



PureTech to Present Results from Phase 2b ELEVATE IPF Trial of Deupirfenidone (LYT-100) at the American Thoracic Society International Conference

May 1, 2025

RNS Number : 9595G

PureTech Health PLC

01 May 2025

1 May 2025

PureTech Health plc

PureTech to Present Results from Phase 2b ELEVATE IPF Trial of Deupirfenidone (LYT-100) at the American Thoracic Society International Conference

Late-breaking oral presentation to highlight further evidence supporting potential for deupirfenidone to serve as a new standard of care for the treatment of idiopathic pulmonary fibrosis (IPF)

Regulatory and strategic planning underway to advance deupirfenidone into Phase 3 development

[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 that the Company will deliver a late-breaking oral presentation at the upcoming American Thoracic Society (ATS) International Conference, taking place in San Francisco, California, from May 16-21, 2025.

The presentation will highlight data from the recently completed Phase 2b ELEVATE IPF trial of deupirfenidone (LYT-100), which [demonstrated](#) unprecedented efficacy outcomes in patients living with idiopathic pulmonary fibrosis (IPF), including the potential to stabilize lung function decline at 26 weeks while maintaining safety and tolerability.

"The Phase 2b ELEVATE IPF trial results represent a major advancement for the treatment of IPF," said Bharatt Chowrira, Ph.D., J.D., Chief Executive Officer of PureTech. "Deupirfenidone demonstrated the potential to stabilize lung function decline over 26 weeks as a monotherapy—something not achieved by marketed or investigational IPF therapies, to our knowledge. The additional data we plan to highlight at ATS provide further confidence in the robust and durable efficacy and favorable tolerability of deupirfenidone. We believe deupirfenidone has the potential to set a new standard of care and make a transformative difference for patients living with this devastating disease."

PureTech is targeting a meeting with the U.S. Food and Drug Administration by the end of the third quarter of 2025 to discuss the results of the Phase 2b trial and align on a potential registrational pathway, with the goal of initiating a Phase 3 trial by the end of 2025. PureTech anticipates providing further guidance later this year following the finalization of the trial design and FDA interactions.

Details of the oral presentation are as follows:

Title: Deupirfenidone Compared to Placebo and Pirfenidone in Idiopathic Pulmonary Fibrosis: ELEVATE IPF Phase 2b Trial

Presenter: Toby Maher, M.D., Ph.D., Professor of Medicine and Director of Interstitial Lung Disease at Keck School of Medicine, University of Southern California

Session: C93 - Advances in interstitial lung disease and pulmonary hypertension: uncovering novel mechanisms, targeted therapies, and

personalized approaches

Date and Time: May 20, 2025 , 2:15 PM Pacific Time

About the ELEVATE IPF Trial

The Phase 2b ELEVATE IPF trial was a global, 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 superior efficacy 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 (LYT-100)

Deupirfenidone (LYT-100) is an investigational therapy in development as a potential new standard of care (SOC) for the treatment of idiopathic pulmonary fibrosis (IPF). It is a deuterated form of pirfenidone, which - along with nintedanib - is one of the two FDA-approved treatments for IPF. Despite achieving blockbuster status, the current SOC treatments only modestly slow lung function decline, with tolerability limiting the ability to achieve higher doses. This results in suboptimal efficacy, reduced patient uptake, and poor adherence - all due to a tolerability ceiling that prevents dosing levels that could significantly improve patient outcomes.

Deupirfenidone may overcome these limitations. In the global Phase 2b ELEVATE IPF trial, deupirfenidone demonstrated the potential to stabilize lung function decline over at least 26 weeks as a monotherapy while maintaining safety and tolerability - a result not previously achieved by other investigational or marketed IPF therapies to the Company's knowledge. These findings support the potential for deupirfenidone to offer a meaningful advance for patients living with this progressive and life-limiting disease. Beyond IPF, deupirfenidone may also address multiple underserved fibrotic diseases, including progressive fibrosing interstitial lung diseases and other fibrotic conditions.

About Idiopathic Pulmonary Fibrosis (IPF)

Idiopathic Pulmonary Fibrosis (IPF) is a rare, progressive and fatal lung disease characterized by irreversible scarring of lung tissue. Median survival following diagnosis is estimated to be two to five years.^[1] IPF affects more than 230,000 people across the United States and EU5 (France, Germany, Italy, Spain, and the United Kingdom).^[2]

Although two therapies are approved to treat IPF, their use remains limited, and nearly three out of four people with IPF in the United States have never received either treatment.^[3] There remains a significant need for therapies that can more effectively slow or stabilize disease progression, while maintaining favorable tolerability, to improve outcomes for people living with IPF.

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 portfolio 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 portfolio 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 deupirfenidone 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, 2024, 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

UK/EU Media

Ben Atwell, Rob Winder

+44 (0) 20 3727 1000

puretech@fticonsulting.com

US Media

Justin Chen

+1 609 578 7230

jchen@tenbridgecommunications.com

[1] Fisher, M., Nathan, S. D., Hill, C., Marshall, J., Dejonckheere, F., Thuresson, P., & Maher, T. M. (2017). Predicting Life Expectancy for Pirfenidone in Idiopathic Pulmonary Fibrosis. *Journal of Managed Care & Specialty Pharmacy*, 23(3-b Suppl), S17-S24. <https://doi.org/10.18553/jmcp.2017.23.3-b.s17>

[2] GlobalData Epidemiology and Market Size Search, EU5= United Kingdom, France, Germany, Italy and Spain

[3] Dempsey TM, Payne S, Sangaralingham L, Yao X, Shah ND, Limper AH. Adoption of the Antifibrotic Medications Pirfenidone and Nintedanib for Patients with Idiopathic Pulmonary Fibrosis. *Ann Am Thorac Soc*. 2021 Jul;18(7):1121-1128

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.

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

NRAEAESFELLSEEA