# PureTech's Founded Entity Gallop Oncology Announces Positive Initial Topline Data from Phase 1b Trial of LYT-200 in Relapsed/Refractory Acute Myeloid Leukemia and High-Risk Myelodysplastic Syndrome

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PureTech's **Founded Entity Gallop Oncology Announces Positive Initial Topline Data from Phase 1b Trial of LYT-200 in Relapsed/Refractory Acute Myeloid Leukemia and High-Risk Myelodysplastic Syndrome**

LYT-200 demonstrated favorable tolerability and strong efficacy in a heavily pretreated population, both in combination with standard of care and as a monotherapy, supporting advancement toward a potentially registrational Phase 2 trial

Initial median overall survival of 13.2 months observed in the combination cohort at the proposed Phase 2 dose, exceeding expected late-line relapsed/refractory setting survival of <2.5 months; overall survival data at this dose continue to mature with final results expected in 1H 2026

Responses observed in patients with high-risk mutations, suggesting potential broad applicability

Further details to be shared at the 67th American Society of Hematology (ASH) Annual Meeting

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, notes that its Founded Entity, Gallop Oncology, today announced initial topline results from the Phase 1b clinical trial evaluating LYT-200, a first-in-class anti-galectin-9 monoclonal antibody, in patients with relapsed/refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). The data demonstrated a favorable tolerability profile and strong efficacy, supporting the advancement of LYT-200 into a potentially registrational Phase 2 trial in AML. Additional details will be shared at the 67th American Society of Hematology (ASH) Annual Meeting on December 6th, 2025.

"Patients with relapsed/refractory AML or high-risk MDS face extremely limited treatment options, and overall survival at this stage is typically less than 2.5 months. With LYT-200, we have demonstrated durable responses, enabled a substantially meaningful proportion of patients to proceed to transplant, and shown initial median overall survival data of 13.2 months at the proposed Phase 2 dose - all alongside a very favorable safety profile. Together, these findings represent a potential step change in the treatment of AML," said Luba Greenwood, JD, Chief Executive Officer of Gallop Oncology. "Importantly, these compelling results were observed in patients across several high-risk mutations, underscoring the central role of galectin-9 in driving this disease as well as the potential broad applicability of LYT-200 in AML and beyond. The strength of the data gives us confidence as we advance toward a potentially registrational Phase 2 study in AML and supports future evaluation of LYT-200 in earlier lines of treatment. We look forward to engaging with regulatory authorities once the maturing overall survival data are finalized."

The Phase 1b, open-label, dose-escalation and dose-expansion trial evaluated LYT-200 both in combination with the standard-of-care (SOC) regimen of venetoclax (VEN) and a hypomethylating agent (HMA) and as a monotherapy in a heavily pretreated patient population (median prior lines of treatment: 3; range: 1-7).

**TOPLINE SAFETY**
LYT-200 demonstrated a favorable safety profile, with no LYT-200-related serious adverse events or dose-limiting toxicities observed in the trial (n=101). Importantly, no overlapping or additive toxicities were seen when LYT-200 was combined with VEN/HMA.

**INITIAL TOPLINE EFFICACY**
*Combination Cohorts*
The majority of participants (87.5%) in the combination cohort had previously been treated with VEN/HMA, and their disease had either returned or failed to respond. Across all evaluable patients[1] treated with LYT-200 in combination with VEN/HMA (n=43), robust antileukemic activity was demonstrated, with a combined complete response (complete response + complete response with incomplete hematological recovery) rate of 33%. Among those who achieved a complete response, 50% proceeded to stem cell transplant. Responses were observed in patients with diverse, high-risk mutations, including KRAS, NRAS, JAK2, and KIT, underscoring LYT-200's mutation-agnostic mechanism of action and potential for broad use.

At the proposed Phase 2 dose of 12 mg/kg (n=32 evaluable), treatment with LYT-200 in combination with VEN/HMA demonstrated:

- 38% combined complete response rate
- 97% disease control rate
- Initial median overall survival of 13.2 months, with data continuing to mature into the first half of 2026

*Monotherapy Cohorts*
As a monotherapy (n=26 evaluable), LYT-200 demonstrated clinical activity and disease stabilization in patients whose disease had progressed following multiple prior lines of treatment, supporting the independent mechanism of galectin-9 blockade as a single agent. Median overall survival in this cohort was 6.5 months, and one partial response has been maintained for 27 months in a patient whose disease previously progressed following five prior rounds of treatment.

"For patients whose AML has progressed, survival is often measured in months, and the toxicities of additional treatments frequently limit what we can realistically offer. What stands out with the LYT-200 data is not only the durable responses we have seen and the ability for some patients to proceed to transplant, but that these outcomes were achieved with a highly favorable tolerability profile," said Amir T. Fathi, MD, Program Director of the Center for Leukemia at the Massachusetts General Hospital Cancer Center and Associate Professor of Medicine at Harvard Medical School. "LYT-200 is not a targeted therapy in the traditional sense; it targets galectin-9, a foundational driver of leukemia biology. The significance of this approach is evidenced by the activity observed across multiple high-risk mutations, suggesting LYT-200 may be uniquely applicable across a broad patient population. Coupled with the emerging overall survival signal at the proposed Phase 2 dose, these data provide strong clinical rationale to advance LYT-200 into late-stage development for the treatment of AML."

LYT-200 has been granted Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration (FDA) for the treatment of AML. Gallop intends to engage with regulatory authorities to discuss the proposed Phase 2 dose and potentially registrational path after the overall survival data have fully matured. Final overall survival results are expected in the first half of 2026.

The poster shared at ASH 2025 will be made available on Gallop's website.

**About AML**
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. Around 450,000 people globally are living with AML.

AML is an area of urgent medical need where new therapies with improved efficacy and durability are critical. 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 therapies that are not only more effective but also applicable across a broader segment of patients.[2]

**About LYT-200**
LYT-200 is a fully human IgG4 monoclonal antibody in development for the treatment of hematological malignancies and solid tumors with otherwise poor survival rates.

LYT-200's target, galectin-9, is a key oncogenic driver and potent immunosuppressor in cancer. Blocking galectin-9 is believed to have a dual mode of action, both killing tumor cells directly while also stimulating anti-tumor immunity. Galectin-9 is the fundamental

driver of the AML disease process. AML stem cells have higher expression of galectin-9 than their healthy counterparts, and higher expression is associated with treatment failure.

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 and driven to deliver meaningful outcomes for patients, Gallop is advancing a novel approach where efficacy, safety, and durability converge. Its lead candidate, LYT-200, is the most advanced candidate targeting galectin-9, a key oncogenic driver, 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 wholly-owned by 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.

**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] Evaluable is defined in the protocol as all patients who received a minimum one full cycle of LYT-200 (four doses) and had a minimum of one on-study disease assessment.

[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 Ð 2030



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