PureTech Acquires New Clinical-Stage Programme LYT-100 to Treat Lymphedema

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Wholly owned programme adds to Company's growing internal pipeline focused on lymphatic targeting and tissue-selective immunomodulation

Clinical proof-of-concept study in adults with secondary lymphedema planned for 2020

PureTech Health plc (LSE: PRTC) ("PureTech"), an advanced biopharmaceutical company developing novel medicines for dysfunctions of the Brain-Immune-Gut (BIG) axis, today announced it has acquired and plans to develop a clinical-stage product candidate for the potential treatment of lymphatic and immunofibrotic diseases, including lymphedema. In preclinical studies, the oral, small molecule candidate, LYT-100, demonstrated anti-fibrotic and anti-inflammatory mechanisms, and in a Phase 1 clinical trial in healthy volunteers, LYT-100 was observed to be well tolerated with a favourable pharmacokinetic profile to support twice daily oral dosing. LYT-100 expands PureTech's internal R&D pipeline and continues its progress in developing new medicines based on insights into the lymphatic system and local modulation of the immune system for the treatment of immune and central nervous system disorders, lymphatic conditions, and cancers.

"Lymphedema is a chronic and incurable secondary disease affecting millions of people, and there has been far too little progress made toward the development of meaningful treatments," said Joe Bolen, Ph.D., chief scientific officer of PureTech. "There are no approved drug therapies on the market that can treat lymphedema. PureTech is working to address this need by pioneering an approach designed to target the underlying fibrosis and inflammation affecting the lymphatics to potentially improve lymphatic function and decrease the symptoms of lymphedema. We look forward to advancing clinical studies and continuing to progress the development of this candidate."

Lymphedema is one of the most common lymphatic diseases. It is a chronic condition that afflicts millions of people and is characterised by severe swelling in parts of the body – usually in the arms or legs – due to the build-up of lymph fluid and inflammation, fibrosis, and adipose deposition. The most prevalent form of the condition, secondary lymphedema, is frequently caused by cancer treatments or infections resulting in damage to or the removal of lymph nodes. For example, of the more than 250,000 Americans diagnosed with breast cancer each year, up to one in five who receive surgery will develop secondary lymphedema. The current standards of care for lymphedema – compression and physical therapy – are cumbersome and non-curative approaches that cannot correct immune cell infiltration or regenerate the dysregulated lymphatics. If left untreated, lymphedema can lead to disfigurement, severe pain, disability, infection, and fibrosis. PureTech's product candidate, LYT-100, has the potential to fulfil a widespread need for an effective approach that can treat secondary lymphedema without surgery.

"PureTech is committed to developing a long-awaited treatment for the millions of people living with lymphedema," said Daphne Zohar, co-founder and chief executive officer of PureTech. "LYT-100 was identified for our internal pipeline through our expertise in the lymphatic system, and it is the first clinical candidate to advance from an ongoing sourcing effort that builds on insights from our team and our network of collaborators and key opinion leaders in the field. We also expect to advance other candidates in pilot clinical studies, and we will progress the ones with the most favourable clinical profile."

LYT-100, an oral small molecule with well-established preclinical anti-fibrotic activity, has been previously studied in healthy volunteers as part of a Phase 1, single ascending dose study. PureTech will continue clinical development in healthy volunteers, looking at additional safety and pharmacokinetics of LYT-100 prior to initiating a human biomarker and proof-of-concept study expected in 2020. LYT-100 was acquired from a large pharmaceutical company where it was originally being developed in another indication.

About Lymphedema

Lymphedema is a chronic condition characterised by severe swelling of the limbs or other tissues due to the build-up of fluid that would normally be drained by the lymphatic system. The most prevalent form of the condition, secondary lymphedema, is frequently caused by cancer treatments or infections resulting in damage to or the removal of lymph nodes. Millions of Americans are affected by the condition, which typically progresses through multiple stages marked by increased fibrosis, limb volume, and tissue changes, ultimately resulting in disfigurement, severe pain, disability, and infection. The current standard of care for lymphedema include compression, physical therapy, and surgery to help reduce symptoms, but none address the underlying condition. There are currently no FDA-approved therapeutics to treat lymphedema, suggesting a major need for millions of patients.

About PureTech

PureTech (LSE: PRTC) is an advanced biopharmaceutical company developing highly differentiated medicines for dysfunctions of the Brain-Immune-Gut (BIG) axis. The company has gained deep insights into the connection between these systems and the resulting role in diseases that have been resistant to established therapeutic approaches. By harnessing this emerging field of human biology, PureTech is developing new categories of medicines with the potential to have great impact on people with serious disorders.

PureTech is advancing a rich pipeline of innovative therapies with an unbiased, nimble, and capital efficient R&D model across its affiliates and its internal R&D pipeline. PureTech's pipeline comprises more than two dozen product candidates, including several clinical-stage programmes, one product that has been cleared by the US Food and Drug Administration (FDA), and a second product candidate that has been filed with the FDA for review. The PureTech pipeline includes ground-breaking platforms and therapeutic candidates that were developed in collaboration with some of the world's leading experts.

PureTech’s internal pipeline is centred on lymphatic targeting and tissue-selective immunomodulation for the potential treatment of immune and central nervous system disorders, lymphatic conditions, and cancers. The company is advancing multiple platforms to enable oral administration of therapies directly into the lymphatic system, regulate lymphatic flow and function, and target immunosuppressive mechanisms in oncology. For more information, visit www.puretechhealth.com or connect with us on Twitter @puretechh.

Forward Looking Statement

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, 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.