

Fixed-duration pirtobrutinib plus venetoclax–rituximab versus venetoclax–rituximab for patients with previously treated CLL/SLL: A phase 3, randomised open-label, multi centre, controlled trial (BRUIN CLL-322)

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

Pirtobrutinib has not been approved in combination with venetoclax and rituximab for relapsed or refractory CLL 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 CLL/SLL who have previously been treated with a covalent BTK inhibitor.



Click to see the full results published in
The Lancet



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Limitations of this analysis of pirtobrutinib plus venetoclax–rituximab in previously treated CLL/SLL:

- OS data remain immature. The relatively short median follow-up precludes definitive conclusions on long-term survival, TTNT, and outcomes with subsequent therapies.
- Some subgroup analyses involve small patient numbers and limited events, warranting cautious interpretation (e.g., IGHV-mutated disease, higher Rai stage, ≥ 3 prior lines of therapy). MRD assessment was constrained by limited availability of end-of-treatment samples and absence of bone marrow evaluation.
- Patients with prior BCL2 inhibitor exposure were excluded; the efficacy of PVR in that population remains unknown as BCL2 regimens become more widely adopted in the frontline setting.

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)