE202 impacts microbiome community structure in addition to measuring metabolites, and the results will be presented in future publications.

About Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is estimated to affect approximately three million people in the United States, with as many as 70,000 new cases of the diseases diagnosed each year. IBD is believed to result from interactions between genetic factors and environmental triggers, such as commensal bacteria with pathogenic potential. It is associated with chronic inflammation in the gastrointestinal (GI) tract, impairing the ability of affected GI organs to function properly. Symptoms can vary but include diarrhea, abdominal pain, cramping, rectal bleeding and fatigue. Patients often endure debilitating cycles of flare-ups and disease progression and may struggle to find a treatment that durably addresses their symptoms.

About VE202

VE202 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. VE202 was designed to induce immune tolerance via the gut and thereby potentially treat inflammatory bowel disease. Results describing the biology and candidate selection of VE202 were previously published in [Science](#) and [Nature \(multiple\)](#).

About Vedanta Biosciences

[Vedanta Biosciences](#) is leading the development of a potential new category of oral therapies based on rationally defined consortia of bacteria derived from the human microbiome. The company's clinical-stage pipeline includes product candidates being evaluated for the treatment of high-risk *C. difficile* infection, inflammatory bowel diseases, advanced or metastatic cancers, and food allergy. These investigational therapies are grounded in pioneering research – published in leading journals including [Science](#), [Nature](#), and [Cell](#) – to identify beneficial bacteria that live symbiotically within the healthy human gut, fight pathogens and induce a range of potent immune responses. *Vedanta Biosciences controls a foundational portfolio of more than 40 patents and has built what is believed to be the world's biggest library of bacteria derived from the human microbiome.* Proprietary capabilities include deep expertise in consortium design, vast datasets from human interventional studies and cGMP-compliant manufacturing of oral live biotherapeutics containing pure, clonally derived bacterial consortia in powdered form. Vedanta Biosciences was founded by [PureTech Health](#) (LSE: PRTC) and a global team of scientific co-founders who pioneered Vedanta's modern understanding of the cross-talk between the microbiome and the immune system.

About PureTech Health

PureTech is a clinical-stage biotherapeutics company dedicated to discovering, developing and commercialising highly differentiated medicines for devastating diseases, including intractable cancers, lymphatic and gastrointestinal diseases, central nervous system disorders and inflammatory and immunological diseases, among others. The Company has created a broad and deep pipeline through the expertise of its experienced research and development team and its extensive network of scientists, clinicians and industry leaders. This pipeline, which is being advanced both internally and through PureTech's Founded Entities, is comprised of 24 products and product candidates, including two that have received US Food and Drug Administration (FDA) clearance and European marketing authorisation. All of the underlying programmes and platforms that resulted in this pipeline of product candidates were initially identified or discovered and then advanced by the PureTech team through key validation points based on the Company's unique insights into the biology of the brain, immune and gut, or BIG, systems and the interface between those systems, referred to as the BIG Axis.

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, the Company's expectations regarding VE202's potential therapeutic benefits or future success and 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.