

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

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

**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.
- 

1. **VOTE:** Can the primary endpoint, progression-free survival (PFS) per blinded independent central review (BICR), be reliably interpreted in CodeBreak200?