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 belimumab works and how safe it is in patients of black race with systemic lupus erythematosus.

Full Scientific Title: A phase 3/4, multi-centre, randomised, double-blind, placebo-controlled, 52-week study to evaluate the efficacy and safety of belimumab in adult subjects of black race with systemic lupus erythematosus.

Study Number: 115471

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 February 2013 and ended in January 2019.

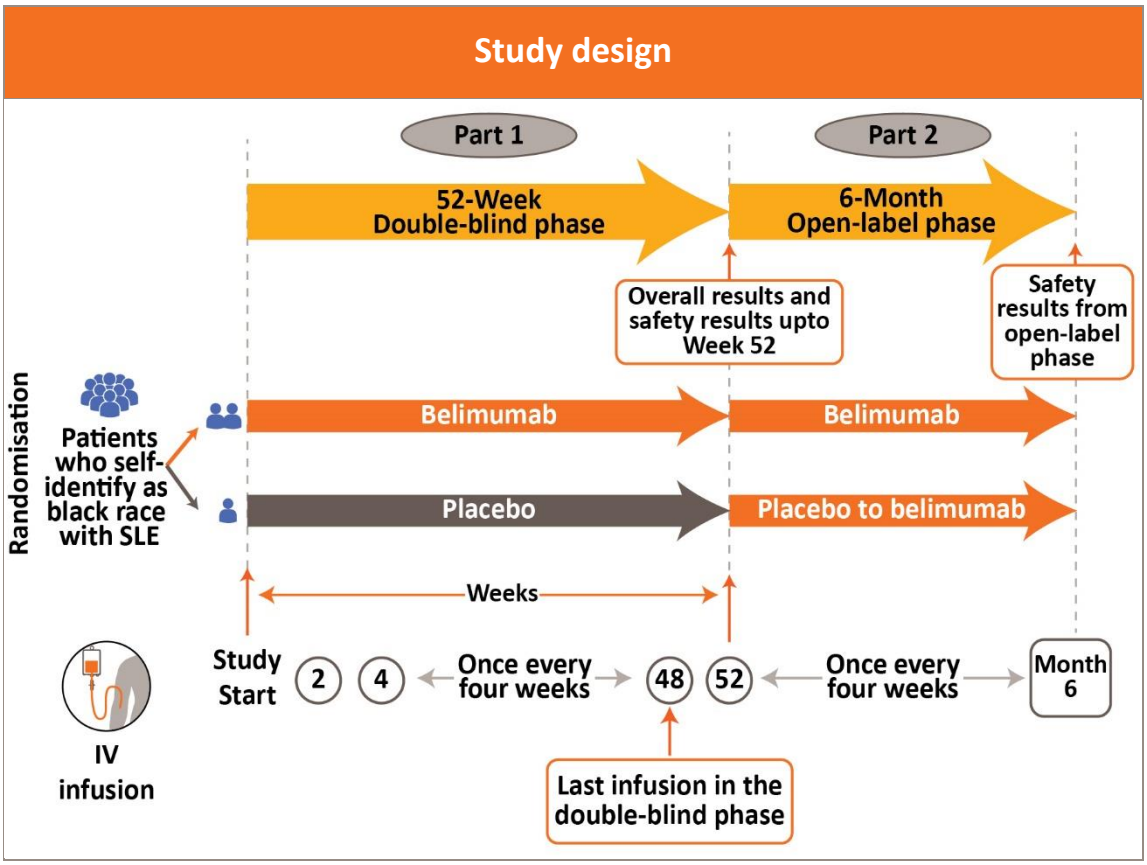
What was the main reason for this study?

Systemic lupus erythematosus (SLE) is a long-term autoimmune disease in which a type of white blood cell (B cells) produces proteins called autoantibodies. Autoantibodies attack the body's own tissues and organs. Systemic lupus erythematosus affects each patient differently. Common symptoms include skin rash and joint pain. Systemic lupus erythematosus can also affect the kidneys, heart, lungs, brain, or other internal organs.

Systemic lupus erythematosus occurs more frequently and is often more severe in people of black race. Belimumab is a medicine that decreases the number of autoantibodies. In this study, researchers wanted to see how well belimumab works when it is given along with regular SLE treatment to patients with SLE who self-identify as black race. They also studied the safety of belimumab.

Which medicines were studied?

As shown in the figure below, patients were placed in one of the two treatment groups by chance (randomisation). Twice as many patients received belimumab compared with placebo (no active medicine). Patients received belimumab or placebo directly through a vein (intravenous [IV] infusion). Throughout the course of the study, patients continued taking their regular SLE treatment.

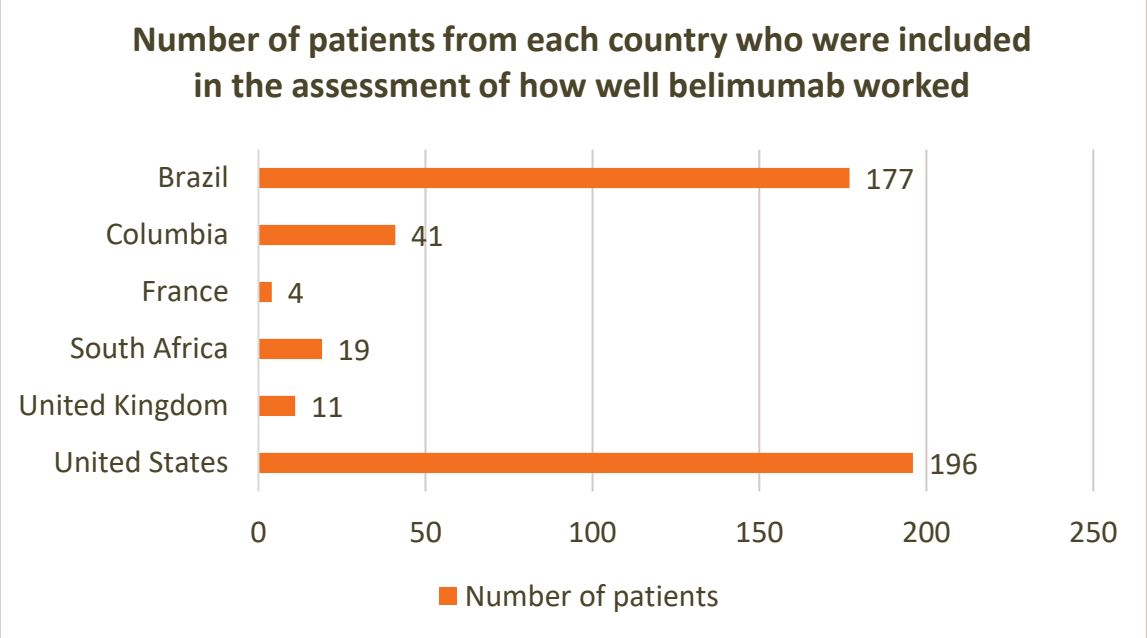


This study took place in two parts (phases). During the first 52 weeks, neither the patients nor the study doctors knew who was receiving which treatment. This is called a double-blind phase. After Week 52, patients could continue in the open-label phase of the study and receive belimumab.

For results reported during the open-label phase, see the scientific results summaries (links to those summaries are provided at the end of this document).

Where was this study done?

Study sites were in six 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 who self-identify as black race were included in the study if they:

- Were at least 18 years old.
- Had SLE with symptoms of at least moderate severity.
- Tested positive for the presence of autoantibodies at two different time points before starting the study treatment.
- Were on stable SLE treatment for at least one month before starting the study treatment.

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

- Received treatment with belimumab before starting the study.
- Received any other treatment(s) that affected B cells.
- Been treated for severe kidney disease caused by SLE or inflammation of the kidneys (nephritis) within three months before starting the study treatment.
- Taken medicine(s) to treat abnormalities of the nervous system caused by SLE (such as seizures, psychosis) within two months before starting the study treatment.
- A major organ transplant (such as heart, lung, kidney, liver) or bone marrow transplant.
- Had any disease (not caused by SLE) that study doctor thought would affect the results of the study.

The table below shows the gender and age of 448 patients who were included in the assessment of how well belimumab worked.

Patients who were included in the assessment of how well belimumab worked		
	Placebo 149 patients	**Belimumab 299 patients**
Gender - Number of patients (percent)		
Female	144 (97%)	290 (97%)
Male	5 (3%)	9 (3%)
Age - In years		
Range	18 to 67	18 to 71
Average	39	39

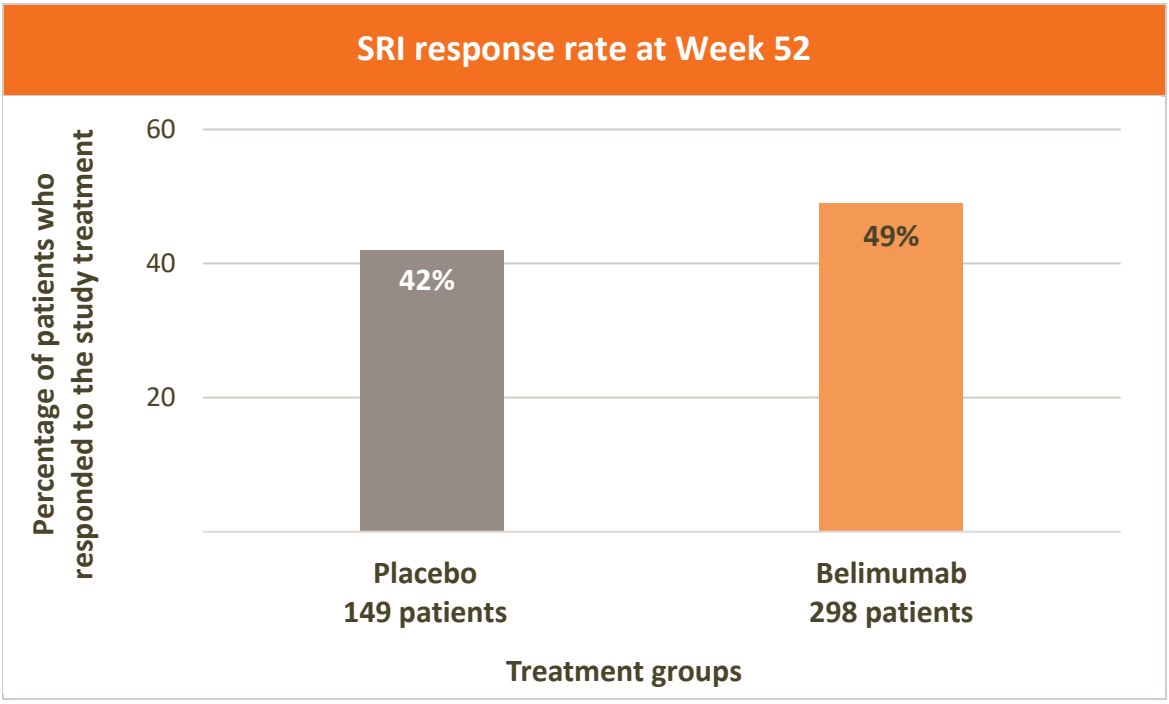
For more detailed information about the patients included in this study, see the scientific results summaries (links to those summaries are provided at the end of this document).

What were the overall results of the study?

The study doctors scored patients' SLE symptoms at the start of the study (baseline) and at Week 52. The scores from three scoring scales were used to decide if the patient responded to the study treatment. Patients were considered to have responded to the study treatment if they met the required change in score on each of the three scales.

For this study, the percentage of patients who responded to the study treatment at Week 52 was calculated. This is called the SLE Responder Index (SRI) response rate. A higher response rate indicates more patients met the required reduction in SLE symptoms.

The baseline SLE symptoms for one patient from the belimumab group were not scored and this patient was not included in the SRI response rate results. The results for the SRI response rates for 447 patients with data that could be evaluated are shown in the figure below.



After 52 weeks of treatment, slightly more patients (7%) in the belimumab group met the required reduction in SLE symptoms compared with the placebo group.

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 belimumab or placebo, 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 belimumab or placebo. In blinded studies, the doctor does not know which study medicine the patient is taking. In some cases, side effects will be assigned to placebo. The side effects in this summary may be different to those in the Informed Consent or other documents related to belimumab or placebo.

Side effects were collected for patients who received at least one dose of belimumab or placebo. An additional 48 patients from three sites in United States received at least one dose of belimumab or placebo. These 48 patients (16 patients in the placebo group and 32 patients in the belimumab group) were included in this summary, but not in the assessment of how well belimumab worked.

During the double-blind phase, the only serious side effect reported by more than one patient in either treatment group was pneumonia. Pneumonia was reported by four patients out of 165 (2%) from the placebo group and one patient out of 331 (less than 1%) from the belimumab group. No other serious side effect was reported by more than one patient in either treatment group.

The table below shows the number of patients (percent) who received at least one dose of belimumab or placebo with non-serious side effects that were reported by three percent or more of patients during the double-blind phase.

Number of patients (percent) with non-serious side effects that were reported by three percent or more of patients during the double-blind phase		
	Placebo 165 patients	**Belimumab 331 patients**
Upper respiratory tract infection	4 (2%)	14 (4%)
Urinary tract infection	2 (1%)	13 (4%)
Inflammation in the sinuses	1 (less than 1%)	13 (4%)
Headache	5 (3%)	11 (3%)
Nausea	5 (3%)	9 (3%)

After Week 52, 117 patients originally randomised to placebo group and 242 patients from belimumab group continued in the open-label phase. All 359 patients received belimumab in this phase.

During the open-label phase, no serious side effect was reported by more than one patient. No non-serious side effect was reported by three percent or more of patients overall. The percentage of patients with side effects were similar regardless of previous study treatment in the double-blind phase.

How has this study helped patients and researchers?

In this study, the percentage of patients who self-identify as black race and who met the required reduction in SLE symptoms was 7% higher in the belimumab group compared with the placebo group. This difference was not big enough for researchers to conclude that addition of belimumab to the patients' regular SLE treatment was better than regular SLE treatment alone. The side effects reported in this study were similar between the treatment groups.

Are there plans for further studies?

Other studies of belimumab in patients with SLE have been conducted and more are underway.

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	2011-005672-42[1]
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT01632241[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.

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 SLE.

The content for this document was finalised by GSK on the 22nd of January 2020. The information in this summary does not include additional information available after this date.

[1] https://www.clinicaltrialsregister.eu/ctr-search/trial/2011-005672-42/results

[2] https://clinicaltrials.gov/ct2/show/results/NCT01632241?term=NCT01632241&rank=1