Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the Oncologic Drugs Advisory Committee Meeting

July 17, 2025

Location: The FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. The public also had the option to participate via an online teleconferencing and/or video conferencing platform, and the meeting presentations were heard, viewed, captioned, and recorded through an online video conferencing platform.

Topic: 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.

These summary minutes for the July 17, 2025, meeting of the **Oncologic Drugs Advisory Committee** of the Food and Drug Administration were approved on

Sept. 10, 2025.

I certify that I attended the July 17, 2025, meeting of the **Oncologic Drugs Advisory Committee** of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
LaToya Bonner, PharmD
Acting Designated Federal Officer
ODAC

/s/
Neil Vasan, MD, PhD
Acting Chairperson, ODAC

Summary Minutes of the Oncologic Drugs Advisory Committee Meeting

July 17, 2025

The Oncologic Drugs Advisory Committee (ODAC) of the Food and Drug Administration, Center for Drug Evaluation and Research, met on July 17, 2025, at the FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503), 10903 New Hampshire Avenue, Silver Spring, Maryland. The public also had the option to participate via an online teleconferencing and/or video conferencing platform, and the meeting presentations were heard, viewed, captioned, and recorded through an online video conferencing platform. Prior to the meeting, the members and temporary voting members were provided the briefing materials from the FDA and GlaxoSmithKline LLC. The meeting was called to order by Neil Vasan, MD, PhD (Acting Chairperson). The conflict-of-interest statement was read into the record by LaToya Bonner, PharmD (Designated Federal Officer). There were approximately 150 people in attendance in-person and approximately 1619 people online. There were 14 Open Public Hearing (OPH) speaker presentations.

A verbatim transcript will be available, in most instances, at approximately ten to twelve weeks following the meeting date.

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.

Attendance:

Oncologic Drugs Advisory Committee Members Present (Voting): William Gradishar, MD (*via video conferencing platform*); Daneil Spratt, MD (*via video conferencing platform*); and Neil Vasan, MD, PhD *(Acting Chairperson)*.

Oncologic Drugs Advisory Committee Member Present (Non-Voting): Tara Frenkl, MD *(Industry Representative)*

Temporary Members (Voting): Paul Beringer, PharmD; Mark R. Conaway, MD; John DeFlice, MD *(Patient Representative)*; Ravi A. Madan, MD; and Grzegorz (Greg) S. Nowakowski, MD, FASCO.

FDA Participants (Non-Voting): Richard Pazdur, MD; Nicole Gormley, MD; Nicholas Richardson, DO, MPH; Bindu Kanapuru, MD; Deepti Telaraja, MD; and Andrea Baines, MD, PhD.

Designated Federal Officer (Non-Voting): LaToya Bonner, PharmD, MBA

Open Public Hearing Speakers Present: Anne Quinn Young *(Multiple Myeloma Research Foundation, via video conferencing platform)*; Saad Z. Usmani, MD; Kathy Cartwright; Dave Teitelman; Deialia "DeDe" Olson; Diane Moran *(International Myeloma Foundation)*; Jenny Ahlstrom *(HealthTree Foundation)*; Sarah Sunshine, MD; Hans Lee, MD *(via video conferencing platform)*; Jesus G. Berdeja *(via video conferencing platform)*; Kathleen Keoghan *(via video conferencing platform)*; Jane M. Gallegos *(via video conferencing platform)*; Diana Zuckerman, PhD; and Frank Caccioppoli *(teleconference platform)*.

The agenda was as follows:

Call to Order and Introduction of Committee	**Neil Vasan, MD, PhD** Acting Chairperson, ODAC
Conflict of Interest Statement	**LaToya Bonner, PharmD, MBA** Acting Designated Federal Officer ODAC
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
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

APPLICANT PRESENTATIONS (CONT.)

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
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

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

Clarifying Questions

BREAK

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

ADJOURNMENT

Questions to the Committee:

1. **DISCUSSION:** Discuss whether appropriate dosages of belantamab mafodotin have been identified for the proposed relapsed /refractory population.

   Committee Discussion*: Overall, the Committee emphasized the missed opportunities to optimize dosing throughout the clinical development program. The panel discussed insufficient exploration of dosing strategies when the drug was first developed; inadequate dose-finding in early phase studies; and limited dose exploration prior to proceeding with the phase 3 randomized controlled trials (RCTs). Despite belantamab mafodotin demonstrating statistical significance for the progression-free survival (PFS) primary endpoint, the panel expressed significant concerns with the high rates of ocular toxicity observed in the population evaluated in the DREAMM-7 and DREAMM-8 trials. One member emphasized the uncertainty regarding the safety profile of the product and the probability, if approved, of subjecting patients to side effects that perhaps could be mitigated with a more optimal dose regimen. The Committee expressed concerns with the population enrolled, questioning the generalizability of the results, as fewer than 5% of the clinical participants enrolled were from the U.S.*

   Please see the transcript for details of the Committee's discussion.

2. **VOTE:** Is the overall benefit-risk of belantamab mafodotin in combination with bortezomib and dexamethasone favorable at the proposed dosage in the proposed patient population?

   Vote Result: Yes: 3 No: 5 Abstain: 0

3. **VOTE:** Is the overall benefit-risk of belantamab mafodotin in combination with pomalidomide and dexamethasone favorable at the proposed dosage in the proposed patient population?

   Vote Result: Yes: 1 No: 7 Abstain: 0

   Committee Discussion: *The Committee voted "No", 5:3 and 7:1 respectively, to whether the overall benefit-risk of belantamab mafodotin in combination with bortezomib and dexamethasone (in the DREAMM-7 trial), and in combination with pomalidomide and dexamethasone (in the DREAMM-8 trial) being favorable at the proposed dosages in the proposed patient populations. The Committee agreed that the product met its primary endpoint (PFS) in both trials but stated that the ocular toxicities observed in over 90% of the treated population and the lack of dose optimization, hindered the panel's decision to support that the benefits of the product outweighed its safety risks. Although the sponsor proposed a risk mitigation strategy to mitigate the risk of ocular toxicity, the panel felt that the specialized ophthalmic monitoring required during treatment may not be universally accessible in a real-world setting, particularly in rural areas.*

Panel members who voted "Yes" to Voting question #1 noted that belantamab mafodotin in combination with bortezomib and dexamethasone has activity as the results met the primary endpoint of PFS and demonstrated significance for the key secondary endpoint of overall survival.

One member, the patient representative, voted "Yes" on both voting questions, expressing concerns of the panel was overlooking the benefits of belantamab mafodotin and its potential of being a novel treatment option for an incurable disease.

Ultimately, the Committee acknowledged that the drug combinations are active and demonstrated clinical benefit. However, the Committee found the efficacy results alone to be unpersuasive, due to the lack of dose optimization, unfavorable risk:benefit profile in the context of the ocular toxicity, homogeneous population enrolled in the study, and questionable feasibility of the mitigation strategies proposed for ocular toxicity to ensure drug safety during treatment.

Please see the transcript for details of the Committee's discussion.

The meeting was adjourned at approximately 12:52 p.m. ET.