STUDY | **Phase III SELENE trial: ibrutinib plus BR/R-CHOP in R/R FL or MZL**

Population: N = 403

Primary endpoint:
CPFS (investigator assessed), OS, CR, ORR, DOR, and safety.

Eligibility: Patients aged ≥18 years with R/R FL or MZL following ≥1 prior treatment with an anti-CD20–containing CIT regimen, ≥1 measurable site of disease, and ECOG PS of 0 or 1

STUDY DESIGN

1:1 randomization

Treatment arm (n = 202)

Ibrutinib | 560 mg/day

Until PD, unacceptable toxicity, or study end

Control arm (n = 201)

Placebo

Until PD, unacceptable toxicity, or study end

Bendamustine (28-day cycles) | 90 mg/m² | **Days 1 and 2 of Cycles 1 –6**

+

Rituximab (28-day cycles) | 375 mg/m² | **Day 1 of Cycles 1–6**

OR

R-CHOP (21-day cycles)

Rituximab, 375 mg/m² | **Cyclophosphamide**, 750 mg/m²
Doxorubicin, 50 mg/m² | **Vincristine**, 1.4 mg/m², and 100 mg | **Day 1 of Cycles 1–6**

Prednisone, 100 mg | **Days 1–5 of Cycles 1–6**

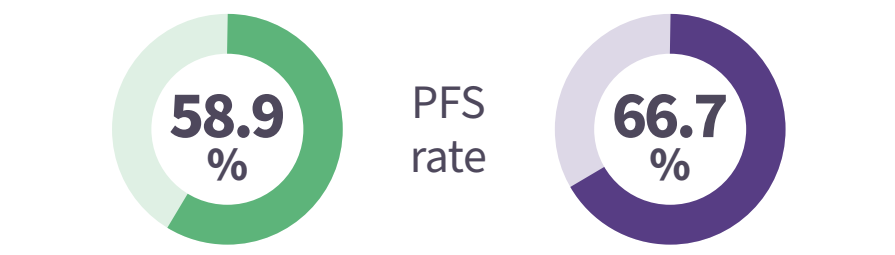
Median follow-up: 84 months

EFFICACY

Treatment arm Control arm

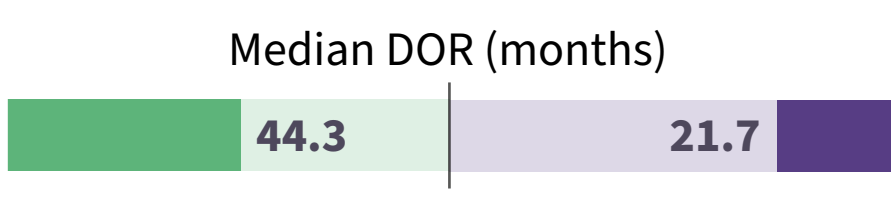
Response rates

PFS



OS

DOR



SAFETY

Treatment arm Control arm

Patients with TEAEs

Grade ≥3	Serious TEAEs	Treatment discontinuation	Leading to dose reduction	Leading to deaths
85.6%	55.7%	30.8%	20.4%	6.5%
75.4%	37.2%	18.6%	10.6%	6.5%

This phase III SELENE study demonstrated that adding ibrutinib to CIT did not significantly improve PFS and yielded similar OS and response rates compared with the placebo plus CIT arm; the safety profile was consistent with previous studies. These data provide insights into the use of BTKis in R/R FL or MZL that could inform future studies.

Abbreviations: BR, bendamustine rituximab; BTKi, Bruton's tyrosine kinase inhibitor; CIT, chemoimmunotherapy; CR, complete response; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; FL, follicular lymphoma; IV, intravenous; NR, not reached; ORR, overall response rate; OS, overall survival; MZL, marginal zone lymphoma; PD, progression of disease; PFS, progression-free survival; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone; R/R, relapsed/refractory; TEAE, treatment-emergent adverse event.

Nastoupil LJ, et al. *Blood Adv.* 2023. Online ahead of print. DOI:10.1182/bloodadvances.2023010298

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