

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

# The DREAMM-6 Study: What Side Effects Were Experienced When Patients With Multiple Myeloma Were Treated With Belantamab Mafodotin in Combination With Another Multiple-Myeloma Treatment, Bortezomib/Dexamethasone, And How Effective Was This Combination In Treating Multiple Myeloma?

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

**Full title of presentation:** DREAMM-6: Safety and Tolerability of Belantamab Mafodotin in Combination with Bortezomib/Dexamethasone in Relapsed/Refractory Multiple Myeloma (RRMM)

**Study number:** 207497; NCT03544281

**Who sponsored the study:** GlaxoSmithKline (GSK)

## Contents

Why was the DREAMM-6 study carried out?

About the DREAMM-6 study

Study patients

What were the initial results of the study in this group of patients?

What were the main conclusions reported by the researchers?

Where can I find more information?

# Why was the DREAMM-6 study carried out?

To find out:



What side effects occur when patients with multiple myeloma are treated with belantamab mafodotin (belamaf) in combination with other multiple-myeloma treatments.

How effective belamaf is at treating myeloma when given in combination with other multiple-myeloma treatments.

## About the DREAMM-6 study

Patients with multiple myeloma could join this study if they had previously received at least one multiple-myeloma therapy.

The study had two arms: A and B.

**A**

In Arm A, patients received belamaf in combination with lenalidomide/dexamethasone (LenDex).

**B**

In Arm B, patients received belamaf in combination with bortezomib/dexamethasone (BorDex).

Here, we focus on Arm B.

► [Back to title page](#)

## Arm B: belamaf with BorDex

### Part 1

No unmanageable side effects in either dosing group in Part 1

### Part 2

12 patients received BorDex  
belamaf 3.4 mg/kg SPLIT

6 patients  
received BorDex  
belamaf 3.4 mg/kg SINGLE

9 patients received BorDex  
belamaf 3.4 mg/kg SINGLE

12 patients received BorDex  
belamaf 2.5 mg/kg SPLIT

6 patients received BorDex  
belamaf 2.5 mg/kg SINGLE

12 patients received BorDex  
belamaf 2.5 mg/kg SINGLE

Results for  
18 patients

1

One group of patients received the following treatments in every cycle\*:

- Belamaf 2.5 mg per kg of their body weight once +
- Bortezomib four times +
- Dexamethasone eight times.

2

As there were no unmanageable side effects, a second group of patients received in every cycle\*:

- Belamaf 3.4mg/kg per kg of their body weight once +
- Bortezomib four times +
- Dexamethasone eight times.

3

In Part 2, everyone received belamaf with BorDex, but they were divided into four groups according to:

- the dose of belamaf (2.5 mg/kg or 3.4 mg/kg)
- whether the belamaf was given all together on 1 day (SINGLE) or in two half doses on 2 different days (SPLIT)

The investigators monitored for any unwanted medical events and other signs of drug safety and recorded how well each patient responded clinically to treatment.

4

Below, we show results from 18 patients treated with belamaf at a dose of 2.5 mg/kg, given all together on 1 day, in combination with BorDex.

\*1 cycle given every 3 weeks

## Study patients

59 patients in total were treated with belamaf and BorDex in Arm B of the study, of which **18 patients** received 2.5 mg/kg of belamaf once every 3 weeks.



The median\* age of the 18 patients was **67 years**  
**7 (39%)** of the 18 patients were **female**



Some of the patients had characteristics suggesting that their multiple myeloma might be difficult to treat. When they joined the study:

**44%**

(8 of 18) patients had received at least 4 previous treatments

**17%**

(3 of 18) patients had advanced disease

**33%**

(6 of 18) patients had genetic markers indicating likely poor outcomes

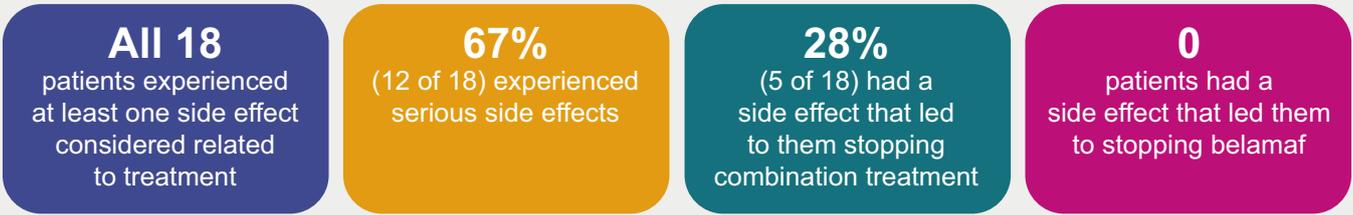
\*The median is the middle value when all values are sorted from lowest to highest, so half of all values fall above the median and half fall below

[▶ Back to title page](#)

# What were the initial results of the study in this group of patients?

## What side effects occurred during the DREAMM-6 study?

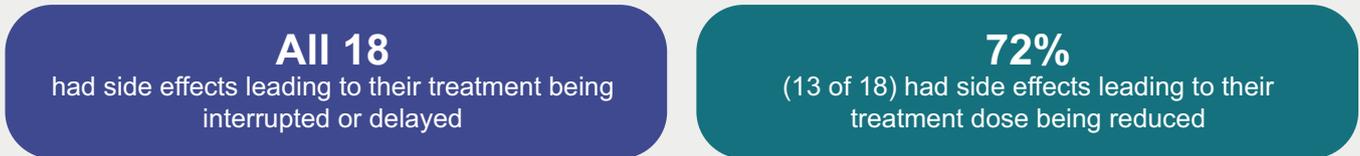
As of **March 30, 2020**, the 18 patients had received a median\* of **18 weeks** of treatment



The **side effects** experienced with **combination treatment** were **similar** to those seen with the **individual components** of the combination.

\*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.

Side effects were managed by **delaying** the next dose of treatment or **reducing** the dose given

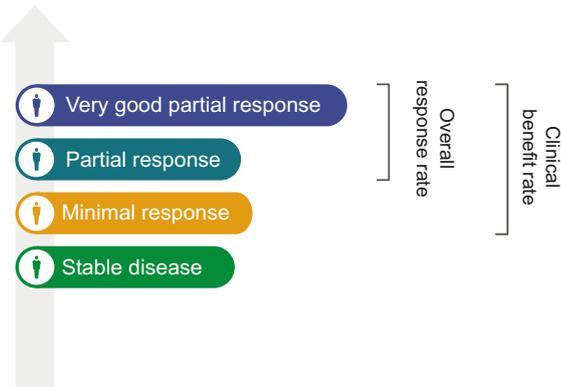


All **dose interruptions/delays** and **dose reductions** were because of **changes in the cornea** (the front part of the eye that covers the colored iris and pupil), which is expected with belamaf,<sup>1</sup> or **reductions in the levels of cells that help to clot the blood (platelets)**, which is common with myeloma treatments.<sup>2,3</sup>

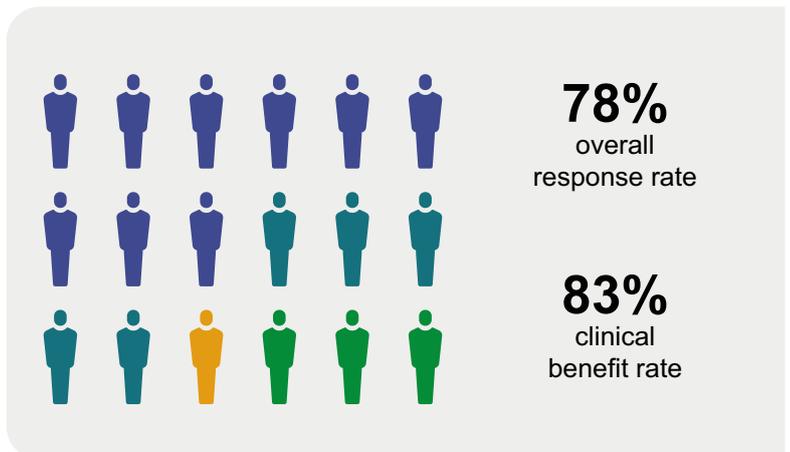
## What were the anti-myeloma effects of combination treatment?

Most patients responded to treatment and showed a clinical benefit.

Best clinical response



Lowest clinical response



[▶ Back to title page](#)

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



- So far, 18 patients have received belamaf 2.5 mg/kg in combination with BorDex in Arm B of the DREAMM-6 study.
- Early data indicate that the side effects experienced with this treatment combination are acceptable.
- The main side effects were:
  - changes to the cornea (expected with belamaf<sup>1</sup> and managed by modifying the dose), and
  - reductions in the levels of cells that help the blood to clot (platelets), which is common with myeloma treatments.<sup>2,3</sup>
- Initial data on the anti-myeloma effects of belamaf 2.5 mg/kg in combination with BorDex showed encouraging results in individuals who had received a median of 3 previous lines of anti-myeloma treatment.
- The DREAMM-6 study is ongoing. Data from the groups of patients who received other treatment doses and combinations are being collected and will be available in the future, to explore these early results further.

[▶ Back to title page](#)

# 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>	NCT02164513
GlaxoSmithKline (GSK)	<a href="http://www.gsk-clinicalstudyregister.com">www.gsk-clinicalstudyregister.com</a>	207497

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## References

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2. Wang X, *et al. Biomed Res Int* 2016;2016.6848902.
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[▶ Back to title page](#)