



PureTech Announces First Participant Dosed in Clinical Trial of Wholly-Owned Lymphoedema Candidate LYT-100

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Multiple ascending dose and food effect study will be a follow-up to a previously conducted single ascending dose clinical trial of LYT-100

Proof-of-concept study in patients with breast cancer-related lymphoedema also expected to begin this year

[PureTech Health plc](#) (LSE: PRTC) (“PureTech,” or the “Company”), a clinical stage biotherapeutics company dedicated to discovering, developing and commercialising highly differentiated medicines for devastating diseases, today announced that the first participant has been dosed in a clinical study of LYT-100, PureTech’s wholly-owned product candidate for the potential treatment of lymphoedema and other fibrotic conditions. There are currently no FDA-approved drugs to treat lymphoedema, which is a painful, progressive, and chronic condition that affects approximately one million individuals in the US alone, including about 500,000 breast cancer survivors.

The Phase 1, multiple ascending dose and food effect study is designed to evaluate the safety, tolerability and pharmacokinetic (PK) profile of LYT-100 in healthy participants. This is a follow-up to the single ascending dose clinical trial of LYT-100 in healthy individuals that was conducted by Auspex. Results from the multiple ascending dose study are expected this year and will enable the initiation of a proof-of-concept study in people with breast cancer-related, upper limb secondary lymphoedema later in 2020.

“Lymphatic diseases cause significant disability and pain, yet there are few meaningful treatment options, most of which involve compression and physical therapy to control swelling,” said Babak Mehrara, MD, chief, plastic and reconstructive surgical service, the Peter G. Cordeiro endowed chair in plastic and reconstructive surgery at Memorial Sloan Kettering Cancer Center and an advisor to PureTech. “LYT-100 is designed to address the underlying cause of lymphoedema by reducing fibrosis and inflammation and restoring lymphatic function, and I believe it holds tremendous potential as a therapeutic candidate for the treatment of lymphoedema.”

LYT-100 is an oral, small molecule drug candidate known as deupirfenidone, which has demonstrated preclinical anti-fibrotic and anti-inflammatory activity. It has previously been studied in healthy volunteers as part of a Phase 1, single-dose study and was observed to be well-tolerated with a favourable pharmacokinetic profile that could support twice daily oral dosing.

LYT-100 is the first clinical programme in PureTech’s Wholly Owned Pipeline, which is focused on harnessing the lymphatic system and related immunology mechanisms for the treatment of cancer, immunological, lymphatic and central nervous system (CNS)-related disorders.

“Our model at PureTech has always been to identify, invent and advance novel therapeutics. We work with the world’s leading experts in a discovery process that breaks down specific diseases and comprehensively reviews and empirically tests unpublished scientific discoveries in a modality agnostic and unbiased way. This approach has enabled us to rapidly convert findings into valuable therapeutic product candidates, which historically have been housed in subsidiaries,” said Daphne Zohar, co-founder and chief executive officer of PureTech. “The advancement of LYT-100 is another example of executing on our strategy to develop a therapeutic solution for significant need, though this time the product candidate will continue to be wholly owned by PureTech.”

About Lymphoedema

Lymphoedema is a chronic condition that afflicts approximately one million people in the United States and is characterised 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 lymphoedema is the most prevalent form of lymphoedema, and it can develop after surgery, infection or trauma and is frequently caused by cancer or cancer treatments. A chronic and progressive disorder, lymphoedema can cause loss of range of motion and function in the affected limb, disfigurement and pain. The standard of care is management, primarily by compression and physical therapy to control swelling. There are no FDA-approved drug therapies to treat lymphoedema.

About LYT-100

LYT-100 is one of PureTech’s wholly-owned product candidates. It is an oral, small molecule drug candidate known as deupirfenidone, which is in development for the potential treatment of lymphoedema and other lymphatic and fibrotic disorders. LYT-100 has demonstrated preclinical anti-fibrotic and anti-inflammatory activity and has shown greater activity when compared to a functional analogue drug. LYT-100 is currently being evaluated in a Phase 1 multiple ascending dose and food effect study in healthy volunteers with subsequent exploration planned in people with breast cancer-related, upper limb secondary lymphoedema. PureTech also plans to evaluate the potential application of LYT-100 in other conditions characterised by impaired lymphatic flow, including fibrotic diseases of the kidney, liver and other organs.

About PureTech Health

PureTech is a clinical stage biotherapeutics company dedicated to discovering, developing and commercialising 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 affiliates, is comprised of 23 product candidates and one product that has been cleared by the US Food and Drug Administration

(FDA). All of the underlying programmes 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 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.