

PureTech Presents Phase 1b Results for LYT-200 in Relapsed/Refractory (R/R) High-Risk Myelodysplastic Syndromes (HR-MDS) and Acute Myeloid Leukemia (AML) at ESMO 2026

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Oral presentation highlights depth of responses in heavily pretreated patients with R/R HR-MDS, including two MRD-negative complete responses enabling stem cell transplantation

LYT-200 demonstrated a favorable safety profile across 101 patients with R/R HR-MDS and AML, with no dose-limiting toxicities or LYT-200-related serious adverse events

PureTech Founded Entity, Gallop Oncology, plans to advance LYT-200 into Phase 2 STRIDE-MDS trial in patients with R/R HR-MDS following successful FDA End-of-Phase 1 meeting and receipt of Fast Track designation

[PureTech Health plc](#) (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 results from the Phase 1b clinical trial of LYT-200 were presented in an oral session at the European Society for Medical Oncology (ESMO) Congress 2026 in Madrid, Spain. LYT-200 is a first-in-class monoclonal antibody targeting galectin-9, an important oncogenic driver and potent immunosuppressor. It is being advanced by PureTech's Founded Entity, Gallop Oncology (Gallop).

The completed Phase 1b trial (NCT05829226) was conducted across nine U.S. sites and evaluated LYT-200 both as a monotherapy and in combination regimens across 101 heavily pretreated patients with relapsed/refractory (R/R) high-risk myelodysplastic syndromes (HR-MDS) or acute myeloid leukemia (AML). The trial included dose escalation of LYT-200 monotherapy, followed by dose escalation of LYT-200 in combination with a hypomethylating agent (HMA; azacitidine or decitabine) in patients with R/R HR-MDS and with venetoclax (VEN) and an HMA in R/R AML.

As [previously disclosed](#), topline results showed encouraging clinical activity and favorable safety in a heavily

pretreated patient population. The oral presentation at ESMO provided further detail on the depth of responses observed. In R/R HR-MDS, LYT-200 at 12 mg/kg in combination with an HMA demonstrated a 36.4% complete response + partial response rate and a 45.5% overall response rate in 11 efficacy-evaluable^[1] patients, all of whom had previously received HMA therapy. Notably, two patients in this treatment cohort achieved MRD-negative complete responses and subsequently proceeded to stem cell transplantation.

Efficacy-evaluable R/R HR-MDS patients had a median of 3 prior lines of therapy (range: 1-5), and all (100%) had previously been treated with an HMA. Importantly, clinical responses were observed across patients with a range of mutations (i.e., BCOR, DNMT3A, SF3B1, TET2, PTPN11, KRAS, and RUNX1-RUNX1T1), and all patients had high-risk cytogenetics, which - coupled with prior exposure to treatment - suggests biologically aggressive, treatment-refractory disease with elevated risk of progression and poor clinical outcomes. Taken together, these attributes underscore the potential mutation-agnostic mechanism of LYT-200 and its potential for broad clinical use.

LYT-200 demonstrated a favorable and consistent safety profile across all cohorts and dose levels studied (N=101), with no dose-limiting toxicities, infusion-related reactions, LYT-200 dose reductions, or LYT-200-related serious adverse events (AEs), discontinuations, or deaths. Importantly, no overlapping or additive toxicities were observed when LYT-200 was combined with an HMA or venetoclax/HMA.

"What is particularly encouraging about these findings is the combination of clinical activity, depth of response and tolerability observed in patients who have already received multiple lines of treatment," said Guenther Koehne, MD, PhD, Deputy Director and Chief of Blood & Marrow Transplant and Hematologic Oncology at Baptist Health Herbert Wertheim Cancer Institute, who presented the Phase 1b results at ESMO. "In high-risk MDS, we need therapies that can achieve meaningful disease control without adding substantial treatment burden. These results provide an encouraging foundation for evaluating LYT-200 in a larger, randomized study and better understanding its potential role in treating this challenging disease."

Following [a successful End-of-Phase 1 meeting with the U.S. Food and Drug Administration \(FDA\) and receipt of Fast Track designation for R/R HR-MDS](#), Gallop plans to advance LYT-200 into Phase 2 development. The **Study of Two Regimens Investigating Dose and Efficacy of LYT-200 in Relapsed/Refractory High-Risk MDS (STRIDE-MDS)** will be a randomized, double-blind, placebo-controlled Phase 2 trial enrolling approximately 125 patients with R/R HR-MDS. Patients will be randomized 2:2:1 to receive LYT-200 at 12 mg/kg plus an HMA, LYT-200 at 7.5 mg/kg plus an HMA, or placebo plus an HMA, respectively. The trial will assess the efficacy of LYT-200 as measured by the rate of complete and partial responses to support dose selection. Gallop plans to initiate the trial after securing external capital.

About Myelodysplastic Syndromes

Myelodysplastic syndromes (MDS) are a group of serious blood cancers characterized by ineffective blood cell production in the bone marrow, leading to anemia, infections, and bleeding complications.^{[2],[3]} MDS affects approximately 60,000-170,000 people in the United States, with an estimated 30-40% of patients diagnosed with the more aggressive form of the disease known as high-risk (HR) MDS.^[4] HR-MDS is associated with poor outcomes, with median survival typically less than two years following diagnosis.

The current standard frontline treatments for HR-MDS are hypomethylating agents (HMAs), such as azacitidine and decitabine; however, most patients do not respond to these therapies or eventually stop benefiting from them.^[5] Once the disease becomes relapsed or refractory (R/R), outcomes are especially poor, with survival often limited to only a few months.^{5,[6]}

Treatment options for patients with R/R HR-MDS remain very limited. Only one therapy has been approved by the U.S. Food and Drug Administration specifically for R/R HR-MDS in the past two decades, and it targets a genetic mutation found in only approximately 3% of patients.⁵ As a result, there remains a significant unmet need for treatments for the overwhelming majority of patients with R/R HR-MDS.

About LYT-200

LYT-200 is a Phase 2-ready, fully human monoclonal antibody in development for the treatment of relapsed/refractory (R/R) high-risk myelodysplastic syndromes (HR-MDS). It is the most advanced therapeutic candidate targeting galectin-9, which is an important oncogenic driver and potent immunosuppressor that plays a central role in some of the most difficult-to-treat cancers. With its mutation-agnostic, dual mechanism of action, LYT-200 is designed to address both the malignant cells and the immunosuppressive environment that sustain disease. LYT-200 has been granted Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of R/R HR-MDS in combination with a hypomethylating agent. LYT-200 has also been granted Fast Track designation from the U.S. FDA for the treatment of acute myeloid leukemia (AML).

About Gallop Oncology

Gallop Oncology is a clinical-stage biotechnology company dedicated to transforming the treatment paradigm for hematological malignancies. Its lead candidate, LYT-200, is a first-in-class, mutation-agnostic antibody in development for the treatment of relapsed/refractory (R/R) high-risk myelodysplastic syndromes (HR-MDS). Gallop Oncology was founded by and is currently wholly owned by PureTech Health plc (LSE: PRTC). 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.

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[1] Efficacy 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 post-baseline disease assessment. The intent-to-treat population for the R/R HR-MDS cohort was n=12.

[2] American Cancer Society. (2023). *What Is Myelodysplastic Syndrome?* Retrieved from <https://www.cancer.org>

- [3] National Comprehensive Cancer Network. (2024). *NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes (Version 2.2024)*. Retrieved from <https://www.nccn.org>
- [4] Greenberg, P. L., Tuechler, H., Schanz, J., Sanz, G., Garcia-Manero, G., Solé, F., Bennett, J. M., Bowen, D., Fenaux, P., Dreyfus, F., Kantarjian, H., Kuendgen, A., Levis, A., Malcovati, L., Cazzola, M., & Haase, D. (2012). Revised International Prognostic Scoring System for myelodysplastic syndromes. *Blood*, 120(12), 2454-2465. <https://doi.org/10.1182/blood-2012-03-420489>
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- [6] Prébet, T., Gore, S. D., Esterni, B., Gardin, C., Itzykson, R., Thepot, S., Quesnel, B., Dreyfus, F., Beyne-Rauzy, O., Vey, N., Recher, C., Adès, L., Fenaux, P., & Groupe Francophone des Myélodysplasies. (2011). Outcome of patients with higher-risk myelodysplastic syndromes after azacitidine treatment failure. *Journal of Clinical Oncology*, 29(24), 3322-3327. <https://doi.org/10.1200/JCO.2011.35.8135>

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