Drugs

PEER-REVIEWED FEATURE

Olverembatinib: Adis Evaluation

Key Points

- An oral, third-generation BCR-ABL1 TKI developed by Ascentage Pharma for the treatment of haematological malignancies, including CML-CP and CML-AP, and solid tumours, such as GIST
- Received its first approval on 24 November 2021 in China
- Approved for use in adults with TKI-resistant CML-CP or CML-AP harbouring the T315I mutation

Summary

Olverembatinib (HQP1351) is an oral, third-generation BCR-ABL1 tyrosine kinase inhibitor (TKI) developed by Ascentage Pharma for the treatment of chronic myeloid leukaemia (CML), acute myeloid leukaemia, acute lymphoblastic leukaemia (ALL) and solid tumours, including gastrointestinal stromal tumours (GIST).

Olverembatinib is an ATP binding-site inhibitor of wild type BCR-ABL1 kinase and a broad spectrum of BCR-ABL1 mutants, including mutant T315I, which confers resistance against all first- and second-generation TKIs.

In November 2021, olverembatinib received its first approval in China for the treatment of adult patients with TKI-resistant chronic-phase CML (CML-CP) or accelerated-phase CML (CML-AP) harbouring the T315I mutation, as confirmed by a validated diagnostic test. Clinical studies are underway in the US for CML and precursor cell ALL, and in China for solid tumours, including GIST.

Dhillon, S. Drugs. 2022. https://doi.org/10.1007/s40265-022-01680-9