

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

# The DREAMM-2 Study: What Were the Effects of Belantamab Mafodotin in Patients With Multiple Myeloma and Reduced Kidney Function?

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 the full study.

<b>Full title of presentation:</b>	DREAMM-2: Single-agent Belantamab Mafodotin (GSK2857916) in Patients With Relapsed/Refractory Multiple Myeloma (RRMM) and Renal Impairment
<b>Study number:</b>	205678; NCT03525678
<b>Who sponsored the study:</b>	GlaxoSmithKline (GSK)

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## 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 September 2019.

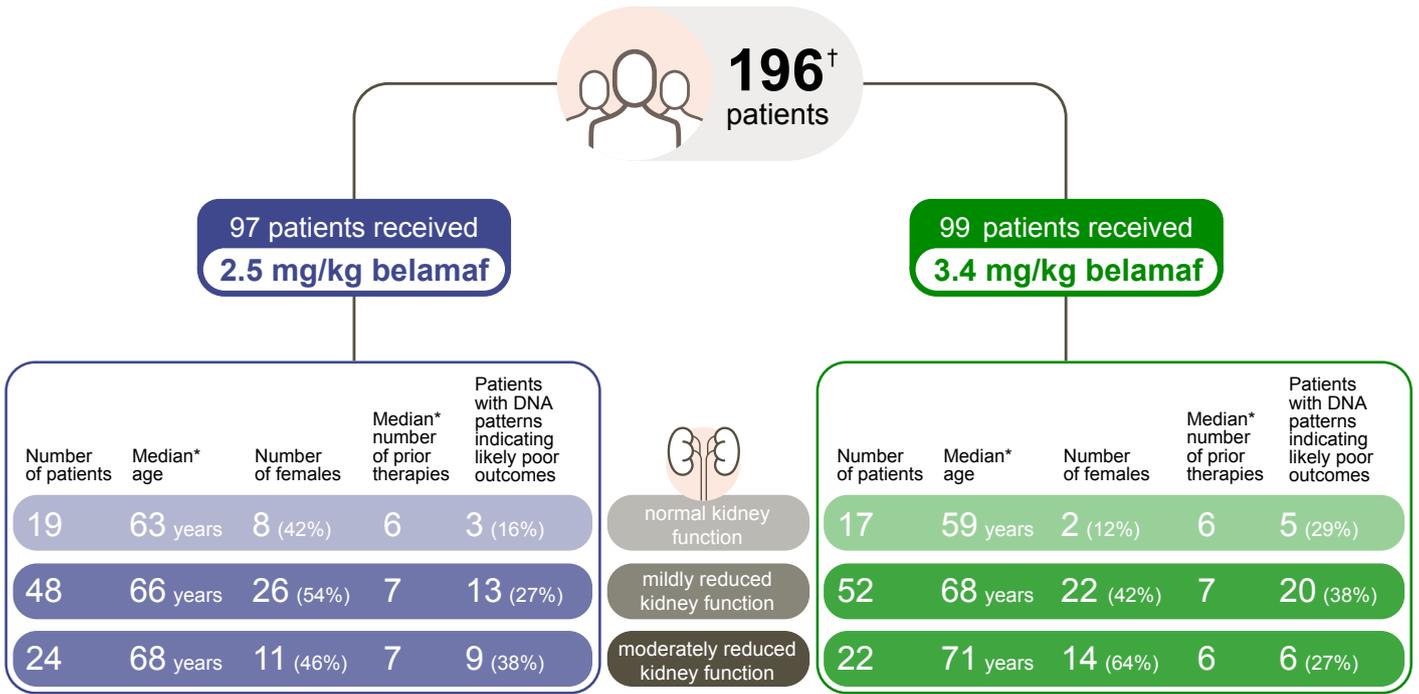
## About this analysis

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

The current analysis was carried out to find out how effective belamaf is, and which side effects occur, in **patients with reduced kidney function** after 9 months of follow-up.

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# Study patients

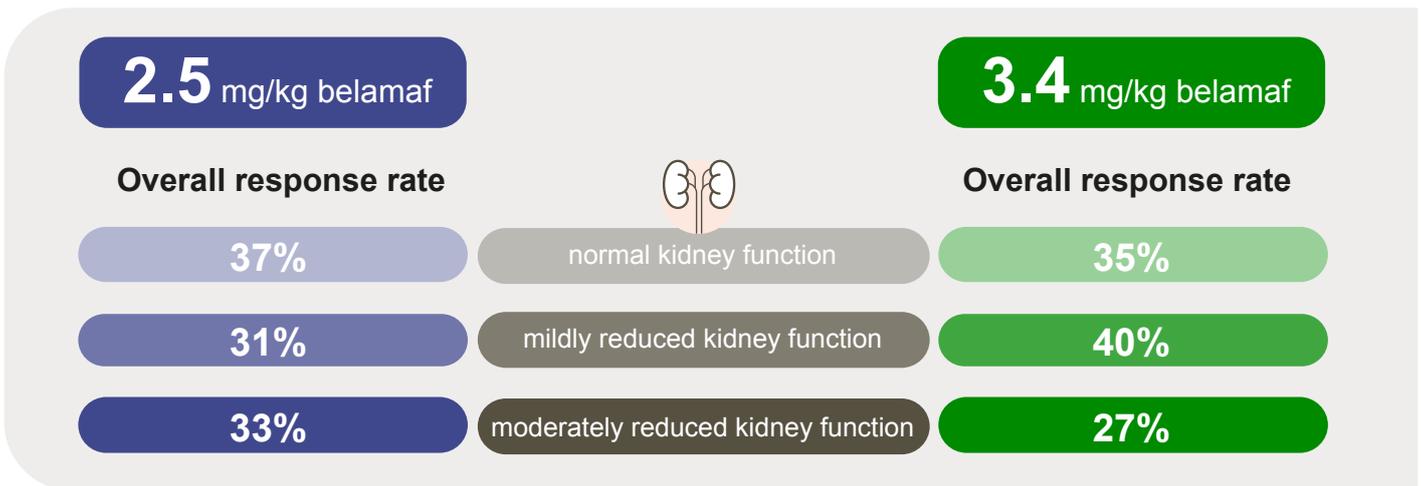


\*The median is the middle value when all values are sorted from lowest to highest, so half of all values fall above the median and half fall below.  
<sup>†</sup>The total number of patients in this study was 196, including 7 patients with severely reduced kidney function and 7 patients whose data were missing.

## What were the results of the study after 9 months of follow-up?

Belamaf was shown to be effective in patients with mildly or moderately reduced kidney function.

Around one-third of patients in all groups responded to belamaf and showed clinical benefit



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The median\* time that patients remained free from multiple myeloma worsening was similar in patients with or without reduced kidney function

**2.5** mg/kg belamaf

3.0 months

2.2 months

3.7 months



normal kidney function

mild kidney impairment

moderate kidney impairment

**3.4** mg/kg belamaf

2.8 months

3.9 months

3.4 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.

## What side effects occurred during the study?

Overall, the rates of side effects were similar among all groups of patients

**2.5** mg/kg belamaf

**3.4** mg/kg belamaf



Changes to the cornea (the front part of the eye that covers the colored iris and the pupil) was the most common side effect in all groups:



95% (18 patients)

normal kidney function

78% (14 patients)

69% (33 patients)

mildly reduced kidney function

77% (40 patients)

63% (15 patients)

moderately reduced kidney function

64% (14 patients)



Serious side effects:



37% (7 patients)

normal kidney function

44% (8 patients)

33% (16 patients)

mildly reduced kidney function

48% (25 patients)

50% (12 patients)

moderately reduced kidney function

50% (11 patients)

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

Compared to those with normal kidney function, **more patients with reduced kidney function had reductions in the levels of various blood cells** (which is common in myeloma treatments)<sup>1,2</sup> or fever

Signs of **active kidney conditions** were rare and **kidney function got worse in less than one-quarter of patients in all groups**

The **most common** side effects of **moderate or severe intensity** were **reductions in the levels of various blood cells** and **changes to the cornea (the front part of the eye that covers the colored iris and the pupil)**

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## What were the main conclusions reported by the researchers?



- Belamaf may be an important new treatment for patients with multiple myeloma and reduced kidney function.
- Most patients in the study had mildly or moderately reduced kidney function; this reflects the real-world multiple myeloma population in which reduced kidney function is relatively common.<sup>3</sup>
- The anti-myeloma effects of belamaf, and the side effects experienced, were similar in patients with reduced kidney function and in patients with normal kidney function.
- The anti-myeloma effects of belamaf in patients with reduced kidney function were similar to those seen in the overall DREAMM-2 study population.<sup>4</sup>
- Further analysis of the effects of belamaf in patients with reduced kidney function, particularly those with severely reduced kidney function, is planned.

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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)	<a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a>	NCT03525678
GlaxoSmithKline (GSK)	<a href="http://www.gsk-clinicalstudyregister.com">www.gsk-clinicalstudyregister.com</a>	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](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. Yadav P, et al. *Kidney Dis* 2015;1:241–57.

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

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