PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Gilead Sciences

Gilead Study Number: GS-US-685-6883

Dates of Study: March 2025 to April 2025 (the study closed earlier than planned)

Short Study Title: Study of Obeldesivir to Treat Children With Respiratory Syncytial Virus (RSV) Infection

Date of this Plain Language Summary: April 2026
The information in this summary does not include any information available after this date.

Thank you

Thank you to the participants who contributed to the clinical study for **obeldesivir**, also known as **GS-5245**. In addition, thank you to the parents and caregivers of the participants.

Gilead Sciences sponsored this study. This summary is prepared for study participants and the general public.

If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

Always talk to a doctor or healthcare provider before making any treatment changes.

This document is a short summary of this study written for a general audience. Links to scientific summaries of this study can be found at the end of this document.

General information about the study

What is respiratory syncytial virus (RSV) infection?

RSV infection is a respiratory disease caused by a virus called respiratory syncytial virus (RSV). It is a common virus that infects the lungs and breathing passages. It is a leading cause of respiratory illness in infants and young children worldwide.

RSV can cause cold-like symptoms such as sneezing, runny nose, cough, and congestion. In young children, especially infants, RSV can cause more serious breathing problems, difficulty feeding, and disturbed sleep. While most children recover on their own, some may need medical care or hospitalization.

Common Symptoms of RSV infection

Runny nose | Cough | Sneezing | Congestion

Currently, there are no approved treatment options available for RSV infection in children. In this study, researchers tested a drug called **obeldesivir**. Researchers wanted to see if obeldesivir could help reduce RSV symptoms in children and if it was safe to be used. They looked at children who were below 5 years of age, who had RSV infection but did not need hospitalization.

This is a **Phase 2 clinical study**. This means that researchers planned to test obeldesivir in a smaller group of about 130 children with RSV infection.

What was the purpose of the study?

The purpose of the study was to learn how safe and how well treatment with obeldesivir works in children with RSV infection.

The main questions the researchers wanted to answer in this study were:

- How many days did it take for the participant's RSV symptoms to get better after they started taking obeldesivir?
- How many participants had **unwanted medical events** during the study, if any?

  An **unwanted medical event** is any unwanted sign or symptom that can happen during a study. It may or may not be caused by the study drug.

- How many participants had **severe or potentially life-threatening** changes in their laboratory test results during the study?

  Laboratory tests included blood and urine tests. A change in the laboratory test result is considered:

  - **Severe**, when the change is serious and indicates major health problems or need of medical treatment.
  - **Potentially life-threatening**, when the change is very serious and could put the person's life at risk if not treated.

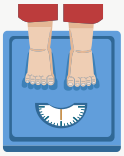
Researchers also wanted to know if there were any **side effects** that participants had during the study. A **side effect** is an unwanted medical event that the study doctors thought might have been caused by the study drug.

Who took part in the study?

The study was planned to enroll at least 130 children from different parts of the world. However, as the study was stopped early, only **4 children** with RSV infection in the United States took part in the study.

Children could take part in the study if they:

Were under 5 years of age, including newborns



Met certain weight requirements based on their age and how early they were born

Had RSV infection confirmed by a suitable test, within 3 days before starting the study

Showed symptoms of RSV infection, within 3 days before starting the study

All **4 participants** were **female**.

The **age** of participants is shown below.

Age	**Number of participants (%)**
Below 2 years of age	3 (75%)
2 to below 5 years of age	1 (25%)

The **race** and **ethnicity** of participants are shown below.

Race	**Number of participants (%)**
White	3 (75%)
Black or African American	1 (25%)

Ethnicity	**Number of participants (%)**
Hispanic or Latino	2 (50%)
Not Hispanic or Latino	2 (50%)

What happened during the study?

Before the study began, children were screened to see if they were a good fit. Screening included physical exams, a review of the children's health, and medication history. Study doctors performed tests to confirm RSV infection.

Researchers had planned to include at least 130 participants. They decided to stop the study early, after 4 participants were enrolled. **Gilead made this internal decision, and it was not related to any safety issues. They discontinued the study because another study testing obeldesivir in adults (GS-US-685-6819; NCT06585150) did not show the desired results at a planned review point of the study.**

This was a **double-blind**, **randomized** study.

Double-blind: This means that none of the participants, doctors or other study staff, and the sponsor personnel knew what treatment each participant took. This was done to make sure that the study results were not influenced in any way. Some study and sponsor staff knew which treatment each participant received, to help monitor participants' safety throughout the study.

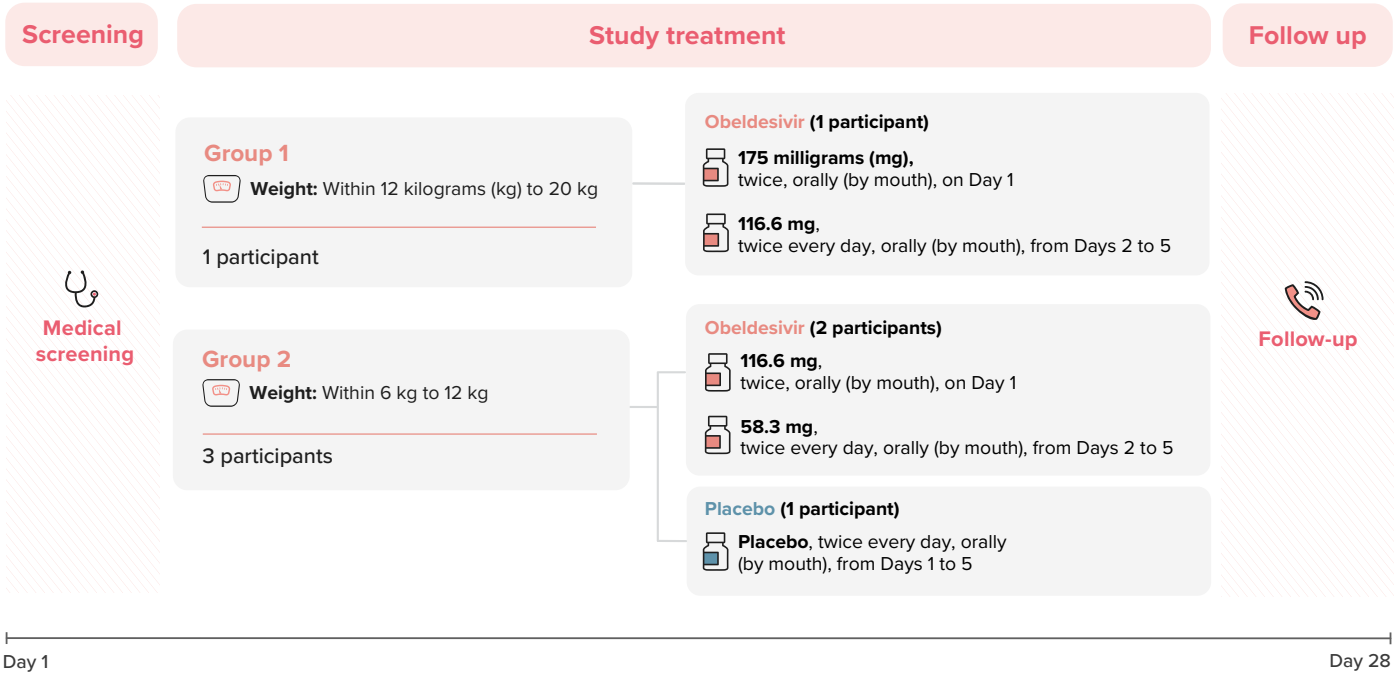
Randomized: This means the researchers used a computer program to assign participants into treatment groups by chance. This helped make sure the treatments were chosen fairly.

Participants were randomized in a 2:1 ratio. This means that twice as many participants were expected to receive obeldesivir compared to **placebo**.

A **placebo** looks like a treatment but does not have any medicine in it. Researchers use a **placebo** as a point of comparison to identify whether a new treatment is effective and safe.

In this study, participants were placed into 1 of 2 groups, based on their weight. Within each of the 2 groups, they were randomly chosen to receive either obeldesivir or placebo. Participants in both groups were also eligible to receive standard of care treatment for their RSV infection. Standard of care treatment is a common therapy used by doctors to treat people for their symptoms related to RSV infection.

The graphic below shows the treatments participants received during the study.



Participants received treatment for 5 days. Participants received the treatment at home with the help of their caregivers. On days when the participant visited the clinic, they could get one of their doses of obeldesivir or placebo at the clinic and one at home.

During the study, participants visited the clinic at least 3 times and up to 5 times for checkups. During the clinic visits, researchers checked participants for their overall health and RSV symptoms. They also checked participants for any medical issues.

Participants had a follow-up phone or video call 23 days after they received study treatments to see how they were doing.

What were the results of the study?

This is a summary of the main results from this study. The individual results of each participant might be different and are not in this summary. A detailed presentation of the results can be found on the websites listed at the end of this summary.

How many days did it take for the participant's RSV symptoms to get better after they started taking obeldesivir?

As the study was stopped early and could not enroll the necessary number of participants, **there was not enough information for researchers to make any meaningful conclusions**. Therefore, no results are available on how well obeldesivir worked to reduce the RSV symptoms in participants by Day 28 of the study.

How many participants had unwanted medical events during the study, if any?

An unwanted medical event is any sign or symptom that participants have during a study. Study doctors keep track of all the unwanted medical events that happen in studies, even if they do not think they might be caused by the study treatment. The researchers kept track of any unwanted medical events that participant had by Day 28 of the study.

All **3 participants** in **Group 2** had unwanted medical events. Researchers concluded that these unwanted medical events were not caused by the study treatments.

The one participant in Group 1 had no unwanted medical events.

How many participants had severe or potentially life-threatening changes in their laboratory test results during the study?

Participants had blood and urine tests done before and after taking the treatment. These tests were done to check for any changes that might be outside the normal range. Doctors described these changes as mild, moderate, severe, or potentially life-threatening.

The researchers kept track of the changes that occurred in the laboratory tests by Day 28 of the study.

Of the 4 participants, one participant in **Group 2** who received **placebo**, had very serious changes in their laboratory test results, which were classified as potentially life-threatening. However, the participant did not have symptoms, and the study doctor judged that these results did not cause health problems.

No other participants had severe or potentially life-threatening laboratory test result changes.

What side effects did participants have during the study?

In this summary, "**side effects**" are defined as unwanted medical events that the study doctors thought might be caused by the study treatment.

The results from several studies are usually needed to help decide if a treatment actually causes a side effect.

None of the participants had any side effects during the study. No participants stopped taking the study treatment or died because of side effects.

How has this study helped researchers?

The researchers learned more about the safety of obeldesivir in children with RSV infection.

The results from several studies are needed to help decide which treatments work and are safe. This summary shows only the main results from this one study. Other studies may provide new information or different results.

This study was stopped early. It could not enroll enough children to draw any meaningful conclusions on how obeldesivir worked in children with RSV infection.

Gilead Sciences does not have any ongoing clinical studies with obeldesivir and do not plan to have further clinical studies with obeldesivir.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

Organization (Website)	Study Identifier
United States National Institutes of Health (NIH) www.clinicaltrials.gov	ClinicalTrials.gov ID: NCT06784973
Gilead Website www.gileadclinicaltrials.com	GS-US-685-6883

Please note that information on these websites may be presented in a different way from this summary.

Full Study Title: A Phase 2, Randomized, Multicenter, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Obeldesivir in Participants From Birth to < 5 Years of Age With Respiratory Syncytial Virus (RSV) Infection

To learn more about clinical trials in general, please visit this page on www.clinicaltrials.gov website.

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Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

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