

An observational study on the efficacy of bendamustine and rituximab as first salvage regimen in chronic lymphocytic leukemia



Retrospective study within the GIMEMA and ERIC networks



Chronic lymphocytic leukemia (CLL) patients; median age 70.7 years [38-79]



Bendamustine + Rituximab (BR) as first-line treatment



Matched-adjusted indirect comparison with ibrutinib given as first salvage treatment in the UK and Italian named patient programs

Primary endpoint

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|---|-----------------------------|------------------|
| • 6-month progression-free survival (PFS) | 78.6% (95% C.I. 73.5-84.1%) | median 25 months |
| • Estimated PFS at 30 months | 30.9% (95% C.I. 24.8-38.5%) | |
| • Estimated PFS at 60 months | 16.2% (95% C.I. 10.6-24.6%) | |

Secondary endpoints

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|---|-----------------------------|-----------------------------|
| • Overall response rate | 82.3% | |
| • Time to next anti-leukemic treatment at 12 months | 18.1% (95% C.I. 12.6-22.2%) | median 24.5 months |
| • Overall survival at 12, 36 and 60 months | 92.7%, 72.2%, and 54% | |
| • Safety | | |
| 24.9% cytopenia | 20.7% grade 3-4 neutropenia | 2.5% thrombocytopenia |
| 1.2% anemia | 6.3% grade 3-5 infections | 0.8% rash and/or dermatitis |

• When restricting the analysis to patients with intact 17p who had received chemoimmunotherapy in first line, the overall survival did not differ between patients treated with ibrutinib (63% alive at 36 months) and patients treated with BR

• BR is an effective first salvage regimen in CLL in a real-life population, including elderly patients, with 2 or more comorbidities and creatine clearance < 70 ml/min