This document provides a short summary of this study for a general audience. You can find more information in the scientific summaries of the study. Links to those summaries are provided at the end of this document.

Study names

Short Title: A study to assess how well belantamab mafodotin (GSK2857916) works and how safe it is in patients with multiple myeloma who stopped responding to previous treatments.

Full Scientific Title: A phase II, open-label, randomised, two-arm study to investigate the efficacy and safety of two doses of the antibody drug conjugate GSK2857916 in participants with multiple myeloma who had three or more prior lines of treatment, are refractory to a proteasome inhibitor and an immunomodulatory agent and have failed an anti-CD38 antibody (DREAMM 2).

Study Number: 205678

Who sponsored this study?

GlaxoSmithKline (GSK)
GSK Clinical Support Help Desk
Website: clinicalsupporthd.gsk.com/contact.html
Email: GSKClinicalSupportHD@gsk.com

General information about the clinical study

When was this study done?

The study started in June 2018. The study is ongoing, but not enrolling new patients.

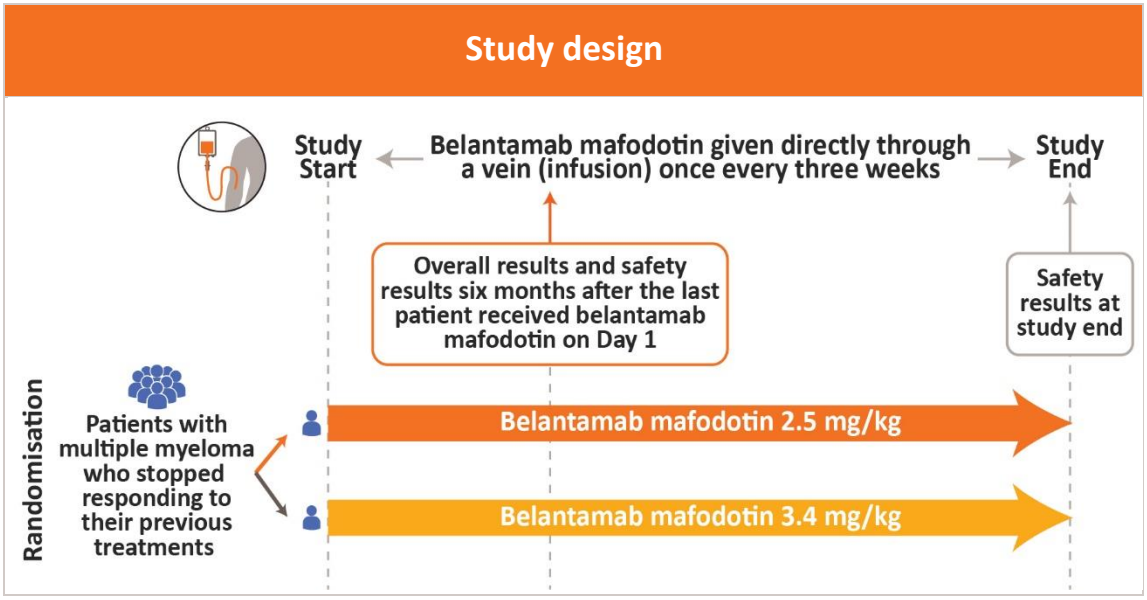
What was the main objective of this study?

Multiple myeloma is a cancer of white blood cells. Common symptoms include repeated infections, bone fractures, pain in bones, kidney problems, tiredness, and weight loss.

Belantamab mafodotin is a medicine that kills cancerous white blood cells. In this study, researchers wanted to see how well two different doses of belantamab mafodotin work in patients with multiple myeloma who stopped responding to previous treatments. They also studied the safety of belantamab mafodotin.

Which medicine was studied?

Patients received one of the two doses of belantamab mafodotin by chance (randomisation), as shown in the figure below. Throughout the course of the study, patients continued taking their supportive treatment(s) to treat multiple myeloma symptoms in addition to belantamab mafodotin.

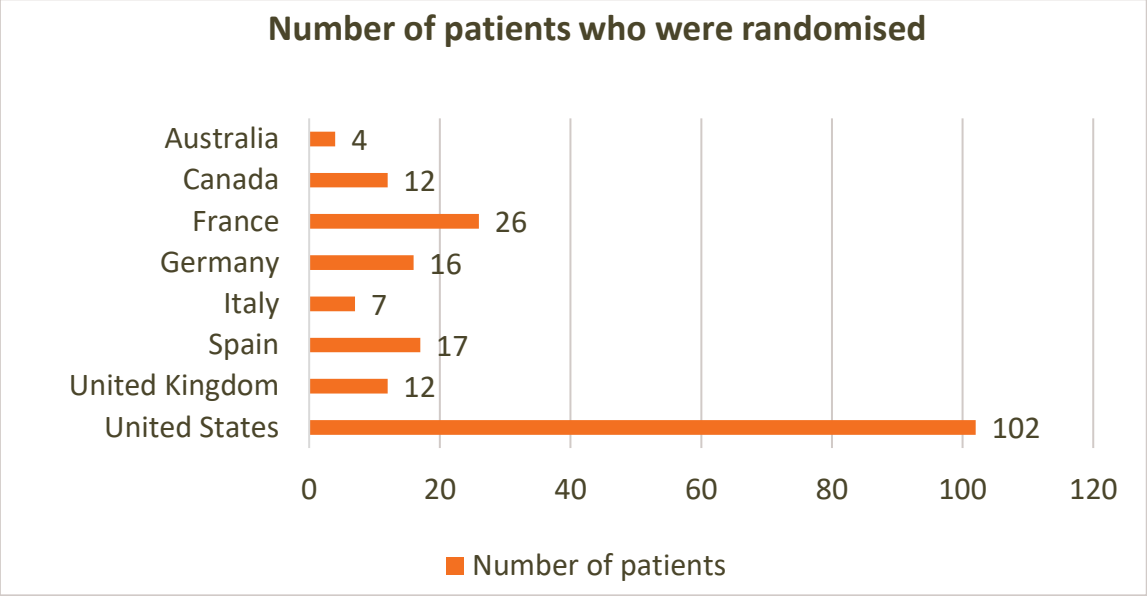


mg/kg = milligram per kilogram of body weight

Patients continued to receive belantamab mafodotin for as long as their disease was responding to treatment. Study doctors continued to assess the safety of belantamab mafodotin during this period.

Where was this study done?

Study sites were in eight countries.



Which patients were included in this study?

Studies have a list of requirements for patients who can enrol (inclusion criteria) and those who can't (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

Men and women with multiple myeloma were included in the study if they:

- Were at least 18 years old.
- Were not eligible for a bone marrow transplant or had a bone marrow transplant (patient's own healthy bone marrow used to replace diseased bone marrow) at least 100 days before starting the study.
- Stopped responding to three or more different types of treatments for multiple myeloma.
- Had specific multiple myeloma-related proteins that could be measured in blood and/or urine tests.
- Were capable of self-care as determined by a scoring scale before starting the study.

Men and women were excluded from the study if they had:

- Taken treatment for multiple myeloma (including certain high dose steroids) within two weeks of starting the study treatment.
- A bone marrow transplant using bone marrow from another person.
- Eye disease affecting the outermost transparent covering of the eye (cornea).
- Any major surgery within four weeks before starting the study.
- Risk of developing heart-related disease during the study.
- Any other disease(s) or treatment(s) that the study doctor thought would affect the results of the study.

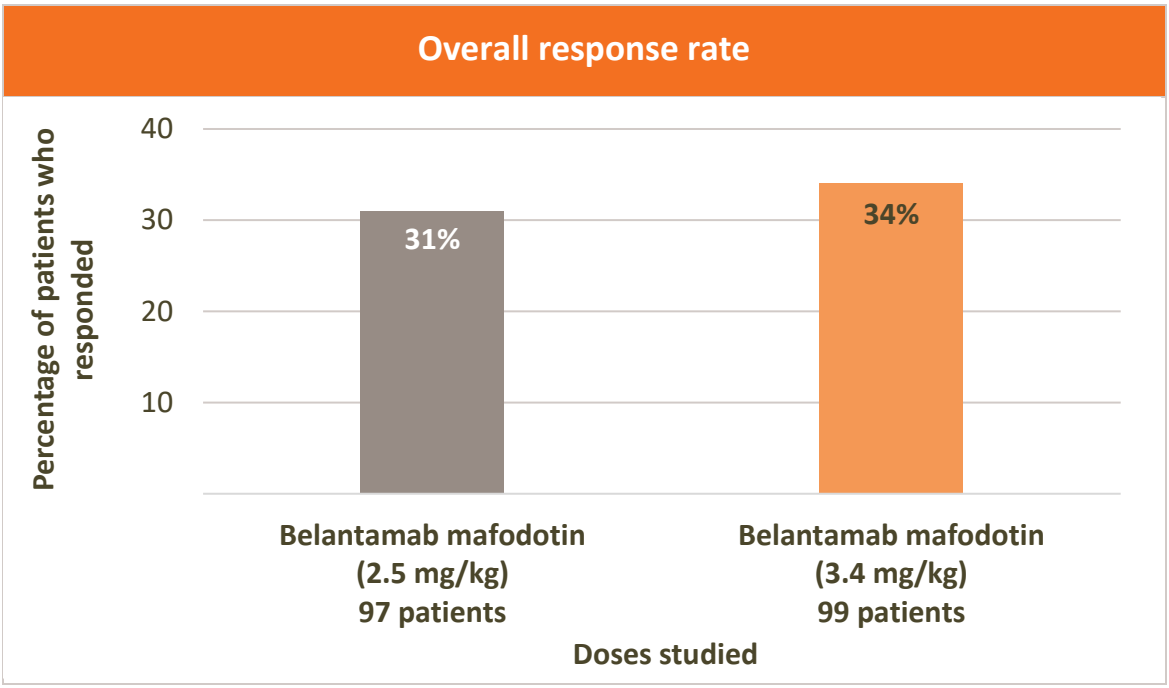
Overall, 196 patients were randomised to receive one of the two doses of belantamab mafodotin. The study included 107 (55%) men and 89 (45%) women. The average age was 65 years. The youngest patient was 34 years old and the oldest patient was 85 years old.

For more detailed information about the patients included in this study, see the scientific results summaries (links to those summaries are provided at the end of this document).

What were the overall results of the study?

The percentage of patients who responded to belantamab mafodotin six months after the last patient received it on Day 1 was calculated. This is called the overall response rate.

The overall response rates are shown in the figure below.



For this study, an overall response rate above 24% was considered to be active in treating patients with multiple myeloma. Belantamab mafodotin was active at both doses.

More information about the study results is available in the scientific results summaries (links to those summaries are provided at the end of this document).

What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a medicine. Study doctors record these events. A summary of these events can be found in the scientific results summaries (links to those summaries are provided at the end of this document).

If the study doctor thinks that the event was caused by the study medicine, they record this as a possible side effect (adverse reaction).

In this summary, “side effects” refer to those events that the study doctor thinks may have been caused by belantamab mafodotin. The side effects in this summary may be different to those in the Informed Consent or other documents related to belantamab mafodotin.

The side effects in this summary were collected for six months after the last patient received belantamab mafodotin on Day 1. A total of 194 patients received at least one dose of belantamab mafodotin.

The table below shows the number of patients (percentage) with serious side effects which were reported by 2% or more of patients who received either dose of belantamab mafodotin.

Number of patients with serious side effects reported by 2% or more of patients		
	Belantamab mafodotin 2.5 mg/kg 95 patients	**Belantamab mafodotin 3.4 mg/kg 99 patients**
Fever	2 (2%)	4 (4%)
Pneumonia	0	3 (3%)
Infusion-related reaction	3 (3%)	2 (2%)
Lung infection	1 (1%)	2 (2%)
Life-threatening response to an infection	2 (2%)	2 (2%)
Lower than normal levels of platelets in the blood	1 (1%)	2 (2%)

Of the patients with serious side effects, two patients died. The table below shows the number of patients (percentage) with fatal side effects.

Number of patients with fatal side effects		
	Belantamab mafodotin 2.5 mg/kg 95 patients	**Belantamab mafodotin 3.4 mg/kg 99 patients**
Life-threatening response to an infection	1 (1%)	0
A condition where immune cells become overactive and attack other blood cells	0	1 (1%)

The table below shows the number of patients (percentage) with non-serious side effects which were reported by 15% or more of patients who received either dose of belantamab mafodotin.

Number of patients with non-serious side effects reported by 15% or more of patients		
	Belantamab mafodotin 2.5 mg/kg 95 patients	**Belantamab mafodotin 3.4 mg/kg 99 patients**
Eye disease affecting cornea	65 (68%)	70 (71%)
Lower than normal levels of platelets in the blood	11 (12%)	30 (30%)
Blurred vision	13 (14%)	24 (24%)
Feeling sick	12 (13%)	19 (19%)
Dry eye	11 (12%)	18 (18%)
Higher than normal levels of a liver protein in the blood	14 (15%)	13 (13%)

How has this study helped patients and researchers?

Researchers concluded that both doses of belantamab mafodotin were active in treating patients with multiple myeloma who stopped responding to previous treatments. Fewer patients receiving the 2.5 mg/kg dose had side effects compared with those receiving the 3.4 mg/kg dose.

Are there plans for further studies?

Other studies on belantamab mafodotin in patients with multiple myeloma are underway and more are planned.

Where can I find more information about this study?

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 scientific summaries and other information.

The scientific summaries include more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events.

Organisation	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2017-004810-25[1]
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03525678[2]

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=205678
[2] https://clinicaltrials.gov/ct2/show/study/NCT03525678

We would like to thank the patients who contributed to this study. The results of this study will help answer scientific questions about treating patients with multiple myeloma.

The content for this document was finalised by GSK on the 15th of April 2020. The information in this summary does not include additional information available after this date.