

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**Center for Drug Evaluation and Research (CDER)**  
***Oncologic Drugs Advisory Committee (ODAC) Meeting***  
July 17, 2025

**DRAFT AGENDA**

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*The Committee will discuss BLA 761440, belantamab mafodotin submitted by GlaxoSmithKline LLC, for the treatment of adults with multiple myeloma in combination with bortezomib and dexamethasone in patients who have received at least one prior line of therapy; and in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide.*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>Neil Vasan, MD, PhD</b> Acting Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	<b>LaToya Bonner, PharmD, MBA</b> Acting Designated Federal Officer ODAC
8:10 a.m.	FDA Introductory Remarks	<b>Deepti Telaraja, MD</b> Clinical Team Leader (Acting) Division of Hematologic Malignancies II (DHM II) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>GlaxoSmithKline, LLC</b>
	Belantamab Mafodotin: Introduction	<b>Hesham A. Abdullah, MD, MSc, RAC</b> Senior Vice President Global Head Oncology, GSK
	Unmet Need in Patients with Relapsed Refractory Metastatic Melanoma	<b>Paul Richardson, MD</b> Clinical Program Leader Director of Clinical Research Dana-Farber Cancer Institute RJ Corman Professor of Medicine Harvard Medical School
	Dose Rationale and DreaMM-7 and DreaMM-8 Efficacy	<b>Pralay Mukhopadhyay, PhD</b> Vice President Medicine Development Leader, GSK
	Characterization of Corneal Safety and Monitoring	<b>Natalie Afshari, MD</b> Chief, Division of Cornea and Refractive Surgery Shiley Eye Center Professor of Ophthalmology, University of California, San Diego

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**DRAFT AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

Belantamab Mafodotin: Safety

**Zeshaan Rasheed, MD, PhD**  
Senior Vice President  
Head of Oncology Clinical Development,  
GSK

Belantamab Mafodotin: Clinical  
Perspective

**Sagar Lonial, MD**  
Chair and Professor  
Chief Medical Officer  
Winship Cancer Institute  
Emory University School of Medicine

9:15 a.m.

**FDA PRESENTATIONS**

BLA 761440 Belantamab Mafodotin  
ODAC Clinical and Clinical  
Pharmacology

**Andrea Baines, MD, PhD**  
Clinical Reviewer  
DHM II, OOD, OND, CDER, FDA

**William Boyd, MD**  
Deputy Director  
OOD, OND, CDER, FDA

**Ankit Shah, PhD**  
Clinical Pharmacology Team Leader  
Division of Cancer Pharmacology I (DCP I)  
Office of Clinical Pharmacology (OCP)  
Office of Translational Sciences (OTS)  
CDER, FDA

10:00 a.m.

Clarifying Questions

10:30 a.m.

**BREAK**

10:45 a.m.

**OPEN PUBLIC HEARING**

11:45 p.m.

Questions to the Committee/Committee  
Discussion

12:45 p.m.

**ADJOURNMENT**