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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 14, 2020

AGENDA

The committee will discuss biologic license application (BLA) 761158, for belantamab mafodotin, submitted by GlaxoSmithKline Intellectual Property Development Ltd. England. The proposed indication (use) for this product is for the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

9:00 a.m.	Call to Order and Introduction of Committee	**Philip C. Hoffman, MD** Chairperson, ODAC
	Conflict of Interest Statement	**Yvette Waples, PharmD** Acting Designated Federal Officer, ODAC
9:15 a.m.	FDA Opening Remarks	**Bindu Kanapuru, MD** Multiple Myeloma Team Lead (Acting) Division of Hematologic Malignancies II (DHM2) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
9:30 a.m.	**APPLICANT PRESENTATIONS**	**GlaxoSmithKline Intellectual Property Development Ltd. England**
	Belantamab Mafodotin Introduction	**Axel Hoos, MD, PhD** Senior Vice President and Therapy Area Head Oncology Research & Development GlaxoSmithKline
	Unmet Need in Patients with Relapsed/ Refractory Multiple Myeloma	**Kenneth Anderson, MD** Professor of Medicine at Harvard Medical School Director of the Lebow Institute for Myeloma Therapeutics and Jerome Lipper Multiple Myeloma Center Dana-Farber Cancer Institute
	Belantamab Mafodotin: Clinical Efficacy	**Ira Gupta, MD** Medicine Development Leader - belantamab mafodotin GlaxoSmithKline

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 14, 2020

AGENDA (cont.)

APPLICANT PRESENTATIONS (cont.)

	Belantamab Mafodotin: Overall Clinical Safety	**Hesham Abdullah, MD, MSc, RAC** Senior Vice President Oncology Clinical Development GlaxoSmithKline
	Belantamab Mafodotin: Characterization of Corneal Safety and Monitoring	**Kathryn Colby, MD, PhD** Louis Block Professor and Chair Department of Ophthalmology & Visual Science President, Cornea Society University of Chicago
	Risk Evaluation and Mitigation Strategy (REMS)	**Hesham Abdullah, MD, MSc, RAC**
	Belantamab Mafodotin: Clinical Perspective	**Sagar Lonial, MD, FACP** Professor and Chair Department of Hematology and Medical Oncology Chief Medical Officer, Winship Cancer Institute Emory University
10:15 a.m.	**FDA PRESENTATION**	
	BLA 761158: Belantamab Mafodotin	**Andrea C. Baines, MD, PhD** Clinical Reviewer DMH2, OOD, OND, CDER, FDA
10:45 a.m.	Clarifying Questions to Presenters	
11:15 a.m.	**BREAK**	
11:30 a.m.	**OPEN PUBLIC HEARING**	
12:30 p.m.	Questions to the Committee/Committee Discussion	
1:30 p.m.	**ADJOURNMENT**	