Guardant360® CDx test can help identify 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**[1]
- Guardant360® CDx has **Medicare coverage for NSCLC**[5]
- 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.
Guardant360® is a trademark owned or licensed by Guardant Health, Inc.
+ symbol indicates censoring.

***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, which may lead to drug-induced liver injury and hepatitis.
- Among 357 patients who received LUMAKRAS™ in CodeBreaK 100, hepatotoxicity occurred in 1.7% (all grades) and 1.4% (Grade 3). A total of 18% of patients who received LUMAKRAS™ had increased alanine aminotransferase (ALT)/increased aspartate aminotransferase (AST); 6% were Grade 3 and 0.6% were Grade 4. In addition to dose interruption or reduction, 5% of patients received corticosteroids for the treatment of hepatotoxicity.
- 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.

Please see additional Important Safety Information on following page and LUMAKRAS™ full Prescribing Information.

ONCE-DAILY ORAL

LUMAKRAS™

(sotorasib) 120 mg tablets

Indication and Important Safety Information

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Interstitial Lung Disease (ILD)/Pneumonitis

- LUMAKRAS™ can cause ILD/pneumonitis that can be fatal. Among 357 patients who received LUMAKRAS™ in CodeBreaK 100 ILD/pneumonitis occurred in 0.8% of patients, all cases were Grade 3 or 4 at onset, and 1 case was fatal. LUMAKRAS™ was discontinued due to ILD/pneumonitis in 0.6% of 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. guardant360cdx.com/wp-content/uploads/2020/09/Guardant360CDx_Label_Technical_Info.pdf. Accessed April 28, 2021. **2.** LUMAKRAS™ (sotorasib) prescribing information. Thousand Oaks, CA: Amgen; 2021. **3.** US Department of Health and Human Services, Food and Drug Administration. www.fda.gov/medical-devices/products-and-medical-procedures/vitro-diagnostics. Accessed April 28, 2021. **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 April 28, 2021. **5.** Center for Medicare and Medicaid Services. NCD for NGS (90.2). www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296. Accessed April 28, 2021. **6.** Bauml JM, et al. Presented at: 112th Annual Meeting of the American Association for Cancer Research; 2021. Abstract CT181. **7.** Sotorasib CSR. Amgen; 2021.

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