PureTech Receives FDA Fast Track Designation for LYT-200 in Acute Myeloid Leukemia (AML)

January 9, 2025

RNS Number : 6677S
PureTech Health PLC
09 January 2025

9 January 2025

PureTech Health plc

PureTech Receives FDA Fast Track Designation for LYT-200 in Acute Myeloid Leukemia (AML)

Single agent and combination data from Phase 1b AML/MDS trial presented at ASH 2024 showed potential of LYT-200 to serve broad range of patients across various lines of treatment

LYT-200 is currently being evaluated in two Phase 1/2 trials for the potential treatment of AML/MDS and head and neck cancers

PureTech Health plc (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to changing the lives of patients with devastating diseases, today announced that the U.S. Food and Drug Administration ("FDA") has granted Fast Track designation to LYT-200, a first-in-class anti-galectin-9 monoclonal antibody, for the treatment of acute myeloid leukemia ("AML"). Fast Track designation is a process designed to streamline the development and accelerate the assessment of drugs that target serious conditions with unmet medical need.

"Fast Track designation from the FDA reinforces our belief in the potential for LYT-200 to address the urgent needs of AML patients," said Luba Greenwood, J.D., Entrepreneur-in-Residence at PureTech who is leading the Gallop Oncology work. "This milestone builds on the FDA's recognition of LYT-200's promise, including Orphan Drug designation for AML and a second Fast Track designation for head and neck cancers, both of which were granted last year. By targeting galectin-9, a key driver of cancer proliferation and immune suppression, LYT-200 represents a novel and promising approach for patients in need, and we look forward to the continued development of this program."

LYT-200 exerts its therapeutic effects in AML by killing cancer cells directly via apoptosis and DNA damage as well as reactivating central anti-cancer effectors of the immune system. LYT-200 is the most advanced clinical program against galectin-9 and is being evaluated in two ongoing clinical trials, including:

1. Phase 1/2 clinical trial evaluating LYT-200 as a monotherapy and in combination with venetoclax and hypomethylating agents in hematological malignancies, including AML and high-risk myelodysplastic syndrome (MDS). In this trial, LYT-200 has demonstrated a favorable safety and tolerability profile as well as early signals of clinical activity as single agent and in combination.

2. Phase 1/2 trial in advanced/metastatic solid tumors, including head and neck

cancers. In this trial, LYT-200 is being evaluated as a monotherapy and in combination with tislelizumab, an anti-PD-1 antibody developed by BeiGene. To date, LYT-200 has demonstrated a favorable safety profile in all cohorts, including the monotherapy and combination arms with BeiGene's tislelizumab, and shown disease control and suggestions of initial anti-tumor activity.

The FDA has also granted orphan drug designation to LYT-200 for the treatment of AML as well as a separate Fast Track designation for the treatment of recurrent/metastatic head and neck squamous cell carcinomas ("head and neck cancers"), in combination with anti-PD1 therapy. PureTech previously announced that it intends to advance LYT-200 via its Founded Entity, Gallop Oncology.

About LYT-200

LYT-200 is a fully human IgG4 monoclonal antibody targeting a foundational oncogenic and immunosuppressive protein, galectin-9, for the potential treatment of hematological malignancies and locally advanced metastatic solid tumors, including head and neck cancers, with otherwise poor survival rates. A wide variety of preclinical data support the potential clinical efficacy of LYT-200 and the importance of galectin-9 as a target and suggest a potential opportunity for biomarker development. PureTech has presented data demonstrating high expression of galectin-9 across various solid tumor types and blood cancers and has found that, in several cancers, galectin-9 levels correlate with shorter time to disease relapse and poor survival. Preclinical work also demonstrates single mechanistic and anti-tumor efficacy of LYT-200 in multiple animal and patient-derived tumor cell models. For example, LYT-200 outperforms anti-PD-1 in solid tumor models models as a single agent. LYT-200 also synergizes with anti-PD-1 in activating CD4 and CD8 T cells in *in vivo* cancer models. LYT-200 is currently being evaluated in two ongoing Phase 1/2 adaptive design trials for the potential treatment of AML/MDS and head and neck cancers.

About PureTech Health

PureTech is a clinical-stage biotherapeutics company dedicated to giving life to new classes of medicine to change the lives of patients with devastating diseases. The Company has created a broad and deep pipeline through its experienced research and development team and its extensive network of scientists, clinicians and industry leaders that is being advanced both internally and through its Founded Entities. PureTech's R&D engine has resulted in the development of 29 therapeutics and therapeutic candidates, including three that have been approved by the U.S. Food and Drug Administration. A number of these programs are being advanced by PureTech or its Founded Entities in various indications and stages of clinical development, including registration-enabling studies. 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.

For more information, visit www.puretechhealth.com or connect with us on X (formerly 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 without limitation those related to development plans for LYT-200, potential benefits to patients, 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, 2023, 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

UK/EU Media

Ben Atwell, Rob Winder

+44 (0) 20 3727 1000

puretech@fticonsulting.com

US Media

Justin Chen

jchen@tenbridgecommunications.com

END

NRAUPUWCGUPAPWR