

**The International Workshop on Waldenstrom's Macroglobulinemia (IWWM 2026
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**Zanubrutinib for patients with Waldenström macroglobulinemia: results of a
Belgian real-world, multicenter, observational study**

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Objectives: The second-generation Bruton tyrosine kinase (BTK) inhibitor zanubrutinib is a potent, highly selective, irreversible agent that has become a standard treatment option for Waldenström macroglobulinemia (WM). Its efficacy and favorable tolerability were demonstrated in the pivotal phase 3 ASPEN trial. In November 2021, the European Medicines Agency approved zanubrutinib for adult patients with WM who had received at least one prior therapy, or as first-line treatment for patients considered unsuitable for immunochemotherapy. The multicenter, observational WIZARD study was designed to generate retrospective and prospective Belgian real-world data on the efficacy and safety of zanubrutinib in adult patients with WM.

Methods: The WIZARD study was a retrospective, prospective, multicenter observational study conducted in Belgium to evaluate the use of zanubrutinib in routine clinical practice. Adult patients with symptomatic WM who initiated zanubrutinib treatment between October 1, 2022, and September 1, 2024, in accordance with Belgian reimbursement criteria, were eligible for inclusion. The primary objective was to assess the real-world effectiveness of zanubrutinib, measured by major response rate

(MRR), overall response rate (ORR), best individual response, and progression-free survival (PFS). Response assessments were performed according to the 11th International Workshop on Waldenström's Macroglobulinemia criteria. Secondary objectives were to evaluate time to response, duration of response, overall survival (OS), and time to next treatment. Baseline demographic and clinical characteristics, together with treatment patterns of zanubrutinib use, were also evaluated.

Results: Eighty-nine patients were included, with a median age of 76 years and a median of two prior lines of therapy. Zanubrutinib was administered as first-line treatment for 37 patients (41.6%), while 20 patients (22.5%) had previously received an ibrutinib-containing regimen. The MRR rate was 64.0% (95% CI, 53.2%–73.9%) and the ORR was 77.5% (95% CI, 67.4%–85.7%), with 23 patients (25.8%) achieving at least a very good partial response. PFS rates at 1 and 2 years were 83.1% and 67.1%, respectively, while corresponding OS rates were 89.8% and 81.4%. Responses were rapid, with 49.5% of responders achieving a response within 6 months, and durable, with 1- and 2-year duration-of-response rates of 77.3% and 70.3%, respectively. Subgroup analyses demonstrated consistent efficacy across baseline patient and disease characteristics.

Zanubrutinib was generally well tolerated, with grade ≥ 3 adverse events (AEs) reported in 8.9% of patients. The most frequently observed AEs were hematoma (5.6%), muscle cramps (4.5%), diarrhea (3.4%), fatigue (3.4%), and hypertension (3.4%). Neutropenia (2.2%) was the only grade ≥ 3 AE reported in more than one patient. Treatment interruptions due to AEs occurred in 5.6% of patients, while 4.5% discontinued treatment because of AEs.

Conclusions: The WIZARD study provide useful insights into the efficacy and safety of zanubrutinib in patients with WM in a Belgian real-world setting, aligning with the outcomes observed in the pivotal ASPEN trial.



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