Ibrutinib: Adis Evaluation

Key Points

- A small molecule BTK inhibitor that has been developed by Pharmacyclics, Inc. and Janssen Pharmaceutical for the treatment of B-cell malignancies and cGVHD
- Received its pediatric first approval on 29 August 2022 in the USA
- Approved for the treatment of adult and pediatric patients aged 1 year and older with cGVHD after failure of one or more lines of systemic therapy

Summary

Ibrutinib (IMBRUVICA®), a small molecule inhibitor of Bruton's tyrosine kinase (BTK) developed by Pharmacyclics, Inc. and Janssen Pharmaceutical, is well established as a treatment for B-cell malignancies and is also approved in the USA in adult patients with chronic graft-versus-host disease (cGVHD) and in Japan in adults and adolescents aged ≥ 12 years with cGVHD.

Ibrutinib was approved in August 2022 in the USA for use in pediatric patients with cGVHD after failure of one or more lines of systemic therapy and is the first treatment approved for use in this group of patients aged < 12 years (ibrutinib is now indicated for the treatment of adult and pediatric patients aged 1 year and older with cGVHD after failure of one or more lines of systemic therapy).

Keam S.J. Pediatr Drugs. 2022. https://doi.org/10.1007/s40272-022-00543-w