

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

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

DRAFT 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

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

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

DRAFT 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**