



PureTech's Vedanta Biosciences Awarded \$5.4 Million Grant from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) to Support Development of a Novel Human Microbiome-Derived Treatment

November 3, 2017

PureTech Health plc (LSE: PRTC), an advanced, clinical-stage biopharmaceutical company, is pleased to note that Vedanta Biosciences, an affiliate of PureTech Health, today announced that it has been awarded a \$5.4 million research grant from CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator) to support clinical testing of its lead oral product candidate, VE303, a novel human-microbiome drug candidate to address serious bacterial infections.

Vedanta also announced that it has completed what is believed to be the first-ever CGMP-compliant manufacturing (Current Good Manufacturing Practices, required by the U.S. Food and Drug Administration) of a rationally-defined live bacterial consortia in powder form.

Bharatt Chowrira, PhD, JD, President and Chief of Business and Strategy at PureTech Health, said: "We are pleased to be recognized as the first microbiome-based anti-infective approach supported by the world's largest public-private partnership devoted to antibacterial preclinical R&D. With antibiotic resistance looming as a major threat, it is inspiring to be working on this new approach for tackling serious infections. We also believe that this manufacturing milestone is an important step in moving the enormous promise of the microbiome field into the realm of serious medicine with a rationally defined product candidate produced from pure cell banks in a reproducible and consistent manner."

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

Vedanta Biosciences Awarded Up To \$5.4 Million from CARB-X to Accelerate Development of VE303, a Novel Human Microbiome-Derived Treatment for Serious Bacterial Infection

Company also completes first-ever CGMP-compliant manufacturing of a rationally-defined bacterial consortia in powder form

CAMBRIDGE, Massachusetts, November 3, 2017—[Vedanta Biosciences](#), an affiliate of PureTech Health (LSE: PRTC), pioneering a novel category of therapies designed to modulate pathways of interaction between the human microbiome and the host immune system, today announced that it has been awarded a research grant of up to \$5.4 million from CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator), a global public-private partnership focused on funding the development of promising new antibacterial products and rapid diagnostics. The funding will be used to support clinical testing of Vedanta Biosciences' lead oral product candidate, VE303, a novel human-microbiome drug candidate to address *Clostridium difficile* (*C. difficile*) and potentially other bacterial infections. VE303 is a rationally-defined live bacterial consortia administered via an oral capsule and is expected to be tested in a human clinical trial this quarter. Also in connection with the VE303 program, Vedanta today announced that it has achieved a key development milestone in the human microbiome field, completing what is believed to be the first-ever CGMP-compliant (Current Good Manufacturing Practices, required by the U.S. Food and Drug Administration) manufacturing of a rationally-defined live bacterial consortia in powder form.

"The Vedanta VE303 microbiome-based anti-infective project is an exciting addition to the CARB-X pipeline. It is CARB-X's first award announced for a microbiome project and also the first for a project targeting *C. difficile*, bringing a novel approach that could potentially protect patients from bacterial infections and save lives," said Kevin Outterson, Executive Director of CARB-X, the world's leading non-profit partnership dedicated to accelerating the development of antibiotics, diagnostics and other products to treat deadly infections.

The Centers for Disease Control and Prevention (CDC) considers *C. difficile* infections one of the most urgent bacterial threats. *C. difficile* infections account for 15,000 deaths each year in the U.S. alone. Existing interventions for *C. difficile* infections include antibiotics, which have an undesirable side effect of damaging the gut microbiome and leaving patients vulnerable to re-infection and building resistance to antibiotics.

"First-generation approaches in the microbiome field for recurrent *C. difficile* infection (rCDI) have relied on uncharacterized faecal material or spore fractions of faecal material, which are inherently inconsistent procedures," said Bernat Olle, Ph.D., Chief Executive Officer of Vedanta Biosciences. "We believe that VE303 is the first rationally-defined microbiome drug advanced to the clinic to tackle rCDI. VE303 is produced from pure cell banks and it consists of a defined consortia of live bacteria designed to restore colonization resistance against gut pathogens following recurrence. We are grateful to CARB-X for their support and look forward to working together to advance this novel therapy."

Vedanta has also continued to expand its internal, state-of-the-art CGMP-compliant manufacturing capability with the addition of a second manufacturing site, dedicated to production, packaging, and labelling of live bacterial consortia drug product capsules. Coupled with existing CGMP-compliant drug substance production capabilities in Cambridge, MA, the addition fully integrates Vedanta's manufacturing capabilities, a distinct competitive advantage in the microbiome field.

"Reproducible CGMP-compliant manufacturing of live bacterial consortia drugs can be a complex activity, and we have worked successfully through those technical hurdles," said Dan Couto, SVP of Operations and Manufacturing for Vedanta Biosciences. "Completion of this technical milestone significantly de-risks the company's ability to supply timely clinical material for our pipeline of programs and provides Vedanta a key strategic advantage in the microbiome field."

Vedanta Biosciences has created one of the leading end-to-end platforms for development of live bacterial consortia-based medicines based on the human microbiome. The platform leverages a vast clinical dataset from interventional studies, what is believed to be the largest collection of

gut-associated bacteria, high-throughput proprietary pharmacology screening tools, state-of-the-art facilities for CGMP-compliant manufacturing, and a leading intellectual property portfolio that includes issued patents that we believe to be among the earliest foundational intellectual property in the microbiome field.

About CARB-X

CARB-X is the world's largest public-private partnership devoted to antibacterial preclinical R&D. Funded by BARDA and Wellcome Trust, with in-kind support from NIAID, we will spend \$455 million from 2016-2021 to support innovative products moving towards human clinical trials. CARB-X focuses on high priority drug-resistant bacteria, especially Gram-negatives. CARB-X is led by Boston University School of Law. Other partners include the Broad Institute of Harvard and MIT, MassBio, the California Life Sciences Institute and RTI International. For more information, please visit www.carb-x.org and follow us on Twitter [@CARB_X](https://twitter.com/CARB_X).

About Vedanta Biosciences

[Vedanta Biosciences](#) is pioneering development of a novel class of therapies for immune and infectious diseases based on rationally designed consortia of bacteria derived from the human microbiome, with clinical trials expected to begin in the second half of 2017. An affiliate of [PureTech Health](#) (PureTech Health plc, PRTC.L), Vedanta's founding team includes a group of world-renowned experts in immunology and microbiology. Vedanta Biosciences is a leader in the microbiome field with capabilities and deep expertise to discover, develop and manufacture drugs based on live bacterial consortia. Leveraging its proprietary technology platform and the expertise of its team of scientific co-founders, Vedanta Biosciences has isolated and maintains what we believe to be the largest collection of human microbiome-associated bacterial strains and has characterized, in collaborations with leading experts, how the immune system recognizes and responds to these microbes. This pioneering work 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 – as well as the characterization of novel molecular mechanisms of microbial-host communication. These advances have been published in leading peer-reviewed journals including [Science](#), [Nature \(multiple\)](#), [Cell](#) and [Nature Immunology](#). Vedanta Biosciences has harnessed these biological insights, its proprietary library of microbiome-derived bacterial strains, as well as data from clinical translational collaborations, to generate a pipeline of programs addressing infectious diseases, autoimmune diseases, inflammation and immune-oncology indications.

Vedanta Biosciences' scientific co-founders have pioneered the fields of innate immunity, Th17 and regulatory T cell biology, and include Dr Ruslan Medzhitov (Professor of Immunobiology at Yale), Dr Alexander Rudensky (tri-institutional Professor at the Memorial Sloan-Kettering Institute, the Rockefeller University and Cornell University), Dr Dan Littman (Professor of Molecular Immunology at NYU), Dr Brett Finlay (Professor at the University of British Columbia) and Dr Kenya Honda (Professor, School of Medicine, Keio University). Vedanta is backed by PureTech Health, Seventure, Invesco Asset Management, and Rock Springs Capital and has collaborations with leading institutions including Janssen Biotech, Inc., NYU Langone Medical Center, Stanford University School of Medicine, Leiden University Medical Center, University of Tokyo, Keio University, and RIKEN.

About PureTech Health

PureTech Health (PureTech Health plc, PRTC.L) is an advanced, clinical-stage biopharmaceutical company developing novel medicines targeting serious diseases that result from dysfunctions in the nervous, immune, and gastrointestinal systems (brain-immune-gut or the "BIG" axis), which together represent the adaptive human systems. PureTech Health is at the forefront of understanding and addressing the biological processes and crosstalk associated with the BIG axis. By harnessing this emerging field of human biology, the Company is pioneering new categories of medicine with the potential to have great impact on people with serious diseases. PureTech Health is advancing a rich pipeline of innovative therapies that includes two pivotal stage programmes, multiple human proof-of-concept studies and a number of early clinical and pre-clinical programmes. PureTech's rich research and development pipeline has been advanced in collaboration with some of the world's leading scientific experts, who along with PureTech's team of biopharma pioneers, entrepreneurs and seasoned Board, identify, invent, and clinically de-risk new medicines. With this experienced team pursuing cutting edge science, PureTech Health is building the biopharma company of the future focused on improving and extending the lives of people with serious disease. For more information, visit www.puretechhealth.com or connect with us on Twitter [@puretechh](https://twitter.com/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.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.