LUMAKRAS®

(sotorasib) 240 mg tablets

Patient Profiles

A first-in-class highly selective* KRAS^{G12C} inhibitor for your patients with non-small cell lung cancer (NSCLC)[1,2]

*Cysteine proteome analysis of 6,451 peptides showed sotorasib only covalently engages with Cys12 of *KRAS*^{G12C}. Preclinical studies in 22 cell lines and xenograft models demonstrated that sotorasib does not inhibit *KRAS* wild type or non–*KRAS*^{G12C} lines/tumors.

1. LUMAKRAS® (sotorasib) prescribing information, Amgen. **2.** Canon J, et al. *Nature*. 2019;575:217-223.

INDICATION

LUMAKRAS is indicated for the treatment of adult patients with *KRAS* G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Hepatotoxicity

- LUMAKRAS can cause hepatotoxicity and increased ALT or AST which may lead to drug-induced liver injury and hepatitis.
- In the pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg hepatotoxicity occurred in 27% of patients, of which 16% were Grade ≥ 3. Among patients with hepatotoxicity who required dosage modifications, 64% required treatment with corticosteroids.
- In this pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg, 17% of patients who received LUMAKRAS had increased alanine aminotransferase (ALT)/increased aspartate aminotransferase (AST); of which 9% were Grade ≥ 3. The median time to first onset of increased ALT/AST was 6.3 weeks (range: 0.4 to 42). Increased ALT/AST leading to dose interruption or reduction occurred in 9% of patients treated with LUMAKRAS. LUMAKRAS was permanently discontinued due to increased ALT/AST in 2.7% of patients. Drug-induced liver injury occurred in 1.6% (all grades) including 1.3% (Grade ≥ 3).
- In this pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg, a total of 40% patients with recent (≤ 3 months) immunotherapy prior to starting LUMAKRAS had an event of hepatotoxicity. An event of hepatotoxicity was observed in 18% of patients who started LUMAKRAS more than 3 months after last dose of immunotherapy and in 17% of those who never received immunotherapy. Regardless of time from prior immunotherapy, 94% of hepatotoxicity events improved or resolved with dosage modification of LUMAKRAS, with or without corticosteroid treatment.
- Monitor liver function tests (ALT, AST, alkaline phosphatase, 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, reduce the dose or permanently discontinue LUMAKRAS based on severity of the adverse reaction. Consider administering systemic corticosteroids for the management of hepatotoxicity.

Please see Important Safety Information throughout and click HERE for LUMAKRAS® full Prescribing Information.

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AMGEN



*Hypothetical patient cases, may not represent all patients.

Gerald*

About

A 65-year-old retired mechanic who enjoys being active with his grandkids and organizing church events

Medical History

Former smoker (quit 10 years ago) currently taking inhaled corticosteroids for asthma and lovastatin for hyperlipidemia

Treatment Journey

1 year ago

Diagnosis
Stage IIIC lung adenocarcinoma, <1% PD-L1 expression

1L Treatment
Chemoradiation followed by durvalumab monotherapy

Disease Progression and Biomarker Testing
Presentation of two new liver metastases, ECOG PS 2, progressed to metastatic

What would be your next steps for Gerald?

1L, first-line; ECOG PS, Eastern Cooperative Oncology Group performance status; PD-L1, programmed death-ligand 1.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Interstitial Lung Disease (ILD)/Pneumonitis

- LUMAKRAS can cause ILD/pneumonitis that can be fatal.
- In the pooled safety population of NSCLC patients who received single agent LUMAKRAS 960 mg, ILD/pneumonitis occurred in 2.2% of patients, of which 1.1% were Grade ≥ 3, and 1 case was fatal. The median time to first onset for ILD/pneumonitis was 8.6 weeks (range: 2.1 to 36.7 weeks). LUMAKRAS was permanently discontinued due to ILD/pneumonitis in 1.3% of LUMAKRAS-treated patients. 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.

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Andrew*

About

A 71-year-old retired musician and youth chorus director who enjoys community gardening

Medical History

Nonsmoker currently taking lisinopril and hydrochlorothiazide for hypertension and inhaled corticosteroids for asthma; he has difficulty swallowing pills

Treatment Journey

8 months ago

Diagnosis and Biomarker Testing

Stage IV lung adenocarcinoma, <1% PD-L1 expression, *KRAS* G12C mutation

1L Treatment

Immuno-oncology/platinum-based chemotherapy combination regimen (pembrolizumab/carboplatin/pemetrexed)

Disease Progression

Worsening cough, two new 4- and 6-mm brain metastases without new symptoms, one liver metastasis, ECOG PS 2

Do you have patients like Andrew in your practice?

1L, first-line; ECOG PS, Eastern Cooperative Oncology Group performance status; *KRAS*, Kirsten rat sarcoma viral oncogene homolog; PD-L1, programmed death-ligand 1.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Most Common Adverse Reactions

- The most common adverse reactions ≥ 20% were diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity, and cough.

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Connie*

About

A 62-year-old retired schoolteacher who enjoys reading to children during story time at the library

Medical History

Former smoker (quit 15 years ago) currently taking metformin for type 2 diabetes and escitalopram for depression

Treatment Journey

13 months ago

Diagnosis and Biomarker Testing

Stage IV lung adenocarcinoma, 65% PD-L1 expression, *KRAS* G12C mutation

1L Treatment

Anti–PD-1/platinum-based chemotherapy regimen

Disease Progression

Connie's follow-up CT scan showed tumor growth in the right lobe, indicating disease progression, ECOG PS 1

How would you manage Connie's treatment plan?

1L, first-line; ECOG PS, Eastern Cooperative Oncology Group performance status; *KRAS*, Kirsten rat sarcoma viral oncogene homolog; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Drug Interactions

- Advise patients to inform their healthcare provider of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, dietary and herbal products.
- Inform patients to avoid proton pump inhibitors and H_2 receptor antagonists while taking LUMAKRAS®.
- If coadministration with an acid-reducing agent cannot be avoided, inform patients to take LUMAKRAS® 4 hours before or 10 hours after a locally acting antacid.

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In *KRAS* G12C–mutated locally advanced or metastatic NSCLC following first line of therapy:[1]

LUMAKRAS® is a first-in-class, once-daily oral KRAS G12C inhibitor[1]

NCCN Guidelines®

NSCLC: NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) list sotorasib as a subsequent therapy option for patients with *KRAS* G12C–positive advanced NSCLC (NCCN Category 2A recommendation)[2,*,†]

CNS: NCCN Guidelines list sotorasib as a subsequent therapy option for patients with *KRAS* G12C–positive NSCLC with CNS involvement (NCCN Category 2B recommendation)[3]

CodeBreaK 100 was a single-arm, open-label, global, multicenter clinical trial with the Phase 2 portion evaluating LUMAKRAS® in 126 patients with locally advanced or metastatic *KRAS* G12C–mutated NSCLC who progressed on prior therapy. Major efficacy outcomes in patients with ≥ 1 measurable lesion (BICR according to RECIST v1.1; n=124) were ORR and DOR (≥ 6 months: 58% of patients observed beyond landmark time).[1]

US Prescribing Information

36%

LUMAKRAS® delivered an ORR‡ of 36% (n=45/124)
(n=124; 95% CI: 28–45; CR: 2%, PR: 35%)[1,4]

- The median DOR was 10 months (range: 1.3+, 11.1)

In CodeBreaK 100 (N=204), the most common adverse reactions ≥ 20% were diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity, and cough[1]

LUMAKRAS® is the only once-daily oral *KRAS* G12C therapy and has a confirmed dose of 960 mg[1]

- Treat until disease progression or unacceptable toxicity

Amgen® SupportPlus can help your patients access their prescribed medications

- Over 1,000,000 patients have been served by Amgen SupportPlus[5]

+ symbol indicates censoring.
*NCCN makes no representations or warranties of any kind regarding their content, use or application and disclaims any responsibility for their application or use in any way.[2]
†Does not include locally advanced.[2]
‡As determined by BICR according to RECIST v1.1.[1]
BICR, Blinded Independent Central Review; CI, confidence interval; CNS, central nervous system; CR, complete response; DOR, duration of response; *KRAS*, Kirsten rat sarcoma viral oncogene homolog; NCCN, National Comprehensive Cancer Network; NSCLC, non-small cell lung cancer; ORR, objective response rate; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors.

1. LUMAKRAS® (sotorasib) prescribing information, Amgen. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer. V.8.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 15, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Central Nervous System Cancers. V.2.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 28, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **4.** Sotorasib CSR. Amgen; 2021. **5.** Data on file, Amgen; [Amgen SupportPlus Patients and HCPs].

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