PureTech Announces Publication of Phase 2b ELEVATE IPF Trial Results in The American Journal of Respiratory and Critical Care Medicine

April 2, 2026

Deupirfenidone 825 mg TID monotherapy significantly slowed lung function decline versus placebo at 26 weeks in people with idiopathic pulmonary fibrosis (adjusted mean FVC difference 91 mL; p=0.02), approaching the lung function change expected in normal, healthy aging

First industry-sponsored IPF trial to include a current standard-of-care treatment as an active comparator in addition to a placebo arm, strengthening interpretation of efficacy and safety findings

PureTech's Founded Entity, Celea Therapeutics, is working to complete a financing to enable the initiation of the Phase 3 SURPASS-IPF trial in the first half of 2026

PureTech Health plc (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a hub-and-spoke biotherapeutics company dedicated to giving life to science and transforming innovation into value, today announced the publication of results from the Phase 2b ELEVATE IPF trial of deupirfenidone for the potential treatment of idiopathic pulmonary fibrosis (IPF) in *The American Journal of Respiratory and Critical Care Medicine* (AJRCCM). The results from this trial informed the design of the upcoming Phase 3 SURPASS-IPF trial, which will evaluate deupirfenidone 825 mg three times a day (TID) monotherapy as compared to pirfenidone 801 mg TID monotherapy, in a head-to-head study powered to test for superiority. PureTech's Founded Entity, Celea Therapeutics, is working to complete a financing to enable the initiation of the Phase 3 SURPASS-IPF trial in the first half of 2026.

"The ELEVATE IPF trial provides a rare opportunity to evaluate an investigational therapy for IPF directly alongside a current standard-of-care treatment within a randomized controlled trial," said Toby Maher, MD, PhD, Professor of Medicine and Director of Interstitial Lung Disease at Keck School of Medicine, University of Southern California, Los Angeles, and lead author of the study. "The inclusion of pirfenidone as an active comparator provides important clinical context for interpreting the efficacy and safety findings and increases confidence as this program moves forward into a head-to-head Phase 3 superiority trial. More broadly, the magnitude of the treatment effect demonstrated in this trial suggests that it may be possible to achieve greater preservation of lung function than has historically been observed with currently available therapies. If confirmed at Phase 3, this would have a major impact on our approach to treating patients with IPF."

Highlights from the publication have been presented in various scientific forums throughout the course of 2025 and include:

- **Primary and key secondary endpoints achieved**: Deupirfenidone demonstrated a 98.5% and 99.6% posterior probability of superiority vs. placebo in slowing forced vital capacity (FVC) and forced vital capacity percent predicted (FVCpp) decline, respectively, at 26 weeks based on the prespecified Bayesian analysis.
- **Statistically significant and clinically meaningful preservation of lung function**: Deupirfenidone 825 mg TID as a monotherapy significantly slowed lung function decline versus placebo at 26 weeks as measured by mean FVC (adjusted difference 91 mL; p=0.02). A secondary analysis of FVCpp also showed a statistically significant benefit (p=0.01).
- **Lung function decline approached the range expected with healthy aging**: In the deupirfenidone 825 mg TID arm, the rate of FVC decline over 26 weeks (-21.5 mL) approached the normal physiological decline expected in healthy older adults (approximately -15.0 mL to -25.0 mL). [1,2] Although not included in the publication, data from the ongoing Phase 2b ELEVATE IPF open-label extension show that this treatment effect was maintained out to at least 52 weeks, with participants experiencing a decline in FVC of -32.8 mL.[3] This is also similar to the expected natural decline in lung function in healthy older adults over that time (approximately -30.0 mL to -50.0 mL).[2]
- **Delay in disease progression**: Time to IPF progression, defined as an absolute decline in FVCpp of ≥5% or death through 26 weeks, was significantly delayed in patients receiving deupirfenidone 825 mg TID compared with placebo (HR 0.439; p=0.0023).
- **Greater drug exposure without sacrificing tolerability**: Pharmacokinetic data show that deupirfenidone 825 mg TID results in an approximately 50% greater drug exposure compared to pirfenidone 801 mg TID (the highest FDA-approved dose). Importantly, the overall incidence of adverse events (AEs) with deupirfenidone 825 mg TID was similar to that of pirfenidone 801 mg TID (85.9% vs. 84.1%, respectively), and AEs were generally mild to moderate. The percentage of patients who remained on deupirfenidone 825 mg TID for 26 weeks (78.1%) was similar to the percentage of patients remaining on placebo (80.0%). Taken together, these data suggest that the higher exposure and improved efficacy observed with deupirfenidone 825 mg TID were achieved without sacrificing tolerability.

"Publication in *AJRCCM* validates the rigor of our Phase 2b trial design and execution and highlights the potential for deupirfenidone to set a new benchmark in the treatment of IPF," said Sven Dethlefs, PhD, Chief Executive Officer of Celea Therapeutics. "This trial provides a strong scientific and clinical foundation as we prepare to advance deupirfenidone into the Phase 3 SURPASS-IPF trial, with the goal of building on these results to deliver a next-generation antifibrotic that meaningfully improves outcomes for people living with IPF."

About the Phase 2b 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 of 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 in development as a potential new standard of care for the treatment of idiopathic pulmonary fibrosis (IPF). It is a next-generation antifibrotic and a deuterated form of pirfenidone, one of three FDA-approved therapies for IPF. The uptake of and adherence to approved antifibrotics has historically been limited by a tradeoff between modest efficacy and tolerability, and only ~25% of people with IPF in the U.S. had ever received treatment as of 2019.[4]

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 a favorable safety and tolerability profile. Initial data from an ongoing open-label extension study suggest this effect may be sustained through at least 52 weeks. These findings support the potential for deupirfenidone to offer a meaningful advance for people living with this progressive and deadly disease. Beyond IPF, deupirfenidone may also address multiple underserved fibrotic conditions, including progressive fibrosing interstitial lung diseases.

About Idiopathic Pulmonary Fibrosis (IPF)

Idiopathic pulmonary fibrosis (IPF) is a rare, progressive, and fatal lung disease characterized by irreversible scarring of lung tissue that leads to a steady decline in lung function. Median survival following diagnosis is estimated to be two to five years,[5] and currently there is no cure.

About Celea Therapeutics

Celea Therapeutics is dedicated to advancing transformative treatments for people with serious respiratory diseases. Drawn from the Latin word for “sky,” the name reflects the company’s mission to rise above the status quo and deliver therapies that change lives. The company’s lead program, deupirfenidone (LYT-100), is a Phase 3-ready therapeutic candidate with the potential to set a new standard of care for idiopathic pulmonary fibrosis (IPF) and other fibrotic lung diseases.

Celea was founded by and is currently a wholly-owned subsidiary of PureTech Health plc (Nasdaq: PRTC, LSE: PRTC), a biotherapeutics company dedicated to giving life to science. PureTech’s innovative R&D model drives the creation of Founded Entities like Celea, enabling the advancement of highly promising medicines to patients in a capital-efficient manner. For more information, please visit www.celeatx.com.

About PureTech Health

PureTech Health is a hub-and-spoke biotherapeutics company dedicated to giving life to science and transforming innovation into value. We do this through a proven, capital-efficient R&D model focused on opportunities with validated pharmacology and untapped potential to address significant patient needs. This strategy has produced dozens of therapeutic candidates, including three that have received U.S. FDA approval. By identifying, shaping, and de-risking these high-conviction assets, and scaling them through dedicated structures backed by external capital, we accelerate their path to patients while creating sustainable value for shareholders.

For more information, visit www.puretechhealth.com or connect with us on LinkedIn and 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 (LYT-100) development program and development plans, 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.

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[1]FVC decline at 6 months was estimated assuming linear decline over time.

[2]Valenzuela, C., Bonella, F., Moor, C., Weimann, G., Miede, C., Stowasser, S., & Maher, T. (2024, September). Decline in forced vital capacity (FVC) in subjects with idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF) compared with healthy references [Poster presentation]. 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. European Respiratory Journal, 53(3), 1701812. ~~https://doi.org/10.1183/13993003.01812-2017~~

[3]Integrated analysis of double-blind (26 weeks) and initial open-label extension data from Phase 2b ELEVATE IPF trial as of May 9, 2025, using a random coefficient regression model with absolute FVC including baseline as response variable and week, treatment and interaction between week and treatment as fixed effect. The analysis was performed based on the predefined Full Analysis Set.

[4]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.

[5]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~~