

# PureTech Showcases Differentiated Development Strategy, Including New Patient Preference Insights, and Spotlights Phase 2b Data Positioning Deupirfenidone as a Potential New Standard of Care in IPF

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## **PureTech Showcases Differentiated Development Strategy, Including New Patient Preference Insights, and Spotlights Phase 2b Data Positioning Deupirfenidone as a Potential New Standard of Care in IPF**

*Deupirfenidone to be advanced by PureTech's newly launched Founded Entity, Celea Therapeutics*

[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, demonstrated its growing leadership in idiopathic pulmonary fibrosis (IPF) at the 2025 IPF Summit this week in Boston. The Company highlighted the strength of its Phase 2b ELEVATE IPF trial data supporting the advancement of deupirfenidone (LYT-100) into Phase 3 by its newest Founded Entity, Celea Therapeutics ("Celea"), and shared new patient preference data and insights shaped by deep engagement across the IPF treatment ecosystem.

"With deupirfenidone demonstrating compelling efficacy, we are taking a holistic approach to Phase 3 planning - one that is informed by a deep understanding of the needs of patients, clinicians, and payers alike," said Camilla Graham, MD, MPH, Senior Vice President of Medical Affairs at PureTech. "After more than a decade without meaningful therapeutic advancement, the IPF treatment landscape is beginning to shift. To deliver real impact, innovation must extend beyond the molecule - into clinical trial design, patient and provider education, and access. That's the bar we've set with deupirfenidone."

### **Balancing Efficacy and Safety of Treatment: Perspectives of People Living with IPF**

As part of its commitment to developing therapies that address real-world needs, PureTech shared new findings from structured interviews with 16 individuals living with IPF, designed to understand how patients weigh the trade-offs between efficacy and tolerability when considering novel treatments. The data highlight that patients are not only open to new options, they are primarily motivated by the potential for better outcomes. Key findings included the following:

- **69%** of participants preferred a hypothetical treatment offering greater efficacy over one with improved tolerability.
- **94%** said they would proactively initiate a conversation with their physician if a new treatment offered a differentiated profile.

"We've seen real hesitation around initiating currently available therapies - even among patients with progressive disease," said Tejaswini Kulkarni, MD, MPH, University of Alabama at Birmingham and co-author on the research. "These findings reflect a shift in mindset. People with IPF want better outcomes, and they're willing to accept manageable tolerability trade-offs in pursuit of a more effective treatment. That perspective is essential to designing trials and therapies that truly resonate with those who matter most."

### **De-risking Late-Stage Development through Sophisticated Trial Design**

Across two expert panels at the IPF Summit, PureTech shared insights into the clinical development strategy behind deupirfenidone, emphasizing how the design of its Phase 2b ELEVATE IPF trial was purposefully built to address persistent challenges in the development of new IPF therapies.

"The ELEVATE IPF trial stands out for its thoughtful design and execution," 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 investigator in the ELEVATE IPF trial. "By selecting a 26-week treatment period, including an active comparator, and applying rigorous data quality controls, the study was designed to generate the type of robust and reliable data that has often been difficult to achieve in early-stage IPF therapeutic development. Just as importantly, deupirfenidone builds on more than a decade of clinical and real-world experience with pirfenidone, reinforcing confidence in the ELEVATE data and its potential to be replicated in Phase 3."

The trial incorporated key features to generate high-confidence data that position deupirfenidone for a Phase 3 program with reduced clinical risk, including:

- **Trial Duration:** Most Phase 2 IPF trials last just 12 weeks. While this design can help establish an early efficacy signal, it often fails to capture the strength and durability of a treatment effect over time. PureTech's Phase 2b ELEVATE IPF trial spanned 26 weeks, enabling a more robust assessment of lung function decline and a clearer view of long-term therapeutic potential. Importantly, open-label extension data further support the durability of deupirfenidone's treatment effect through at least 52 weeks while reinforcing safety and tolerability.
- **Data Quality:** Spirometry, the primary efficacy measure in IPF trials, is inherently variable. To ensure data integrity, ELEVATE IPF employed training to 2019 ATS standards and centrally-read spirometry with rigorous quality control systems, resulting in clean, consistent data.
- **Active Comparator Arm:** ELEVATE IPF was the first industry-sponsored trial to include an approved antifibrotic agent as an active comparator. In the trial, both pirfenidone and placebo performed in line with historical expectations, reinforcing the credibility and reproducibility of the deupirfenidone data.
- **Consistency of Development Plan:** PureTech intends to discuss a Phase 3 trial design with the U.S. Food and Drug Administration that recapitulates key aspects of ELEVATE IPF, thereby minimizing technical risk from protocol changes.

Together, these elements reinforce the strength and reliability of the Phase 2b data and underscore why deupirfenidone is poised to set a new benchmark as it advances into Phase 3.

#### **Deupirfenidone: A Potential New Standard of Care**

In a dedicated clinical update at the IPF Summit, PureTech presented data from its global, randomized, double-blind, active- and placebo-controlled Phase 2b ELEVATE IPF trial, which support the advancement of deupirfenidone into Phase 3 as a potential new standard of care. The trial met its primary endpoint and demonstrated a statistically significant and clinically meaningful reduction in lung function decline at 26 weeks with deupirfenidone 825 mg three times a day (TID) compared to placebo.

Patients treated with deupirfenidone 825 mg TID experienced a slower rate of lung function decline, as measured by change from baseline of Forced Vital Capacity (FVC), at 26 weeks versus those who were treated with pirfenidone 801 mg TID or placebo (-21.5 mL vs. -51.6 mL vs. -112.5 mL, respectively).<sup>[1]</sup> Based on their respective reductions in lung function decline versus placebo, the treatment effect with deupirfenidone 825 mg TID was approximately 50% greater than that of pirfenidone 801 mg TID (80.9% vs. 54.1%). This effect is supported by pharmacokinetic data showing that treatment with deupirfenidone 825 mg TID achieved ~50% higher drug exposure than pirfenidone 801 mg TID, without a corresponding increase in tolerability challenges.

Notably, initial data from the ongoing open-label extension (OLE) study showed that the treatment effect with deupirfenidone 825 mg TID was sustained out to at least 52 weeks. As of May 9, 2025, a total of 101 patients had received at least 52 weeks of treatment with deupirfenidone. Those in the deupirfenidone 825 mg TID arm experienced a decline in FVC of -32.8 mL over the 52-week period,<sup>[2]</sup> which is similar to the expected natural decline in lung function in healthy older adults over one year (approximately -30.0 mL to -50.0 mL).<sup>[3]</sup> These longer-term data support the durability of the treatment effect observed with this dose and reinforce its potential improvements over current IPF treatments to stabilize lung function decline over time, while maintaining favorable safety and tolerability.

Additional data, including outcomes in participants who transitioned to deupirfenidone in the OLE after initially receiving placebo or pirfenidone during the blinded portion of the trial, will be presented at the upcoming European Respiratory Society (ERS) International Congress in September 2025.

Celea, PureTech's newly launched Founded Entity focused on respiratory diseases, is advancing the development and potential commercialization of deupirfenidone. The company is led by Sven Dethlefs, PhD, who has played a central role in driving the program forward over the past year and brings deep expertise in respiratory therapeutics and commercial execution.

"The ELEVATE IPF trial has delivered some of the most compelling data the IPF field has seen, and it's a privilege to now be leading the

effort to advance deupirfenidone into Phase 3 through PureTech's newest Founded Entity, Celea Therapeutics," said Dr. Dethlefs. "With a foundation of rigorous science, differentiated efficacy, and strong stakeholder alignment, we believe deupirfenidone has the potential to become a new standard of care for people with IPF."

#### **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 deuterated form of pirfenidone, which - along with nintedanib - is one of the two FDA-approved treatments for IPF. Both approved therapies offer only modest efficacy in slowing lung function decline, largely due to tolerability challenges that limit the ability to achieve higher doses that could significantly improve patient outcomes. These limitations have contributed to low treatment uptake and poor adherence, with approximately 25% of people with IPF in the U.S. ever receiving either drug.<sup>[4]</sup> Despite this, combined peak global sales exceed \$5 billion, representing a significant market opportunity in IPF and other fibrotic lung diseases. <sup>[5]</sup>

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 that 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, and currently there is no cure.<sup>[6]</sup>

#### **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 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](http://www.celeatx.com) and [www.puretechhealth.com](http://www.puretechhealth.com).

#### **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](http://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 statements that relate to continued development of and regulatory interactions related to deupirfenidone, the potential of deupirfenidone in IPF and other indications, our expectations around our therapeutic candidates and approach towards addressing major diseases, our plans to advance our programs and deliver on our milestones, our future plans, 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] The efficacy analysis used 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. The rate of FVC decline at week 26 with deupirfenidone 825 mg TID compared to placebo was statistically significant (-21.5 mL vs. -112.5 mL, respectively;  $p=0.02$ ).  $p$  value is two-sided and has not been corrected for multiplicity. The rate of FVC decline at week 26 with pirfenidone 801 mg TID compared to placebo was consistent with previously reported pirfenidone clinical trial data (Roche). ELEVATE-IPF was not designed to demonstrate the superiority of deupirfenidone 825 mg TID vs. pirfenidone 801 mg TID.

[2] Analysis conducted using the same methodology to assess rate of decline in FVC at 26 weeks from the double-blind portion of the trial. Efficacy analysis used 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.

[3] 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>

[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] Esbriet peak sales (2020) per Roche 2021 Financial Results & Ofev peak sales (2024) per Boehringer Ingelheim 2024 Financial Results. Ofev sales include those for all approved indications - IPF, PF-ILD, and systemic sclerosis-associated interstitial lung disease (SSc-ILD).

[6] 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>

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