Abstract 1548812

Zanubrutinib vs Bendamustine + Rituximab (BR) in Patients With Treatment-Naive Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: Extended Follow-Up of the SEQUOIA Study

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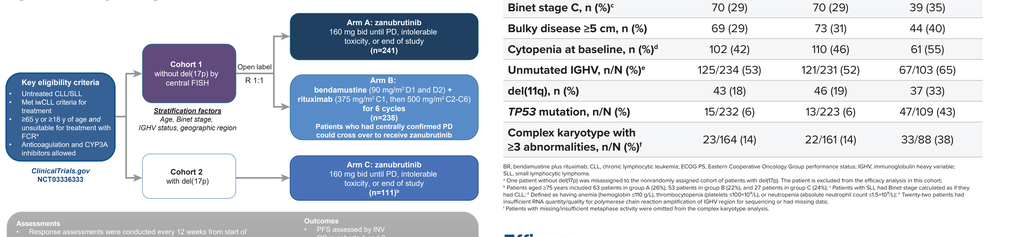
BACKGROUND

- BTK inhibitors have transformed the therapeutic landscape for CLL/SLL by demonstrating prolonged PFS and OS over chemoimmunotherapy, the traditional standard of care[1]
- Zanubrutinib, a next-generation BTK inhibitor designed to minimize off-target binding and limit associated side effects,[2] is approved in the US,[3] EU,[4] and China[5] for CLL/SLL
- Results from the SEQUOIA study (NCT03336333), at a median follow-up of 26.2 months, demonstrated superior PFS in treatment-naive patients with CLL/SLL without del(17p) who received zanubrutinib vs BR (HR, 0.42; 95% CI, 0.28-0.63; 2-sided *P*<.0001); results were similar in treatment-naive patients with del(17p) who received zanubrutinib monotherapy[6]
- An independent data monitoring committee determined that the SEQUOIA study met its primary endpoint at the interim analysis[6]
- Here, we report the updated efficacy and safety results from the SEQUOIA study after approximately 18 months of additional follow-up (data cutoff: 31 October 2022)

METHODS

- Methodological details have been published[6] and are summarized in **Figure 1**

Figure 1. Study Design



C, cycle; CLL/SLL, chronic lymphocytic leukemia/small lymphocytic lymphoma; CRi, CR with incomplete hematologic recovery; FCR, fludarabine, cyclophosphamide, rituximab; FISH, fluorescence in situ hybridization; IGHV, immunoglobulin heavy variable; INV, investigator; iwCLL, International Workshop on Chronic Lymphocytic Leukemia; pt, patient.

ᵃ Defined as Cumulative Illness Rating Scale >6, creatinine clearance <70 mL/min, or a history of previous severe infection or multiple infections within the last 2 years; ᵇ One patient without del(17p) was misassigned to the nonrandomly assigned cohort of patients with del(17p). The patient was excluded from the efficacy analysis in this cohort; ᶜ Defined as the time from randomization to death or the date of progression on the next line of therapy subsequent to study treatment.

RESULTS

Patients

- As of 31 October 2022, 479 patients without del(17p) had been randomized to receive zanubrutinib (n=241) or BR (n=238), and 111 patients with del(17p) received zanubrutinib monotherapy; 180 patients (74.7%) without del(17p) and 78 patients (70.3%) with del(17p) were still receiving zanubrutinib
- The median follow-up was 43.7 months (range, 0-60.0 months) in cohort 1 and 47.9 months (range, 5.0-56.9 months) in cohort 2
- In arm B, 188 patients (79.0%) completed their BR regimen, 86 (36.1%) had progression irrespective of completing the full 6 cycles, and 41 (17.2%) crossed over to receive zanubrutinib after centrally confirmed disease progression
- Zanubrutinib discontinuation rates in patients without and with del(17p) were 24.9% and 29.7%, respectively
- Baseline demographics and disease characteristics were similar across treatment groups (**Table 1**)

Table 1. Patient Characteristics and Baseline Demographics

	Patients without del(17p)		Patients with del(17p)
	Arm A: zanubrutinib (n=241)	Arm B: BR (n=238)	Arm C: zanubrutinib (n=111)ᵃ
Age, median (range), years	70 (40-86)	70 (35-87)	71 (42-87)
Age ≥65 years, n (%)ᵇ	198 (82)	195 (82)	95 (86)
Male, n (%)	154 (64)	144 (61)	79 (71)
ECOG PS 2, n (%)	15 (6)	20 (8)	14 (13)
Geographic region, n (%)			
North America	34 (14)	28 (12)	12 (11)
Europe	174 (72)	172 (72)	52 (47)
Asia-Pacific	33 (14)	38 (16)	47 (42)
Binet stage C, n (%)ᶜ	70 (29)	70 (29)	39 (35)
Bulky disease ≥5 cm, n (%)	69 (29)	73 (31)	44 (40)
Cytopenia at baseline, n (%)ᵈ	102 (42)	110 (46)	61 (55)
Unmutated IGHV, n/N (%)ᵉ	125/234 (53)	121/231 (52)	67/103 (65)
del(11q), n (%)	43 (18)	46 (19)	37 (33)
***TP53* mutation, n/N (%)**	15/232 (6)	13/223 (6)	47/109 (43)
Complex karyotype with ≥3 abnormalities, n/N (%)ᶠ	23/164 (14)	22/161 (14)	33/88 (38)

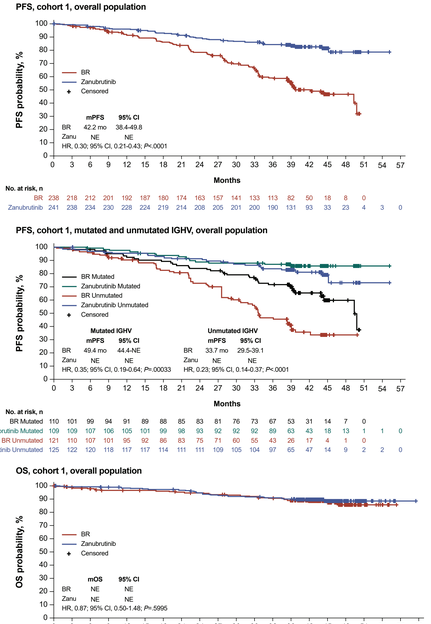
BR, bendamustine plus rituximab; CLL, chronic lymphocytic leukemia; ECOG PS, Eastern Cooperative Oncology Group performance status; IGHV, immunoglobulin heavy variable; SLL, small lymphocytic lymphoma.

ᵃ One patient without del(17p) was misassigned to the nonrandomly assigned cohort of patients with del(17p). The patient is excluded from the efficacy analysis in this cohort; ᵇ Patients aged ≥75 years included 63 patients in group A (26%), 53 patients in group B (22%), and 27 patients in group C (24%); ᶜ Patients with SLL had Binet stage calculated as if they had CLL; ᵈ Defined as having anemia (hemoglobin <110 g/L), thrombocytopenia (platelets <100×10⁹/L), or neutropenia (absolute neutrophil count ≤1.5×10⁹/L); ᵉ Twenty-two patients had insufficient RNA quantity/quality for polymerase chain reaction amplification of IGHV region for sequencing or had missing data;
ᶠ Patients with missing/insufficient metaphase activity were omitted from the complex karyotype analysis.

Efficacy

- In cohort 1, median PFS was not reached in patients who received zanubrutinib; in patients who received BR, median PFS was 42.2 months (**Figure 2A**)
  - Estimated 42-month PFS rates with zanubrutinib and BR were 82.4% and 50.0%, respectively
- PFS was significantly improved with zanubrutinib vs BR in patients with mutated IGHV (2-sided *P*=.00033) and unmutated IGHV (2-sided *P*<.0001) (**Figure 2B**)
- CR/CR with incomplete hematologic recovery (CRi) rates in patients without del(17p) who received zanubrutinib vs BR were 17.4% vs 21.8%, respectively
- Median OS was not reached in either group; the estimated 42-month OS rates were 89.4% and 88.3%, respectively (**Figure 2C**)
- In cohort 2, the median PFS and OS were not reached; the estimated 42-month rates were 79.4% and 89.5%, respectively (**Figure 2D**), and the CR/CRi rate was 14.5%

Figure 2. PFS and OS in Cohort 1 [Without del(17p)] and Cohort 2 [With del(17p)][a]



BR, bendamustine plus rituximab; IGHV, immunoglobulin heavy variable; m, median; NE, not evaluable; zanu, zanubrutinib.

[a] All *P* values are 2-sided.

Safety

- AEs of interest (AEIs) in patients without del(17p) receiving zanubrutinib vs BR and in patients with del(17p) are shown in **Table 2**
- Exposure-adjusted incidence rates for hypertension were similar between arms and lower than previously reported (**Table 3**)

Table 2. Treatment-Emergent and Posttreatment AEIs[a] in Cohorts 1 and 2 (Any Grade and Grade ≥3)[b]

	Patients without del(17p)				Patients with del(17p)	
	Arm A: zanubrutinib (n=240)ᵃ		Arm B: BR (n=227)ᵇ		Arm C: zanubrutinib (n=111)	
AEIs, n (%)	**Any grade**	**Grade ≥3**	**Any grade**	**Grade ≥3**	**Any grade**	**Grade ≥3**
Infections	175 (72.9)	57 (23.8)	142 (62.6)	50 (22.0)	89 (80.2)	30 (27.0)
Bleeding	117 (48.8)	14 (5.8)	28 (12.3)	4 (1.8)	64 (57.7)	6 (5.4)
Other malignancies	45 (18.8)	22 (9.2)	28 (12.3)	11 (4.8)	27 (24.3)	8 (7.2)
Hypertension	42 (17.5)	22 (9.2)	31 (13.7)	15 (6.6)	15 (13.5)	7 (6.3)
Diarrhea	41 (17.1)	4 (1.7)	32 (14.1)	5 (2.2)	22 (19.8)	1 (0.9)
Neutropenia	40 (16.7)	30 (12.5)	129 (56.8)	116 (51.1)	21 (18.9)	18 (16.2)
Arthralgia	37 (15.4)	2 (0.8)	23 (10.1)	1 (0.4)	26 (23.4)	1 (0.9)
Anemia	17 (7.1)	1 (0.4)	47 (20.7)	5 (2.2)	7 (6.3)	0 (0)
Thrombocytopenia	15 (6.3)	5 (2.1)	41 (18.1)	18 (7.9)	9 (8.1)	2 (1.8)
Atrial fibrillation/flutter	12 (5.0)	3 (1.3)	6 (2.6)	3 (1.3)	7 (6.3)	5 (4.5)
Myalgia	9 (3.8)	0 (0)	4 (1.8)	0 (0)	8 (7.2)	1 (0.9)
Opportunistic infection	6 (2.5)	1 (0.4)	4 (1.8)	3 (1.3)	1 (0.9)	1 (0.9)

AEI, AE of interest; BR, bendamustine plus rituximab.

[a] Patients who did not receive zanubrutinib are not included in the safety analysis; [b] Patients who did not receive BR are not included in the safety analysis.

Table 3. Summary of EAIRs[a] for Select AEIs

	Patients without del(17p)		Patients with del(17p)
	Arm A: zanubrutinib (n=240)ᵇ	Arm B: BR (n=227)ᶜ	Arm C: zanubrutinib (n=111)
Atrial fibrillation and flutter	0.13	0.08	0.15
Hemorrhage	2.02	0.40	2.73
Major hemorrhage	0.20	0.05	0.20
Hypertension	0.49	0.45	0.35

AEI, AE of interest; BR, bendamustine plus rituximab; EAIR, exposure-adjusted incidence rate.

[a] EAIR was calculated as the number of patients with an event in each TEAE category divided by the total time from the first dose date to the first event date, or the exposure time if no event occurred; [b] Patients who did not receive zanubrutinib are not included in the safety analysis; [c] Patients who did not receive BR are not included in the safety analysis.

CONCLUSIONS

- The extended follow-up in the SEQUOIA study showed that the efficacy of zanubrutinib was maintained in previously untreated patients with CLL/SLL without del(17p) and that PFS rates were similar in patients with and without del(17p); OS rates were high in all arms of the trial
- Additionally, patients with mutated IGHV who received zanubrutinib demonstrated significant improvements in PFS with extended follow-up vs those who received BR; patients with unmutated IGHV who received zanubrutinib maintained the PFS benefit vs patients who received BR that was observed at the interim analysis
- Zanubrutinib was well tolerated over this extended treatment period and aligned with the known profile of BTK inhibitors; atrial fibrillation events remained low
- The results of this extended follow-up in the SEQUOIA study support the use of zanubrutinib as a valuable first-line treatment option for elderly patients with CLL/SLL and those with del(17p)

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