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

Oncologic Drugs Advisory Committee (ODAC) Meeting

October 5, 2023

DRAFT AGENDA

The Committee will discuss supplemental new drug application (sNDA) 214665/S-005, for LUMAKRAS (sotorasib) tablets, submitted by Amgen Inc., for the proposed 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. This supplement proposes to convert the NDA to full approval based on the confirmatory study, CodeBreaK 200. The Committee will consider the results of the CodeBreaK 200 study and discuss the benefit-risk profile of LUMAKRAS.

9:30 a.m.	Call to Order	**Ravi A. Madan, MD** Chairperson, ODAC
9:35 a.m.	Introduction of Committee/ Conflict of Interest Statement	**Joyce Frimpong, PharmD** Acting Designated Federal Officer, ODAC
9:40 a.m.	FDA Opening Remarks	**Harpreet Singh, MD** Director Division of Oncology 2 (DO2) OOD, OND, CDER, FDA
10:00 a.m.	**APPLICANT PRESENTATIONS**	**Amgen Inc.**
	Introduction	**Jackie Kline, PhD** Vice President, Global Regulatory Affairs Amgen Inc.
	Efficacy	**Bhakti Mehta, MD, MPH** Executive Medical Director Global Clinical Development Amgen Inc.
	Safety	**Osa Eisele, MD, MPH** Executive Medical Director Global Patient Safety Amgen Inc.
	Evidence Supports CodeBreak 200 as an Adequate and Well-Controlled Trial	**Gregory Friberg, MD** Vice President, Global Medical Amgen Inc.
	Clinical Perspective	**Melissa Johnson, MD** Program Director, Lung Cancer Research Sarah Cannon Research Institute

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Benefit: Risk and Conclusion	**Giuseppe Giaccone, MD, PhD** Vice President, Global Oncology Clinical Development Amgen Inc.
10:45 a.m.	**FDA PRESENTATIONS**	
	Sotorasib for KRAS G12C Mutated Locally Advanced or Metastatic Nonsquamous Non-Small Cell Lung Cancer	**Jeevan Puthiamadathil, MD** Clinical Reviewer DO2, OOD, OND, CDER, FDA **Chi (Chuck) Song, PhD** Statistical Reviewer Division of Biometrics V (DBV) Office of Biostatistics (OB) Office of Translation Sciences (OTS) CDER, FDA **Paz Vellanki, MD, PhD** Cross Disciplinary Team Lead DO2, OOD, OND, CDER, FDA
11:30 a.m.	Clarifying Questions	
12:30 p.m.	**LUNCH**	
1:15 p.m.	**OPEN PUBLIC HEARING**	
2:15 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**ADJOURNMENT**	