PureTech Presents Data from Phase 1 Trial of LYT-200 Targeting Galectin-9 in Solid Tumors at the ESMO Immuno-Oncology Congress 2023

December 7, 2023
RNS Number : 9545V
PureTech Health PLC
07 December 2023

7 December 2023

PureTech Health plc

PureTech Presents Data from Phase 1 Trial of LYT-200 Targeting Galectin-9 in Solid Tumors at the ESMO Immuno-Oncology Congress 2023

LYT-200 demonstrates favorable safety profile and anti-tumor activity in combination with anti-PD-1 agent, tislelizumab

Three out of four patients treated so far with head and neck cancers experienced disease control, with one complete response and one partial response observed in the first subset of patients

Initial results are promising, particularly for patients with head and neck cancers, where historical outcomes are poor with response rates of less than 20 percent on current standard-of-care treatments[1]

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 a poster presentation with results from the Phase 1 portion of the Phase 1/2 dose escalation and expansion clinical trial of LYT-200 at the ESMO Immuno-Oncology Congress 2023. LYT-200 is an anti-galectin-9 antibody being evaluated as a monotherapy and in combination with tislelizumab, an anti-PD-1 antibody developed by BeiGene, in metastatic solid tumors, including urothelial and head and neck cancers. LYT-200 is also in development for the treatment of hematological malignancies, such as acute myeloid leukemia.

The data being presented from an ongoing study including all evaluable patients demonstrate that LYT-200 has a favorable safety profile in all cohorts, including the monotherapy and combination arms, and shows disease control and initial anti-tumor activity in combination with tislelizumab. In the combination cohort, anti-tumor activity was observed in patients with relapsed or refractory head and neck squamous cell carcinoma, a patient population that has historically demonstrated a low response rate to anti-PD-1 agents of around 20 percent and 10 percent with chemotherapy[1].

"Galectin-9 is thought to play a foundational role in suppressing immune-mediated activity against tumor cells, and increases in galectin-9 expression have been shown to correlate with aggressive disease and higher mortality, as is seen in patients with head and neck and urothelial cancers," said Julie Krop, M.D., Chief Medical Officer at PureTech Health. "LYT-200 is the most advanced clinical program against this target, and we are very encouraged by the initial

results and look forward to completing this study and advancing this program into late-stage development."

The Phase 1/2 clinical trial includes a dose finding/dose escalation phase (part 1) and an expansion cohort phase (part 2) in patients with relapsed and refractory, locally advanced/metastatic solid tumors. In the monotherapy cohort, 20 patients received LYT-200 across seven escalation doses, with dose levels of 0.2 mg/kg to 16 mg/kg once every two weeks or 10 mg/kg once a week. LYT-200 was well-tolerated with no observed dose-limiting toxicities and only low-grade adverse events, as well as long-term disease stabilization exceeding one year in patients with heavily pre-treated pancreatic cancer and in one patient with colorectal cancer. The monotherapy arm of the trial has been completed, and the clinically relevant dose was selected for the Phase 2 portion of the trial.

In the combination arm, 11 patients have been dosed, and the initial subset of all evaluable patients treated so far includes four patients with head and neck cancers and two patients with urothelial cancer. In the evaluable patients with head and neck cancers, disease control was observed in three of the four patients, with one patient experiencing a complete response for nine months, one patient with a deepening partial response for eight months, and one patient with disease stabilization for four months, and treatment in these patients remains ongoing. The two evaluable patients with urothelial cancer experienced disease stabilization for seven months and three months, and both remain on treatment. The combination arm continues to enroll patients with urothelial and head and neck cancers.

"Galectin-9 is a promising target for the treatment of solid tumors, and the initial results from the LYT-200 Phase 1 trial support its clinical potential," said Zev Wainberg, M.D., Professor of Medicine at UCLA and Co-director of the UCLA GI Oncology Program, and the lead primary investigator of the study.

The poster titled "Phase 1/2 Trial of Galectin-9 Antibody LYT-200 +/- Tislelizumab" will be presented today at The ESMO Immuno-Oncology Congress 2023, which is taking place in Geneva, Switzerland.

About LYT-200
LYT-200 is a fully human IgG4 monoclonal antibody targeting a foundational immunosuppressive protein, galectin-9, for the potential treatment of metastatic/locally advanced solid tumors, including urothelial and head and neck cancers, with otherwise poor survival rates. A wide variety of preclinical data supports the potential clinical efficacy of LYT-200 and the importance of galectin-9 as a target and suggests 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 that 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 preclinical models as a single agent. LYT-200 also synergizes with anti-PD-1 in activating CD4 and CD8 T cells in cancer in vivo models. LYT-200 is currently being evaluated in a Phase 1/2 adaptive design trial for the potential treatment of advanced solid tumors and in a Phase 1b clinical trial for the potential treatment of acute myeloid leukemia (AML).

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 27 therapeutics and therapeutic candidates, including two (Plenity® and EndeavorRx®) that have received both US FDA clearance and European marketing authorization and a third (KarXT) that has been filed for FDA approval. 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 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 our expectations around the design of and the timelines and key milestones associated with clinical trials for LYT-200, including the initial results from the Phase 1 portion of the Phase 1/2 dose escalation and expansion clinical trial in solid tumors, our expectations regarding the potential treatment indications, and PureTech's 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, 2022 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.

[1] Vermorken JB, Mesia R, Rivera F, Remenar E, Kawecki A, Rottey S, Erfan J, Zabolotnyy D, Kienzer HR, Cupissol D, Peyrade F, Benasso M, Vynnychenko I, De Raucourt D, Bokemeyer C, Schueler A, Amellal N, Hitt R. Platinum-based chemotherapy plus cetuximab in head and neck cancer. N Engl J Med. 2008 Sep 11;359(11):1116-27. doi: 10.1056/NEJMoa0802656. PMID: 18784101.

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 Bobbyn
+1 774 278 8273
nichole@tenbridgecommunications.com

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

NRAEAFAKEAADFAA