

Pirtobrutinib: Adis Evaluation

Key Points

- A highly selective, non-covalent, reversible BTK inhibitor being developed by Lilly for the treatment of B-cell leukemias and lymphomas
- Received its first approval on 27 January 2023 in the USA under the Accelerated Approval pathway
- Approved for use in adult patients with relapsed or refractory MCL after at least two lines of systemic therapy, including a BTK inhibitor

Summary

Pirtobrutinib (Jaypirca™), a highly selective, non-covalent, reversible Bruton's tyrosine kinase (BTK) inhibitor, is being developed by Eli Lilly and Company (Lilly) for the treatment of B-cell leukemias and lymphomas.

In January 2023, pirtobrutinib was approved in the USA under the Accelerated Approval pathway for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) 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.

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