JSMO 2026 Abstract: ALPINE LTE1 Zanu Patients

Congress: JSMO 2026; March 26-28, 2026

Abstract Submission Deadline: Sept 17 Noon JST (Sept 16 EOD US time/Sept 17 AM NZ time)

Abstract Guidelines

- Author information and abstracts must be submitted in English
- Abstract title must be up to 120 single-byte characters (including spaces)
- Abstract text must be up to 2000 single-byte characters (including spaces)
- Maximum of 20 authors (first author and coauthors) can be registered
- Maximum of 20 affiliations (including the affiliation of the first author) can be registered
- Please structure your abstract as follows:
    - Background:
    - Methods:
    - Results:
    - Conclusion:
- No charts or diagrams can be included

Abstract category

04. Hematologic Malignancies: 04-02 Leukemia

Abstract Title (max 120 characters incl. spaces)

Zanubrutinib sustained benefit in R/R CLL/SLL: 6 years' follow-up in phase 3 ALPINE study and continued in LTE1 study [117/120]

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Abstract Character Count:

Main text: 1993/2000 (including spaces)

Background: In ALPINE (NCT03734016), zanubrutinib (zanu) showed superiority over ibrutinib in progression-free survival (PFS) and overall response rate, with a favorable safety profile in patients (pts) with relapsed/refractory chronic lymphocytic leukemia or small lymphocytic lymphoma (R/R CLL/SLL). Upon ALPINE completion, eligible pts from both treatment (tx) arms could enroll in long-term extension (LTE1; NCT04170283) for ongoing zanu tx or survival follow-up (fwp). We report up to 6 years' fwp for pts initially enrolled in the ALPINE zanu arm who continued in LTE1.

Methods: This ad hoc analysis included all 327 pts in the ALPINE zanu arm. In LTE1, pts continued zanu at their last ALPINE dose. Efficacy was assessed every ≤6 mo and safety every 3 mo.

Results: Baseline characteristics were previously reported (Brown 2023 *NEJM*). 189/327 pts entered LTE1 (176 continued zanu, 13 survival fwp only) 11/09/2023-02/28/2024. As of 04/01/2025, median fwp (ALPINE+LTE1) was 54.2 mo (range 0.1-73.5).

Median PFS was 52.5 mo (60-mo rate 47.3% [50.4% adjusted for COVID-19]). In pts with del17p (13.8%), median PFS was 49.9 mo (60-mo rate 38.2% [40.5% adjusted for COVID-19]). With approximately 12 mo extended fwp, rate of complete response (CR)/CR with incomplete bone marrow recovery increased to 12.8% (95% CI 9.4-17.0) from 11.6% per last report.

Median tx exposure was 52.5 mo (range 0.39-73.4); 79.9% received zanu for ≥24 mo. In pts with del17p, median exposure was 40.7 mo (range 0.39-73.4). Serious adverse events (AEs) occurred in 60.2% of pts, grade ≥3 AEs in 79.0%, grade ≥3 tx-related AEs in 42.3%, 20.4% discontinued due to AEs, and 14.5% had fatal tx-emergent AEs (infections, 9%). The safety profile in pts with del17p was similar to that of all pts. Most AEs of special interest remained stable over time.

Conclusion: With up to 6 years' fwp in pts with R/R CLL/SLL, zanu continued to demonstrate durable efficacy and a consistent safety profile, including in those with del17p.