

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
October 28, 2022

DRAFT AGENDA

The committee will discuss biologics license application (BLA) 761176, for ¹³¹I-omburtamab solution for injection, submitted by Y-mAbs Therapeutics, Inc. The proposed indication (use) for this product is for the treatment of central nervous system/leptomeningeal (CNS/LM) metastases in pediatric patients with neuroblastoma following standard multimodality treatment for CNS disease.

10:00 a.m.	Call to Order	Jorge Garcia, MD, FACP Chairperson, ODAC
10:05 a.m.	Introduction of Committee and Conflict of Interest Statement	Philip Bautista, PharmD, MPH Acting Designated Federal Officer, ODAC
10:15 a.m.	FDA Introductory Comments	Amy Barone, MD Cross-Disciplinary Team Leader Division of Oncology 2 (DO2) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
10:30 a.m.	APPLICANT PRESENTATION	Y-mAbs Therapeutics, Inc.
	Introduction	Rikke Valentin Oxholm Lillesø Vice President, Global Regulatory Affairs Y-mAbs Therapeutics, Inc.
		Thomas Gad Founder Y-mAbs Therapeutics, Inc.
	Disease Background & Unmet Need	Kim Kramer, MD Attending, MSK KIDS Department of Pediatrics Director, Faculty Development and Wellness Memorial Sloan Kettering Cancer Center Professor of Pediatrics New York Presbyterian Hospital - Weill Cornell Medical Center

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATION (cont.)

Efficacy

Vignesh Rajah, MD
Chief Medical Officer
Y-mAbs Therapeutics, Inc.

René dePont Christensen, MSc, PhD
Vice President of Biometrics
Y-mAbs Therapeutics, Inc.

Safety

Vignesh Rajah, MD

Clinical Perspective

Daniel A. Morgenstern, MB BChir, PhD
Staff Physician, Solid Tumor Program,
Hematology/Oncology
Associate Scientist, Translational Medicine
SickKids Research Institute
Associate Professor, Department of Pediatrics
University of Toronto

11:20 a.m. **FDA PRESENTATIONS**

¹³¹I-Omburtamab for neuroblastoma with
central nervous system or leptomeningeal
metastases

Gautam U. Mehta, MD
Clinical Reviewer, Nervous System, Pediatrics
and Rare Cancers
DO2, OOD, OND, CDER, FDA

12:00 p.m. Clarifying Questions to Presenters

12:30 p.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Questions to the Committee/Committee
Discussion

3:00 p.m. **ADJOURNMENT**