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 patients. 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 (Dazukibart)
Protocol Number:	C0251008
Dates of Study:	20 December 2021 to 20 November 2023
Title of this Study:	A Study to Investigate the Safety of PF-06823859 Administered to Adult Participants with Active Dermatomyositis [An Open Label, Long-Term Extension Study to Investigate the Safety of PF-06823859 Administered to Adult Participants ⩾18 and ⩽80 With Active Dermatomyositis]
Date(s) of this Report:	04 August 2024

– 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)?

Dermatomyositis (dur-muh-toe-my-uh-SY-tis) is a rare disease that causes muscle weakness and/or inflammation and skin rashes. Symptoms can include a red skin rash around the eyelids, red bumps around the joints, and muscle weakness in the arms and legs. It is a type of myopathy (my-o-pa-thy). This is a general term referring to diseases that affect the muscles.

What is dazukibart (PF-06823859)?

The study drug, dazukibart (dah-zoo-kee-bart) is an investigational medicine. It is not currently approved for use by health authorities in countries where this study was held. It is given as an infusion in a vein. Dazukibart targets a signalling protein in the immune system. A signalling protein tells the cells in the body how to respond, such as fighting infections. In a disease like DM, this signalling protein is found at high levels. It is thought that blocking this signalling protein may help treat DM. The researchers have been studying it as a potential treatment for DM. In the 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 determine how safe and tolerable dazukibart is when used for a long time. In this study, dazukibart was given to participants who have taken this study drug in a previous study (C0251002).

Researchers wanted to know:

How safe and tolerable is dazukibart when taken long-term?

Did the participants taking dazukibart for long term have unwanted changes in any of the following?

- **Vital signs**
- **Laboratory tests**
- **Electrocardiogram (ECG) test. ECG is a test that looks at how well the heart is working).**

What happened during the study?

How was the study done?

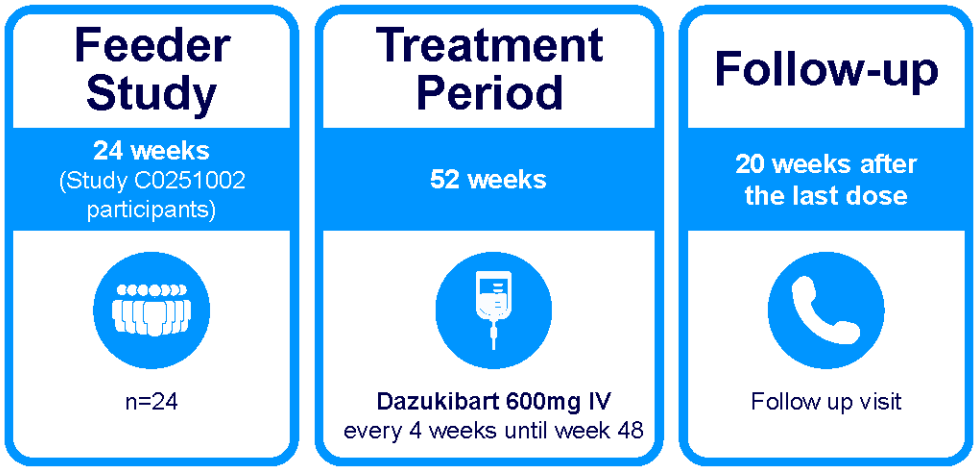
Researchers tested dazukibart on a group of study participants who had DM and who participated in a previous study (C0251002) to find out if study participants taking dazukibart long-term had any unwanted medical problems.

This was an “open-label” study which means the study participants and researchers knew what the participants were taking.

Participants were “screened” to make sure that they were eligible to participate in this study. All eligible participants (participants who had participated in the C0251002 study) were given 600 mg of dazukibart intravenously (through the vein) every 4 weeks up to 52 weeks during the

treatment period. All participants were followed for 16 weeks after the treatment period, during the follow-up period as shown in Figure 1. Participants who discontinued from the treatment also entered the follow-up period.

Participants' vital signs (blood pressure, heart rate, pulse, and temperature) were checked every 4 weeks. ECG test and blood collection were done every 12 weeks. Researchers asked the participants how they felt at every visit.



n = number of participants *IV = Intravenous (through the vein)*

Where did this study take place?

The Sponsor ran this study at 15 locations in 4 countries (United States, Hungary, Poland, and Spain).

When did this study take place?

It began 20 December 2021 and ended 20 November 2023.

Who participated in this study?

The study included participants who were between the ages of 22 and 66 years, had moderate to severe DM, and completed the Study C0251002.

- A total of 4 men participated
- A total of 20 women participated
- All participants were between the ages of 22 and 66 years.

Participants were to be treated for 48 weeks and had the last assessment at Week 52. Of the 24 participants who entered the Treatment phase, 21 finished.

Of the 3 participants that did not finish the Treatment phase, 1 participant discontinued due to the medicine not working well, and 2 participants withdrew by their choice.

Of the 22 participants who entered the Follow-Up phase, 1 participant discontinued by their choice.

How long did the study last?

Study participants were in the study for 68 weeks. The entire study took approximately 23 months to complete.

When the study ended in November 2023, 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?

Did the participants taking dazukibart for a long time have unwanted changes in vital signs, lab tests, or ECG?

How many participants had changes in vital signs (heart rate, pulse, and blood pressure) that were medically important?

No participants had changes in vital signs that were clinically significant. One participant showed increase in blood pressure and one participant had low blood pressure. Both were not clinically significant and were not related to the treatment.

How many participants had laboratory test values that were clinically significant?

During the treatment period, a total of 5 abnormal laboratory values were reported. One participant had decrease in blood potassium, 1 participant had protein in the urine, 1 participant had low red blood cell count, 1 participant had low blood sodium level, and 1 participant had a decrease in estimated glomerular filtration rate (eGFR) which means there was decrease in how the kidneys were filtering waste products. All laboratory abnormalities were considered as unrelated to study drug and were mild to moderate in severity.

Based on these results, the researchers have decided that dazukibart was generally safe and well tolerated.

How many participants had ECG data that were clinically significant?

No participants had changes in ECG that were clinically significant.

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 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.

Twenty out of 24 (83.3%) participants in this study had at least 1 medical problem at some point during the 68-week study. No participants left the study because of medical problems. The most common medical problems – those reported by more than 5% of participants – 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 commonly reported during the study. All medical problems reported by more than 5% of participants are listed.
- The **2nd** column tells how many of the 24 participants taking the study medication reported each medical problem. Next to this number is the percentage of the 24 participants taking the study medication who reported the medical problem.

- Using these instructions, you can see that 2 out of the 24 (8.3%) participants taking the study medication had low red blood cell count.

Table 1. Medical problems reported by more than 5% of the study participants

Medical Problem	Dazukibart (24 Participants)
Low red blood cell count	2 out of 24 participants (8.3%)
Stomach pain	2 out of 24 participants (8.3%)
Infection affecting the larger airways (Bronchitis)	2 out of 24 participants (8.3%)
COVID-19	6 out of 24 participants (25.0%)
Swelling of the tissues in the sinuses (Sinusitis)	2 out of 24 participants (8.3%)
Upper respiratory tract infections	2 out of 24 participants (8.3%)
Urinary tract infection	3 out of 24 participants (12.5%)
Back pain	2 out of 24 participants (8.3%)

Table 1. Medical problems reported by more than 5% of the study participants	
Medical Problem	**Dazukibart (24 Participants)**
Arm or leg pain	2 out of 24 participants (8.3%)
Headache	2 out of 24 participants (8.3%)
Cough	2 out of 24 participants (8.3%)
Itchy red bumps/welts on the skin (Urticaria)	2 out of 24 participants (8.3%)

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.

Three participants (12.5%) had serious medical problems. 1 participant had gall stones, 1 participant had high sugar and high ketones (chemicals released when your body breaks down fat) in blood, and 1 participant had lower limb fracture. No participants had herpes zoster infections (shingles).

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:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number C0251008

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

www.clinicaltrials.gov	Use the study identifier **NCT05192200**
www.clinicaltrialsregister.eu	Use the study identifier 2021-004787-10

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!