UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of December, 2024

Commission File Number 001-39670

PURETECH HEALTH PLC
(Translation of registrant's name into English)

6 Tide Street, Suite 400
Boston, Massachusetts 02210
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On December 16, 2024, PureTech Health plc (LSE: PRTC, Nasdaq: PRTC) (the "Company") issued a press release titled "PureTech's Deupirfenidone (LYT-100) Slowed Lung Function Decline in People with Idiopathic Pulmonary Fibrosis (IPF) as Measured by Forced Vital Capacity (FVC), Achieving the Primary and Key Secondary Endpoints in the ELEVATE IPF Phase 2b Trial."

The press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

Exhibits

99.1 Press Release of PureTech Health plc, dated December 16, 2024, titled "PureTech's Deupirfenidone (LYT-100) Slowed Lung Function Decline in People with Idiopathic Pulmonary Fibrosis (IPF) as Measured by Forced Vital Capacity (FVC), Achieving the Primary and Key Secondary Endpoints in the ELEVATE IPF Phase 2b Trial."

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PURETECH HEALTH PLC

Date: December 16, 2024

By: /s/ Bharatt Chowrira
Name: Bharatt Chowrira
Title: Chief Executive Officer

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF THE UK VERSION OF THE MARKET ABUSE REGULATION (EU 596/ 2014) AS IT FORMS PART OF UK LAW BY VIRTUE OF THE EUROPEAN UNION (WITHDRAWAL) ACT 2018, AS AMENDED

16 December 2024

PureTech Health plc

PureTech's Deupirfenidone (LYT-100) Slowed Lung Function Decline in People with Idiopathic Pulmonary Fibrosis (IPF) as Measured by Forced Vital Capacity (FVC), Achieving the Primary and Key Secondary Endpoints in the ELEVATE IPF Phase 2b Trial

Dose-ranging trial evaluated deupirfenidone 550 mg three times a day (TID) (approximately equivalent exposure to pirfenidone 801 mg TID[1]) and deupirfenidone 825 mg TID and successfully demonstrated dose-dependent response

Decline in lung function seen with deupirfenidone 825 mg TID as a monotherapy was -21.5 mL; natural lung function decline expected in healthy adults >60 years is ~-15 to ~-25 mL[2]; decline in lung function with pirfenidone 801 mg TID was -51.6 mL

Deupirfenidone 825 mg TID showed strong, consistent and durable efficacy with a treatment effect versus placebo of 80.9% with favorable tolerability, while pirfenidone 801 mg TID had a 54.1% treatment effect versus placebo

Deupirfenidone was generally well-tolerated with a favorable adverse event profile at both doses studied

Data support continued development of deupirfenidone and highlight its potential to serve as a new standard-of-care treatment for IPF Company to host a webcast and conference call today at 9:00am EST / 2:00pm GMT

PureTech Health plc (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to changing the lives of patients with devastating diseases, today announced positive results from ELEVATE IPF, a Phase 2b randomized, double-blind, active- and placebo-controlled, dose-ranging trial evaluating deupirfenidone (LYT-100) at two dose levels three times a day (TID) over 26 weeks in patients with idiopathic pulmonary fibrosis (IPF).

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1 Maher, T., Chen, M., Korth, C., Elenko, E., Harnett, M., Garg, V., Graham, C., Fares, W., Krop, J. (2023). *Deupirfenidone (LYT-100) dose-selection rationale for a Phase 2b idiopathic pulmonary fibrosis study — ELEVATE IPF*. Poster presented at the CHEST Annual Meeting, Honolulu, HI.

2 FVC decline at 6 months was estimated assuming linear decline over time. Valenzuela, C., Bonella, F., Moor, C., Weimann, G., Miede, C., Stowasser, S., Maher, T. (2024). *Decline in forced vital capacity (FVC) in subjects with idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF) compared with healthy references*. Poster presented at the European Respiratory Society International Congress, Vienna, Austria; and Luoto, J., Pihlsgård, M., Wollmer, P., & Elmståhl, S. (2019). Relative and absolute lung function change in a general population aged 60-102 years. *The European Respiratory Journal*, *53*(3), 1701812. https://doi.org/10.1183/13993003.01812-2017

“The ELEVATE IPF trial broke new ground in Phase 2 trial design in IPF; this was the first time that a new therapy (deupirfenidone) has been evaluated alongside one of the two existing standard-of-care treatments (pirfenidone),” said Toby Maher, M.D., Ph.D., Professor of Medicine and Director of Interstitial Lung Disease at Keck School of Medicine, University of Southern California, Los Angeles, and lead investigator in the ELEVATE IPF trial. “Deupirfenidone 825 mg TID reduced lung function decline to near-physiologic levels over 26 weeks and had an effect size, compared with placebo, that was approximately 50% greater than that seen with pirfenidone. Deupirfenidone has the potential to offer patients a highly effective and tolerable treatment option. These are extremely exciting results from a Phase 2b trial, and I am very enthusiastic about the continued development of deupirfenidone.”

Participants in the trial were randomized 1:1:1:1 to receive deupirfenidone 550 mg, deupirfenidone 825 mg, pirfenidone 801 mg (the FDA-approved dose), or placebo TID for 26 weeks, and had the option to enroll in an ongoing, open-label extension study. The two doses of deupirfenidone were chosen based on PureTech’s Phase 1 data, which showed that a 550 mg TID dose of deupirfenidone provided approximately equivalent drug exposure to pirfenidone, 801 mg TID.[1]

The trial achieved its primary endpoint based on the prespecified Bayesian analysis, with a 98.5% posterior probability. This means there is a 98.5% probability that the pooled deupirfenidone arms were superior to placebo in slowing the rate of lung function decline in people with IPF, as measured by forced vital capacity (FVC) at 26 weeks. The trial also successfully demonstrated a dose-dependent response.

The rate of FVC decline[3] at week 26 with:

- deupirfenidone 825 mg TID compared to placebo was statistically significant (-21.5 mL vs. -112.5 mL, respectively; p=0.02)[4] and represents a robust treatment effect of 80.9% as a monotherapy; for context, the level of six-month natural decline in lung function as measured by FVC expected in healthy adults over 60 years old is approximately -15.0 mL to -25.0 mL.[2]
- pirfenidone 801 mg TID showed a treatment effect of 54.1% compared to placebo (-51.6 mL vs. -112.5 mL, respectively), which is consistent with previously reported pirfenidone clinical trial data.[5]

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3 Efficacy analyses used a random coefficient regression model with absolute FVC or FVCpp including baseline as response variable and week, treatment and interaction between week and treatment as fixed effect. The analyses were performed based on the predefined Full Analysis Set.

4 All p values are two-sided and have not been corrected for multiplicity.

5 Roche**.** (2014). *Esbriet® (pirfenidone) prescribing information*. Retrieved from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022535s000lbl.pdf

The trial also achieved its key secondary endpoint based on a prespecified Bayesian analysis, with a posterior probability of 99.6%. This means that there is a 99.6% probability that the pooled deupirfenidone arms were superior to placebo in slowing the rate of lung function decline in people with IPF, as measured by the forced vital capacity percent predicted (FVCpp) from baseline to week 26. While FVCpp and FVC (the primary endpoint) are both measures of lung function, FVCpp accounts for key patient characteristics (age, sex, height, race) and therefore normalizes the results at the patient level. Deupirfenidone 825 mg TID also demonstrated a benefit on this endpoint compared to placebo that was statistically significant (-0.43 vs. -3.43, respectively; p=0.01),[3,4] reinforcing the robustness of the treatment's impact.

	Placebo TID (N=65)	Pirfenidone 801 mg TID (N=61)	Deupirfenidone 550 mg TID (N=65)	Deupirfenidone 825 mg TID (N=63)
Change from Baseline in FVC (mL) over 26 Weeks (SE)	-112.5 (27.84)	-51.6 (29.13)	-80.7 (29.32)	-21.5 (28.86)
Difference in FVC (mL) vs. Placebo (95% CI)		60.9 (-18.3, 140.0)	31.8 (-47.6, 111.2)	91.0† (12.2, 169.7)
Change from Baseline in FVCpp (%) over 26 Weeks (SE)	-3.43 (0.842)	-1.46 (0.881)	-1.81 (0.886)	-0.43 (0.872)
Difference in FVCpp (%) vs. Placebo (95% CI)		1.97 (-0.42, 4.37)	1.62 (-0.78, 4.02)	3.00† (0.62, 5.38)

† Statistically significant at 0.05 level; p values are two-sided and have not been corrected for multiplicity.

Efficacy analyses used a random coefficient regression model with absolute FVC or FVCpp including baseline as response variable and week, treatment and interaction between week and treatment as fixed effect. The analyses were performed based on the predefined Full Analysis Set.
SE = standard error; CI = confidence interval

"Our goal in developing deupirfenidone is to offer better outcomes to people living with IPF. The adoption and adherence of currently approved antifibrotics has been limited by a tradeoff between efficacy and tolerability, specifically related to gastrointestinal adverse events. This prevents many patients from initiating treatment or maintaining optimal therapeutic doses and, in turn, achieving the best possible outcomes," said Eric Elenko, Ph.D., President and Co-founder of PureTech. "I could not be more pleased that deupirfenidone showed a favorable tolerability profile at both doses evaluated and – most importantly – has demonstrated the potential to offer patients enhanced efficacy at the higher dose."

Both doses of deupirfenidone were generally well-tolerated in the trial. The overall number of patients experiencing any gastrointestinal (GI)-related adverse events (AEs) was similar across the deupirfenidone 825 mg TID and pirfenidone 801 mg TID arms. Deupirfenidone 825 mg TID demonstrated a favorable tolerability profile compared to pirfenidone 801 mg TID, with a lower percentage of patients reporting key GI AEs that occurred in ≥5% of participants in at least one arm: nausea (20.3% vs. 27.0%), dyspepsia (14.1% vs. 22.2%), diarrhea (7.8% vs. 11.1%), constipation (4.7% vs. 6.3%) and vomiting (1.6% vs. 3.2%). The only key GI AE increase observed was abdominal pain (14.1% vs. 7.9%). There were five deaths in the pirfenidone arm, two deaths in the placebo arm and one death in each of the deupirfenidone arms. None of the deaths was deemed to be treatment related.

Overall, 187 out of 257 patients completed the trial: 43 out of 63 patients in the pirfenidone 801 mg TID arm; 42 out of 65 patients in the deupirfenidone 550 mg TID arm; 50 out of 64 patients in the deupirfenidone 825 mg TID arm; and 52 of 65 patients in the placebo arm.

Of those who completed the trial, 170 patients (more than 90%) opted to enroll in an ongoing open-label extension (OLE) evaluating the two doses of deupirfenidone. To date, preliminary data support a durable treatment effect and a consistent tolerability profile with deupirfenidone 825 mg. Across the randomized trial and OLE, the longest treatment duration with deupirfenidone 825 mg TID is 79 weeks and with deupirfenidone 550 mg TID is 81 weeks.

“These data are remarkable, particularly for a monotherapy, and – if supported by a Phase 3 trial – would represent a step change in the treatment of IPF,” said Bharatt Chowrira, Ph.D., J.D., CEO of PureTech. “At PureTech, our approach is centered on identifying simple and elegant solutions to big problems that underlie tremendous patient need, and we are proud that our R&D engine has generated another potentially transformative treatment. We are committed to the rapid advancement of deupirfenidone, with the goal of delivering a new standard of care to patients while generating value for our shareholders. On behalf of the entire PureTech team, I extend my sincere gratitude to the people living with IPF, their caregivers, the clinical trial investigators and advocacy groups as well as our talented team for supporting this mission.”

PureTech is committed to continuing development of deupirfenidone and intends to discuss the Phase 2b results with regulatory authorities to align on the appropriate path forward. Additional data from this trial will be presented at a future forum.

Webcast and Conference Call Details

Members of the PureTech management team will host a conference call at 9:00am EST / 2:00pm GMT today, December 16, 2024, to discuss these results. A live webcast and presentation slides will be available on the investors section of PureTech’s website under the Events and Presentations tab. To join by phone, please dial:

United Kingdom (Local): +44 20 3936 2999
United Kingdom (Toll-Free): +44 800 358 1035
United States (Local): +1 646 787 9445
United States (Toll-Free): +1 855 9796 654
International: +44 20 3936 2999
Access Code: 860033

For those unable to listen to the call live, a replay will be available on the PureTech website.

About the ELEVATE IPF Trial

The Phase 2b ELEVATE IPF trial was a randomized, double-blind, active- and placebo-controlled, dose-ranging trial designed to evaluate the efficacy, tolerability, safety and dosing regimen of deupirfenidone (LYT-100) in patients with IPF compared to placebo. 257 participants were randomized in a ratio of 1:1:1:1 to receive either 550 mg of deupirfenidone, 825 mg of deupirfenidone, 801 mg pirfenidone or placebo three times a day (TID) for 26 weeks. Participants who completed the trial had the option to enroll in an open-label extension, which is ongoing.

The primary endpoint of the trial was the rate of decline in Forced Vital Capacity (FVC) for the combined deupirfenidone arms versus placebo over the 26-week treatment period. FVC is a measure of the maximum amount of air (in mL) that an individual can forcibly exhale after fully inhaling. It is a standard measurement in clinical trials for IPF and is used to assess disease progression as well as to predict mortality.

A prespecified Bayesian analysis was utilized to assess the primary endpoint and provided a posterior probability, which is the probability of a positive treatment difference for deupirfenidone compared to placebo. This also allowed for augmentation of the placebo arm with placebo data from historical IPF trials. This approach enabled a more patient-centric clinical trial design by minimizing the number of trial participants exposed to placebo—a key consideration since IPF is progressive and fatal—while delivering a robust, placebo-controlled dataset.

About Deupirfenidone

Deupirfenidone is a deuterated form of pirfenidone, which is one of the two standard-of-care treatments approved to treat IPF, in addition to nintedanib. Deuteration is intended to make deupirfenidone break down more slowly in the body than pirfenidone.

About Idiopathic Pulmonary Fibrosis (IPF)

IPF is a rare, progressive and fatal lung disease with a median survival of 2-5 years.[6] Pirfenidone is one of only two drugs approved to treat IPF, and for those patients able to tolerate treatment, it has been shown to improve survival by approximately 2.5 years compared to supportive care alone.[6] However, tolerability issues with both of the standard-of-care medications result in patients discontinuing treatment or reducing their dose. This contributes to nearly three out of every four people with IPF in the US not receiving treatment with these otherwise efficacious medicines.[7] There are over 232,000 people in the US and the EU5 countries (Italy, Spain, France, Germany and the United Kingdom) living with IPF.[8]

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6 Fisher M, Nathan SD, Hill C, et al. Predicting Life Expectancy for Pirfenidone in Idiopathic Pulmonary Fibrosis. *J Manag Care Spec Pharm*. 2017;23(3-b Suppl):S17-S24. doi:10.18553/jmcp.2017.23.3-b.s17

7 Dempsey, T. M., Payne, S., Sangaralingham, L., Yao, X., Shah, N. D., & Limper, A. H. (2021). Adoption of the Antifibrotic Medications Pirfenidone and Nintedanib for Patients with Idiopathic Pulmonary Fibrosis. *Annals of the American Thoracic Society*, *18*(7), 1121–1128. https://doi.org/10.1513/AnnalsATS.202007-901OC

8 GlobalData Epidemiology and Market Size Search, EU5=United Kingdom, France, Germany, Italy and Spain

About PureTech Health

PureTech is a clinical-stage biotherapeutics company dedicated to giving life to new classes of medicine to change the lives of patients with devastating diseases. The Company has created a broad and deep pipeline through its experienced research and development team and its extensive network of scientists, clinicians and industry leaders that is being advanced both internally and through its Founded Entities. PureTech's R&D engine has resulted in the development of 29 therapeutics and therapeutic candidates, including three that have been approved by the U.S. Food and Drug Administration. A number of these programs are being advanced by PureTech or its Founded Entities in various indications and stages of clinical development, including registration-enabling studies. 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.

For more information, visit www.puretechhealth.com or connect with us on X (formerly 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 the LYT-100 development program and development plans, and its potential benefits to patients, plans for discussions with regulatory authorities, the further development of the program, future presentation of additional data from the trial and our future prospects, developments 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, 2023, 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.

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulations (EU) No. 596/2014 which forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018 ('MAR'). Upon the publication of this announcement via a Regulatory Information Service ('RIS'), this inside information is now considered to be in the public domain.

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