Clinical Study Results

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 medication works, how it works, and if it is safe to prescribe to study participants. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine(s) Studied: PF-06823859

Protocol Number: C0251005

Dates of Study: 28 September 2021 to 27 March 2022

Title of this Study: A Study Looking at the Safety and Levels of PF-06823859 in Healthy Japanese Participants, and to see if Participants Had an Immune Response Against PF-06823859

[A Phase 1, Randomized, Double-Blind, Sponsor-Open, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Immunogenicity and Pharmacokinetics Following Single Intravenous Dose of PF-06823859 in Japanese Healthy Participants]

Date(s) of this Report: 20 April 2023

– 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. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is dermatomyositis (DM) and systemic lupus erythematous (SLE)?

Dermatomyositis (dur-muh-toe-my-uh-SY-tis) is a rare disease that causes muscle weakness and/or inflammation and skin rashes. It is a type of myopathy (my-o-PA-thy). This is a general term referring to diseases that affect the muscles that connect to your bones.

Systemic lupus erythematosus (also called lupus or SLE) is an "autoimmune disease". An autoimmune disease occurs when a person's immune system is overactive and attacks healthy parts of the body by mistake. SLE can cause permanent damage to the tissues or joints if it goes untreated.

What is PF-06823859?

The study drug (PF-06823859) is an investigational medicine. It is not currently approved for use by health authorities in Japan, where this study was held. PF-06823859 is given as an infusion in a vein of the arm. PF-06823859 targets a signaling protein in the immune system. A signaling protein tells the cells in the body how to respond to things like infections. A signaling protein helps fight infections, especially those caused by viruses. In some diseases like DM and SLE, this signaling protein is found at high levels. It is thought that blocking this signaling protein may help treat these diseases. The researchers have been studying it as a protentional treatment for DM or SLE. In future it may also be studied for the treatment of different / related conditions.

What was the purpose of this study?

The main purpose of this study was to learn about the safety of different doses of PF-06823859 compared to placebo in Japanese participants.

This study was done in healthy participants and did not test if the study drug (PF-06823859) helps to improve DM, SLE or any other disease.

Researchers wanted to know:

- **How safe and well tolerated was PF 06823859?**
- **What medical problems did participants have during the study?**

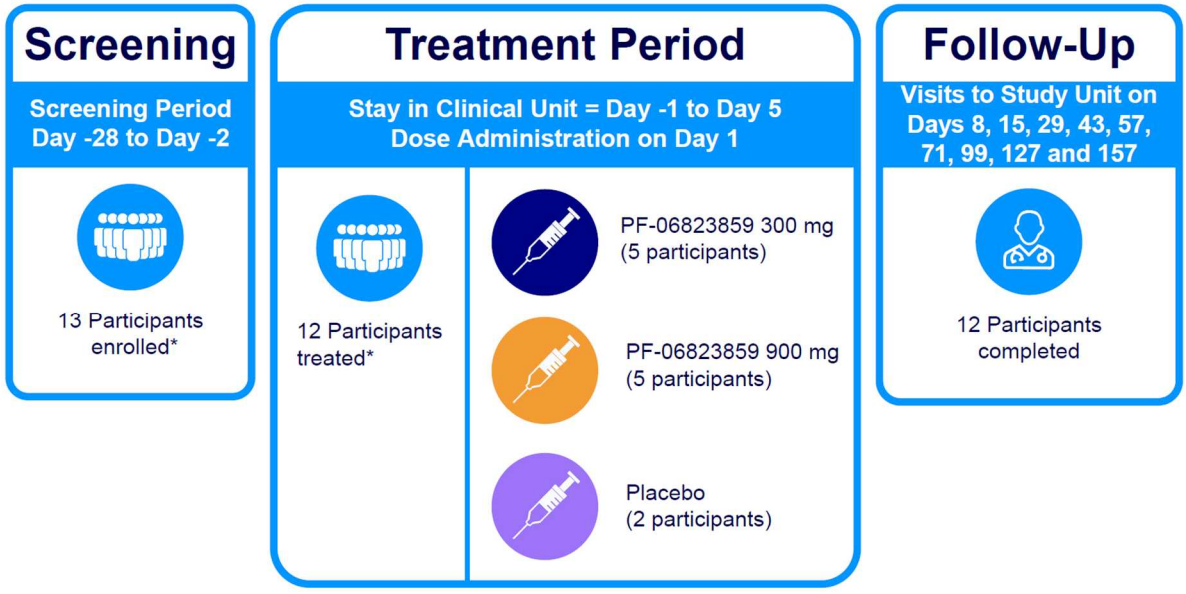
What happened during the study?

How was the study done?

Researchers tested different doses of PF-06823859 on a group of healthy Japanese participants to learn how PF-06823859 acted in the body.

Participants were assigned to receive a single dose of either PF-06823859 (300 mg [milligrams] or 900 mg) or placebo. A placebo does not have any medicine in it, but it looks just like the study medication. The study was divided into 3 main parts (or "periods") as shown in the study design in Figure 1.

Figure 1. Study Design



**One participant was enrolled but did not receive treatment.*

All participants were "screened" to see if they qualify to be in the study. Participants who qualified for treatment after screening entered the Treatment Period. They were required to stay in the study unit for 5 days during this period. Participants returned to the study unit every 1, 2 or 4 weeks during the Follow-up Period. Please refer to the study schema above for planned days participants returned for follow-up visits.

Researchers took samples of blood and urine from participants during the study and measured the amount of study medication. Researchers also checked the participants' health during the study and asked them how they were feeling.

Researchers then compared the results of participants who received different doses of PF-06823859. Researchers also compared results of participants who received PF-06823859 to those who received placebo. They did this to see if medical problems experienced during the study could be related to the study medication or something else.

The participants and researchers did not know who received different doses of PF-06823859 and who received the placebo. This is known as a "blinded" study. Participants were assigned to each group by chance alone.

Where did this study take place?

The Sponsor ran this study at 1 location in Japan.

When did this study take place?

It began on 28 September 2021 and ended on 27 March 2022.

Who participated in this study?

The study included healthy adult participants who met the inclusion/exclusion criteria. All participants were required to have 4 biologically Japanese grandparents who were born in Japan.

A total of 13 participants were included in the study, but only 12 participants received the study medication.

- A total of 8 men were treated
- A total of 4 women were treated
- All treated participants were between the ages of 21 and 52

Of the 13 participants who started the study, 12 finished the study. One participant was withdrawn from the study, because they did not comply with site instructions. This participant did not receive any study medication.

How long did the study last?

Study participants were in the study for about 26 weeks. The entire study took 5 and half months to complete.

When the study ended in March 2022, 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?

How safe and well tolerated was PF-06823859?

In this study, researchers looked at the safety and tolerability of PF-06823859 when given as a single dose of 300 mg or 900 mg. The researchers did this by looking at medical problems that participants had during the study. Researchers were specifically interested in seeing if participants had the following:

- Medical problems related to infusion of the study medication (also called "infusion-related reactions" or IRRs).
- Medical problems related to the infusion site. This is the place where the needle was inserted to give the study medication.
- Viral infections.

Medical problems overall are described in the next section.

They also looked at the results of laboratory tests, blood pressure, pulse rate, and electrocardiogram (ECG) tests. An ECG is a machine that looks at how well the heart is working when it pumps blood around the body.

Did participants have any medical problems of specific interest to researchers?

- No participants had any IRRs or medical problems related to the infusion site.

- One participant had mild viral infection of the nose and throat during the study. Researchers did not think this was related to receiving the study medication.
- Other medical problems during the study are described later in this document.

What was the result of laboratory tests after participants received PF-06823859 or placebo?

- Abnormal laboratory results were reported in 7 out of the 12 participants: 2 participants in the 300 mg PF-06823859 group, 4 participants in the 900 mg group, and 1 participant in the placebo group.
- Only 1 participant had an abnormal laboratory test result that was considered as a medical problem. One participant in 900 mg had an increased liver enzyme result that was considered a medical problem. The researchers did not think this medical problem was related to receiving PF-06823859.

What was the result of the blood pressure and pulse rate tests after participants received PF-06823859 or placebo?

- All 12 participants had blood pressure and pulse rate tests during the study.
- None of the participants had blood pressure and pulse rate values that met specific reporting criteria.
- No participants had changes in their blood pressure or pulse rate that were considered medically important.
- No blood pressure or pulse rate values or changes were reported as medical problems.

What was the result of the ECG tests after participants received PF-06823859 or placebo?

- All 12 participants had ECG tests during the study.
- None of the participants had ECG values that met specific reporting criteria or were considered abnormal.
- No participants had changes in their ECG values that were considered medically important.
- No ECG results were reported as medical problems.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

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 unknown 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 medication might have on a participant.

Five out of 12 (42%) participants in this study had at least 1 medical problem. No participants left the study because of medical problems. All medical problems are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were reported during the study. All medical problems reported by participants are listed.
- The **2nd** column tells how many of the 5 participants who received PF-06823859 300 mg reported each medical problem. Next to this number is the percentage of the 5 participants who received PF-06823859 300 mg reported the medical problem.
- The **3rd** column tells how many of the 5 participants who received PF-06823859 900 mg reported each medical problem. Next to this number is the percentage of the 5 participants who received PF-06823859 900 mg reported the medical problem.
- The **4th** column tells how many of the 2 participants who received placebo reported each medical problem. Next to this number is the percentage of the 2 participants who received placebo reported the medical problem.
- Using these instructions, as an example, you can see that 1 out of the 5 participants who received 300 mg PF-06823859 had lower stomach pain. Neither of the participants who received placebo reported any medical problems.

Table 1. Commonly reported medical problems by study participants			
Medical Problem	**PF-06823859 300 mg (5 Participants)**	**PF-06823859 900 mg (5 Participants)**	**Placebo (2 Participants)**
Lower stomach pain	1 out of 5 participants (20%)	0 out of 5 participants (0%)	0 out of 2 participants (0%)
Vaccination site pain	1 out of 5 participants (20%)	0 out of 5 participants (0%)	0 out of 2 participants (0%)
Infection of nose and throat (cold)	0 out of 5 participants (0%)	1 out of 5 participants (20%)	0 out of 2 participants (0%)
Road traffic accident	1 out of 5 participants (20%)	0 out of 5 participants (0%)	0 out of 2 participants (0%)
Burn due to contact with heat	1 out of 5 participants (20%)	0 out of 5 participants (0%)	0 out of 2 participants (0%)
Increased liver enzyme (ALT) in blood	0 out of 5 participants (0%)	1 out of 5 participants (20%)	0 out of 2 participants (0%)
Increased liver enzyme (AST) in blood	0 out of 5 participants (0%)	1 out of 5 participants (20%)	0 out of 2 participants (0%)
Joint pain	0 out of 5 participants (0%)	1 out of 5 participants (20%)	0 out of 2 participants (0%)
Slipped disc	1 out of 5 participants (20%)	0 out of 5 participants (0%)	0 out of 2 participants (0%)

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 in this study had serious medical problems, and no participants died during the study.

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:

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

www.clinicaltrials.gov	Use the study identifier **NCT05037409**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number C0251005

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!