PureTech Founded Entity Vedanta Biosciences Unveils State-of-the-Art Manufacturing Facility to Provide Clinical and Commercial Supply of Oral Therapies Based on Defined Bacterial Consortia

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PureTech Founded Entity Vedanta Biosciences Unveils State-of-the-Art Manufacturing Facility to Provide Clinical and Commercial Supply of Oral Therapies Based on Defined Bacterial Consortia

Multi-product CGMP facility designed to meet global regulatory standards for the manufacture of oral therapies based on defined bacterial consortia

Facility will supply planned Phase 3 clinical trial and potential commercial launch of VE303 in Clostridioides difficile *infection*

PureTech Health plc (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company noted that its Founded Entity, Vedanta Biosciences, Inc. ("Vedanta"), today announced the opening of a new facility designed to manufacture clinical and commercial supply for its therapeutic portfolio, including for the planned Phase 3 study and potential commercial launch of its lead candidate, VE303, in *Clostridioides difficile* infection. The large-scale Current Good Manufacturing Practice (CGMP) facility builds on the company's existing manufacturing capabilities and can produce multiple drug candidates in a manner compliant with global regulatory standards, supporting Vedanta's clinical expansion. With this facility, Vedanta has CGMP capabilities from clinical development to commercial launch, underscoring its leadership in the discovery, development, and manufacture of drugs based on defined bacterial consortia.

Vedanta believes it was the first company to manufacture CGMP-grade defined bacterial consortia in powdered form, which enables stable, consistent oral formulations. Vedanta has also demonstrated its ability to reliably produce defined bacterial consortia, by manufacturing several hundred CGMP batches encompassing over 30 phylogenetically-diverse anaerobic bacterial species that are representative of the biodiversity in the human gut and advancing five product candidates to the clinic.

The first production runs at the new facility will supply a planned Phase 3 study of VE303, an orally administered, defined bacterial consortium candidate for high-risk *Clostridioides difficile* (CDI) infection.

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

Vedanta Unveils State-of-the-Art Manufacturing Facility to Provide Clinical and Commercial Supply of Oral Therapies Based on Defined Bacterial Consortia

Multi-product CGMP facility designed to meet global regulatory standards for the manufacture of oral therapies based on defined bacterial consortia

Facility will supply planned Phase 3 clinical trial and potential commercial launch of VE303 in Clostridioides difficile *infection*

CAMBRIDGE, MA - Vedanta Biosciences, a clinical-stage biopharmaceutical company pioneering the development of oral therapies based on defined bacterial consortia, today announced the opening of a new facility designed to manufacture clinical and commercial supply for its therapeutic portfolio, including for the planned Phase 3 study and potential commercial launch of its lead candidate, VE303, in *Clostridioides difficile* infection. The large-scale Current Good Manufacturing Practice (CGMP) facility builds on the company's existing manufacturing capabilities and can produce multiple drug candidates in a manner compliant with global regulatory standards, supporting Vedanta's clinical expansion. With this facility, Vedanta has CGMP capabilities from clinical development to commercial launch, underscoring its leadership in the discovery, development, and manufacture of drugs based on defined bacterial consortia.

"We believe that taking a targeted approach to modulation of the human microbiota, using rigorously controlled and defined pharmaceutical-grade compositions, will be instrumental to the evolution of microbiome-based therapies into a reliable new drug modality for patients across a range of indications," said Bernat Olle, Ph.D., Chief Executive Officer of Vedanta Biosciences. "This facility, combined with the expertise and talent of our team, is designed to manufacture our microbiome product candidates as standardized compositions with consistent quality attributes at a large scale."

"We saw early on in Vedanta's existence that the manufacturing capabilities required for this new drug modality were not yet established in our field, particularly those involving consortia of anaerobes or spore-forming strains, which comprise the majority of human intestinal bacteria," said Dan Couto, Chief Operating Officer of Vedanta Biosciences. "Today, we have industrialized an end-to-end manufacturing process for this class of product candidates, at commercial scale, by solving an array of technical challenges related to CGMP production of defined bacterial consortia. We believe this in-house capability mitigates potential delays associated with technology transfer to third parties, empowers us to expedite advancing product candidates that show promise in early studies, and protects key intellectual property and know-how."

Vedanta believes it was the first company to manufacture CGMP-grade defined bacterial consortia in powdered form, which enables stable, consistent oral formulations. The company has also demonstrated its ability to reliably produce defined bacterial consortia, by manufacturing several hundred CGMP batches encompassing over 30 phylogenetically-diverse anaerobic bacterial species that are representative of the biodiversity in the human gut and advancing five product candidates to the clinic.

The first production runs at the new facility will supply a planned Phase 3 study of VE303, an orally administered, defined bacterial consortium candidate for high-risk *Clostridioides difficile* (CDI) infection. Every year, CDI contributes approximately 45,000 deaths in the U.S. In a Phase 2 study that enrolled patients at high risk of recurrence, VE303 met its primary endpoint of preventing CDI recurrence at eight weeks. This was the most advanced clinical trial of an investigational drug based on a defined bacterial consortium to date.

About Vedanta's Manufacturing Platform

Vedanta's industry-leading process for the manufacture of defined bacterial consortia is based on the isolation and storage of individual strains of bacteria in clonal cell banks, their subsequent fermentation, lyophilization, blending into defined consortia, and filling into capsules for oral administration to the patient. The company's platform spans end-to-end capabilities, from master cell banking to drug substance and drug product manufacturing, from early clinical phase to commercial launch. The process consists of the following key steps:

Isolation and Banking of Individual Strains: The manufacturing process begins with cell banks of individually isolated strains of bacteria, identified through proprietary screens as being essential members of a consortium with therapeutic potential. This approach bypasses the reliance on fecal matter donations of inconsistent composition from human donors, and eliminates the risk of pathogen transfer from such donations. Vedanta has established CGMP master cell banks for over 30 different strains of gut-dwelling bacterial species and intends to more than double its number of CGMP cell banks in 2022.

Fermentation: The bacterial strains used in Vedanta's product candidates are anaerobic (requiring an oxygen-free environment) and many are spore-formers (requiring containment), which present unique manufacturing challenges. The company has developed proprietary processes, including growth media and precise control conditions, that enable fermentation of anaerobes. The company's' in-house facilities are configured to ensure segregation and process containment. These features provide Vedanta the flexibility to operate a multi-product facility and to handle both spore-forming and non-spore-forming bacteria.

Formulation and Lyophilization: Lyophilization is a freeze-drying process, whereby a product is dried by removing water under low temperature and vacuum conditions. This process can place considerable stress on bacteria and hinder their ability to regain metabolic activity when delivered to the gut of a patient. The company has developed proprietary formulations to stabilize a wide range of bacterial strains and has demonstrated stability at refrigerated temperatures for multi-year storage of its drug product capsules.

Blending, Fill, and Finish: The individual strains in lyophilized powder form are blended into defined consortia and filled in capsules for oral administration that are designed to resist stomach acid and release the bacteria in the intestine. Vedanta can precisely adjust and blend each strain during drug product manufacturing to ensure that every capsule contains the same composition and dose. In contrast, human fecal donations

intrinsically vary from donor to donor and from donation to donation, resulting in a final product with different composition and dose of each bacterial species across every batch.

The company utilizes proprietary processes at each step and has accumulated a wealth of institutional knowledge that has proven broadly applicable to product processing and stabilization. In addition to the new multi-product launch-scale CGMP facility, Vedanta has manufacturing facilities in Cambridge and Acton, MA, which supply Phase 1 and Phase 2 clinical trials.

About Vedanta Biosciences

Vedanta Biosciences is leading the development of a potential new category of oral therapies based on defined consortia of bacteria isolated from the human microbiome and grown from pure clonal cell banks. The company's clinical-stage pipeline includes product candidates being evaluated for the treatment of high-risk *C. difficile* infection, inflammatory bowel diseases, food allergy, liver disease, and cancer. 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 45 patents and has built what it believes is one of the largest libraries 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 Biotherapeutic Product (LBP) candidates containing pure, clonally-derived bacterial consortia in powdered form. Vedanta Biosciences was founded by PureTech Health (Nasdaq: PRTC, LSE: PRTC) and a global team of scientific co-founders who pioneered the 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 commercializing highly differentiated medicines for devastating diseases, including inflammatory, fibrotic and immunological conditions, intractable cancers, lymphatic and gastrointestinal diseases and neurological and neuropsychological disorders, 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 27 therapeutics and therapeutic candidates, including two that have received both U.S. FDA clearance and European marketing authorization, as of the date of PureTech's most recently filed Annual Report and corresponding Form 6-K. All of the underlying programs and platforms that resulted in this pipeline of therapeutic candidates were initially identified or discovered and then advanced by the PureTech team through key validation points based on unique insights in immunology and drug development.

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

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements that relate to Vedanta's future prospects, development plans, and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks, uncertainties and other important factors that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risks, uncertainties and other important factors described under the caption "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2021 filed with the SEC and in our other regulatory filings. 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, we disclaim any obligation to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

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