summary abstract

Orelabrutinib monotherapy in patients with relapsed or refractory Waldenström's macroglobulinemia in a single-arm, multicenter, open-label, phase 2 study: long term follow-up results

Introduction

Orelabrutinib is a novel, small molecule, selective irreversible Bruton tyrosine kinase inhibitor. The previous publication of this study reported that orelabrutinib is highly active in R/R Waldenström's macroglobulinemia (WM), with a well-tolerated safety profile (EClinicalMedicine. 2022;52:101682). We present here the long-term results of this study.

Main point(s)

- Between August 2019 and December 2020, 66 R/R WM patients were assessed for eligibility. Forty-seven eligible patients were evaluated for efficacy.
- The median duration of treatment was 34.8 months (range: 0.5 - 47.2 months), MRR was 80.9%, ORR was 91.5%, and DCR was 97.9%. The PFS rates was estimated as 86.4% at 30 months and the median PFS has not been reached.
- The most common ≥ Grade 3 TRAEs were neutrophil count decreased (10.6%) and pneumonia (10.6%).

Conclusion

Orelabrutinib has high, deep and durable response in patients with relapsed or refractory WM with the primary study endpoint reached. It is expected to serve as a safer and more effective treatment option for patients with relapsed/refractory WM.