

(PS1486) CD19 CAR-T CELLS FEATURING A CD8A HINGE GLYCINE DELETION EXHIBIT FAVORABLE SAFETY AND EFFICACY IN R/R ALL

Topic: 02. Acute lymphoblastic leukemia - Clinical

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Background

To evaluate the safety and efficacy of CD19 chimeric antigen receptor T (CAR-T) cells featuring a glycine–glycine deletion (GG-deletion) in the CD8 α hinge region in patients with relapsed or refractory B-cell acute lymphoblastic leukemia (R/R B-ALL).

Aims

This study aims to provide evidence to support further clinical development of this modified CAR-T platform.

Methods

Patients with R/R ALL who received CD19(GG) CAR-T cell infusion were enrolled. CAR-T cells were administered at dose levels of $1 \times 10^6/\text{kg}$ and $2 \times 10^6/\text{kg}$. The primary endpoint was safety, including the incidence and severity of cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS). Secondary endpoints included objective response rate, complete remission rate, minimal residual disease negativity rate, event-free survival, and in vivo expansion kinetics of CAR-T cells.

Results

Between November 2022 and November 2025, a total of 16 patients were enrolled. The median age was 30 years (range, 14–60), and the median number of prior treatment lines was 3 (range, 2–7). CRS occurred in 62.5% of patients, with grade 3 CRS observed in only 6.3%; no grade 4–5 adverse events were reported. ICANS occurred in 12.5% of patients, all of which were grade 1. At 1 month after infusion, the objective response rate was 100%, and the rate of complete remission or complete remission with incomplete hematologic recovery was 93.8%. The minimal residual disease-negative rate was 93.3%. With a median follow-up of 14.2 months (95% CI, 12.104–16.269), the 1-year event-free survival rate was 59.2%, and the 1-year overall survival rate was 87.5%. The peak expansion of CAR-T cells reached 36,596.1 copies/ μg DNA (range, 4,580–259,437).

Summary/Conclusion

CD19(GG) CAR-T cell therapy demonstrated a favorable safety profile with a low incidence of severe toxicities and induced deep remissions in patients with R/R ALL, representing a promising therapeutic option for this population.

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Abstract Book Citations: Authors, Title, HemaSphere, 2026;10;(S1):pages. The abstract book DOIs can be found on the “Author Information” page.

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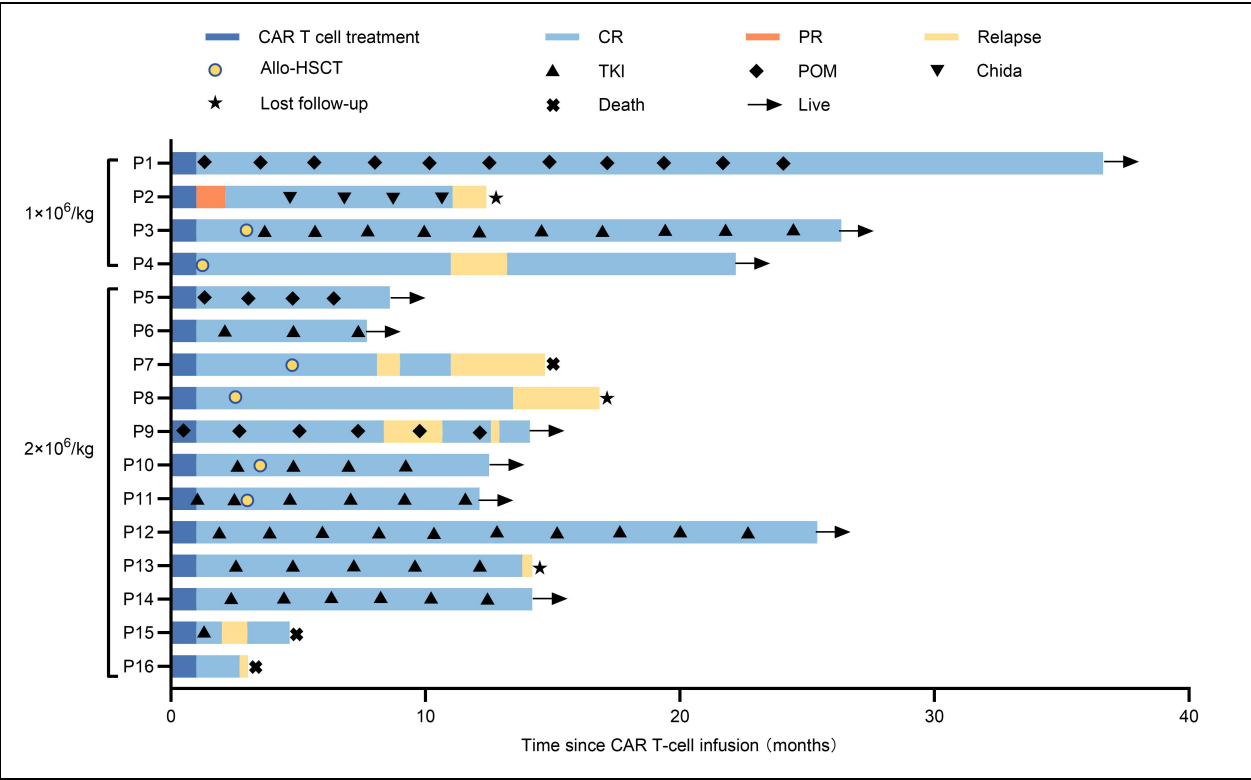


Figure. Swimmer plot of follow-up and clinical outcomes after CD19(GG) CAR-T cell therapy Each horizontal bar represents an individual patient treated with CD19(GG) CAR-T cells, plotted from the day of infusion to the last follow-up or occurrence of an event. Patients are ordered by infused CAR-T cell dose from lowest to highest, and bar length indicates follow-up duration. Colors and symbols denote disease status and key clinical events: color changes specifically reflect transitions in disease status; circles indicate allogeneic hematopoietic stem cell transplantation (allo-HSCT); triangles and squares denote maintenance therapy with tyrosine kinase inhibitors (TKIs), pomalidomide, or chidamide; crosses indicate death. Patients alive and event-free at last follow-up are shown as censored. This figure is descriptive and not intended for statistical inference of dose–outcome relationships.