

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

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

**DRAFT AGENDA**

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*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.*

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9:00 a.m.	Call to Order and Introduction of Committee	<b>Philip C. Hoffman, MD</b> Chairperson, ODAC
	Conflict of Interest Statement	<b>Yvette Waples, PharmD</b> Acting Designated Federal Officer, ODAC
9:15 a.m.	FDA Opening Remarks	<b>Bindu Kanapuru, MD</b> 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.	<b>APPLICANT PRESENTATIONS</b>	<b>GlaxoSmithKline Intellectual Property Development Ltd. England</b>
	Belantamab Mafodotin Introduction	<b>Axel Hoos, MD, PhD</b> Senior Vice President and Therapy Area Head Oncology Research & Development GlaxoSmithKline
	Unmet Need in Patients with Relapsed/ Refractory Multiple Myeloma	<b>Kenneth Anderson, MD</b> 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	<b>Ira Gupta, MD</b> Medicine Development Leader - belantamab mafodotin GlaxoSmithKline

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**DRAFT AGENDA (cont.)**

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**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**