PureTech Founded Entity Vedanta Biosciences Awarded Up to $76.9 Million Including $7.4 Million Upfront from BARDA to Advance the Development of VE303

September 30, 2020

Award is first-ever by BARDA directed to advance development of a microbiome drug

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 it has been awarded funding of $7.4 million, with the potential for up to an additional $69.5 million, from the Biomedical Advanced Research and Development Authority (BARDA) to advance clinical development of VE303 for high-risk *Clostridioides difficile* infection (CDI).

Vedanta Biosciences is the first-ever recipient of a BARDA award in the microbiome field. The funding will support completion of an ongoing Phase 2 trial and further clinical development of VE303, a rationally-defined, orally-administered live biotherapeutic product (LBP) consisting of eight well-characterised commensal bacterial strains designed to effect robust and durable therapeutic changes in a patient's gut microbiota. A previous Phase 1a/1b study demonstrated rapid, durable, dose-dependent colonisation and accelerated restoration of gut microbiota in healthy volunteers who were pretreated with antibiotics.

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

Vedanta Biosciences Awarded Up to $76.9 Million Including $7.4 Million Upfront from BARDA to Advance the Development of VE303, a Defined Bacterial Consortium for Prevention of *C. difficile* Infection in High-Risk Patients

Award is first-ever by BARDA directed to advance development of a microbiome drug

CAMBRIDGE, Mass., September 30, 2020 – 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 it has been awarded funding of $7.4 million, with the potential for up to an additional $69.5 million, from the Biomedical Advanced Research and Development Authority (BARDA) to advance clinical development of VE303 for high-risk *Clostridioides difficile* infection (CDI).

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The ongoing Phase 2 study is a multi-centre, randomised, double-blind, placebo-controlled trial designed to evaluate the safety and efficacy of two doses of VE303 compared to placebo in patients with high-risk CDI. The study is enrolling patients with a recent confirmed diagnosis of CDI who have completed a course of antibiotics but remain at high risk for recurrence. The primary endpoint is prevention of infection recurrence at eight weeks.

"We are honoured to be the first-ever recipient of a BARDA award in the microbiome field and look forward to collaborating with the US Government to advance the clinical development of VE303 and to potentially fulfil its promise in public health and biodefense," said Bernat Olle, PhD, co-founder and chief executive officer of Vedanta Biosciences. "CDI accounts for approximately 12,800 deaths each year in the US alone and are the result of damage to the gut microbiota caused by both necessary and unnecessary antibiotic use. We believe restoration of the gut microbiota after antibiotic use is a new paradigm in infection control that could improve patient outcomes following a broad range of procedures that rely on antibiotics, as well as a key underappreciated potential strategy in antimicrobial stewardship."

BARDA, a division within the Office of the Assistant Secretary of Preparedness in the US Department of Health and Human Services, supports a diverse portfolio of emerging therapeutics and devices. Programmes supported by BARDA have received a total of 55 FDA approvals, licensures or clearances.

"The concept of rationally-designed live biotherapeutic products has strong merit for treating infectious diseases such as *C. difficile*," said Gary Disbrow, PhD, BARDA Acting Director. "If successful, VE303 could prevent high-risk *C. difficile* and reduce our dependency on antibiotics, which would be a major win for public health. We're enthusiastic about the opportunity to address both of these issues and proud to support clinical development of VE303."

The grant from BARDA includes $7.4 million of guaranteed initial funding and up to an additional $69.5 million, subject to BARDA exercising multiple options under the award.

About VE303

VE303 is an orally-administered, investigational live biotherapeutic product (LBP). It is produced 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 donor faecal material of inconsistent composition. VE303 consists of a defined consortium of live bacteria designed to restore colonisation resistance against gut pathogens, including C. *difficile*. Vedanta Biosciences received a $5.4 million research grant from CARB-X in 2017 and a grant from BARDA in 2020 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).

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 BARDA

The Biomedical Advanced Research and Development Authority (BARDA), an agency within the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), provides a comprehensive, integrated, portfolio approach to the advanced research and development, innovation, acquisition, and manufacturing infrastructure for vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health emergency threats. These threats include chemical, biological, radiological, and nuclear threats, pandemic influenza and emerging infectious diseases. For more information, visit https://www.phe.gov/about/barda/. Members of the media can contact ASPRMedia@hhs.gov.

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 the use of BARDA funding to continue development of VE303 and the potential for additional funding 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.