

Weekly New Drug Approvals

Aug. 26th 2024

Fulzerasib

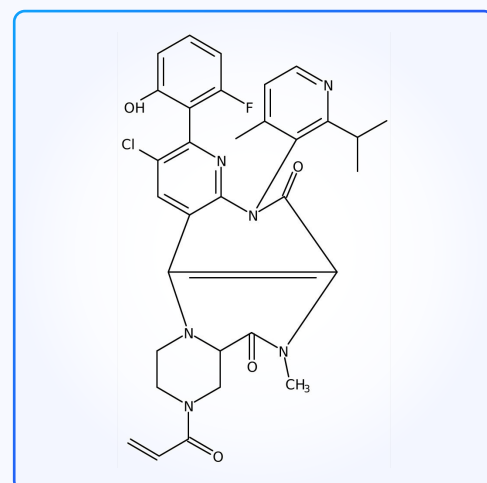
NMPA Approval Date: Aug 21st, 2024

Indication: KRAS G12C mutant Non-small Cell Lung Cancer

Mechanism: KRAS G12C inhibitors

Dosage form: Tablet

Company: Innovent Biologics



Fulzerasib is a potent oral novel molecular entity that effectively inhibits the KRAS protein by covalently and irreversibly modifying the cysteine residue of the KRAS G12C mutant protein. This inhibition interferes with the GTP/GDP exchange mediated by this protein, thereby reducing KRAS protein activation levels. Additionally, following the inhibition of the KRAS protein, Fulzerasib further inhibits downstream signaling pathways, effectively inducing tumor cell apoptosis and cell cycle arrest, thereby achieving an anti-tumor effect.

This approval is based on the results of an open-label, single-arm, Phase II registrational clinical study conducted in China (NCT05005234).

- As of December 13, 2023, a total of 116 NSCLC patients were enrolled, of which 91.4% had an ECOG performance status of 1; 30.2% had brain metastases; and 84.5% had previously received anti-PD-1/PD-L1 inhibitors and platinum-based chemotherapy. The trial results showed that the confirmed objective response rate (ORR), as assessed by the Independent Radiology Review Committee (IRRC), was 49.1%, with a disease control rate (DCR) of 90.5%. The median duration of response (DoR) was not yet reached. The median progression-free survival (PFS) was 9.7 months, and the median overall survival (OS) had not yet been reached.
- In terms of safety, 107 patients (92.2%) experienced treatment-related adverse events (TRAEs), with 48 patients (41.4%) experiencing TRAEs of grade 3 or higher.