Belantamab mafodotin is not approved to treat the condition discussed in this summary.

The DREAMM-2 Study: Effects of Belantamab Mafodotin in Patients With Multiple Myeloma Who Had Already Been Treated With Several Anti-Myeloma Treatments

This document provides a short summary of information about this Phase II multiple myeloma clinical study presented at the 2020 American Society of Clinical Oncology Congress (virtual format). At the end of this document, there are links to websites where you can find more information about this study.

Full title of presentation:	Pivotal DREAMM-2 Study: Single-agent Belantamab Mafodotin (GSK2857916) in Patients With Relapsed/Refractory Multiple Myeloma (RRMM) Refractory to Proteasome Inhibitors (PIs), Immunomodulatory Agents, and Refractory and/or Intolerant to Anti-CD38 Monoclonal Antibodies (mAbs)
Study number:	205678; NCT03525678
Who sponsored the study:	GlaxoSmithKline (GSK)

Contents

Why was the DREAMM-2 study carried out?

To find out:

- How effective belantamab mafodotin (belamaf) is at treating patients with multiple myeloma who have already received several treatments (the disease can be more difficult to treat in these individuals)
- Which side effects occur and how these compare with findings from earlier studies of the drug
- Which dose of belamaf is the best

About the DREAMM-2 study

Patients could join this study if they had previously received at least 3 separate therapies. These must have included certain regular, standard treatments for multiple myeloma.

Everyone in the study received belamaf, but they were split into two groups:

2.5 mg/kg

One group received a dose of 2.5 milligrams per kilogram (mg/kg) of their body weight. This was given once every 3 weeks.

3.4 mg/kg

One group received a dose of 3.4 milligrams per kilogram (mg/kg) of their body weight. This was given once every 3 weeks.

The investigators recorded how well each patient responded clinically to treatment, and the impact on outcomes. They also monitored any side effects and other signs relating to drug safety.

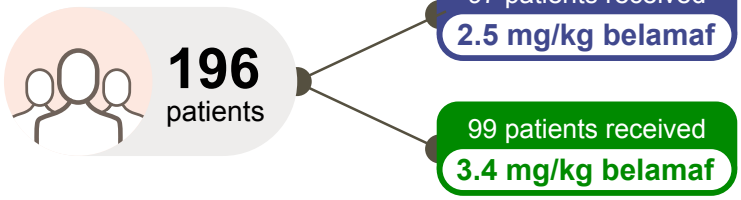
Timeline: June 2018 to January 2019 (enrollment); data cut-off date January 2020.

About this analysis

The initial results from this study after **6 months** showed that belamaf had **anti-myeloma effects** in many patients, with **acceptable side effects**.

The current analysis of the study was carried out to find out how effective belamaf is at treating multiple myeloma, and which side effects occur, after **13 months** of follow-up.

Study patients



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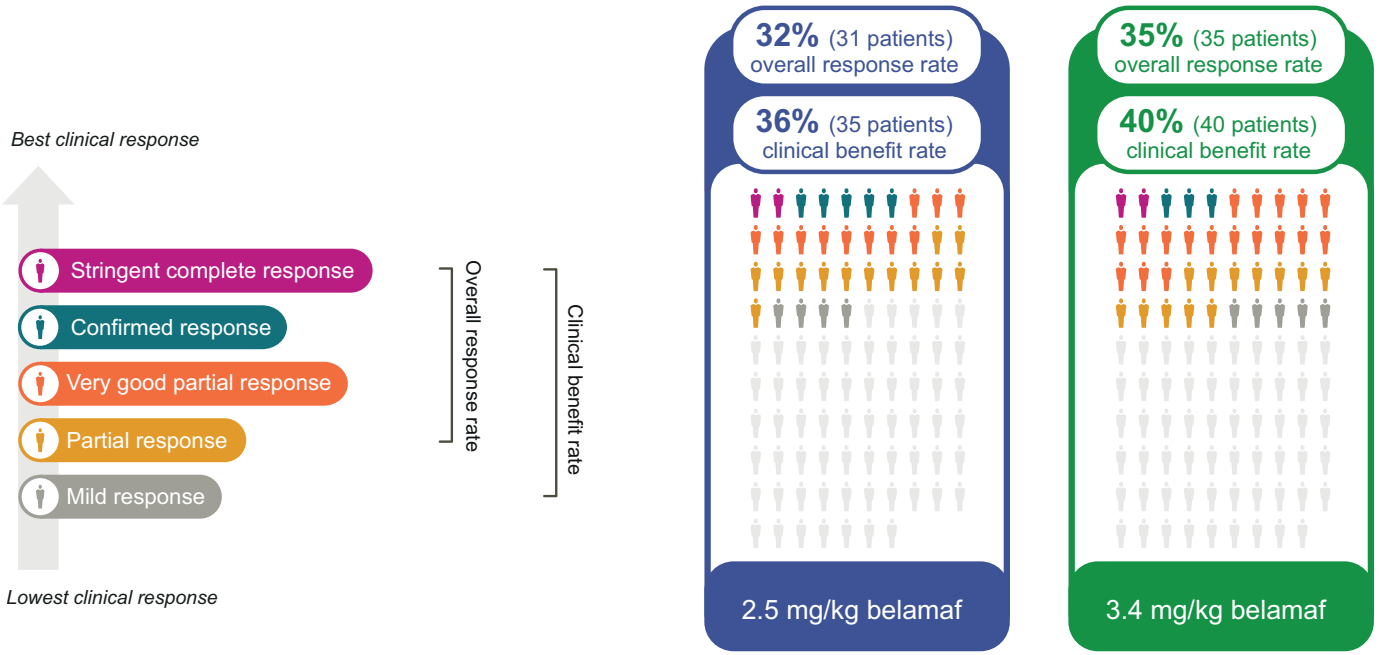
What were the results of the study after 13 months of follow-up?

Over one-third of patients responded to belamaf and showed clinical benefit.



Response Criteria	Response Categories	DREAMM-2 Results

How did belamaf treatment impact outcomes?

The median* length of time that patients showed a clinical response was:

2.5 mg/kg	3.4 mg/kg
11.0 months	6.2 months

Median* time that patients remained free from multiple myeloma worsening:

2.5 mg/kg	2.8 months
3.4 mg/kg	3.9 months

Median* time that patients survived:

2.5 mg/kg	13.7 months
3.4 mg/kg	13.8 months

*The median is the middle value when all values are sorted from lowest to highest, so half of all values fall above the median and half fall below.

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What side effects occurred during the study?

Most patients experienced at least one side effect

2.5 mg/kg belamaf		3.4 mg/kg belamaf	
42% (40 of 95 patients)	Reported a serious side effect	47% (47 of 99 patients)	Reported a serious side effect
9% (9 of 95 patients)	Stopped treatment due to side effects	12% (12 of 99 patients)	Stopped treatment due to side effects

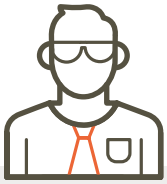
The most common side effects of moderate or severe intensity were:

- reductions in the levels of red blood cells and cells that help the blood to clot (platelets), which are common in myeloma treatments.[1,2]
- changes to the cornea (the front part of the eye that covers the colored iris and the pupil).

Although changes to the cornea were the most common reason for reducing the dose or delaying treatment, most patients whose treatment was delayed continued to benefit from the anti-myeloma effects of belamaf during their time off treatment.

Guidance on where to find further information is available at the bottom of this summary.

What were the main conclusions reported by the researchers?



- **Belamaf may be an important new treatment option for patients with multiple myeloma.**
- **The anti-myeloma effects of belamaf were sustained after 13 months of follow-up in this group of patients who had previously been treated with several anti-myeloma treatments.**
- **The side effects of belamaf remained consistent with those reported previously.[3]**
- **Although patients commonly needed to have their dose of belamaf reduced to manage side effects, such as changes to the cornea, the anti-myeloma effects continued, or even improved, despite long interruptions in belamaf treatment.**

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Where can I find more information?

Clinical studies have unique study numbers that are included in publications and other information about the study. The unique study numbers associated with this study are shown below with internet links to other information.

Organization	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03525678
GlaxoSmithKline (GSK)	www.gsk-clinicalstudyregister.com	205678

- Full DREAMM-2 study publication: Lonial S, et al. Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM-2): a two-arm, randomised, open-label, phase 2 study. *Lancet Oncol* 2020;21(2):207–21: https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(19)30788-0/fulltext

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References

1. Wang X, *et al. Biomed Res Int* 2016;2016:6848902.

2. Zhang T, *et al. Oncotarget* 2017;8:34001–17.

3. Lonial S, *et al. Lancet Oncol* 2020;21(2):207–21.

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