

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC) Meeting
October 5, 2023

DRAFT QUESTIONS

sNDA 214665/S-005

LUMAKRAS (sotorasib)

Applicant: Amgen Inc.

PROPOSED INDICATION:

- treatment of adult patients with KRAS G12C mutated locally advanced or metastatic non-small cell lung cancer, as determined by an FDA approved test, who have received at least one prior systemic therapy.
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1. **VOTE:** Can the primary endpoint, progression-free survival (PFS) per blinded independent central review (BICR), be reliably interpreted in CodeBreak200?