Pirtobrutinib, a highly selective, noncovalent (reversible) BTKi in relapsed/ refractory marginal zone lymphoma: phase 1/2 BRUIN study

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 marginal zone lymphoma 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 published in **Blood Advances**



This study was supported by Eli Lilly and Company.

The following authors, editors and contributors to the publications were employees of, consultants to, or received compensation from Eli Lilly & Co: Krish Patel, Jennifer Brown, Kami Maddocks, Jennifer Woyach, Nirav Shah, Bita Fakhri, Shuo Ma, Catherine Coombs, Chan Cheah, Talha Munir, David Lewis, Lydia Scarfo, Toby Eyre, Alvaro Alencar, Jonathon Cohen, Donald Tsai, Mei Li, Yuanyuan Bian, Paolo Abada, and Minna Balbas.

Limitations of this analysis of pirtobrutinib in marginal zone lymphoma:

- 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.
- The study enrolled a limited number of patients with marginal zone lymphoma.

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)

MMAT-04483

© 2026 Lilly USA, LLC. All rights reserved.

Lilly
A MEDICINE COMPANY