14 November 2024
EMA/CHMP/515529/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lazcluze

lazertinib

On 14 November 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lazcluze, intended in combination with amivantamab, for the treatment of non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations.

The applicant for this medicinal product is Janssen-Cilag International NV.

Lazcluze will be available as 80 mg and 240 mg film-coated tablets. The active substance of Lazcluze is lazertinib, an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (ATC code: L01EB09). Lazertinib selectively inhibits EGFR with exon 19 deletions and exon 21 L858R substitution mutations. By doing so, lazertinib inhibits the proliferation of cancer cells and promotes their death. Because lazertinib preferentially targets EGFR mutants, it minimises undesirable effects on normal cell functions typically associated with EGFR inhibition.

The benefit of first-line treatment with Lazcluze in combination with amivantamab is an improvement in progression-free survival (PFS) compared with osimertinib monotherapy in patients with EGFR-mutated locally advanced or metastatic NSCLC not amenable to curative therapy.

The most common side effects are rash, nail toxicity, infusion-related reaction, hepatotoxicity, stomatitis, venous thromboembolism, paraesthesia, fatigue.

The full indication is:

> Lazcluze in combination with amivantamab is indicated for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with *EGFR* exon 19 deletions or exon 21 L858R substitution mutations.

Lazcluze should be prescribed by physicians experienced in the use of anticancer medicinal products.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.