Plain Language Clinical Study

Summary

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine Studied: Dazukibart (also called PF-06823859)

Protocol Number: C0251013

Dates of Study: 07 July 2023 to 18 November 2025

Title of this Study: A Study to Learn About the Study Medicine (PF-06823859) in Adults With Active CLE or SLE With Skin Symptoms

[A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Clinical Effect, Pharmacodynamic, Pharmacokinetic and Safety Profile of PF-06823859 in Adult Participants With Active CLE or SLE With Cutaneous Manifestations]

Date of this Report: 05 November 2026

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– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. Do you have any questions about the study or the results? If so, please contact the doctor or staff at your study site.

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Why was this study done?

What are cutaneous lupus erythematosus and systemic lupus erythematosus?

Cutaneous lupus erythematosus (or **CLE**) and **systemic lupus erythematosus** (or **SLE**) are types of lupus, a long-term condition in which the body's immune system mistakenly attacks healthy tissues. SLE can affect many parts of the body, while CLE mainly affects the skin. People with these conditions may have **skin symptoms**, such as rashes, sores, or patches that can become worse after being in the sun.

What is dazukibart?

Dazukibart (also known as PF-06823859) is a medicine that is given through a needle into a vein. This is called intravenous infusion.

Researchers think that dazukibart may help people with CLE or SLE, who also had skin symptoms, by blocking a specific protein, called type 1 interferon (or IFN), which is more active than usual in CLE and SLE. People with SLE have high levels of this protein.

What was the purpose of this study?

The main goals of this study were to find out whether dazukibart can change the activity of type 1 IFN and improve skin symptoms in participants with CLE and SLE.

To measure the activity of type 1 IFN, researchers used a tool called type 1 interferon gene signature (or **GS**) score. To measure skin symptoms, researchers used a form called cutaneous lupus erythematosus disease area and severity index activity score (or **CLASI-A**).

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Type 1 IFN GS score measures the activity of several genes that are different in people with SLE and CLE compared with people without these diseases.

CLASI-A measures the activity of skin symptoms in people with SLE and CLE.

Researchers wanted to know:

- **Can dazukibart reduce the type 1 IFN GS score in areas with skin symptoms after about 3 months of treatment?**
- **Can dazukibart improve participants' skin symptoms?**

The Sponsor stopped the study early because of a business decision. This decision was not because of safety reasons or requests from any health authorities.

A much smaller number of participants joined the study than what was planned. Therefore, no meaningful conclusions can be made from the results of this study.

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What happened during the study?

How was the study done?

The study planned to include 48 participants. However, the study stopped early and only 8 participants joined the study.

Researchers tested whether participants who received dazukibart had a lower type 1 IFN GS score than those who received placebo. A placebo does not have any medicine in it, but it looks just like dazukibart. Researchers also looked to see if skin symptoms improved in participants.

Participants were assigned by chance to receive either dazukibart or placebo. The participants and researchers did not know which treatment they received. This is known as a "blinded" study. After about 3 months, researchers compared the groups to see whether dazukibart reduced the type 1 IFN GS score and improved skin symptoms.

Six (6) participants received **dazukibart** 600 milligram (or mg) and 2 participants received **placebo** once a month for about 3 months. After about 3 months, participants who received dazukibart continued with dazukibart once every 2 months. Participants receiving placebo who had not improved switched to dazukibart once every 2 months, while those who had improved continued receiving placebo for up to about 9 months.

Participants had 2 check-up visits at about 2 months and 5 months after their last treatment.

Figure 1 on the next page shows how the study was done.

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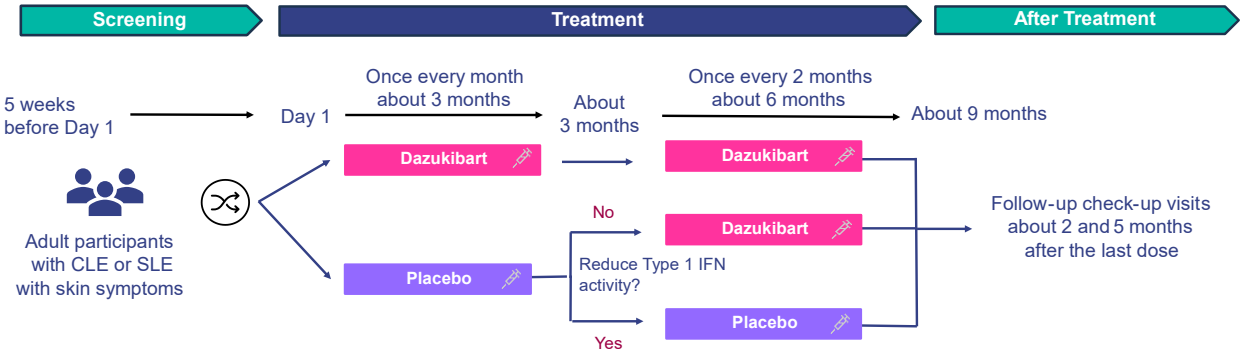
Figure 1. How was the study done?



Throughout the study, the study doctors checked on the participants' health and asked them how they were feeling.

Where did this study take place?

The Sponsor ran this study at 13 locations in Canada, Greece, Spain, and the United States.

When did this study take place?

It began on 07 July 2023 and ended on 18 November 2025.

Who participated in this study?

The study included adult participants who had CLE or SLE with skin symptoms.

A total of 8 participants took part in this study.

- A total of 3 men and 5 women participated.
- All participants were between the ages of 37 years and 64 years.

Of the 8 participants who started the study,

- 4 finished the Treatment Period.

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- 4 did not finish the Treatment Period because the study was stopped early or they chose to leave the study.

How long did the study last?

The entire study took about 2 years and 4 months before it was stopped early due to a business decision. This decision was not because of safety reasons or requests from any health authorities.

When the study ended in November 2025, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

Can dazukibart reduce the type 1 IFN GS score in areas with skin symptoms after about 3 months of treatment?

To answer this question, researchers checked the participants' type 1 IFN GS scores before starting treatment and after about 3 months of treatment. Researchers then compared the results between participants who received dazukibart and those who received placebo. There was no meaningful difference in type 1 IFN GS scores between participants who received dazukibart and those who received placebo.

This study stopped early and was not completed as planned. Because so few participants took part, the results below cannot show whether dazukibart had an effect on the type 1 IFN GS scores.

Can dazukibart improve participants' skin symptoms?

Researchers compared skin symptoms of participants who received dazukibart and those who received placebo after about 3 months of treatment. Some

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participants who received dazukibart showed improvement in skin symptoms compared to those who received placebo.

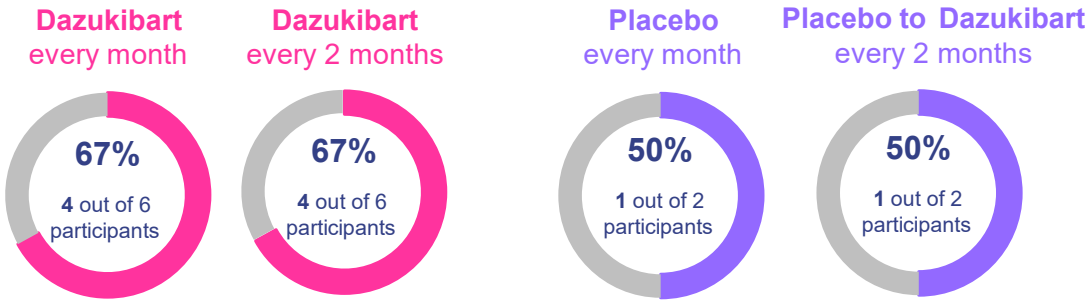
This study was stopped early and was not completed as planned. Because so few participants took part, the results cannot determine if dazukibart caused this improvement in skin symptoms.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medicine might have on a participant.

Figure 2 below shows the number of participants who had at least 1 medical problem in this study.

Figure 2. Number of participants with medical problems



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No participants stopped receiving study treatment because of medical problems. No more than 1 participant reported the same medical problem.

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

No participants had serious medical problems or died during the study.

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Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **C0251013**

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT05879718**
https://euclinicaltrials.eu	Use the study identifier **2023-503343-33-00**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study, **thank you** for volunteering.
We do research to try to find the best ways to help patients, and you helped us to do that!

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