PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Kite, a Gilead company

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

Date of Study: November 2022 to December 2024 (the study closed earlier than planned)

Short Study Title: A Study of Brexucabtagene Autoleucel (KTE-X19) in People with Relapsed/Refractory Burkitt Lymphoma

Study Nickname: ZUMA-25C

Date of this Plain Language Summary: November 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.

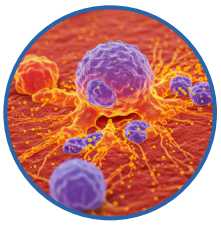
If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

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.

General information about the study

What is Burkitt Lymphoma?



Burkitt lymphoma (BL) is a rare and fast-growing type of blood cancer. It affects a kind of white blood cells (WBC) called B-cells, which help fight infections. In BL, these cells grow too quickly and crowd out the healthy ones, making it harder for the body to fight off illness. People with BL may feel very tired, get sick more often, and have symptoms like belly pain, fever, swollen lumps in the neck, armpits, or groin, and weight loss.

BL mostly affects children and teenagers, but also occurs in adults. It can happen because of a change in a gene called MYC, which controls how cells grow. It's also linked to certain viruses like **Epstein-Barr virus (EBV)** and **Human Immunodeficiency Virus (HIV)**. **EBV** is a common virus that can cause B-cells to grow abnormally, and **HIV** weakens the immune system, making it easier for cancers like BL to develop.

Chemotherapy is the standard treatment for people with (BL). These are medicines that help kill cancer cells. However, chemotherapy may not work for everyone or may not be suitable for some people. If cancer cells respond to treatment at first but come back later, this is called a **relapse**. If the treatment doesn't 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 certain types of blood cancers.

CAR T cell therapy is a form of cancer treatment that uses the patient's own immune cells. **CAR** stands for **chimeric antigen receptor**, a special protein made in a laboratory. To prepare brexu-cel, T cell lymphocytes—a type of WBC that helps fight infection—are collected from the patient's blood through a process called leukapheresis. These cells are then modified in the laboratory to express the CAR protein. Once ready, the modified cells (called CAR T cells, brexu-cel) are infused back into patient's bloodstream through an injection into a vein, where they work to identify and destroy cancer cells.

ZUMA-25C 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) BL in a **substudy** under the main study.

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 BL.

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 participants had any side effects during the study.

Who took part in the study?

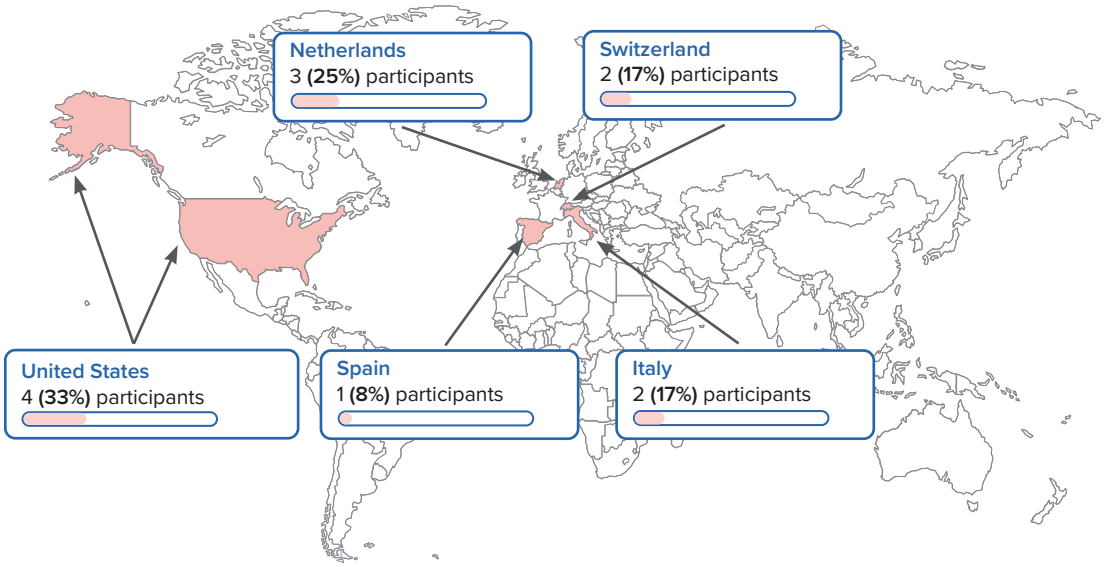
12 participants with r/r BL from **Italy**, **Netherlands**, **Spain**, **Switzerland** and **the United States** took part in the study.

People could take part in the study if they:

- Were at least 18 years of age
- Had confirmed r/r BL
- Took treatment for BL before, but either failed to respond or they responded at first but their cancer came back later.

The study participants were between the ages of **36** and **70** years.

The participants from each country are shown below (Number (%) of participants).



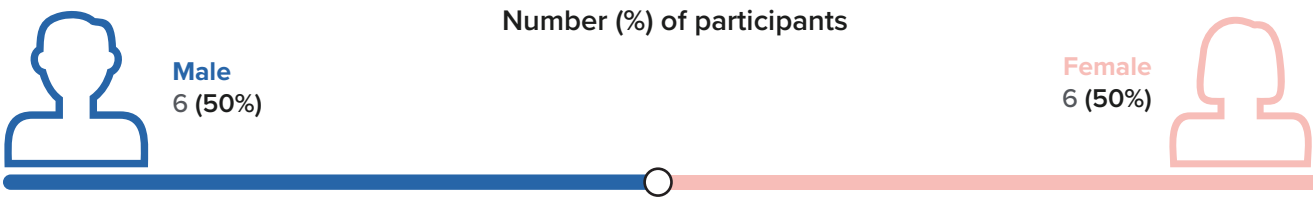
The race of participants is shown below (Number (%) of participants).

White	11 (92%)
Other or More Than One Race	1 (8%)

The ethnicity of participants is shown below (Number (%) of participants).

Not Hispanic or Latino	8 (67%)
Hispanic or Latino	3 (25%)
Not Collected	1 (8%)

Sex of participants is shown below
Number (%) of participants



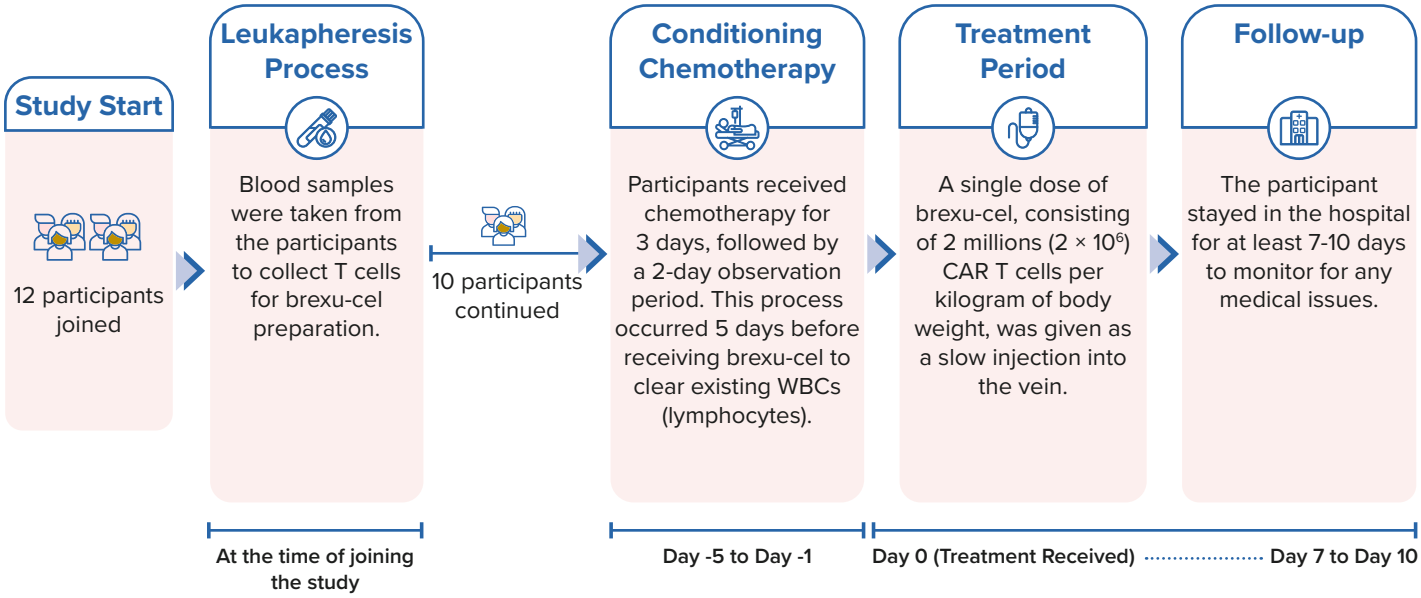
What happened during the study?

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

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

The researchers planned to include and treat 30 participants with r/r BL, 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 12 participants had joined. All 12 participants had leukapheresis. Of these, 10 received chemotherapy followed by brexu-cel treatment. The remaining 2 participants did not receive chemotherapy or brexu-cel.

The graphics below show the study plan:



Study doctors monitored participants in the hospital for at least 7 to 10 days after they received brexu-cel. After discharge, they advised participants to stay near the hospital for at least 4 weeks after brexu-cel treatment, in case they needed any urgent care.

When the study closed, 6 out of 10 participants discontinued the study: 4 died during the study, 1 chose to stop participating, and 1 had worsening of their disease. The remaining 4 participants were moved to a different long-term follow-up study (Study KT-US-982-5968; NCT Number: NCT05041309; EU CT Number: 2023-507041-28). In this new study, doctors can continue monitoring their health and safety for up to 15 years.

What were the results of the study?

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

The study closed earlier than planned. Because only a small number of participants were enrolled, the researchers didn't have enough information to answer this main question of the study or to tell whether the treatment worked in participants with BL.

What side effects did participants have during the study?

Unwanted medical events can happen to the study participants when they take a study drug. In this summary, "**side effects**" are defined as unwanted medical events that the study doctors thought might be caused by the study drug.

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

The results below include only 10 participants, who received brexu-cel.

A side effect is considered "**serious**" if it:

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

Below is the summary of side effects that participants had during the study:

- All 10 (100%) participants had some side effects during the study.
- 4 out of 10 (40%) participants had serious side effects.
- **None of the participants died due to any side effects during the study.**

What were the serious side effects?

The table below shows the serious side effects that occurred during the study.

Serious Side Effects	Brexu-cel Treatment (Out of 10 participants)
	Number (%) of participants
Confusional state	2 (20%)
A condition that makes it hard for a person to talk, understand others, read, or write, because of damage to the brain (Aphasia)	1 (10%)
A condition that makes it hard for people to do movement without muscle weakness (Apraxia)	1 (10%)
A condition that makes a person less awake, alert, and responsive than normal (Depressed level of consciousness)	1 (10%)
Low blood pressure (Hypotension)	1 (10%)
Tiredness (Lethargy)	1 (10%)
Low number of WBCs called neutrophils (Neutropenia)	1 (10%)
A severe infection of the blood caused by a bacteria (Pseudomonal sepsis)	1 (10%)
Low number of platelets (cells that help clot the blood) (Thrombocytopenia)	1 (10%)

What were the non-serious side effects?

The table below lists the most common non-serious side effects that occurred in at least 40% of the study participants. These side effects were not serious in nature and did not meet the definition of 'serious side effects' mentioned in the section above in this summary.

The table below shows the non-serious side effects that occurred during the study.

Non-Serious Side Effects	Brexu-cel Treatment (Out of 10 participants)
	Number (%) of participants
Fever (Pyrexia)	10 (100%)
Neutrophil count gone down (Neutrophil count decreased)	5 (50%)
A liver enzyme increased (Alanine aminotransferase increased)	4 (40%)
WBCs count gone down (WBC count decreased)	4 (40%)

There were other non-serious side effects, but those occurred in fewer participants. Some participants may have had more than 1 serious or non-serious side effects.

? How has this study helped researchers?

Even though the study ended early, the little information the researchers got may still be helpful. They can use the 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.

Kite, a Gilead company, has ongoing studies with brexu-cel.

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: 2022-501261-46
United States National Institutes of Health (NIH) www.clinicaltrials.gov	NCT05537766
Gilead Website www.gileadclinicaltrials.com	KT-US-568-0138-C

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 C – Relapsed/Refractory Burkitt Lymphoma (BL)**

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

GILEAD