Guardant360® CDx test can help identify adult patients with *KRAS G12C*-mutated locally advanced or metastatic NSCLC who may be appropriate for LUMAKRAS®[1,2]

GUARDANT360® CDx

FDA-Approved Liquid Biopsy Companion Diagnostic (CDx) for LUMAKRAS®[3]

- The first **FDA-approved** liquid biopsy test that uses NGS[4]
- Whole blood specimens are processed within **7 days of collection**[5]
- Guardant360® CDx has **Medicare coverage for NSCLC**[1]
- In LUMAKRAS® clinical studies, **consistent efficacy* results** were seen in patients with ***KRAS G12C* mutation identified in either tissue or plasma** specimens.[6] Plasma samples from 112 patients were tested retrospectively using the Guardant360® CDx[2]

For more information: www.guardant360cdx.com | **Client Services:** 855.698.8887

Physicians should use their own medical judgment in determining which test is most appropriate for their patients.
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***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 objective response rate (36% [95% CI: 28–45]; CR: 2%, PR: 35%) and duration of response (median: 10.0 months [1.3+, 11.1]; ≥6 months: 58% of patients observed beyond landmark time).[2,7]**

BICR, Blinded Independent Central Review; CI, confidence interval; CR, complete response; FDA, Food and Drug Administration; *KRAS*, Kirsten rat sarcoma viral oncogene homolog; NGS, next-generation sequencing; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors.

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 additional Important Safety Information on following page and LUMAKRAS® full Prescribing Information.

LUMAKRAS® (sotorasib) 240 mg tablets

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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.

Most Common Adverse Reactions

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

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.

Please see LUMAKRAS® full Prescribing Information.

References: 1. Guardant360. Technical Information. guardant360cdx.com/wp-content/uploads/2020/09/Guardant360CDx_Label_Technical_Info.pdf. Updated July 2021. November 14, 2025. **2.** LUMAKRAS® (sotorasib) prescribing information. Thousand Oaks, CA: Amgen; 2025. **3.** US Department of Health and Human Services, Food and Drug Administration. www.fda.gov/medical-devices/products-and-medical-procedures/vitro-diagnostics. Accessed November 14, 2025. **4.** US Department of Health and Human Services, Food and Drug Administration. www.fda.gov/news-events/press-announcements/fda-approves-first-liquid-biopsy-next-generation-sequencing-companion-diagnostic-test. Accessed November 14, 2025. **5.** Guardant360 CDx. Guardant360 Specification Sheet. Guardant Health; 2023. https://www.therapyselect.de/sites/default/files/downloads/guardant360/guardant360_specification-sheet_en.pdf. Accessed November 14, 2025. **6.** Bauml JM, et al. CT181-Clinical Validation of Plasma Cell-Free DNA Sequencing in a Phase 2 Trial of Sotorasib in Patients With KRAS p.G12C Mutated NSCLC. Presented at: 112th Annual Meeting of the American Association for Cancer Research; 2021. **7.** Sotorasib CSR. Amgen; 2021.

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