PureTech's Founded Entity Gallop Oncology to Present New Data from Ongoing Phase 1b Trial of LYT-200 in Relapsed/Refractory Acute Myeloid Leukemia (AML) at the American Society of Hematology (ASH) Annual Meeting

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LYT-200 continues to demonstrate strong evidence of clinical activity, survival benefit and a highly favorable safety profile in heavily pretreated relapsed/refractory AML patients, both as a monotherapy and in combination with standard of care

Compelling responses achieved in population with diverse tumor molecular subtypes

Data continue to mature and will be presented during ASH 2025; topline efficacy readout and overall survival data expected in Q4 2025 and 1H 2026, respectively

PureTech Health plc (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a hub-and-spoke biotherapeutics company dedicated to giving life to science and transforming innovation into value, today announced that new data from its ongoing Phase 1b clinical trial evaluating LYT-200, a first-in-class anti-galectin-9 monoclonal antibody, in relapsed/refractory acute myeloid leukemia (AML) will be shared on December 6th, 2025, during the 67th Annual American Society of Hematology (ASH) Annual Meeting in Orlando, Florida, by its Founded Entity Gallop Oncology. The accepted abstract reflects data as of July 8, 2025, and additional analyses based on a later data cut-off are expected to be presented during the ASH meeting.

The ongoing, open-label, dose-ranging trial is evaluating LYT-200 both as a monotherapy and in combination with the standard-of-care (SOC) regimen of venetoclax (VEN) and hypomethylating agents (HMA) in a very vulnerable population. All participants in the trial have previously been treated with SOC (median prior lines of treatment: 3; range: 1-7), and their disease had either returned or failed to respond.

The data submitted to ASH reflect efficacy and safety findings for 31 participants in the monotherapy arm and 39 participants in the combination arm who received LYT-200 weekly at doses ≥7.5mg/kg. As a monotherapy, treatment with LYT-200 resulted in 1 marrow complete response (CR) and 3 partial responses (PRs). Notably, one PR in the monotherapy arm was maintained for 24 months as of the data cut off in an individual whose disease previously progressed following five prior rounds of treatment with SOC. When administered in combination with VEN/HMA, LYT-200 treatment resulted in 12 CRs, 1 PR, and 1 morphological leukemia-free state (MLFS). Importantly, CRs were achieved in this cohort across a diverse range of tumor subtypes, including KRAS, NRAS, HRAS, and JAK2 mutations, in patients who were previously fully refractory to SOC.

When evaluating patients with AML, a CR is the primary goal of treatment and means that no leukemia cells are detectable in the blood, fewer than 5% blasts remain in the bone marrow, and blood counts have returned to normal. Achieving a CR is generally associated with improved outcomes, including longer overall survival. A PR reflects a significant reduction in leukemia burden, with at least a 50% decrease in blasts, while an MLFS indicates that there are no leukemia cells visible and fewer than 5% blasts in the marrow, though blood counts have not yet recovered. While SOC in this advanced relapsed/refractory population typically achieves CR rates of 6-12% and median overall survival is less than 2.5 months,[1] LYT-200 has demonstrated a >30% CR rate in the combination cohort as of the data cut off, underscoring its potential to serve as a meaningful new treatment option.

Across all dose levels and treatment arms, LYT-200 was well tolerated. No dose-limiting toxicities were reported, and there were no LYT-200-related serious adverse events, discontinuations, or deaths. The most common adverse events potentially related to LYT-200 were mild and transient.

"The combination of this level of efficacy with a clean safety profile underscores the importance of advancing LYT-200 into its next phase of development, especially given the high relapse rates and poor survival outcomes in AML," said Luba Greenwood, JD, Chief Executive Officer of Gallop Oncology. "As survival data mature, we believe they could add another compelling dimension to LYT-200's potential clinical profile for patients with relapsed/refractory AML, including those who have failed VEN/HMA or have mutations associated with poorer prognosis, where the need for new therapies remains urgent."

PureTech intends to share further matured data at ASH, including updated efficacy across dose levels, as well as survival and pharmacokinetic/pharmacodynamic data. Topline efficacy data are expected in the fourth quarter of 2025, with topline survival data anticipated in the first half of 2026. PureTech intends to engage with regulatory authorities to advance LYT-200 into a Phase 2 trial.

About AML and MDS

Acute myeloid leukemia (AML) is an aggressive blood cancer characterized by the rapid growth of abnormal myeloid cells in the bone marrow and blood. It is the most common form of acute leukemia in adults, with a five-year survival rate of less than 30%. Despite available therapies, many patients relapse or fail to respond, and outcomes are especially poor in the relapsed/refractory setting.

Myelodysplastic syndromes (MDS) are a group of rare blood cancers in which the bone marrow does not produce enough healthy blood cells. High-risk MDS often progresses to AML and is associated with limited treatment options and poor survival.

Together, AML and high-risk MDS represent areas of urgent unmet medical need where new therapies with improved efficacy and durability are critically needed. Importantly, the incidence of AML is increasing and the market is expected to grow to $6 billion by 2030, underscoring the scale of the opportunity to bring forward more effective therapies.[2]

About LYT-200

LYT-200 is a fully human IgG4 monoclonal antibody targeting galectin-9, a key oncogenic driver and potent immunosuppressor in cancer. It is being developed for the potential treatment of hematological malignancies and solid tumors with otherwise poor survival rates. In an ongoing acute myeloid leukemia (AML) trial, LYT-200 has demonstrated clinical activity and disease stabilization in heavily pretreated patients, both as a monotherapy and in combination with standard-of-care therapy.

LYT-200 has been granted Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration (FDA) for the treatment of acute myeloid leukemia, underscoring the high unmet need in this disease and the potential for LYT-200 to serve as a meaningful therapeutic option.

About Gallop Oncology

Gallop is a clinical-stage biopharmaceutical company committed to transforming treatment paradigms for hematologic malignancies. Guided by science, designed for patients, and driven to deliver meaningful outcomes, Gallop is advancing a novel approach where efficacy, safety, and durability converge. Its lead candidate, LYT-200, leverages a dual mechanism of action facilitated by galectin-9 -direct tumor cell killing coupled with potent immune activation-offering a differentiated strategy to address some of the most challenging cancers. LYT-200's lead indication is acute myeloid leukemia (AML).

Gallop Oncology was founded by and is currently a wholly-owned subsidiary of PureTech Health plc (Nasdaq: PRTC, LSE: PRTC), a hub-and-spoke biotherapeutics company dedicated to giving life to science. PureTech's innovative R&D engine powers Founded Entities like Gallop, advancing highly promising medicines to patients in a capital-efficient manner. For more information, please visit www.galloponcology.com and www.puretechhealth.com.

About PureTech Health

PureTech Health is a hub-and-spoke biotherapeutics company dedicated to giving life to science and transforming innovation into value. We do this through a proven, capital-efficient R&D model focused on opportunities with validated pharmacology and untapped potential to address significant patient needs. This strategy has produced dozens of therapeutic candidates, including three that have received U.S. FDA approval. By identifying, shaping, and de-risking these high-conviction assets, and scaling them through dedicated structures backed by external capital, we accelerate their path to patients while creating sustainable value for shareholders.

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 the LYT-200 development program and development plans, its potential benefits to patients, plans for discussions with regulatory authorities, the further development of the program, future presentation of additional data from the program 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, 2024, 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.

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[1] Maiti, N. A., Rausch, N. C. R., Cortes, N. J. E., Pemmaraju, N. N., Daver, N. N. G., Ravandi, N. F., Garcia-Manero, N. G., Borthakur, N. G., Naqvi, N. K., Ohanian, N. M., Short, N. N. J., Alvarado, N. Y., Kadia, N. T. M., Takahashi, N. K., Yilmaz, N. M., Jain, N. N., Kornblau, N. S., Bravo, N. G. M., Sasaki, N. K., . . . Konopleva, N. M. Y. (2020). Outcomes of relapsed or refractory acute myeloid leukemia after frontline hypomethylating agent and venetoclax regimens. *Haematologica*, *106*(3), 894-898. https://doi.org/10.3324/haematol.2020.252569

[2] Grand View Research, Acute Myeloid Leukemia Treatment Market Size, Share & Trends Analysis Report By Disease, By Treatment (Chemotherapy, Targeted Therapy, Immunotherapy), By Route of Administration, By End Use, By Region, And Segment Forecasts, 2025 - 2030

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