



PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Kite, A Gilead Company

Kite Protocol Number: KT-US-568-0138-D

Date of Study: March 2023 to June 2024 (the study closed earlier than planned)

Short Study Title: A Study of Brexucabtagene Autoleucel (KTE-X19) in People with Relapsed/Refractory Hairy Cell Leukemia

Study Nickname: ZUMA-25D

Date of this Plain Language Summary: June 2025

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 **brexucabtagene autoleucel (brexu-cel)**, also known as **KTE-X19**.

Kite, A Gilead Company, sponsored this study. We believe it is important to share the results with study participants and the general public.

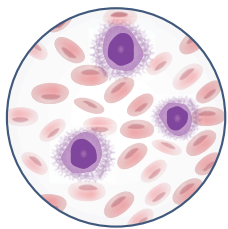
If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

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.

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General information about the study



What is Hairy Cell Leukemia?

Hairy cell leukemia (HCL) is a rare type of blood cancer. The cancer cells have a hairy appearance, therefore, it is called hairy cell leukemia. HCL starts in the bone marrow, the spongy material inside the bones. **Bone marrow** makes stem cells that mature into red blood cells (RBCs), white blood cells (WBCs), and platelets. RBCs carry oxygen to different parts of the body, WBCs help fight infections, and platelets help the blood to clot. A clot is a thickened lump of blood that forms to stop bleeding.

In HCL, the stem cells become faulty and make too many abnormal blood cells. Not having enough healthy blood cells can make a person feel weak, tired, and cause infections more easily. Having low platelets make it harder for the blood to clot during injury, so the person may bruise or bleed more.

Chemotherapy has been the standard treatment for people with HCL. **Chemotherapy** are medicines used to kill cancer cells. However, these treatments may not be suitable for everyone or may not work for some people. When cancer cells initially respond to treatment but grow back later, the cancer is said to have **relapsed**. If the cancer treatment does not work at all, the cancer is called **refractory**.

Brexu-cel is a type of **CAR T cell therapy**. Brexu-cel has been approved as a treatment for other types of blood cancers.



CAR T cell therapy: **CAR** stands for **chimeric antigen receptor** made in a laboratory and inserted into T cells to better attack cancer cells. To prepare brexu-cel, T cells are taken from the patient's blood, modified in a laboratory, and then put back into the patient's body to help destroy the cancer.

ZUMA-25D is a **substudy** of the main study called ZUMA-25. This is a Phase 2 clinical substudy. This means that researchers tested brexu-cel in a small number of people with relapsed or refractory (r/r) HCL in a **substudy** under the main study. This was done in participants who had failed to respond or were not responding to earlier used chemotherapy treatments.



A **substudy** looks at specific details or questions related to the main study, helping researchers get more detailed information without starting a whole new study.



What was the purpose of the study?

The purpose of this substudy was to learn how safe and effective was brexu-cel in treating participants with r/r HCL.

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

- How many participants achieved a **complete or partial response** after taking the treatment?
 - **Complete response** means that the cancer has completely gone away from both the blood and bone marrow and there is a rise of healthy blood cells.
 - **Partial response** means the cancer has responded to treatment, but it hasn't completely disappeared. The cancer cells have reduced in number or size, but some still remain.

Together, complete and partial response is known as objective response.

Researchers also wanted to know if there were any side effects that participants had during the study.



Who took part in the study?



Only **1 participant** with r/r HCL in the Netherlands took part in the study.

People could take part in the study if they:



Were at least 18 years of age



Had confirmed r/r HCL



Took treatment for r/r HCL before, but failed to respond



What happened during the study?

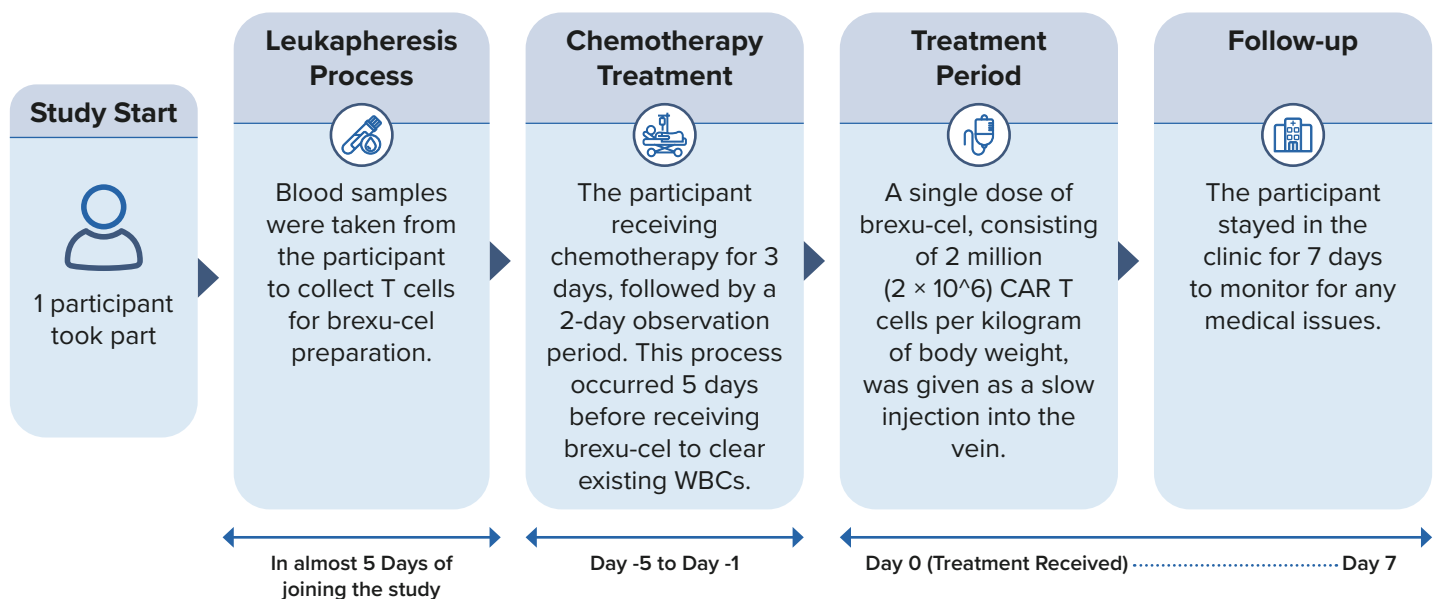
This was an **open-label** study.



Open-label means the participant, the doctors and the study staff knew that they were taking brexu-cel.

The researchers planned to include and treat 20 participants with r/r HCL, to check the effectiveness of brexu-cel in this substudy. **However, the sponsor decided to close the study early. The early closure of the study was not due to any safety concerns.** At the time the sponsor decided to close the study, only 1 participant joined and received the treatment.

The graphics below show the study plan:



The participant was monitored for 12 months after receiving the brexu-cel treatment. Subsequently, the participant joined another long-term follow-up study for brexu-cel (Study KT-US-982-5968; NCT Number: NCT05041309; EU CT Number: 2023-507041-28), where they will be monitored for safety over a period of 15 years.



What were the results of the study?

How many participants achieved a complete or partial response after taking the treatment?

As the study closed too early, the researchers did not have enough information to determine how the treatment worked. The information from a single participant was not enough to draw any meaningful conclusions about the treatment's effectiveness or results.



What side effects did participants have during the study?

Unwanted medical events can happen to the study participants when they take study treatment. 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.

A side effect is considered “serious” if it:

- results in death
- is life-threatening
- considered by the study doctor to be medically important
- causes lasting problems
- requires hospital care
- causes a birth defect

The participant did not have any serious side effect and was known to be alive until the last contact in this study.

The participant had **non-serious** side effects that did not meet the above definition of serious side effects.

The side effects were related to:

- Blood and immune system
- Heart
- Brain, spinal cord, and nerves
- Lungs and chest



How has this study helped researchers?

Even though the study ended early, the little bit of information the researchers got may still be helpful. They can use the single participant's information to plan future studies. The results from several studies are needed to help decide which treatments work and are safe.

Always talk to a doctor before making any treatment changes.

At this time, Kite, A Gilead Company, does not plan to have further clinical studies with brexu-cel for r/r HCL.



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
European Medicines Agency (www.euclinicaltrials.eu)	EU CT number: 2022-501262-21
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT05537766
www.gileadclinicaltrials.com	KT-US-568-0138-D

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

Full Study Title: A Phase 2, Open-Label, Multicenter, Basket Study Evaluating the Efficacy of Brexucabtagene Autoleucel in Adults with Rare B-cell Malignancies (ZUMA-25) – **Substudy D – Relapsed/Refractory Hairy Cell Leukemia**

To learn more about clinical trials in general,
please visit this [page](#) on www.clinicaltrials.gov website

Kite Pharma, a division of Gilead Sciences
2400 Broadway, Santa Monica, CA 90404, USA
Email: medinfo@kitepharma.com



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.

