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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 17, 2025

AGENDA

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.

8:00 a.m.	Call to Order and Introduction of Committee	**Neil Vasan, MD, PhD** Acting Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	**LaToya Bonner, PharmD, MBA** Acting Designated Federal Officer ODAC
8:10 a.m.	FDA Introductory Remarks	**Deepti Telaraja, MD** 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.	**APPLICANT PRESENTATIONS**	**GlaxoSmithKline, LLC**
	Belantamab Mafodotin: Introduction	**Hesham A. Abdullah, MD, MSc, RAC** Senior Vice President Global Head Oncology, GSK
	Unmet Needs in Relapsed and/or Refractory Multiple Myeloma (RRMM)	**Paul Richardson, MD** 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	**Pralay Mukhopadhyay, PhD** Vice President Medicine Development Leader, GSK
	Characterization of Ocular Events and Safety Monitoring	**Natalie Afshari, MD** Chief, Division of Cornea and Refractive Surgery Shiley Eye Center Professor of Ophthalmology, University of California, San Diego

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Safety Results	**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**	