Drugs

PEER-REVIEWED FEATURE

Futibatinib: Adis Evaluation

Key Points

- An irreversible FGFR1–4 inhibitor is being developed by Taiho Oncology and Taiho Pharmaceutical for the treatment of cancers
- Received its first approval on 30 September 2022 in the USA
- Approved for use in adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harbouring FGFR2 gene fusions or other rearrangements

Summary

Futibatinib (Lytgobi®) is an oral, small-molecule, irreversible inhibitor of fibroblast growth factor receptors (FGFR) that is being developed by Taiho Oncology for the treatment of cancers, including cholangiocarcinoma (bile duct cancer).

Futibatinib received its first approval on 30 September 2022 in the USA for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harbouring FGFR2 gene fusions or other rearrangements.

Futibatinib as second line and beyond therapy for cholangiocarcinoma is filed for approval in the EU and Japan. Phase I or II trials of futibatinib are underway for breast cancer with FGFR1 and FGFR2 amplification, urothelial and oesophageal cancers (in combination with pembrolizumab) and NSCLC with KRAS mutations (in combination with binimetinib).