PureTech Announces Orphan Drug Designations Granted by the U.S. Food and Drug Administration and European Commission for Deupirfenidone (LYT-100) in Idiopathic Pulmonary Fibrosis

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Designations provide market exclusivity as well as other development incentives

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 that the U.S. Food and Drug Administration (FDA) and European Commission have granted Orphan Drug Designation to deupirfenidone (LYT-100) for the treatment of idiopathic pulmonary fibrosis (IPF), a rare, progressive, and fatal lung disease. Deupirfenidone is being advanced by Celea Therapeutics, a Founded Entity established by PureTech to lead its late-stage development and potential commercialization.

Orphan Drug Designation is intended to support the development of therapies for rare diseases, defined as conditions affecting fewer than 200,000 people in the United States or fewer than 5 in 10,000 individuals in the European Union. These designations provide sponsors with a range of incentives intended to encourage the development of medicines for diseases with high unmet medical needs.

"Orphan Drug Designation from both the FDA and European Commission underscores the urgent need for more effective therapies for people living with IPF," said Robert Lyne, Chief Executive Officer of PureTech Health. "Critically, only a minority of patients with this progressive and fatal disease have ever been treated with currently approved therapies, largely due to the tradeoff between tolerability challenges and modest efficacy. We believe deupirfenidone represents a potentially transformative option for this underserved population and is a compelling example of how PureTech's model can advance differentiated medicines toward meaningful patient impact."

"The Phase 2b data for deupirfenidone suggest a new benchmark for efficacy in IPF, with slowing of lung function decline to a level that more closely mirrors healthy aging, without compromising tolerability," said Sven Dethlefs, PhD, Chief Executive Officer of Celea Therapeutics. "Orphan Drug Designation further validates both the seriousness of this disease and the importance of advancing our program, which we believe has the potential to redefine treatment expectations for patients living with IPF."

Results from the global Phase 2b randomized, double-blind, active- and placebo-controlled, dose-ranging ELEVATE IPF trial underscored the differentiated profile of deupirfenidone. In that trial, participants treated with deupirfenidone 825 mg three times a day (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 the FDA-approved dose of 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 ($p = 0.02$). Following the completion of the blinded portion of the trial, 90% of trial completers (170 participants) 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, intends to finalize financing in the first half of 2026 to support the initiation of the Phase 3 SURPASS-IPF trial in the first half of 2026. SURPASS-IPF will compare deupirfenidone 825 mg TID to pirfenidone 801 mg TID in a head-to-head study powered to test for superiority. Based on feedback from the FDA and other global health authorities, 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.

About Orphan Drug Designation

Orphan Drug Designation is intended to encourage the development of medicines for rare diseases that affect relatively small patient populations and often lack effective treatment options. Regulatory authorities such as the U.S. Food and Drug Administration (FDA) and European Commission provide orphan designation to improve the feasibility of rare disease drug development through enhanced regulatory interactions, financial incentives, and, upon approval, defined periods of market exclusivity.

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.[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, 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 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] 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

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