

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
February 26, 2020

DRAFT AGENDA

During the morning session, the committee will discuss new drug application 212578 for padeliporfin di-potassium powder for solution for injection, submitted by STEBA Biotech, S.A. The proposed indication (use) for this product is for the treatment of patients with localized prostate cancer, meeting the following criteria: Stage T1-T2a and prostate specific antigen less than or equal to 10 ng/mL and Gleason Grade Group 1 based on transrectal ultrasound guided biopsy or unilateral Gleason Grade Group 2 based on multiparametric magnetic resonance imaging-targeted biopsy with less than 50 percent of cores positive.

8:00 a.m.	Call to Order and Introduction of Committee	Philip C. Hoffman, MD Chairperson, ODAC
	Conflict of Interest Statement	Lauren Tesh Hotaki, PharmD, BCPS, BCIDP Designated Federal Officer, ODAC
8:10 a.m.	FDA Opening Remarks	Chana Weinstock, MD Team Leader, Genitourinary Cancers Team Division of Oncology 1 (DO1) Office of Oncologic Diseases Office of New Drugs (OND), CDER, FDA
8:15 a.m.	GUEST SPEAKER PRESENTATION	Jim C. Hu, MD, MPH Ronald P. Lynch Professor of Urologic Oncology Director of the LeFrak Center for Robotic Surgery, Weill Cornell Medicine New York Presbyterian/Weill Cornell New York, New York
8:45 a.m.	APPLICANT PRESENTATIONS	STEBA Biotech, S.A.
	Introduction	John C. Rewcastle, PhD Head, US Regulatory STEBA Biotech, S.A.

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Current Management of Clinically
Localized Prostate Cancer

Peter T. Scardino, MD

Attending Surgeon and Member
Departments of Surgery and Molecular
Pharmacology and Therapeutics
Memorial Sloan Kettering Cancer Center
Professor of Urology
Weill Cornell College of Medicine
New York, New York

Prostate Hemiablation with TOOKAD
VTP: Procedure and Mechanism of
Action

Neal D. Shore, MD, FACS

Medical Director, CPI
Carolina Urologic Research Center
National Urology Research Director
21st Century Oncology
Atlantic Urology Clinics
Myrtle Beach, South Carolina

Efficacy and Safety and Confirmatory
Study

Henri W. Boodée, MD

Head, US Medical Affairs and Clinical
Development
STEBA Biotech, S.A.

Clinical Perspective

Inderbir S. Gill, MD

Chair and Distinguished Professor of Urology
Keck School of Medicine
University of Southern California
Los Angeles, California

9:30 a.m.

FDA PRESENTATION

NDA 202578: padeliporfin di-potassium
powder for solution for injection
(TOOKAD)

Sundeep Agrawal, MD

Clinical Reviewer, Genitourinary Cancers Team
DO1, OOD, OND, CDER, FDA Office of
Oncologic Diseases

10:15 a.m.

Clarifying Questions to Presenters

10:45 a.m.

BREAK

11:00 a.m.

OPEN PUBLIC HEARING

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DRAFT AGENDA (cont.)

11:30 a.m. Questions to the Committee/Committee
Discussion

12:15 p.m. **LUNCH**

DRAFT

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DRAFT AGENDA (cont.)

During the afternoon session, the committee will discuss supplemental biologics license application 125477/S-034, for CYRAMZA (ramucirumab) injection for intravenous use, submitted by Eli Lilly and Company. The proposed indication (use) for this product is in combination with erlotinib, for first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 (L858R) substitution mutations.

1:15 p.m.	Call to Order and Introduction of Committee	Philip C. Hoffman, MD Chairperson, ODAC
	Conflict of Interest Statement	Lauren Tesh Hotaki, PharmD, BCPS, BCIDP Designated Federal Officer, ODAC
1:25 p.m.	FDA Opening Remarks	Erin Larkins, MD, CDR, USPHS Cross-Discipline Team Lead Thoracic and Head & Neck Cancers Team Division of Oncology 2 (DO2) OOD, OND, CDER, FDA
1:30 p.m.	APPLICANT PRESENTATIONS	Eli Lilly and Company
	Introduction	Allen Melemed, MD, MBA Distinguished Medical Scholar and Senior Director Global Regulatory Affairs, Oncology Eli Lilly and Company
	Unmet Medical Need	Everett Vokes, MD John E. Ulmann Professor of Medicine and Radiation Oncology Physician-in-Chief, University of Chicago Medicine and Biological Sciences Chair Department of Medicine
	Efficacy	Paolo Abada, MD, PhD Senior Medical Director Cyramza Global Product Development, Oncology Eli Lilly and Company
	Safety	Carla Visseren, MD Global Medical Lead RELAY Eli Lilly and Company

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Clinical Perspective

John Heymach, MD, PhD

Chair, Department of Thoracic Head and Neck
Medical Oncology
MD Anderson Cancer Center
David Bruton, Jr. Chair in Cancer Research

2:15 p.m.

FDA PRESENTATION

sBLA: 125477/S-034 CYRAMZA

Barbara Scepura, MS, CRNP

Clinical Reviewer
Thoracic and Head & Neck Cancers Team
DOP2, OOD, OND, CDER, FDA

3:00 p.m.

Clarifying Questions to Presenters

3:30 p.m.

BREAK

3:45 p.m.

OPEN PUBLIC HEARING

4:15 p.m.

Questions to the Committee/Committee
Discussion

5:00 p.m.

ADJOURNMENT