



PureTech Provides End of Year Report on Key Progress Across Wholly Owned Programs and Founded Entities

December 16, 2021

RNS Number : 8203V
PureTech Health PLC
16 December 2021

16 December 2021

PureTech Health plc

PureTech Provides End of Year Report on Key Progress Across Wholly Owned Programs and Founded Entities

Three clinical-stage, wholly-owned candidates being advanced across range of indications, including two Phase 2 trials of LYT-100 (deupirfenidone), a Phase 1/2 trial of LYT-200 (anti-galectin-9 mAb) and a Phase 1 study of LYT-300 (oral allopregnanolone)

Key milestones achieved across Founded Entities position them for value inflection, including manufacturing scale up and commercial launch and launch preparations for Gelesis' Plenity® and Akili's EndeavorRx®, respectively, as well as multiple positive clinical results across Founded Entities

Continued validation of four lymphatic and inflammation platforms, including advancement of therapeutic candidates from these platforms and the achievement of preclinical proof-of-concept data for Orasome™

Catalyst-rich 2022 anticipated, with results from multiple studies and further growth and advancement of therapeutics, which have the potential to impact serious diseases with limited treatment options

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to discovering, developing and commercializing highly differentiated medicines for devastating diseases, today reported on the key progress made across its Wholly Owned Programs¹ and Founded Entities² in 2021, including some updates that were not previously reported.

Daphne Zohar, Founder and Chief Executive Officer of PureTech, commented: "2021 has been a year of profound achievements and fundamental growth across our Wholly Owned Programs and our Founded Entities. With the support of our shareholders, we have pioneered a unique R&D model that has been successful in identifying, inventing and advancing novel therapeutic candidates for serious diseases and creating wholly-owned programs as well as both public and private Founded Entities with substantial value. We are proud of our execution and successes and are excited about using that strong foundation to catalyze value as we enter into an important, milestone-rich 2022, having the benefit of a strong balance sheet from which to drive value."

PureTech's Wholly Owned Programs are comprised of six therapeutic candidates and four lymphatic and inflammation platforms. Additionally, PureTech's Founded Entities are advancing 19 therapeutics and therapeutic candidates, of which two have been cleared for marketing by the U.S. Food and Drug Administration (FDA) and granted marketing authorization in the European Economic Area, and 14 are clinical stage. Key highlights include the following:

Wholly Owned Programs

- **LYT-100** (deupirfenidone), in development for potential treatment of conditions involving inflammation and fibrosis:
 - Progressed Phase 2 clinical trial in patients with Long COVID respiratory complications. Enrollment is expected to be completed by the end of 2021, with topline results anticipated in the first half of 2022.
 - Progressed Phase 2a clinical trial in patients with breast cancer-related, upper limb secondary lymphedema. Results are anticipated in 2022.
 - Presented the results of the Phase 1 multiple ascending dose and food effect study of LYT-100 at the virtual European Respiratory Society (ERS) International Congress. The results from the study were subsequently published in the journal *Clinical Pharmacology in Drug Development*.
 - PureTech plans to provide further details around its development plans for LYT-100 in additional inflammatory and fibrotic conditions, such as idiopathic pulmonary fibrosis, myocardial fibrosis and other organ system fibrosis.

- **LYT-200** (anti-galectin-9 mAb) & **LYT-210** (anti-gamma delta-1 mAb), in development for the potential treatment of a range of cancer indications:
 - LYT-200 was granted orphan drug designation by the U.S. FDA for the treatment of pancreatic cancer.
 - Progressed Phase 1/2 trial of LYT-200 for the potential treatment of a range of solid tumors. Results from the Phase 1 portion are anticipated in the first half of 2022.
 - Entered into a clinical trial and supply agreement with BeiGene to evaluate LYT-200 in combination with tislelizumab in solid tumors.
 - Presented new research at the American Association for Cancer Research (AACR) Annual Meeting demonstrating that LYT-210 is both highly specific and highly potent, rapidly inducing cell death of immune-suppressive $\gamma\delta 1$ T cells, while sparing other T cells that play important roles in a healthy immune response. The research was conducted using both patient blood and cancer tissue.

- **LYT-300** (oral allopregnanolone), in development for the potential treatment of neurological and neuropsychological conditions, & **Glyph™ Technology Platform**:
 - Initiated a Phase 1 clinical study in healthy volunteers to evaluate safety, tolerability, and pharmacokinetic profile, as well as explore the impact of LYT-300 on b-EEG, a marker of GABA_A target engagement, thus potentially providing early insights into the mechanistic effects of LYT-300. Results from the study will inform the design of possible future studies in indications that could include depression, anxiety, sleep disorders, fragile X tremor-associated syndrome, essential tremor and epileptic disorders, among others.
 - Presented preclinical proof-of-concept data at the American College of

Neuropsychopharmacology (ACNP) Annual Meeting showing that systemic exposure of natural allopregnanolone was achieved after oral administration of LYT-300 in multiple preclinical animal models.

- Published preclinical proof-of-concept work in *Nature Metabolism* and the *Journal of Controlled Release* supporting the Glyph technology platform's ability to directly target the lymphatic system with a variety of therapies.
- **LYT-500** (oral IL-22 + anti-inflammatory), in development for the potential treatment of inflammatory bowel disease, **LYT-503** (partnered non-opioid pain program), in development for the potential treatment of interstitial cystitis/bladder pain syndrome, & **Alivio™ Technology Platform:**
 - Declared LYT-500 therapeutic candidate. Progressed preclinical proof-of-concept work.
 - Advancing LYT-503 as a potential targeted non-opioid treatment for interstitial cystitis or bladder pain syndrome in collaboration with a partner, following the exercise of a license option under an existing research and development collaboration. An Investigational New Drug Application is planned to be filed in 2022.
 - Evaluating other potential therapeutic candidates leveraging Alivio technology platform for Wholly Owned Pipeline expansion.
- **Orasome Technology Platform:**
 - Established preclinical proof-of-concept supporting the platform's potential to achieve therapeutic levels of proteins in circulation following the oral administration of therapeutic protein expression systems. PureTech intends to generate additional preclinical data in 2022. Using the Orasome technology platform, it may be possible for a patient to take an oral drug product that will permit their own gastrointestinal tract cells to make virtually any type of therapeutic protein. This approach also has the potential to provide a more convenient and significantly less expensive means to administer biological medicines.
- **Meningeal Lymphatics Program:**
 - Published preclinical research in *Nature* suggesting that restoring lymphatic flow in the brain has the potential to address a range of neurodegenerative diseases, such as Alzheimer's and Parkinson's diseases and associated neuroinflammation. The work also uncovered a link between dysfunctional meningeal lymphatics and damaging microglia activation in Alzheimer's disease, suggesting another route by which restoring healthy drainage patterns could improve clinical outcomes.

Founded Entities:

- **Gelesis**
 - Broadly launching Plenity®, an FDA-cleared weight management approach, in the U.S. to adults who meet the prescription criteria. Gelesis' first commercial-scale manufacturing line at the facility is also now complete and validated.
 - Achieved both primary endpoints in LIGHT-UP study of GS200 in adults with overweight or obesity who also have prediabetes or type 2 diabetes. Gelesis continues to analyze these data as it plans its next steps in the development of GS200 and plans to present the detailed results in a scientific venue.
 - Initiated Phase 2 study of GS300, which is in development for the potential treatment of nonalcoholic fatty liver disease/non-alcoholic steatohepatitis (NAFLD/NASH).
 - Entered into definitive business combination agreement with Capstar Special Purpose

Acquisition Corp. Upon completion of the transaction, the combined company's securities are expected to be traded on the New York Stock Exchange (NYSE) under the symbol "GLS".

· **Akili**

- Completed a \$160 million financing, a new licensing agreement with Australian digital health company, TALi®, and new gaming features and functionalities for EndeavorRx®.
- Initiated Phase 2 study of AKL-T01 for COVID brain fog in collaboration with Weill Cornell and Vanderbilt.
- Published full data in *Nature Digital Medicine* from STARS Adjunct study, which evaluated impact of EndeavorRx (AKL-T01) on symptoms and functional impairments in children with attention-deficit/hyperactivity disorder (ADHD).
- Announced results from Shionogi's Phase 2 study of SDT-001 (Japanese version of AKL-T01) that showed treatment was well-received by patients and demonstrated improvements in ADHD inattention symptoms consistent with those seen across previous studies of AKL-T01.

· **Karuna**

- Announced all four Phase 3 trials in the EMERGENT program, the clinical program evaluating KarXT (xanomeline-trospium) for the treatment of psychosis in adults with schizophrenia, are enrolling. Karuna anticipates reporting topline data from the Phase 3 EMERGENT-2 trial in mid-2022 and from the Phase 3 EMERGENT-3 trial in the second half of 2022.
- Initiated the Phase 3 ARISE trial evaluating KarXT for the treatment of schizophrenia in adults who experience an inadequate response to current standard of care.
- Reported data from completed Phase 1b trial evaluating safety and tolerability of KarXT in healthy elderly volunteers. Karuna plans to initiate a Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer's disease in mid-2022.
- Published results from the Phase 2 EMERGENT-1 clinical trial evaluating KarXT for the treatment of schizophrenia in the *New England Journal of Medicine* (NEJM).
- Announced entry into an exclusive license agreement with Zai Lab for the development, manufacturing and commercialization of KarXT in Greater China, including mainland China, Hong Kong, Macau, and Taiwan.

· **Vor**

- Completed initial public offering on Nasdaq under ticker symbol "VOR".
- Initiated a Phase 1/2a trial of VOR33 in acute myeloid leukemia (AML).
- Granted Fast Track designation by the FDA for VOR33.
- Entered into collaboration with Janssen Biotech, Inc. (Janssen), to investigate the combination of Vor's "invisible" eHSC transplant platform with one of Janssen's bi-specific antibodies in development for AML.

· **Follica**

- Announced the appointment of two leaders in aesthetic medicine and dermatology to its Board of Directors, Tom Wiggans, former CEO of Dermira, and Michael Davin, former CEO of Cynosure.
- Continued to advance regenerative biology platform, including preparing for a Phase 3 registration program in male androgenetic alopecia, which is expected to be initiated in 2022.

- **Vedanta**
 - Achieved primary endpoint in Phase 2 clinical trial of VE303, an orally administered investigational live biotherapeutic product (LBP) in development for the prevention of recurrent *C. difficile* infection (CDI) in high-risk patients.
 - Completed a \$68 million financing, which included a \$25 million investment from Pfizer as part of the Pfizer Breakthrough Growth Initiative.

- **Sonde**
 - Launched Sonde Mental Fitness, a voice-enabled mental health detection and monitoring technology that uses a brief voice journal entry to evaluate mental well-being, expanding Sonde beyond respiratory health.
 - Announced strategic collaboration with Qualcomm Technologies to embed Sonde vocal biomarker technology into its latest Snapdragon mobile chipsets to provide smartphone OEMs with native, voice-enabled health tracking capabilities.

- **Entrega**
 - Continued advancement of ENT-100 platform for the oral administration of biologics, vaccines and other drugs that are otherwise not efficiently absorbed when taken orally.
 - Continued collaboration with Eli Lilly to investigate the application of the Entrega peptide administration technology to certain Eli Lilly therapeutic candidates.

- 1) References to "Wholly Owned Programs" refer to the Company's six therapeutic candidates (LYT-100, LYT-200, LYT-210, LYT-300, LYT-500 and LYT-503/IMB-150), four lymphatic and inflammation platforms and potential future therapeutic candidates and platforms that the Company may develop or obtain. References to "Wholly Owned Pipeline" refer to LYT-100, LYT-200, LYT-210, LYT-300, LYT-500 and LYT-503/IMB-150. On July 23, 2021, Imbrium Therapeutics exercised its option to license LYT-503/IMB-150 pursuant to which it is responsible for all future development activities and funding for LYT-503/IMB-150.
- 2) Founded Entities represent companies founded by PureTech in which PureTech maintains ownership of an equity interest and, in certain cases, is eligible to receive sublicense income and royalties on product sales. As of June 30, 2021, PureTech maintained control over Follica Incorporated, Vedanta Biosciences, Inc., Sonde Health, Inc. and Entrega, Inc. by virtue of (a) majority voting control or (b) the right to elect representation to the entity's Board of Directors. As of June 30, 2021, PureTech did not have a controlling interest in Gelesis, Inc., Karuna Therapeutics, Inc., Akili Interactive Labs, Inc. and Vor Biopharma Inc.

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 25 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 Half Year 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 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.

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are or may be 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, those related to our anticipation of catalysts in 2022 and beyond, the treatment potential of our Wholly Owned Programs, our expectations around the completion of enrollment and the timing for results with respect to the Phase 2 and Phase 2a clinical trials for LYT-100, our plans to provide further detail around our development plans for LYT-100, our anticipation of results from the Phase 1 portion our clinical trial for LYT-200, our expectations related to the potential uses of the results from the LYT-300 Phase 1 clinical study, the plans to file an Investigation New Drug Application for LYT-503, our evaluation of potential therapeutics candidates leveraging the Alivio Technology Platform, our expectation for data generation and potential approaches utilizing the Orasome Technology Platform, the treatment potential of therapeutic candidates of our Founded Entities, our expectations related to the business combination between Gelesis and Capstar Special Purpose Acquisition Corp., our expectations with respect to Karuna's Phase 3 clinical programs, and our expectations regarding Follica's potential commencement of Phase 3 registration program. 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, 2020 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.

Contact:

PureTech

Public Relations

publicrelations@puretechhealth.com

Investor Relations

IR@puretechhealth.com

EU Media

Ben Atwell, Rob Winder

+44 (0) 20 3727 1000

ben.atwell@FTIconsulting.com

US Media

Nichole Sarkis

+1 774 278 8273

nichole@tenbridgecommunications.com

###

This information is provided by Reach, the non-regulatory press release distribution service of RNS, part of the London Stock Exchange. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

Reach is a non-regulatory news service. By using this service an issuer is confirming that the information contained within this announcement is of a non-regulatory nature. Reach announcements are identified with an orange label and the word "Reach" in the source column of the News Explorer pages of London Stock Exchange's website so that they are distinguished from the RNS UK regulatory service. Other vendors subscribing for Reach press releases may use a different method to distinguish Reach announcements from UK regulatory news.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

NRADXBDDDBDGBU