

# Safety and activity of pirtobrutinib in patients with relapsed or refractory Waldenström macroglobulinemia: 5-year follow-up of the open-label, multicentre, phase 1/2 BRUIN trial

*This information is intended for U.S HCPs for medical, scientific and educational purposes. Not intended for product promotion.*

*Pirtobrutinib has not been approved for relapsed or refractory Waldenström macroglobulinemia by the FDA and the safety and effectiveness of this unapproved use have not been established.*

***Pirtobrutinib is approved for the treatment of adult patients with relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a BTK inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.***

***Pirtobrutinib is also approved for the treatment of adult patients with relapsed or refractory CLL/SLL who have previously been treated with a covalent BTK inhibitor.***



Click to see the full results  
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## Limitations of this analysis of pirtobrutinib in Waldenström macroglobulinemia:

- The BRUIN Phase 1/2 clinical trial is an open-label, single-arm study, and formal comparison to other available therapies was not possible. Endpoints were investigator-assessed.
- Small subgroup sizes and heterogeneous mutation testing methods limit the reliability of biomarker-based conclusions. No post-baseline NGS was performed in the Waldenström macroglobulinaemia cohort, preventing any analysis of resistance mechanisms at progression.

Click here to access the full [Prescribing Information](#) for pirtobrutinib.

## Highlights of Prescribing Information | Warnings and Precautions:

- Infections: Monitor for signs and symptoms of infection, evaluate promptly, and treat. [\(5.1\)](#)
- Hemorrhage: Monitor for bleeding and manage appropriately. [\(5.2\)](#)
- Cytopenias: Monitor complete blood counts during treatment. [\(5.3\)](#)
- Cardiac Arrhythmias: Monitor for symptoms of arrhythmias and manage appropriately. [\(5.4\)](#)
- Second Primary Malignancies: Other malignancies have developed, including skin cancers and other carcinomas. Monitor and advise patients to use sun protection. [\(5.5\)](#)
- Hepatotoxicity, Including Drug-Induced Liver Injury: Monitor hepatic function throughout treatment. [\(5.6\)](#)
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of potential risk to a fetus and to use effective contraception. [\(5.7, 8.1, 8.3\)](#)