HemaSphere

EHA EUROPEAN HEMATOLOGY ASSOCIATION

P864 A PHASE 1 STUDY OF BELANTAMAB MAFODOTIN IN COMBINATION WITH STANDARD OF CARE IN NEWLY DIAGNOSED MULTIPLE MYELOMA: AN INTERIM ANALYSIS OF DREAMM-9

Topic: 14. Myeloma and other monoclonal gammopathies - Clinical

Saad Z Usmani*[1], Michał Mielnik[2], Ja Min Byun[3], Aránzazu Alonso Alonso[4], Al-Ola Abdallah[5], Mamta Garg[6], Hang Quach[7], Chang-Ki Min[8], Wojciech Janowski[9], Enrique Maria Ocio San Miguel[10], Katja Weisel[11], Albert Oriol[12], Irwindeep Sandhu[13], Paula Rodríguez-Otero[14], Karthik Ramasamy[15], Jacqueline Egger[16], Danaè Williams, Jie Ma, Morrys Kaisermann, Marek Hus[2]

[1]Memorial Sloan Kettering Cancer Center, New York City, United States; [2]Medical University Of Lublin, Lublin, Poland; [3]Seoul National University Hospital, Seoul, Korea, Rep. Of South; [4]Hospital Quirón Madrid, Madrid, Spain; [5]University Of Kansas Medical Center, Us Myeloma Research Innovations Research Collaborative (Usmirc), Westwood, United States; [6]Leicester Royal Infirmary, Leicester, United Kingdom; [7]St Vincent's Hospital Melbourne, University Of Melbourne, Melbourne, Australia; [8]The Catholic University Of Korea Seoul St. Mary's Hospital, Seoul, Korea, Rep. Of South; [9]Calvary Mater Newcastle, Newcastle, Australia; [10]Hospital Universitario Marqués De Valdecilla (Idival), Universidad De Cantabria, Santander, Spain; [11]University Medical Center Hamburg-Eppendorf, Hamburg, Germany; [12]Institut Català D'oncologia And Institut Josep Carreras - Hospital Universitari Germans Trias I Pujol (Hugtp), Badalona, Spain; [13]University Of Alberta, Alberta, Canada; [14]Department Of Hematology, Clínica Universidad De Navarra, Pamplona, Spain; [15]Churchill Hospital, Oxford, United Kingdom; [16]Gsk, Herfordshire, United Kingdom

Background:

Belantamab mafodotin (belamaf) is a B-cell maturation antigen-binding antibody-drug conjugate that eliminates myeloma cells via direct cell killing and anti-myeloma immune responses. DREAMM-9 (NCT04091126) is an ongoing Phase 1, randomized, dose and schedule evaluation study. Herein, we report updated interim-analysis data.

Aims:

DREAMM-9 aims to evaluate belamaf plus bortezomib, lenalidomide, and dexamethasone (VRd) in adult patients with transplant-ineligible newly diagnosed multiple myeloma and to establish the recommended dose for future development of belamaf combination therapies in the first-line setting.

Methods:

Belamaf dose cohorts are shown in the **Table**. VRd was given every 3 weeks until cycle 8, and Rd every 4 weeks thereafter (Q3/4W). Following safety data from Cohorts 2–5, Cohorts 6–7 were opened in parallel (randomized 1:1) and have shorter follow-up (**Table**). Safety was the primary endpoint; efficacy and tolerability were secondary endpoints. Minimal residual disease (MRD) was assessed by next-generation sequencing (10^{-5}).

Results:

As of data cutoff (October 20, 2022), 93 patients were treated across Cohorts 1–7. Median age (range) was 73 (51–88) years, 55% of patients were male, and 84% were white. The most commonly reported non-ocular adverse events (AEs) across all cohorts were thrombocytopenia (46%), constipation (36%), diarrhea (34%), and peripheral sensory neuropathy (31%). Overall, belamaf-related Grade ≥3 AEs occurred in 35% of patients and led to belamaf dose reductions in 7% and dose delays in 63% of all treated patients. Grade ≥3 ocular AEs (keratopathy and visual acuity [KVA] scale) occurred in 53% of all patients and led to dose reductions in 12% and dose delays in 52% of overall patients. Fatal AEs occurred in 7 patients, all unrelated to study treatment. Efficacy results and ocular AEs are summarized in the **Table**: 100% of patients responded in Cohort 1 (1.9 mg/kg Q3/4W) and Cohort 3 (1.9 mg/kg Q6/8W). Median time to very good partial response or better (≥VGPR) ranged from 2.1 to 3.1 months across

Copyright Information: (Online) ISSN: 2572-9241
© 2023 the Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the European Hematology Association. This is an open access Abstract Book distributed under the Attribution-NonCommercial-NoDerivs (CC BY-NC-ND) which allows third parties to download the articles and share them with others as long as they credit the author and the Abstract Book, but they cannot change the content in any way or use them commercially.

Abstract Book Citations: Authors, Title, HemaSphere, 2023;7(S3):pages. The individual abstract DOIs can be found at https://journals.lww.com/hemasphere/pages/default.aspx.

Disclaimer: Articles published in the journal HemaSphere exclusively reflect the opinions of the authors. The authors are responsible for all content in their abstracts including accuracy of the facts, statements, citing resources, etc.

cohorts. Highest MRD negativity rates (≥VGPR) were seen in Cohort 1 (83%) and Cohort 3 (67%).

Summary/Conclusion:

This updated interim analysis demonstrates that belamaf plus VRd has no new safety signals and provides early and deep anti-myeloma responses in patients with transplant-ineligible newly diagnosed multiple myeloma, with high MRD negativity rates.

Funding:

GSK (Study 209664); drug linker technology licensed from Seagen Inc.; monoclonal antibody produced using POTELLIGENT Technology licensed from BioWa.

This abstract was previously submitted to the American Society of Clinical Oncology (ASCO) Annual Meeting, June 2–6, 2023, and is submitted on behalf of the original authors with their permission. ©2023 American Society of Clinical Oncology, Inc. Reused with permission. All rights reserved.

Table. Efficacy and Safety Summary

Cohorts	1 **1.9 mg/kg Q3/4W n=12	2 **1.4 mg/kg Q6/8W n=12	3 **1.9 mg/kg Q6/8W n=12	4 **1.0 mg/kg Q3/4W n=15*	5 **1.4 mg/kg Q3/4W n=13	6 1.4 mg/kg then 1.0 mg/kg Q9/12W n=14	7 1.9 mg/kg then 1.4 mg/kg Q9/12W n=15*
Grade ≥3 ocular AEs (KVA; N=91), %	83	58	92	57	85	7	0
Median follow-up, months	27.6	16.0	16.2	15.3	15.2	2.5	2.0
ORR, %	100	92	100	80	92	79	53
**≥CR	75	83	83	53	62	14	7
VGPR	17	8	17	20	23	21	27
PR	8	0	0	7	8	43	20
MR/SD	0	8	0	7	0	7	7
MRD							

Copyright Information: (Online) ISSN: 2572-9241
© 2023 the Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the European Hematology Association. This is an open access Abstract Book distributed under the Attribution-NonCommercial-NoDerivs (CC BY-NC-ND) which allows third parties to download the articles and share them with others as long as they credit the author and the Abstract Book, but they cannot change the content in any way or use them commercially.

Abstract Book Citations: Authors, Title, HemaSphere, 2023;7(S3):pages. The individual abstract DOIs can be found at https://journals.lww.com/hemasphere/pages/default.aspx.

Disclaimer: Articles published in the journal HemaSphere exclusively reflect the opinions of the authors. The authors are responsible for all content in their abstracts including accuracy of the facts, statements, citing resources, etc.

[-], % **≥CR ≥VGP R Coho rts	75 83 1 **1.9 mg/kg Q3/4W n=12	33 33 2 **1.4 mg/kg Q6/8W n=12	58 67 3 **1.9 mg/kg Q6/8W n=12	33 33 4 **1.0 mg/kg Q3/4W n=15 *	46 46 5 **1.4 mg/kg Q3/4W n=13	7 6 14 1.4 mg/kg then 1.0 mg/kg Q9/12W n=14	0 7 7 1.9 mg/kg then 1.4 mg/kg Q9/12W n=15 *
*Safe ty popula tion n=14. AEs, advers e events ; CR, comple te respon se; KVA, kerato pathy and visual acuity scale; MR, minor respon se; MRD, minima l residu al diseas e; ORR, overal l respon se rate; OS, overal l surviv al; PR, partia l respon se; Q, every; SD, stable diseas e; VGPR, very good partia l respon se; W, weeks.							

Copyright Information: (Online) ISSN: 2572-9241
© 2023 the Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the European Hematology Association. This is an open access Abstract Book distributed under the Attribution-NonCommercial-NoDerivs (CC BY-NC-ND) which allows third parties to download the articles and share them with others as long as they credit the author and the Abstract Book, but they cannot change the content in any way or use them commercially.

Abstract Book Citations: Authors, Title, HemaSphere, 2023;7(S3):pages. The individual abstract DOIs can be found at https://journals.lww.com/hemasphere/pages/default.aspx.

Disclaimer: Articles published in the journal HemaSphere exclusively reflect the opinions of the authors. The authors are responsible for all content in their abstracts including accuracy of the facts, statements, citing resources, etc.