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PureTech Presents Data for LYT-100 (Deupirfenidone) Supporting Design of Dose-Ranging Trial in Idiopathic Pulmonary Fibrosis (IPF) at European Respiratory Society International Congress 2022

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PureTech **Presents Data for LYT-100 (Deupirfenidone) Supporting Design of Dose-Ranging Trial in Idiopathic Pulmonary Fibrosis (IPF) at European Respiratory Society International Congress 2022**

LYT-100 was well-tolerated compared to pirfenidone in a healthy older adult crossover trial, informing dose selection for recently initiated trial in IPF

PureTech Health plc (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to changing the treatment paradigm for devastating diseases, today announced a poster presentation describing the rationale and design for the Phase 2 trial of LYT-100 in patients with IPF at the European Respiratory Society (ERS) International Congress. The poster also reviews the results from a Phase 1 crossover trial of LYT-100 in healthy older adults, which supports the dose selection for the Phase 2 trial. LYT-100 is a therapeutic candidate in PureTech's Wholly Owned Pipeline and is being advanced for the treatment of conditions involving inflammation and fibrosis, including IPF.

The data from the Phase 1 trial demonstrated that LYT-100 showed a lower incidence of adverse events (AEs) compared to pirfenidone at comparable exposure levels. Key outcomes of this trial that are supportive of the observed improved tolerability of LYT-100 were reported in January 2022. Additionally, this trial supports the dosages that were selected for the Phase 2 trial of LYT-100, which began in June 2022.

"These Phase 1 data provide additional evidence of LYT-100's tolerability compared to pirfenidone and further support testing a higher dose of LYT-100 in our dose-ranging clinical trial in patients with IPF," said Julie Krop, M.D., Chief Medical Officer at PureTech. "Pirfenidone's tolerability profile impacts patient adherence to an otherwise efficacious IPF treatment, resulting in dose adjustments, discontinuations and ultimately poorer patient outcomes. We're encouraged by the data we've seen thus far and we look forward to progressing our Phase 2 trial in patients living with IPF."

LYT-100 is a selectively deuterated form of pirfenidone that is designed to retain the potent and clinically validated anti-fibrotic and anti-inflammatory activity of pirfenidone with a differentiated pharmacokinetic (PK) profile that has translated into favorable safety and tolerability, as demonstrated by data from more than 400 subjects. Pirfenidone is one of the two standard of care treatments approved for IPF, along with nintedanib, both of which are efficacious but associated with significant GI-related tolerability issues. The tolerability issues associated with pirfenidone result in treatment discontinuations and/or dose reductions

below the FDA-approved dose of 801 mg three times a day (TID), thereby limiting its effectiveness in patients.

"For a devastating and progressive disease like IPF, more tolerable and effective treatment options are critical to curbing premature discontinuation or sub-optimal dosing," said Toby Maher, M.D., Ph.D., Professor of Medicine at Keck Medicine of USC Academic Medical Center at the University of Southern California who is presenting the poster at ERS and is an investigator in the dose-ranging trial. "The tolerability advantage of LYT-100 over pirfenidone may enable better patient compliance and potentially lead to improved outcomes, both for those currently taking standard of care drugs and - perhaps more importantly - for the approximately 75% of patients with IPF who are not currently on any approved therapies, often due to tolerability issues."

Phase 1 safety results in healthy older adults

The Phase 1 trial was a double-blind, randomized, two-period crossover trial of LYT-100 conducted in healthy older adults in the fed state to determine the safety, tolerability and PK parameters of LYT-100 administered TID for three days compared to pirfenidone administered TID for three days under fed conditions. Subjects were randomized to one of two treatment sequences.

Results from the Phase 1 trial were announced in January 2022. The expanded analysis details the safety, tolerability and favorable PK profile of LYT-100 at the 550 mg TID dose in fed healthy volunteers. LYT-100 550 mg TID administration substantially reduced incidence of GI (50% reduction) and nervous system (45% reduction) related treatment-emergent adverse events (TEAEs) compared to pirfenidone in this crossover trial, consistent with a lower Cmax. The demonstrated tolerability supports testing a higher dose of LYT-100 in the IPF trial.

Dose-ranging trial (ELEVATE) design

The scientific poster also reviews the design of PureTech's dose-ranging trial of LYT-100 in patients with IPF. The clinical trial's primary objective will be focused on obtaining clinical data establishing the efficacy, tolerability, safety and dosing regimen of LYT-100 compared to placebo in order to determine the dose for a potential Phase 3 trial. The primary efficacy endpoint is the rate of decline in Forced Vital Capacity (FVC) over 26 weeks. The secondary endpoints include change in FVC percentage predicted from baseline to week 26, time to hospitalization or mortality due to respiratory cause through 26 weeks and time to IPF progression through 26 weeks, as defined by a decline in FVC percentage of greater than or equal to five percent. Both doses of LYT-100 will be compared to placebo and pirfenidone with respect to safety and efficacy during the 26-week trial.

The global IPF ELEVATE trial has initiated and is enrolling patients. Visit clinicaltrial.gov (NCT05321420) for more details.

About Idiopathic Pulmonary Fibrosis (IPF)

Idiopathic Pulmonary Fibrosis is a terminal, orphan condition that is progressive and characterized by irreversible scarring of the lungs that worsens over time and makes it difficult to breathe. The prognosis of IPF is poor, with the median survival after diagnosis generally estimated at two to five years. Currently available treatment options are associated with significant tolerability issues and dose-limiting toxicities, which can hamper treatment compliance and leave patients and physicians needing new treatment options.

About LYT-100

LYT-100 is one of seven therapeutic candidates within PureTech's Wholly Owned Pipeline. It is a selectively deuterated form of pirfenidone that is designed to retain the potent and clinically-validated anti-fibrotic and anti-inflammatory activity of pirfenidone but has a highly differentiated PK profile that has translated into improved tolerability, as supported by data from multiple human clinical studies. LYT-100 is being advanced for the potential treatment of conditions involving inflammation and fibrosis, including IPF. PureTech is also exploring the potential evaluation of LYT-100 in other inflammatory and fibrotic conditions such as myocardial and other organ system fibrosis, radiation induced fibrosis, and lymphedema based on the strength of existing clinical data around the use of pirfenidone in these indications.

About PureTech Health

PureTech is a biotherapeutics company dedicated to changing the treatment paradigm for devastating diseases. The Company has created a broad and deep pipeline through the expertise of its experienced research and development team and its extensive network of scientists, clinicians and industry leaders. This pipeline, which is being advanced both internally and through PureTech's Founded Entities, is comprised of 27 therapeutics and therapeutic candidates, including two that have received both U.S. FDA clearance and European marketing authorization and a third that will soon be filed for FDA approval, as of the date of PureTech's most recently filed Half-Year Report and corresponding Form 6-K. All of the underlying programs and platforms that resulted in this pipeline of therapeutic candidates were initially identified or discovered and then advanced by the PureTech team through key validation points based on unique insights in immunology and drug development.

For more information, visit www.puretechhealth.com or connect with us on 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 those related to our trial of LYT-100 for the treatment of idiopathic pulmonary fibrosis, the treatment potential of LYT-100 for patients with idiopathic pulmonary fibrosis, including its ability to address a significant unmet need for patients with IPF and certain shortcomings with respect to current standards of care, expectations regarding the potential of clinical data to support clinical development of LYT-100 for indications beyond IPF, our therapeutic candidates and approach towards addressing major diseases, 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, 2021 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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