FIRST-IN-CLASS KRAS G12C-INHIBITOR

In 2L KRAS G12C-mutated locally advanced or metastatic NSCLC,

Light the way forward with LUMAKRAS®

Introducing LUMAKRAS, a first-in-class, highly selective KRAS G12C inhibitor designed to give patients with locally advanced or metastatic NSCLC a new way forward.[1]

Reference: 1. LUMAKRAS® (sotorasib) Singapore Prescribing Information. Approved June 2022

Please review full product information before prescribing

ABBREVIATED PRODUCT INFORMATION
LUMAKRAS® (sotorasib) Film-Coated Tablet 120 mg
INDICATIONS: LUMAKRAS is indicated for the treatment of adult patients with *KRAS G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), who have received at least one prior systemic therapy.
CONTRAINDICATIONS: None.
PRECAUTIONS: Hepatotoxicity: LUMAKRAS can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis. Monitor liver function tests (ALT, AST, and total bilirubin) prior to the start of LUMAKRAS, every 3 weeks for the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop transaminase and/or bilirubin elevations. Withhold, dose reduce or permanently discontinue LUMAKRAS based on severity of adverse reaction. Interstitial Lung Disease (ILD)/Pneumonitis: LUMAKRAS can cause ILD/pneumonitis that can be fatal. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold LUMAKRAS in patients with suspected ILD/pneumonitis and permanently discontinue LUMAKRAS if no other potential causes of ILD/pneumonitis are identified.
FERTILITY, PREGNANCY AND LACTATION: Fertility/early embryonic development studies were not conducted with sotorasib. There are no available data on LUMAKRAS use in pregnant women. There are no data on the presence of sotorasib or its metabolites in human milk, the effects on the breastfed child, or on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with LUMAKRAS and for 1 week after the final dose.
INTERACTIONS: Coadministration of LUMAKRAS with gastric acid-reducing agents and strong CYP3A4 inducer decreased sotorasib concentrations. Avoid coadministration of LUMAKRAS with proton pump inhibitors (PPIs), H2 receptor antagonists, locally acting antacids and strong CYP3A4 inducers. Coadministration of LUMAKRAS with a CYP3A4 substrate decreased its plasma concentrations. Avoid coadministration of LUMAKRAS with CYP3A4 sensitive substrates. Coadministration of LUMAKRAS with a P-gp substrate (digoxin) increased digoxin plasma concentrations. Avoid coadministration of LUMAKRAS with P-gp substrates.
ADVERSE REACTIONS: The most common adverse reactions (≥ 20%) were diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity, and cough. The most common laboratory abnormalities (≥ 25%) were decreased lymphocytes, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, decreased calcium, increased alkaline phosphatase, increased urine protein, and decreased sodium.
DOSAGE & ADMINISTRATION: Select patients for treatment of locally advanced or metastatic NSCLC with LUMAKRAS based on the presence of *KRAS G12C* mutation in tumor or plasma specimens. If no mutation is detected in a plasma specimen, test tumor tissue. The recommended dosage of LUMAKRAS is 960 mg (eight 120 mg tablets) orally once daily until disease progression or unacceptable toxicity. If adverse reactions occur, a maximum of two dose reductions are permitted. Discontinue LUMAKRAS if patients are unable to tolerate the minimum dose of 240 mg once daily.
Dose Reduction Level: First dose reduction – 480 mg (4 tablets) once daily; Second dose reduction – 240 mg (2 tablets) once daily.
Dosage Modifications for Adverse Reactions: Hepatotoxicity ≥ Grade 2 AST or ALT with symptoms – Withhold LUMAKRAS until recovery to ≤ Grade 1 or baseline; Resume LUMAKRAS at the next lower dose level. AST or ALT > 3 × ULN with total bilirubin > 2 × ULN in the absence of alternative causes: Permanently discontinue LUMAKRAS. ILD/pneumonitis: Any Grade – Withhold LUMAKRAS if suspected. Permanently discontinue LUMAKRAS if confirmed. Grade 3 to 4 Nausea or vomiting, diarrhea and/or other adverse reactions: Withhold LUMAKRAS until recovery to ≤ Grade 1 or baseline; Resume LUMAKRAS at the next lower dose level.

Based on approved PI dated 28 June 2022.
Amgen internal reference: SGLUMPI01

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