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: Inclacumab (also known as PF-07940370)

Protocol Number: C5361003 or GBT2104-133

Dates of Study: 29 March 2022 to 07 November 2025

Title of this Study: A Study to Evaluate the Long-term Safety of Inclacumab Administered to Participants With Sickle Cell Disease

[An Open-Label Extension Study to Evaluate the Long-Term Safety of Inclacumab Administered to Participants With Sickle Cell Disease Who Have Participated in an Inclacumab Clinical Trial]

Date of this Report: 12 May 2026

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– Thank You –

If you or your child 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.

Why was this study done?

What is sickle cell disease?

Sickle cell disease (SCD) is a genetic condition where red blood cells are shaped like a crescent moon (sickle cells). Compared to round (normal) red blood cells, these sickled red blood cells do not carry oxygen well around the body.

SCD leads to problems like anemia (low number of red blood cells), pain attacks (also called vaso-occlusive crisis or VOC), extreme tiredness, and more frequent infections. SCD lasts a lifetime and can shorten a person's lifespan.

What is inclacumab?

Inclacumab, also known as PF-07940370, is a medicine given into a vein through a needle (also called intravenous or IV).

Researchers thought that inclacumab might help reduce the number of VOCs in people with SCD. One of the causes of painful VOCs is obstruction (blockage) in the blood vessels. Inclacumab is designed to prevent such blockage from happening so that blood flows normally.

The use of inclacumab in people with SCD in this study is investigational, which means it is not approved for use outside of research studies.

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What was the purpose of this study?

The main goal of this study was to find out if participants with SCD from earlier inclacumab studies can safely take (tolerate) inclacumab for a long time.

Researchers wanted to know:

Can participants with SCD safely tolerate inclacumab for a long time?

This study was stopped early because the results from an earlier inclacumab study did not show that it reduced the number of VOCs in participants with SCD. This decision was not because of safety reasons or requests from any health authorities.

What happened during the study?

How was the study done?

Researchers tested inclacumab in participants with SCD who had completed an earlier inclacumab study to find out if participants could safely take inclacumab for a long time.

Participants received inclacumab 30 milligram per kilogram (mg/kg) in this study. This means that for every kilogram of body weight, the participant received 30 mg of inclacumab. Participants were to receive inclacumab every 12 weeks (about 3 months) in this study until study was stopped or they could get inclacumab from another source (like buying it).

Participants and researchers knew that all participants received inclacumab in this study. This is called an “open-label” study.

During the study, researchers checked the participants' health and asked how they were feeling and what medications they were taking.

Where did this study take place?

The Sponsor ran this study at 41 locations in 10 countries in North and South America, East and West Africa, and Western and Southwest Asia.

When did this study take place?

It began on 29 March 2022 and ended on 07 November 2025.

Who participated in this study?

The study included participants with SCD who had completed an earlier inclacumab study. A total of 241 participants received at least 1 dose of inclacumab.

- A total of 119 men and 122 women participated.
- All participants were between the ages of 16 years and 50 years.

None of the participants finished the study. The most common reason was because the Sponsor stopped the study early.

How long did the study last?

The entire study ran for about 3 years and 7 months until it stopped early. This was because the results from an earlier inclacumab study did not show that it reduced the number of VOCs in participants with SCD. The decision to stop the study 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 participants with SCD safely tolerate inclacumab for a long time?

To answer this question, researchers looked at all the information collected on the participants' health throughout the study.

Based on the data collected until the study stopped early, researchers found that inclacumab was safe and well tolerated in participants with SCD. No new safety concerns were found in this study compared to earlier studies of inclacumab.

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.

A total of 211 out of 241 participants (88%) in this study had at least 1 medical problem. The most common medical problems – those reported by at least 10% of participants – were:

- **Malaria**, a disease caused by a bite of a mosquito that was infected with a parasite, in 69 out of 241 participants (29%)
- **SCD with pain attack** in 68 out of 241 participants (28%)
- **Low number of red blood cells** in 49 out of 241 participants (20%)
- **Headache** in 42 out of 241 participants (17%)
- **Nose and throat infection** in 42 out of 241 participants (17%)
- **Urinary tract infection** or UTI in 29 out of 241 participants (12%)
- **Joint pain** in 26 out of 241 participants (11%)

A total of 19 out of 241 participants (8%) had medical problems that caused them to stop receiving inclacumab.

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.

A total of 97 out of 241 participants (40%) in this study had serious medical problems. The most common serious medical problem – reported by more than 10% of participants – was **low number of red blood cells** in 35 out of 241 participants (15%).

Seventeen (17) out of 241 participants (7%) died during the study. None of the deaths were reported to be related to inclacumab by researchers.

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 **C5361003 (or GBT2104-133)**

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

www.clinicaltrials.gov	Use the study identifier **NCT05348915**
https://euclinicaltrials.eu	Use the study identifier **2020-005289-32**

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 or your child 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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