11 November 2021
EMA/624008/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lumykras

sotorasib

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Lumykras, intended for the treatment of patients with KRAS G12C mutation non-small cell lung cancer (NSCLC). The applicant for this medicinal product is Amgen Europe B.V..

Lumykras will be available as 120 mg film-coated tablets. The active substance of Lumykras is sotorasib, a KRAS *G12C* (Kirsten rat sarcoma viral oncogene homolog) inhibitor (ATC code: L01XX73) which covalently and irreversibly binds to the unique cysteine of KRAS *G12C*. Inactivation of KRAS *G12C* by sotorasib blocks tumour cell signalling and survival, inhibits cell growth and promotes apoptosis selectively in tumours harbouring KRAS G12C, an oncogenic driver of tumourigenesis.

The benefits of Lumykras are its objective response rate and response duration in patients with KRAS G12C-mutated NSCLC who had disease progression after receiving prior therapy. The most common side effects are diarrhoea, nausea, fatigue, increased aspartate aminotransferase and arthralgia.

The full indication is:

> LUMYKRAS as monotherapy is indicated for the treatment of adults with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation and who have progressed after at least one prior line of systemic therapy.

Lumykras should be initiated by a physician experienced in the use of anticancer medicinal products.

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.

[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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union