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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 25, 2024

AGENDA

The Committee will discuss supplemental biologics license application (sBLA) 761069/S-043, for IMFINZI (durvalumab) injection, submitted by AstraZeneca UK Limited. The proposed indication (use) is IMFINZI in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements. The Committee will also be asked to discuss whether drug sponsors should be required to adequately justify treatment of patients both before and after surgery for resectable NSCLC prior to an approval that would include both neoadjuvant and adjuvant therapy.

9:00 a.m.	Call to Order and Introduction of Committee	**Daniel Spratt, MD** Acting Chairperson, ODAC
9:05 a.m.	Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Acting Designated Federal Officer, ODAC
9:10 a.m.	FDA Opening Remarks	**Erin Larkins, MD** Director (Acting) Division of Oncology 2 (DO2) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	**APPLICANT PRESENTATIONS**	**AstraZeneca UK Limited**
	Introduction	**Leora Horn, MD, MSC, MHPE, FRCPC** Vice President, Head of Clinical Development Late Development Oncology Global Clinical Strategy Head for Lung Cancer AstraZeneca
	Disease Background	**Marina Garassino, MD** Professor of Medicine Director, Thoracic Programs Department of Hematology/Oncology University of Chicago
	Clinical Efficacy	**Gary Doherty, MB, BChir, MA, PhD, FRCP** Global Clinical Program Lead - Oncology, Lung AstraZeneca
	Clinical Safety	**Mayur Patel, PharmD** Vice President, Patient Safety Oncology AstraZeneca

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Perspective	**John Heymach, MD, PhD** Chair and Professor, Department of Thoracic/Head and Neck Medical Oncology Division of Cancer Medicine University of Texas MD Anderson Cancer Center
	Concluding Remarks & Future Perspectives	**Leora Horn, MD, MSC, MHPE, FRCPC**
10:10 a.m.	**FDA PRESENTATIONS**	
	Durvalumab Before and After Surgery for the Treatment of Resectable Non-Small Cell Lung Cancer (AEGEAN)	**Bernardo Haddock Lobo Goulart, MD** Clinical Reviewer Cures Senior Physician DO2, OOD, OND, CDER, FDA
	Contribution of Treatment Phase in Perioperative Trials	**Shabnam Ford, PhD** Senior Mathematical Statistician Division of Biometrics V Office of Biostatistics Office of Translational Sciences, CDER, FDA
10:55 a.m.	Clarifying Questions	
11:30 a.m.	**LUNCH**	
12:15 p.m.	**OPEN PUBLIC HEARING**	
1:15 p.m.	Questions to the Committee/Committee Discussion – AEGEAN	
1:45 p.m.	Questions to the Committee/Committee Discussion – Future Perioperative Trial Designs to Support Contribution of Sequence	
3:00 p.m.	**ADJOURNMENT**	