Food and Drug Administration
Center for Drug Evaluation and Research

Final Summary Minutes of the Oncologic Drugs Advisory Committee Meeting
July 14, 2020

Location: Please note that due to the impact of the COVID-19 pandemic, all meeting participants joined this advisory committee meeting via an online teleconferencing platform.

Topic: The committee discussed 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.

These summary minutes for the July 14, 2020 meeting of Oncologic Drugs Advisory Committee (ODAC) of the Food and Drug Administration were approved on November 13, 2020.

I certify that I attended the July 14, 2020 meeting of the ODAC meeting of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/	**/s/**
Yvette Waples, PharmD	Philip C. Hoffman, MD
Acting Designated Federal Officer, ODAC	Chairperson, ODAC

Final Summary Minutes of the Oncologic Drugs Advisory Committee Meeting
July 14, 2020

The Oncologic Drugs Advisory Committee (ODAC) of the Food and Drug Administration, Center for Drug Evaluation and Research met on July 14, 2020. The meeting presentations were heard, viewed, captioned, and recorded through an online teleconferencing platform. Prior to the meeting, the members and temporary voting members were provided the briefing materials from the FDA and GlaxoSmithKline Intellectual Property Development Ltd. England. The meeting was called to order by Philip Hoffman, MD (Chairperson). The conflict of interest statement was read into the record by Yvette Waples, PharmD (Acting Designated Federal Officer). There were approximately 1300 people online. There were nine (9) 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 discussed 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.

Attendance:
ODAC Members Present (Voting): Massimo Cristofanilli, MD, FACP; Jorge A. Garcia, MD, FACP; Susan Halabi, PhD; Christian S. Hinrichs, MD; Philip C. Hoffman, MD (Chairperson); David E. Mitchell (Consumer Representative); Anthony D. Sung, MD

ODAC Members Not Present (Voting): Jaffer A. Ajani, MD; Alberto S. Pappo, MD

ODAC Member Present (Non-Voting): Jonathan D. Cheng, MD (Industry Representative)

Temporary Members (Voting): James Chodosh, MD, MPH; John DeFlice, MD (Patient Representative); Brad H. Feldman, MD; Heidi D. Klepin, MD, MS; Grzegorz S. Nowakowski, MD; Gita Thanarajasingam, MD; Thomas S. Uldrick, MD, MS

FDA Participants (Non-Voting): Richard Pazdur, MD; Nicole Gormley, MD; Bindu Kanapuru, MD; Andrea Baines, MD, PhD; Wiley Chambers, MD

Designated Federal Officer (Non-Voting): Yvette Waples, PharmD (Acting)

Open Public Hearing Speakers: Jenny Ahlstrom (Myeloma Crowd); Chris Greklek; Anne Quinn Young, MPH (Multiple Myeloma Research Foundation; *statement read by Mary Derome*); Edwina Moscaritolo; Marguerite McDonald, MD, FACS; Meg Seymour, PhD (National Center for Health Research); Ola Landgren, MD, PhD (*statement read by Paul G.*

Richardson, MD); Paul G. Richardson, MD (Dana-Farber Cancer Institute); Sue Glick *(statement read by Chris Greklek*)

The agenda was as follows:

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
TECHNICAL BREAK	
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
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
Belantamab Mafodotin: Overall Clinical Safety	**Hesham Abdullah, MD, MSc, RAC** Senior Vice President Oncology Clinical Development GlaxoSmithKline

APPLICANT PRESENTATIONS (cont.)

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

FDA PRESENTATION

BLA 761158: Belantamab Mafodotin	**Andrea C. Baines, MD, PhD** Clinical Reviewer DMH2, OOD, OND, CDER, FDA

Clarifying Questions to Presenters

LUNCH

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

ADJOURNMENT

Questions to the Committee:

1. **DISCUSSION:** Discuss whether the risk of ocular toxicity has been adequately characterized in Study 205678 (DREAMM-2) to allow for an assessment of the benefit-risk profile.

   Committee Discussion: *There was not a consensus on whether the risk of ocular toxicity was adequately characterized in the DREAMM-2 study. One committee member agreed that the ocular toxicity was adequately characterized during the trial period, but stated the concern that there is not clear data of this toxicity with longer duration of use. On the other hand, another committee member stated that the DREAMM-2 study was not able to adequately characterize the risks of ocular toxicity that was noted in the trial; however, there are*

existing data regarding ocular toxicity across other malignancies. A couple of members also commented that the ocular toxicity profile should have been studied for a longer period of time as it was not fully explored. Please see the transcript for details of the committee discussion.

2. **DISCUSSION:** Discuss the impact of ocular toxicity on the benefit-risk profile for belantamab mafodotin.

   Committee Discussion: *Overall, the committee members agreed that the impact of ocular toxicity on the benefit-risk profile of belantamab mafodotin is reasonable and likely to be tolerated by patients considering the limited options. The members further commented that the Risk Evaluation and Mitigation Strategy (REMS), which includes ophthalmic exams, would help identify ocular adverse events early. The following concerns were stated: 1) the feasibility of access to ocular specialists in a community setting who are knowledgeable in the drug and its adverse events (due to the need of consistent monitoring); 2) the level of reversibility in patients with an ocular adverse event. Please see the transcript for details of the committee discussion.*

3. **VOTE:** Does the demonstrated benefit of belantamab mafodotin outweigh the risks in the proposed patient population with multiple myeloma?

   Vote Result: Yes: 12 No: 0 Abstain: 0 No Vote: 2

   Committee Discussion: *With the exception of the two members not in attendance for the vote, the committee unanimously voted "Yes", that the demonstrated benefit of belantamab mafodotin outweigh the risks in the proposed patient population with relapsed or refractory multiple myeloma. The committee agreed that there is lack of therapeutic options available and that belantamab mafodotin was shown to be effective in the data presented. In regards to the concern of ocular toxicity, the committee noted the importance of the REMS and the collaboration between oncologists and ophthalmologists for early identification and/or management of the adverse event. Please see the transcript for details of the committee discussion.*

The meeting was adjourned at approximately 4:00 p.m.