



## PureTech Founded Entity Vedanta Biosciences Completes \$68 Million Series D Financing

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### **PureTech Founded Entity Vedanta Biosciences Completes \$68 Million Series D Financing**

*Proceeds expected to be used primarily to support a Phase 3 trial of Vedanta's lead candidate VE303 in Clostridioides difficile infection (CDI) and a Phase 2 trial of VE202 in inflammatory bowel disease (IBD)*

*Topline data from Phase 2 trial of VE303 in CDI are anticipated in Q3 2021*

*Vedanta plans to initiate Phase 2 trial of VE202 for treatment of mild to moderate ulcerative colitis in H2 2021*

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company announces that its Founded Entity, Vedanta Biosciences ("Vedanta"), completed a \$68 million Series D financing and provided a pipeline update.

The Series D financing was led by affiliates of Magnetar Capital. Other participants in the financing were new and existing investors including Verition Fund Management, Fosun Health Capital, co-founder PureTech Health, Rock Springs Capital, Skyviews Life Science, JSR Corporation, Symbiosis LLC, Shumway Capital, Health for Life Capital (Seventure Partners) and other institutional investors. The round also includes a \$25 million investment from Pfizer as part of the Pfizer Breakthrough Growth Initiative, which was announced in January 2021.

Vedanta plans to use the proceeds to advance its pipeline of defined bacterial consortia, including progressing VE303 into a Phase 3 clinical trial in patients at high risk for recurrent CDI, initiating a Phase 2 clinical trial of VE202 in mild to moderate ulcerative colitis and continuing to advance programs in additional indications.

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

**Vedanta Biosciences Completes \$68 Million Series D Financing**

*Proceeds expected to be used primarily to support a Phase 3 trial of lead candidate VE303 in Clostridioides difficile infection (CDI) and a Phase 2 trial of VE202 in inflammatory bowel disease (IBD)*

*Topline data from Phase 2 trial of VE303 in CDI are anticipated in Q3 2021*

*Plans to initiate Phase 2 trial of VE202 for treatment of mild to moderate ulcerative colitis in H2 2021*

**CAMBRIDGE, MA, July 21, 2021** - [Vedanta Biosciences, Inc.](#), a leading clinical-stage microbiome company developing a new category of oral therapies using defined bacterial consortia manufactured from clonal cell banks, today announced the closing of a \$68 million Series D financing and provided a pipeline update.

The Series D financing was led by affiliates of Magnetar Capital. Other participants in the financing were new and existing investors including Verition Fund Management, Fosun Health Capital, co-founder PureTech Health, Rock Springs Capital, Skyviews Life Science, JSR Corporation, Symbiosis LLC, Shumway Capital, Health for Life Capital (Seventure Partners), and other institutional investors. The round also includes a \$25 million investment from Pfizer as part of the Pfizer Breakthrough Growth Initiative, which was announced in January 2021.

Vedanta plans to use the proceeds to advance its pipeline of defined bacterial consortia, including progressing VE303 into a Phase 3 clinical trial in patients at high risk for recurrent CDI, initiating a Phase 2 clinical trial of VE202 in mild to moderate ulcerative colitis, and continuing to advance programs in additional indications.

"We are delighted to welcome the new investors in our Series D round and are grateful to our existing shareholders and partners for their continued support," said Bernat Olle, Ph.D., Co-Founder and Chief Executive Officer of Vedanta Biosciences. "Since our last funding round, we have made significant progress advancing defined bacterial consortia as a new modality for infectious and immune-mediated diseases. This most recent financing, together with the support we receive from BARDA for our CDI program, will enable us to advance mid- and late-stage programs in CDI and IBD, as well as support early exploratory clinical studies in additional indications."

"Drugs based on defined bacterial consortia are a promising new therapeutic modality with the potential to transform medicine, and Vedanta is the leader in this category, with a state-of-the-art discovery platform, field-leading GMP manufacturing capabilities, and an advanced pipeline," said Ted Koutouzis, M.D., Managing Director of Fiscus Venture and Reimagined Ventures, affiliates of Magnetar. "We are proud to support the company's efforts."

### **Vedanta's Pipeline**

Vedanta Biosciences is developing a potential new category of oral therapies based on rationally defined consortia of bacteria derived from the human microbiome. All of the company's pipeline programs are wholly owned.

### **Company-Sponsored Programs**

#### **VE303 for the Prevention of Recurrence in High-risk Patients with *Clostridioides difficile* (CDI) Infection**

- VE303 consists of 8 clonal human commensal bacterial strains selected for their ability to provide colonization resistance to *C. difficile*.
- In a Phase 1 healthy-volunteer study, VE303 showed rapid, durable, and dose-dependent colonization and accelerated gut microbiota restoration after a course of antibiotics.
- Vedanta is currently evaluating VE303 in a Phase 2 clinical trial in patients at high

- risk of recurrent CDI and will report results from this trial in Q3 2021.
- In 2020, Vedanta was awarded up to \$76.9 million of federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00177, to partially fund the development of VE303. This was the first-ever grant from BARDA in the microbiome field.
- The company expects to complete the build-out of its Phase 3 and commercial launch cGMP manufacturing facility for supply of VE303 by the end of 2021.
- The company plans to initiate a Phase 3 trial in mid-2022.

#### **VE202 for the Treatment of Inflammatory Bowel Disease (IBD)**

- VE202 consists of 16 clonal human commensal bacterial strains selected for their ability to induce regulatory T cells in the gut mucosa, decolonize pro-inflammatory organisms, and strengthen the epithelial barrier.
- In June 2021, Vedanta presented positive Phase 1 topline data of VE202 in healthy volunteers at the International Human Microbiome Consortium Congress. VE202 was generally safe and well tolerated at all doses and demonstrated durable and dose-dependent colonization.
- Vedanta plans to initiate a Phase 2 clinical trial of VE202 in patients with mild to moderate ulcerative colitis in the second half of 2021.
- VE202 is being developed in part through funding provided by the Pfizer Breakthrough Growth Initiative.

#### **VE800 for the Treatment of Advanced and Metastatic Tumors**

- VE800 consists of 11 clonal human commensal bacterial strains selected for their ability to induce CD8+ T cells, potentiate anti-tumor activity, and enhance the effects of checkpoint inhibitors.
- The company is nearing completion of Stage 1 of an open-label Phase 1 study to evaluate the safety and initial clinical activity of VE800 in combination with Bristol Myers Squibb's *Opdivo*<sup>®</sup> (nivolumab) in 54 patients across select types of advanced or metastatic cancers.
- This trial is being done under a collaboration and supply agreement with Bristol Myers Squibb.
- To date, VE800 has demonstrated an acceptable safety and tolerability profile, though the observed response rates did not meet the prespecified criteria to expand into the next stage of the study. Vedanta is analyzing blood, stool, and tumor samples from patients in whom response or disease control was observed, to profile patient subtypes that might benefit from microbiome manipulation. The company plans to present the results at a future medical conference.
- The company will continue work to identify cancer settings and patient populations that might benefit from microbiome manipulation with its defined bacterial consortia.

#### **Preclinical Programs**

- VE707 is a preclinical program for the prevention of infection by several problematic Gram-negative Enterobacteriaceae, which are some of the most common hospital-acquired pathogens. Vedanta has received funding from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) of up to \$7.4 million, plus up to \$3.5 million more if certain milestones are met, to advance VE707. The company expects to select a development candidate in H2 2021.

#### **Investigator-Sponsored Studies**

##### **VE416 in Peanut Allergy**

- VE416 consists of 7 bacterial strains of the Clostridia class, which were selected based on the ability to induce immune tolerance in the gut.
- A Phase 1/2, investigator-sponsored clinical study is underway at Massachusetts General Hospital, exploring use of VE416 both as a monotherapy and in combination with an oral peanut immunotherapy over the course of several

months.

- Topline data from the Phase 1/2 clinical trial is expected to be reported in 2022, subject to investigator timelines.

### **VE303 in Hepatic Encephalopathy**

- A new Phase 2 investigator-sponsored trial evaluating VE303 in patients with hepatic encephalopathy (HE) was recently initiated by the University of Michigan Hospitals-Michigan Medicine. The randomized, double-blind, placebo-controlled trial is planned to enroll up to 18 adult patients with a confirmed diagnosis of cirrhosis and history of at least one episode of overt HE.

FJS Consultants Limited acted as a placement agent for Vedanta's investors in China. BARDA is the Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.

### **About Vedanta Biosciences**

Vedanta Biosciences is leading the development of a potential new category of oral therapies for immune-mediated diseases using defined bacterial consortia manufactured from clonal cell banks. The company's approach bypasses the need to rely on direct sourcing of donor fecal material of inconsistent composition, thus overcoming challenges related to safety, quality, and scalability that limit donor-derived approaches. The clinical pipeline includes product candidates being evaluated for the treatment of *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* - that identified bacteria that induce a range of beneficial immune responses. The company's platform includes what is believed to be the largest library of bacteria derived from the human microbiome, high-throughput methods for bacterial consortium design, vast datasets from human interventional studies, and state-of-the-art capabilities for cGMP-compliant manufacturing of defined bacterial consortia. Vedanta Biosciences controls a foundational intellectual property portfolio covering compositions of matter and methods of use for classes of bacteria that play key roles in human health. 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 interaction between the immune system and the microbiome.

### **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 26 therapeutics and therapeutic candidates, including two that have received FDA clearance and European marketing authorization, as of the date of PureTech's most recently filed Annual Report on Form 20-F. 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 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](http://www.puretechhealth.com) or connect with us on Twitter @puretechh.

### **Ownership Information**

PureTech's percentage ownership of Vedanta Biosciences following the financing is

approximately 41.4% on a diluted basis. This calculation of PureTech's holding includes issued and outstanding shares as well as options and warrants to purchase shares, but excludes unallocated shares authorized to be issued pursuant to equity incentive plans.

#### **Cautionary Note Regarding Forward-Looking Statements**

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, expectations regarding Vedanta's use of proceeds from the Series D financing, including expectations regarding the use of the funding to support a Phase 3 trial of VE303 and a Phase 2 trial of VE202, the potential clinical benefit of VE303, VE202 and Vedanta's other product candidates, the anticipated timing of initiation and topline data from Vedanta's planned and ongoing clinical trials 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.

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#### **DISCLAIMER**

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