



## PureTech Initiates Phase 2a trial of LYT-100 (Deupirfenidone) in Lymphedema

December 10, 2020

RNS Number : 1495I  
PureTech Health PLC  
10 December 2020

10 December 2020

PureTech Health plc

### **PureTech Initiates Phase 2a trial of LYT-100 (Deupirfenidone) in Lymphedema**

*Study will further evaluate safety and tolerability of LYT-100 and explore clinical efficacy endpoints in patients with breast-cancer related, upper limb secondary lymphedema*

*Previously announced results from multiple ascending dose and food effect study in healthy volunteers demonstrated favorable tolerability and pharmacokinetic proof-of-concept for LYT-100*

*A separate Phase 2 study evaluating LYT-100 in Long COVID respiratory complications and related sequelae was recently initiated*

*Registration-enabling studies are also being planned for LYT-100 in idiopathic pulmonary fibrosis (IPF)*

[PureTech Health plc](#) (LSE: PRTC, Nasdaq: 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 initiation of a Phase 2a proof-of-concept study of LYT-100 (deupirfenidone) in patients with breast cancer-related, upper limb secondary lymphedema, a chronic and progressive disorder for which there are no FDA-approved drug therapies. LYT-100 is PureTech's wholly-owned product candidate that is being advanced for the potential treatment of conditions involving inflammation and fibrosis and disorders of lymphatic flow.

LYT-100 is a deuterated, oral small molecule designed to overcome the challenges associated with pifrenidone, an approved and marketed anti-inflammatory and anti-fibrotic drug. LYT-100, a new chemical entity, retains the pharmacology of pifrenidone but has a differentiated pharmacokinetic (PK) profile, which is designed to enable improved tolerability, less frequent dosing and potentially increased efficacy. PureTech recently completed a Phase 1 multiple ascending dose and food effect study of LYT-100 in healthy volunteers, which demonstrated a favorable tolerability and PK profile for LYT-100. LYT-100 has also been evaluated in preclinical lymphedema models, where it halted progression of lymphedema and reduced swelling volume.

"Lymphedema is a debilitating condition that affects approximately one million people in the U.S., and it is particularly prevalent in women recovering from breast cancer. It can restrict range of motion in the arms,

cause significant pain and lead to disfiguring swelling and recurring infections," said Babak J. Mehrara, M.D., chief, plastic and reconstructive surgical service at Memorial Sloan Kettering Cancer Center and an advisor to PureTech. "There are no approved drugs to address lymphedema and there's little relief that can be offered to patients other than compression bandages, exercise and massage. We have a very real need for a therapeutic that could effectively treat this condition, which has been overlooked for far too long."

The randomized, placebo-controlled, Phase 2a proof-of-concept study of LYT-100 is expected to enroll up to 50 patients with breast cancer-related, upper limb secondary lymphedema. The primary endpoints for this trial will be safety and tolerability, with secondary clinical efficacy and biomarker endpoints. The study is not powered to evaluate statistical significance compared to placebo, but PureTech expects to use data emerging from the trial to shape future clinical protocols, including selection of potential future efficacy study endpoints. Results from this proof-of-concept study are expected in the fourth quarter of 2021.

"Lymphedema is a condition that has drawn far too little attention from the healthcare industry. That oversight means there are, to date, no standardized clinical endpoints for the treatment of lymphedema," said Michael Chen, Ph.D., head of innovation at PureTech. "This proof-of-concept study will be extremely valuable in helping us identify the most compelling clinical endpoints for future studies."

### **About Lymphedema**

Lymphedema is a chronic condition that afflicts approximately one million people in the United States and is characterized by severe swelling in parts of the body, typically the arms or legs, due to the build-up of lymph fluid and inflammation, fibrosis and adipose deposition. Secondary lymphedema is the most prevalent form of lymphedema, and it can develop after surgery, infection or trauma and is frequently caused by cancer or cancer treatments. A chronic and progressive disorder, lymphedema can cause loss of range of motion and function in the affected limb, disfigurement and pain. Inflammation and fibrosis play important roles in the pathophysiology of secondary lymphedema. Targeting fibrosis in addition to inflammation may be a potentially effective way of ameliorating lymphedema in patients. The current standard of care for lymphedema is management, primarily by compression and physical therapy to control swelling. There are no FDA-approved drug therapies to treat lymphedema.

### **About LYT-100**

LYT-100 is PureTech's most advanced wholly-owned product candidate. A deuterated form of pifrenidone, an approved anti-inflammatory and anti-fibrotic drug, LYT-100 is being advanced for the potential treatment of conditions involving inflammation and fibrosis and disorders of lymphatic flow, including lung dysfunction conditions (e.g., IPF, unclassifiable interstitial lung diseases (uILDs), Long COVID respiratory complications and related sequelae) and lymphedema. PureTech completed a Phase 1 multiple ascending dose and food effect trial evaluating LYT-100 in healthy volunteers and found it to be well-tolerated at all doses tested. PureTech is evaluating LYT-100 in a Phase 2 trial as a potential treatment for Long COVID respiratory complications and related sequelae as well as in a Phase 2a proof-of-concept study in patients with breast cancer-related, upper limb secondary lymphedema. PureTech is also advancing LYT-100 for the treatment of IPF and is planning registration-enabling studies.

### **About PureTech Health**

PureTech is a clinical-stage biotherapeutics company dedicated to discovering, developing and commercializing highly differentiated medicines for devastating diseases, including intractable cancers, lymphatic and gastrointestinal diseases, central nervous system disorders and inflammatory and immunological diseases, 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 24 products and product candidates, including two that have received FDA clearance and European marketing authorization. All of the underlying programs and platforms that resulted in this pipeline of product candidates were initially identified or discovered and then advanced by the PureTech team through key validation points based on the Company's unique insights into the biology of the brain, immune and gut, or BIG, systems and the interface between those systems, referred to as the BIG Axis.

For more information, visit [www.puretechhealth.com](http://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, including statements that relate to the Company's future prospects, developments, and strategies. The forward looking statements are based on current expectations and are subject to known and unknown risks and uncertainties that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, our expectations regarding the potential therapeutic benefits of LYT-100 in patients with breast cancer-related, upper limb secondary lymphedema, the expected timing of results from our Phase 2a proof-of-concept trial of LYT-100 and those risks and uncertainties described in the risk factors included in the regulatory filings for PureTech Health plc. 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, neither the company nor any other party intends to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

### **Contact:**

#### **Investors**

Allison Mead Talbot  
+1 617 651 3156  
[amt@puretechhealth.com](mailto:amt@puretechhealth.com)

#### **EU media**

Ben Atwell, Rob Winder  
+44 (0) 20 3727 1000  
[ben.atwell@FTIconsulting.com](mailto:ben.atwell@FTIconsulting.com)

#### **US media**

Adam Silverstein  
+1 917 697 9313  
[adam@tenbridgecommunications.com](mailto:adam@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](mailto:rns@lseg.com) or visit [www.rns.com](http://www.rns.com).

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

NRAUPGPCPUPUPWB