PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Kite, a Gilead Company

Kite Protocol Number: KTE-C19-102

Date of Study: November 2015 to June 2025

Short Study Title: Study of Brexucabtagene Autoleucel (KTE-X19) in Participants With Relapsed/ Refractory Mantle Cell Lymphoma

Study Nickname: ZUMA-2

Date of this Plain Language Summary: June 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 **brexucabtagene autoleucel**, also known as **KTE-X19**.

Kite, a Gilead company sponsored this study. This summary is prepared for study participants and the general public.

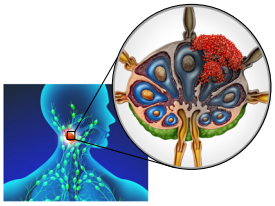
If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

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 Mantle Cell Lymphoma?



Mantle Cell Lymphoma (MCL) is a rare and fast-growing type of blood cancer that originates in B-cell lymphocytes—a type of white blood cells (WBC) produced in the bone marrow. In MCL, abnormal B-cells start to build up in the **lymph node's** outer layer—the mantle zone. **Lymph nodes** are small, pea-sized structures located throughout the body. Together B-cell lymphocytes and lymph nodes are part of the body's immune system (body's defense system), which helps fight infections. Having too many abnormal B-cells can cause infections and other problems in the body.

Chemotherapy is the standard treatment for people with MCL. 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 responds to treatment at first but comes back later, this is called a **relapse**. If the treatment doesn't work at all, the cancer is called **refractory**.

Brexucabtagene autoleucel (Brexu-cel) is a type of **CAR T-cell therapy**. It 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.

This is a **Phase 2** clinical study. This means that researchers tested brexu-cel in a small number of people with relapsed or refractory (r/r) MCL.

What was the purpose of the study?

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

The main question the researchers wanted to answer in this study was:

- **How many participants achieved a complete or partial response after taking brexu-cel?**

Complete response means that the cancer has completely gone away. No signs of cancer outside the lymph nodes, the bone marrow appears normal. No new areas of cancer detected.

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. However, no new areas of cancer detected.

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?

200 participants with r/r MCL around the world took part in the study:

- 14 participants initially joined to receive axicabtagene ciloleucel (axi-cel)
- 186 participants joined later to receive brexu-cel

People could take part in the study if they:

Were at least 18 years of age	Had confirmed r/r MCL	Took up to 5 previous courses of treatment, with or without Bruton's tyrosine kinase (BTK) inhibitor—a type of cancer medicine, but failed to respond

In the beginning of the study, 14 participants received a closely related but different CAR T-cell therapy, axi-cel, while the final manufacturing process for the study treatment was still being established. These participants were from the United States and aged between 43 and 75 years. All were White and not Hispanic or Latino in ethnicity. 12 participants were male and 2 were female.

The 186 study participants who received brexu-cel were between the ages of **38** and **82** years. The other details of these participants are mentioned below.

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

United States	115 **(62%)**	France	13 **(7%)**
Netherlands	30 **(16%)**	Germany	11 **(6%)**
Spain	15 **(8%)**	United Kingdom	2 **(1%)**

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

White	168 **(90%)**	Black or African American	2 **(1%)**
Other or More Than One Race	7 **(4%)**	American Indian or Alaska Native	1 **(below 1%)**
Not Collected	6 **(3%)**	Asian	1 **(below 1%)**
		Native Hawaiian or Other Pacific Islander	1 **(below 1%)**

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

Not Hispanic or Latino	160 **(86%)**	Hispanic or Latino	17 **(9%)**
		Not Collected	9 **(5%)**

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

What happened during the study?

This was a **single-arm**, **open-label** study.

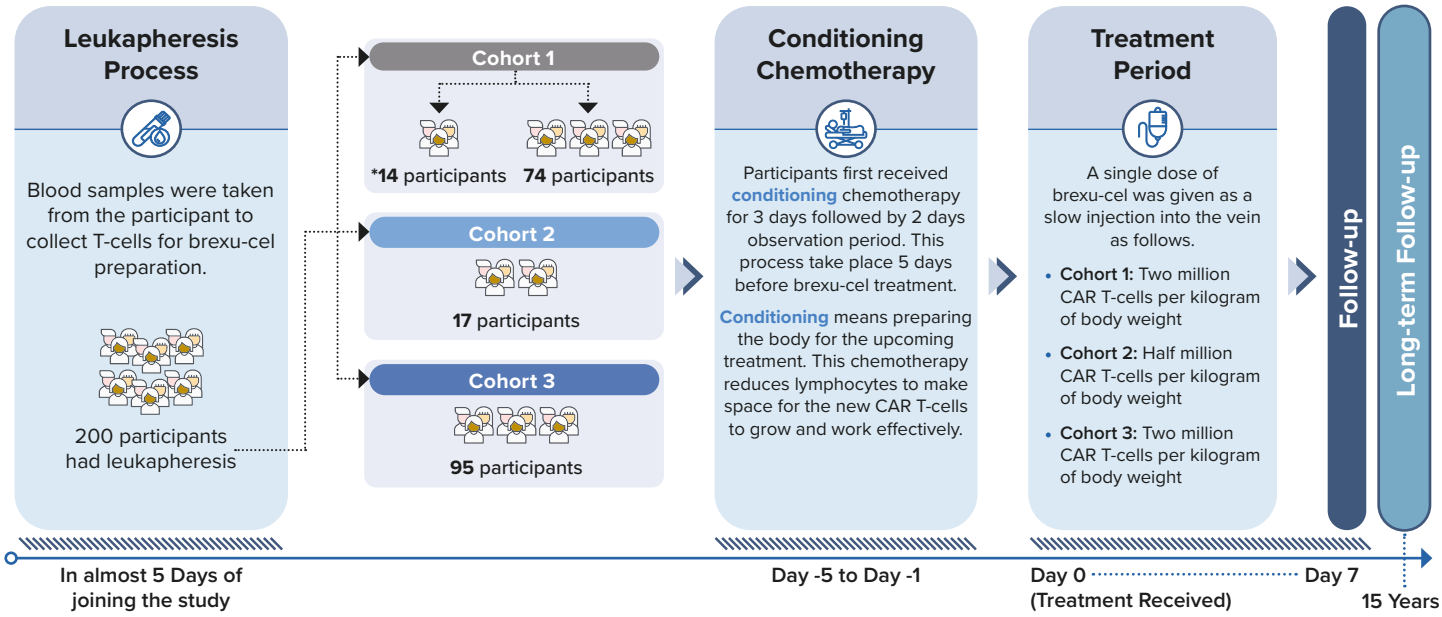
Single-arm means all participants received the same drug, brexu-cel.
Open-label means the participant, the doctors and the study staff knew that the participants were taking brexu-cel.

Researchers enrolled participants into 3 groups called cohorts. A cohort is a group of individuals who share something in common.

- Cohorts 1 and 2 included participants with r/r MCL, these participants received up to 5 previous treatments including BTK inhibitor.
- Cohort 3 included participants with r/r MCL who did not receive BTK inhibitor as a previous treatment.

Cohort 1	Cohort 1 included 74 participants. 69 out of 74 participants received conditioning chemotherapy and 68 received brexu-cel, at a dose of two million anti-CD19 CAR T-cells per kilogram of body weight.
Cohort 2	Cohort 2 included 17 participants. 15 out of 17 participants received conditioning chemotherapy and 14 received a lower dose of brexu-cel, which was half million anti-CD19 CAR T-cells per kilogram of body weight.
Cohort 3	Cohort 3 included 95 participants. 87 out of 95 participants received conditioning chemotherapy and 86 received brexu-cel, at a dose of two million anti-CD19 CAR T-cells per kilogram of body weight.

The graphics below show the study treatment:



*10 out of 14 participants received axi-cel. The results from these 10 participants are not included in this summary, as the study was designed to evaluate brexu-cel. These participants were not part of the main research question of the study.

Follow-up: Study doctors monitored participants in the hospital for 7 days after they received brexu-cel.

Long-term Follow-up: All participants were transitioned to a separate long-term follow-up study (Study KT-US-982-5968; NCT number: NCT05041309; EU CT number: 2023-507041-28), so their safety could continue to be monitored for a total duration of 15 years.

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 mentioned in this summary. A detailed presentation of the results can be found on the websites listed at the end of this summary.

How many participants achieved a complete or partial response after taking Brexu-cel?

The researchers wanted to find out how many participants had a complete or partial response to the brexu-cel treatment. To do this, they compared scans and blood tests taken before and after treatment. They checked if the lymph nodes and other affected areas had returned to normal and whether the levels of normal blood cells had increased.

Of the 186 participants who started the study, the results for 68 participants in Cohort 1, 14 in Cohort 2, and 86 in Cohort 3, who received brexu-cel, are presented below.

The table below shows the participants who achieved complete or partial response in each cohort.

Participants Who Achieved Complete or Partial Response		
Cohort 1 (Out of 68 participants)	**Cohort 2** (Out of 14 participants)	**Cohort 3** (Out of 86 participants)
Number of participants (%)		
62 participants (91%)	13 participants (93%)	78 participants (91%)

Researchers found that the study met its main purpose. There were 62 out of 68 participants (91%) in Cohort 1, 13 out of 14 (93%) in Cohort 2, and 78 out of 86 (91%) in Cohort 3 who achieved a complete or partial response after brexu-cel treatment. The target dose of 2 million CAR T cells showed similar effectiveness in participants who had received BTK inhibitor therapy in the past (Cohort 1) and those who had not (Cohort 3).

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, brexu-cel.

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

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

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

The table below shows how many participants had side effects during the study.

Overall Side Effects

	Cohort 1 (Out of 68 participants)	Cohort 2 (Out of 14 participants)	Cohort 3 (Out of 86 participants)	Total (Out of 168 participants)
	Number (%) of participants			
How many participants had **any** side effects?	66 (97%)	14 (100%)	86 (100%)	166 (99%)
How many participants had **any serious** side effects?	37 (54%)	7 (50%)	42 (49%)	86 (51%)
How many participants **died** due to side effects during the study?	1 (1%)	0	3 (3%)	4 (2%)

None of the participants stopped the treatment due to any side effects.

4 out of 168 participants (2%) died due to serious side effects during the study.

- **Cohort 1**: 1 out of 68 participants (about 1%), died due to a serious bloodstream infection caused by a bacteria (staphylococcal bacteremia).
- **Cohort 3**: 3 out of 86 participants (3%), died due to side effects. One participant had infection, 1 had brain infection caused by the virus, John Cunningham virus (progressive multifocal leukoencephalopathy), and 1 had a life-threatening condition that happens when the sepsis causes blood pressure to drop to a dangerously low level (septic shock).

What were the serious side effects?

The table below shows the serious side effects that occurred in **more than 5%** of the total number of study participants.

Serious Side Effects

	Cohort 1 (Out of 68 participants)	Cohort 2 (Out of 14 participants)	Cohort 3 (Out of 86 participants)	Total (Out of 168 participants)
	Number (%) of participants			
Fever (Pyrexia)	12 (18%)	2 (14%)	19 (22%)	33 (20%)
Low blood pressure (Hypotension)	9 (13%)	3 (21%)	9 (10%)	21 (13%)
A brain condition that seriously affects how a person thinks and acts (Encephalopathy)	12 (18%)	1 (7%)	4 (5%)	17 (10%)
A condition that makes it hard for a person to talk, understand others, read, or write, because of damage to the brain (Aphasia)	3 (4%)	1 (7%)	7 (8%)	11 (7%)
A condition where a person feels confused and less alert or aware than usual (Confusional state)	5 (7%)	0	6 (7%)	11 (7%)
A condition where not enough oxygen reaches the body's tissues (Hypoxia)	5 (7%)	0	6 (7%)	11 (7%)
Presence of fluid in the lungs, usually as a result of infection (Pneumonia)	7 (10%)	0	4 (5%)	11 (7%)

What were the non-serious side effects?

The table below lists the most common non-serious side effects that occurred in **more than 25%** of the total number of study participants. These side effects were not serious in nature and did not meet the definition of 'serious side effects' mentioned in this summary.

The table below shows how many participants had non-serious side effects during the study.

Non-Serious Side Effects

	Cohort 1 (Out of 68 participants)	Cohort 2 (Out of 14 participants)	Cohort 3 (Out of 86 participants)	Total (Out of 168 participants)
	Number (%) of participants			
Fever (Pyrexia)	60 (88%)	11 (79%)	73 (85%)	144 (86%)
Low blood pressure (Hypotension)	30 (44%)	10 (71%)	36 (42%)	76 (45%)
Low number of red blood cells (Anemia)	25 (37%)	2 (14%)	29 (34%)	56 (33%)
Rhythmic muscle contraction leading to shaking movements in one or more parts of the body (Tremor)	24 (35%)	5 (36%)	20 (23%)	49 (29%)
Type of white blood cells gone down called neutrophils (Neutrophil count decreased)	22 (32%)	3 (21%)	21 (24%)	46 (27%)
A feeling of being cold without an apparent cause (Chills)	25 (37%)	6 (43%)	14 (16%)	45 (27%)
Low number of white blood cells called neutrophils (Neutropenia)	12 (18%)	2 (14%)	31 (36%)	45 (27%)
Levels of white blood cells in the blood gone down (White blood cell count decreased)	23 (34%)	4 (29%)	17 (20%)	44 (26%)
A condition where a person feels confused and less alert or aware than usual (Confusional state)	13 (19%)	6 (43%)	24 (28%)	43 (26%)
A condition where not enough oxygen reaches the body's tissues (Hypoxia)	21 (31%)	6 (43%)	16 (19%)	43 (26%)

? How has this study helped researchers?

The researchers learned more about the safety of brexu-cel and how it works in people with r/r MCL.

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.

Gilead Sciences does plan to have further clinical 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.clinicaltrialsregister.eu	EudraCT number: 2023-506641-35-00
United States National Institutes of Health (NIH) www.clinicaltrials.gov	*ClinicalTrials.gov Number: NCT02601313 NCT04880434
Gilead Website www.gileadclinicaltrials.com	KTE-C19-102

*On Clinicaltrials.gov, the study is registered separately for Cohorts 1 and 2 (NCT02601313), and Cohort 3 (NCT04880434)

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

Full Study Title: A Phase 2 Multicenter Study Evaluating the Efficacy of KTE-X19 in Subjects with Relapsed/Refractory Mantle Cell Lymphoma (ZUMA-2)

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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