PURETECH

GIVING LIFE TO SCIENCE®

# PureTech Reports Results from Phase 2 Study of LYT-100-COV in Post-Acute "Long" COVID with Respiratory Complications

June 14, 2022

RNS Number : 7277O
PureTech Health PLC
14 June 2022

14 June 2022

PureTech Reports Results from Phase 2 Study of LYT-100-COV in Post-Acute "Long" COVID with Respiratory **Complications**

*No treatment effect observed in this patient population; substantial improvement in 6-minute walk test seen in both placebo and active groups*

*Study adds to growing body of data supporting strong safety and tolerability profile of LYT-100 (deupirfenidone)*

*Company will drive LYT-100 forward in other indications, with a focus on IPF where human clinical efficacy has been previously shown with pirfenidone*

PureTech Health plc (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to discovering, developing and commercializing highly differentiated medicines for devastating diseases, today announced results from a Phase 2 study of LYT-100-COV (deupirfenidone) in patients with post-acute "Long" COVID with respiratory complications. There was no treatment effect observed in this indication with LYT-100, though the strong safety and tolerability profile of LYT-100 seen in previous studies was reaffirmed. Based on these data, PureTech will not pursue further studies in this patient population and remains on track to initiate registration-enabling studies of LYT-100 in idiopathic pulmonary fibrosis (IPF) later this month. LYT-100 is a selectively deuterated form of pirfenidone. Pirfenidone has been proven effective in IPF, a devastating condition where the tolerability, safety and potentially higher exposure of LYT-100 could have an important impact on patient adherence and outcomes.

"Early in the COVID-19 pandemic, we identified a potential application for LYT-100 given the hypothesis that inflammation and fibrosis may play a role in prolonging respiratory symptoms experienced by many patients. We undertook this exploratory study, guided by a desire to address this emerging need, while further expanding the safety and tolerability data for our LYT-100 development program at large," said Daphne Zohar, Founder and Chief Executive Officer of PureTech. "Although we had hoped to offer a treatment to Long COVID patients, these data further strengthen our confidence that LYT-100 has the potential to offer improved tolerability and therefore potentially improved treatment adherence and patient outcomes in IPF, a devastating condition that has been well-studied and where pirfenidone has proven efficacy. We are very grateful to the participants and researchers who were involved in this study, and we believe this additional tolerability and safety data will help to support our registration-enabling program in IPF, which we plan to initiate later this month."

The global, double-blind, randomized, placebo-controlled study is one of few to complete in patients with post-acute

COVID. The study enrolled 177 patients averaging 55 years of age who experienced continued respiratory complications following hospitalization for acute COVID-19 infection that required treatment with supplemental oxygen. The primary efficacy endpoint was a three-month change from baseline compared to placebo on the six-minute walk test (6MWT) distance. The 6MWT determines how far a patient can walk in six minutes and is a commonly used measure of functional capacity in a variety of cardio-pulmonary diseases. Individuals in both the treatment and placebo arms meaningfully improved walking distance on the 6MWT as compared to baseline, and no statistically significant differences between treatment groups were observed.

"This was a well-executed study that sought to understand whether survivors of severe COVID-19 pneumonia might benefit from treatment with an anti-fibrotic therapy following discharge from hospital. Importantly, the study demonstrated that - in contrast to patients with IPF who inevitably decline - the majority of the COVID-19 patients studied experienced meaningful functional improvements over time, independent of treatment arm," said Toby Maher, M.D., Ph.D., Professor Clinical Medicine and Director of Interstitial Lung Disease at Keck School of Medicine of the University of Southern California and Principal Investigator of the study. "To me, a key takeaway from the study was the strong safety and tolerability profile of LYT-100. This, coupled with the established efficacy of pirfenidone, encourages me to believe that LYT-100 has the potential to be an important treatment option for patients with idiopathic pulmonary fibrosis, a progressive and life shortening disorder of the lungs that is quite distinct from the acute lung injury seen with COVID-19."

LYT-100 was well-tolerated in this relatively sick patient population with multiple comorbidities and concomitant medications. There were no drug-related serious adverse events (SAEs) or deaths. Nausea was the only AE judged to be at least possibly related to LYT-100 with an incidence ≥5% (8.7% vs 2.4% with placebo). Other AEs that have been commonly associated with pirfenidone and were considered to be at least possibly related to LYT-100 treatment included headache (4.3% vs. 1.2% with placebo), dizziness (3.3% vs. 1.2% with placebo), fatigue (2.2% vs. 0% with placebo), and rash (3.3% vs. 1.2% with placebo). Discontinuation rates due to AEs that were considered at least possibly related to LYT-100 were low in both arms (8.6% with LYT-100 vs. 2.4% with placebo) and the majority of discontinuations in the LYT-100 arm were due to idiosyncratic events and not AEs commonly associated with pirfenidone.

These results are consistent with the previously demonstrated safety and tolerability profile of LYT-100, including the recently announced results of a crossover study in healthy older adults, which showed that approximately 50% fewer subjects experienced gastrointestinal-related AEs with LYT-100 compared with pirfenidone (17.4% vs. 34.0%) and that substantially fewer subjects experienced AEs with LYT-100 vs. pirfenidone. PureTech has also recently shown that LYT-100 can be safely dosed with a higher total drug exposure than the currently approved dose of pirfenidone, which could translate into improved efficacy over pirfenidone. The safety and tolerability data generated to date with LYT-100, along with the established efficacy of pirfenidone in IPF, support the advancement of registration-enabling studies of LYT-100 in IPF.

"Our limited understanding of post-acute COVID-19 makes this therapeutic area particularly challenging for a variety of reasons, yet this trial yielded some important insights into this patient population and the natural recovery process of patients," said Robert A. Wise, M.D., Chair of the Data and Safety Monitoring Board. "The disease course in patients with acute COVID-19 is mostly self-limiting and differs significantly from that of a chronic, progressive disease like IPF, where patients do not improve over time without intervention. I am particularly pleased to see how well-tolerated LYT-100 was in this relatively sick patient population, which suggests that it will also be well-tolerated in IPF."

PureTech intends to share these data with clinicians to further the understanding of the natural history of post-acute COVID-19. These data will also be included in future filings to support the safety and tolerability of LYT-100.

**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 with a differentiated pharmacokinetic profile that has translated into favorable 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 idiopathic pulmonary fibrosis and breast cancer-related, upper limb secondary lymphedema. PureTech is also exploring the potential evaluation of LYT-100 in other inflammatory and fibrotic conditions such as myocardial and other organ system fibrosis based on the strength of existing clinical data around the use of pirfenidone in these indications.

**About PureTech Health**

PureTech is a clinical-stage biotherapeutics company dedicated to discovering, developing and commercializing highly differentiated medicines for devastating diseases, including inflammatory, fibrotic and immunological conditions, intractable cancers, lymphatic and gastrointestinal diseases and neurological and neuropsychological disorders, among others. 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, as of the date of PureTech's most recently filed Annual 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 initiation of registration-enabling studies with LYT-100 for the treatment of IPF, the treatment potential of LYT-100, including its ability to address a significant unmet need for patients with IPF, its potential to have improved tolerability as compared to pirfenidone and to have an impact on patient adherence and outcomes, our intention to conduct no further studies in patients experiencing Post-Acute "Long" COVID with Respiratory Complications 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.

**Contact:**
**PureTech**
Public Relations
publicrelations@puretechhealth.com
Investor Relations
IR@puretechhealth.com

**EU Media**
Ben Atwell, Rob Winder
+44 (0) 20 3727 1000
ben.atwell@FTIconsulting.com

**U.S. Media**
Nichole Sarkis
+1 774 278 8273
nichole@tenbridgecommunications.com



END

NRAGPUUUQUPPPWW