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, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
February 26, 2020

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 (OOD) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	Contemporary Diagnosis and Treatment of Localized Prostate Cancer	**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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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
10:15 a.m.	Clarifying Questions to Presenters	
10:45 a.m.	**BREAK**	
11:00 a.m.	**OPEN PUBLIC HEARING**	

AGENDA (cont.)

11:30 a.m.	Questions to the Committee/Committee Discussion
12:15 p.m.	**LUNCH**

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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. Ultmann 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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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**	
	BLA: 125477 s34: Ramucirumab	**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**	