SEQUOIA 5-year follow-up (arm C): zanubrutinib in patients with del(17p) and treatment-naïve CLL/SLL

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ABSTRACT

Background: SEQUOIA (NCT03336333) demonstrated superior PFS with zanubrutinib (zanu) vs bendamustine+rituximab (arms A and B) in treatment-naive (TN) CLL/SLL without del(17p), as well as high ORR and PFS benefit in patients (pts) with del(17p) (arm C). We report updated results in SEQUOIA arm C, in pts with del(17p), after 5 y of follow-up (data cutoff: April 30, 2024).

Method: Arm C is a nonrandomized cohort of SEQUOIA pts with del(17p) that received zanu. PFS, OS, ORR, and safety/tolerability were evaluated. Adverse events (AEs) were recorded until disease progression or start of next-line therapy.

Results: Between Feb 2018-Mar 2019, 111 TN pts with del(17p) were enrolled; median age was 71 y (range, 42-87) and 60% had unmutated IGHV. At a median follow-up of 65.8 mo (range, 5-75), median PFS was not reached. The estimated 60-mo PFS rate was 72.2% (62.4%-79.8%) or 73.0% (63.3%-80.6%) when adjusted for COVID-19. For pts with unmutated IGHV and mutated IGHV, estimated 60-mo PFS was 70.7% (57.4%-80.6%), and 74.6% (56.9%-85.9%), respectively. Median OS was not reached; estimated 60-mo OS rate was 85.1% (76.9%-90.6%), or 87.0% (79.0%-92.1%) when adjusted for COVID-19. ORR was 97.3%, and the CR/CRi was 18.2%. Zanu was ongoing in 62.2% of pts. Most common AEs of interest (AEI) included any-grade infection (82%), bleeding (60%) and neutropenia (19%). Grade ≥3 AEI included infection (33%), neutropenia (16%) and hypertension (8%).

Conclusion: With this 5-y follow-up, the efficacy of zanu in TN higher-risk pts with del(17p) was maintained and no new safety signals were identified.