



PureTech Presents Additional Phase 1 Data for LYT-100 at American Thoracic Society 2022

May 16, 2022

RNS Number : 5217L
PureTech Health PLC
16 May 2022

16 May 2022

PureTech Presents Additional Phase 1 Data for LYT-100 at American Thoracic Society 2022

Further data from Phase 1 study in healthy older adults demonstrate improved tolerability profile of LYT-100 compared to pirfenidone

Data support the planned LYT-100 dose-ranging registration-enabling studies in idiopathic pulmonary fibrosis, with topline results expected in 2023

[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 the presentation of additional data for PureTech's LYT-100 (deupirfenidone) at the American Thoracic Society 2022 International Conference. The data were shared in a scientific poster session and detailed the outcomes of a study in healthy older adults showing that LYT-100 demonstrated a lower incidence of adverse events (AEs) compared to pirfenidone at comparable exposure levels. Key outcomes of this study that are supportive of the observed improved tolerability of LYT-100 [were reported](#) in January 2022. The data support the upcoming registration-enabling studies in which PureTech plans to investigate LYT-100 in patients with idiopathic pulmonary fibrosis (IPF) at the planned 550 mg three times daily dose (TID) as well as a dose with a higher total drug exposure than the currently approved dose of pirfenidone to evaluate if higher exposure could translate into improved efficacy.

Pirfenidone is approved by the U.S. Food and Drug Administration (FDA) for the treatment of IPF but is associated with significant tolerability issues that LYT-100, as a deuterated form of pirfenidone, is intended to reduce. PureTech intends to advance LYT-100 into late-stage clinical development for the treatment of IPF using a 505(b)(2) development path, beginning with a dose-ranging study evaluating six months of treatment with LYT-100 with topline results expected by the end of 2023.

"Although approved antifibrotics for the treatment of IPF delay the progression of lung fibrosis and increase life expectancy, a large proportion of patients are unable to tolerate these treatments, leading to premature discontinuation or sub-optimal dosing," said Michael Chen, Ph.D., Head of Innovation at PureTech Health. "These data further support the favorable tolerability profile of LYT-100, which has been studied in over 400 patients and healthy volunteers to date. LYT-100 is designed to retain the pharmacological activity of pirfenidone, but has a differentiated pharmacokinetic profile which enables a lower peak systemic concentration (C_{max}), while still retaining AUC bioequivalence compared with the standard dosing of pirfenidone. We believe the lower C_{max} we demonstrated at

the 550 mg TID dose accounted for the lower incidence of adverse events we observed in the study."

The double-blind, randomized, crossover Phase 1 study evaluated the tolerability of LYT-100 550 mg TID versus pirfenidone 801 mg TID in 49 healthy older adults aged 60-79, an age group consistent with that of the IPF patient population. As previously announced, the study was supportive of an improved tolerability profile for LYT-100 with 38% fewer subjects treated with LYT-100 experiencing any AEs compared with those treated with pirfenidone (30.4% vs. 48.9%). The poster presented today details the incidence of AEs in the study population including the reduction in incidence of AEs in LYT-100 vs. pirfenidone administration in both fed and fasted subjects. Notably, LYT-100 at 550 mg TID (fed state) dose met the criteria for bioequivalence for exposure compared to the FDA-approved dosage of pirfenidone - 801 mg TID - but with a lower Cmax. Higher dosages of LYT-100 may provide enhanced antifibrotic and anti-inflammatory activity.

The scientific poster presented today is available at <https://puretechhealth.com/LYT-100-ATS2022-poster>.

About LYT-100

LYT-100 is PureTech's most advanced therapeutic candidate from within its Wholly Owned Pipeline. A deuterated form of pirfenidone, an approved anti-inflammatory and anti-fibrotic drug, LYT-100 is being advanced for the potential treatment of conditions involving inflammation and fibrosis, including lung disease (IPF and post-acute COVID respiratory complications and related sequelae) and disorders of lymphatic flow, such as lymphedema. PureTech is also exploring the potential evaluation of LYT-100 in other inflammatory and fibrotic conditions such as radiation induced fibrosis, myocardial fibrosis and other organ system fibrosis based on the strength of existing clinical data around the use of pirfenidone in these indications.

In the fourth quarter of 2020, PureTech initiated a Phase 2 study evaluating LYT-100 as a potential treatment for post-acute COVID respiratory complications and related sequelae and a Phase 2a proof-of-concept study evaluating LYT-100 in patients with breast cancer-related, upper limb secondary lymphedema. Enrollment in the post-acute COVID respiratory complications study is complete, and topline results are anticipated in the first half of 2022. Topline results from the Phase 2a proof-of-concept breast cancer-related, upper limb secondary lymphedema study are anticipated in 2022. PureTech also expects to initiate registration-enabling studies of LYT-100 in patients with IPF in the first half of 2022.

About Idiopathic Pulmonary Fibrosis (IPF)

Idiopathic Pulmonary Fibrosis (IPF) is an 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 leaves patients and physicians needing new treatment options.

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 with a streamlined 505(b)(2) development path and the design and timing for the initiation of the dose-ranging and Phase 3 studies supporting the clinical development of LYT-100 for IPF in accordance with our development plan, our belief that the results of these studies could serve as the basis for registration of LYT-100 in the United States, the treatment potential of LYT-100, 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, the timing for topline results from our current Phase 2 post-acute COVID respiratory and 2a proof-of-concept breast cancer-related, upper limb secondary lymphedema studies of LYT-100, 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

This information is provided by Reach, the non-regulatory press release distribution service of RNS, part of the London Stock Exchange. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

Reach is a non-regulatory news service. By using this service an issuer is confirming that the information contained within this announcement is of a non-regulatory nature. Reach announcements are identified with an orange label and the word "Reach" in the source column of the News Explorer pages of London Stock Exchange's website so that they are distinguished from the RNS UK regulatory service. Other vendors subscribing for Reach press releases may use a different method to distinguish Reach announcements from UK regulatory news.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

NRASFAFWDEESED