Bristol Myers Squibb™

June 8, 2022

Steven D. Pearson, MD, MSc
Institute for Clinical and Economic Review
14 Beacon Street, Boston, MA 02108

Re: ICER's Multiple Myeloma Review: 12 Month Follow-up

Dear Dr. Pearson,

Bristol Myers Squibb (BMS) appreciates the opportunity to provide further evidence in response to the Institute for Clinical and Economic Review (ICER) 12-month assessment update of the Anti B-Cell Maturation Antigen CAR T-cell and Antibody Drug Conjugate Therapy for Heavily Pre-Treated Relapsed and Refractory Multiple Myeloma (MM).

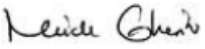
BMS would like to make stakeholders aware of the following new data for idecabtagene vicleucel (ide-cel, Abecma®):

- Hansen DK, Sidana S, Peres L, et al. Idecabtagene vicleucel (Ide-cel) chimeric antigen receptor (CAR) T-cell therapy for relapsed/refractory multiple myeloma (RRMM): Real-world experience**.** Poster presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting; June 3-7, 2022.
- Rytlewski J, Fuller J, Mertz DR, et al. Correlative analysis to define patient profiles associated with manufacturing and clinical endpoints in relapsed/refractory multiple myeloma (RRMM) patients treated with idecabtagene vicleucel (ide-cel; bb2121), an anti-BCMA CAR T cell therapy**.** Poster presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting; June 3-7, 2022
- Anderson LD, Munshi NC, Shah N, et al. Idecabtagene vicleucel (ide-cel), a BCMA-directed CAR T cell therapy, in relapsed and refractory multiple myeloma: updated KarMMa results. Poster presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting; June 4-8, 2021; Virtual Meeting.
- Rodriguez-Otero P, Mojebi A, Ayers D, et al. Matching-adjusted indirect comparisons of efficacy outcomes in patients with relapsed and refractory multiple myeloma for idecabtagene vicleucel (KarMMa) versus selinexor plus dexamethasone (STORM part 2) and belantamab mafodontin (DREAMM-2): updated analysis with longer follow-up. Poster presentation at the 63rd American Society of Hematology (ASH) Annual Meeting; December 11-14, 2021; Atlanta, GA.
- Shah N, Mojebi A, Ayers D, et al. Indirect treatment comparison of idecabtagene vicleucel versus conventional care in triple-class exposed multiple myeloma. *J Comp Eff Res.* 2022 Apr 29. doi: 10.2217/cer-2022-0045. Epub ahead of print. PMID: 35485211.

BMS would like to thank ICER for the opportunity to submit additional evidence.

Sincerely,

Kaleen Barbary, PharmD
Director, Worldwide Scientific Content & US Market Capabilities, Hematology/ Cell Therapy



Mecide Gharibo, MD
Vice President, US Medical Affairs, Hematology

Anthony Barisano
Vice President, US Health Economics and Outcomes Research

June 6, 2022

Sumati Rao Ph.D.
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Boston, MA 02108

Re: ICER's Assessment of Treatments for Multiple Myeloma: 12-month update

Dear Dr. Pearson,

GlaxoSmithKline (GSK) appreciates the opportunity to provide further evidence in response to the Institute for Clinical and Economic Review's (ICER) 12-month assessment update for treatments in heavily pre-treated relapsed and refractory multiple myeloma.

GSK would like to make ICER aware of publication[1] of the longer-term efficacy and safety outcomes in DREAMM-2 after 13 months of follow-up amongst patients who received belantamab mafodotin 2.5 mg/kg. Median estimated duration of response, overall survival and progression-free survival were 11.0 months (95% CI, 4.2 months to not reached), 13.7 months (95% CI, 9.9 months to not reached) and 2.8 months (95% CI, 1.6-3.6 months), hence demonstrating sustained efficacy. No new safety signals were identified.

- Lonial S, Lee HC R, Badros A, et al. Longer term outcomes with single-agent belantamab mafodotin in patients with relapsed or refractory multiple myeloma: 13-month follow-up form the pivotal DREAMM-2 study. *Cancer*. 2021;127(22):4198-4212. DOI: https://doi.org/10.1002/cncr.33809

Additionally, the following publication[2] shows results of a matching indirect comparison on safety and efficacy of belantamab mafodotin (2.5 mg/kg; n=97) versus selinexor plus low-dose dexamethasone (80 mg + 20 mg, respectively; n=123) using population weights for clinically validated effect modifiers and prognostics factors. The relative efficacy of belantamab mafodotin versus standard of care (from MAMMOTH study) on OS was then obtained by Bucher's indirect treatment comparison demonstrating a significantly improved OS of 0.29 (95% CI, 0.16, 0.54).

- Prawitz T, Popat R, Suvannasankha A, et al. DREAMM-2: Indirect comparisons of Belantamab mafodotin vs Selinexor + Dexamethasone and Standard of Care Treatments in Relapsed/ Refractory Multiple Myeloma. *Advances in Therapy*. 2021; 38:5501-5518. DOI: https://doi.org/10.1007/s12325-021-01884-7

We would like to thank ICER for the opportunity to submit additional evidence.

Sincerely,

Sumati Rao Ph.D.,
Sr Director and Therapy Area Head, Oncology,
US Value, Evidence and Outcomes.

References

1. Lonial S, Lee HC R, Badros A, et al. Longer term outcomes with single-agent belantamab mafodotin in patients with relapsed or refractory multiple myeloma: 13-month follow-up form the pivotal DREAMM-2 study. *Cancer*. 2021;127(22):4198-4212. DOI: https://doi.org/10.1002/cncr.33809

2. Prawitz T, Popat R, Suvannasankha A, et al. DREAMM-2: Indirect comparisons of Belantamab mafodotin vs Selinexor + Dexamethasone and standard of care treatments in relapsed/ refractory multiple myeloma. *Advances in Therapy*. 2021; 38:5501-5518. DOI: https://doi.org/10.1007/s12325-021-01884-7