RNS Number : 6178K
PureTech Health PLC
08 December 2025

8 December 2025

PureTech Health plc

PureTech Announces Successful End-of-Phase 2 Meeting with FDA for Deupirfenidone (LYT-100) in Idiopathic Pulmonary Fibrosis

Feedback from U.S. Food and Drug Administration (FDA) supports advancement into a pivotal Phase 3 trial and a 505(b)(2) regulatory pathway

Phase 3 SURPASS-IPF trial remains on track to be initiated by PureTech's Founded Entity, Celea Therapeutics, 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 successful completion of the End-of-Phase 2 (EOP2) meeting with the U.S.Food and Drug Administration (FDA) regarding the development of deupirfenidone (LYT-100) for the treatment of idiopathic pulmonary fibrosis (IPF). Deupirfenidone is being advanced by Celea Therapeutics, a Founded Entity established by PureTech to lead its late-stage development and potential commercialization.

"Our discussion with the FDA was productive and provided helpful feedback on key elements of our Phase 3 program and the overall data expectations for registration," said Sven Dethlefs, Ph.D., Chief Executive Officer of Celea Therapeutics. "The forthcoming Phase 3 SURPASS-IPF trial builds on the strong foundation established by the Phase 2b ELEVATE IPF trial, which demonstrated deupirfenidone's robust and durable treatment effect as a monotherapy and its potential to become a new standard of care. In shaping the Phase 3 design, we incorporated learnings from recent IPF trials and collaborated closely with patients and clinicians to reflect the latest thinking in the field. We are now advancing this pivotal program with urgency to bring forward a therapy with the potential to stabilize lung function and meaningfully improve care for people with IPF."

The pivotal Phase 3 SURPASS-IPF trial will be a global, randomized, double-blind, head-to-head trial comparing deupirfenidone 825 mg three times-a-day (TID) to pirfenidone 801 mg TID in adults with IPF who are not on background therapy. The primary efficacy endpoint is the change from baseline in absolute forced vital capacity (FVC) at week 52, which will assess the superiority of deupirfenidone compared with pirfenidone. The 52-week trial will use the same active comparator and dosing regimen as the Phase 2b ELEVATE-IPF trial, providing continuity and confidence that the favorable safety profile and strong treatment effect observed previously can be replicated and confirmed in a larger, global population. Based on feedback from the FDA, PureTech believes that the results from this single Phase 3 trial, if successful, and supported by the totality of data from the overall deupirfenidone development program, could complete the data package required to support potential registration of deupirfenidone via a streamlined 505(b)(2) pathway.

The EOP2 meeting was supported by results from the global Phase 2b randomized, double-blind, active- and placebo-controlled, dose-ranging ELEVATE IPF trial. In that trial, participants 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), with a 91 mL difference between deupirfenidone 825 mg and placebo at 26 weeks. Following the completion of the blinded portion of the trial, 170 participants (more than 90%) enrolled in the open-label extension. Those who continued treatment with deupirfenidone 825 mg TID maintained a robust treatment effect and experienced an overall FVC decline of -32.8 mL over a 52-week period,[1] which is 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]

PureTech's Founded Entity, Celea Therapeutics, expects to finalize financing in early 2026 to support the initiation of the Phase 3 SURPASS-IPF trial in the first half of 2026.

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 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.[3]

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, and currently there is no cure.[4]

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, visitwww.puretechhealth.comor 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.

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
jchen@tenbridgecommunications.com

[1] 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.

[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] 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.

[4] 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

END

NRAUPGCAPUPAPUM