

# Loncastuximab tesirine in previously treated diffuse large B-cell lymphoma: a plain language summary of the LOTIS-2 study

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## Where can I find the original article on which this summary is based?

You can read the original article, 'Loncastuximab tesirine in relapsed/refractory diffuse large B-cell lymphoma: Long-term efficacy and safety from the phase II LOTIS-2 study', which is free to access, at: <https://doi.org/10.3324/haematol.2023.283459>

## Summary

### What is this summary about?

This article provides a plain-language summary of the results of a clinical trial called the LOTIS-2 study.

The LOTIS-2 study included 145 participants with an aggressive type (one that forms, grows, or spreads quickly) of non-Hodgkin lymphoma called diffuse large B-cell lymphoma (a type of blood cancer), or DLBCL for short, whose disease came back or did not respond after 2 or more previous treatments. The LOTIS-2 study was conducted from August 2018 to September 2022.

Participants received loncastuximab tesirine, also referred to as Lonca, for up to 1 year, or longer if the treatment was working, and their health was monitored. The primary purpose of the LOTIS-2 study was to find out if participants' lymphoma shrank partially or completely after receiving Lonca.

### What were the results?

A total of 145 participants who were treated with Lonca lived a median (meaning the middle value in a set of numbers) of 9.5 months after starting Lonca treatment. The lymphoma shrank partially or completely in nearly half of participants and shrank completely in 1 in 4 participants. Among participants whose disease either shrank partially or completely in response to Lonca treatment, responses happened relatively quickly, with a median time to response (the time between starting treatment and when the participant's lymphoma either partially or completely shrank) of 41 days. In these participants, the lymphoma did not grow or come back for a median of 13.4 months. Researchers estimated that 83% of participants whose disease shrank completely remained disease free for at least 1 year.

Nearly all participants had a side effect from Lonca treatment. The most common side effects were abnormal liver tests (increased gamma-glutamyl transferase), decreased white blood cells (neutropenia), and decreased platelets (thrombocytopenia). One in 4 participants had their treatment stopped due to side effects. The most common side effects that resulted in participants needing to stop Lonca treatment were abnormal liver tests (increased gamma-glutamyl transferase), swelling in the arms or legs (peripheral edema), swelling in an individual spot (localized edema), and fluid around the lungs (pleural effusion).

**How to say** (download PDF and double click sound icon to play sound)...

- **Loncastuximab tesirine:**  
LON-kas-TUK-sih-mab TEH-sih-reen
- **Diffuse large B-cell lymphoma:**  
dih-FYOOS larj B sel lim-FOH-muh



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### What do the results of the study mean?

These results show that Lonca is a treatment option with controllable side effects for many patients with DLBCL whose disease did not respond or came back after 2 or more previous treatments. For participants whose lymphoma completely shrank while taking Lonca, those responses to treatment occurred quickly and lasted for over a year.

### Who should read this article?

This summary may be helpful for patients with DLBCL and their caregivers. Patient advocates and healthcare providers searching for treatment options for patients with DLBCL may also find this article useful.

### Who sponsored this study?

ADC Therapeutics SA **sponsored** this work.

**Sponsor:** A company organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information that was generated during the study.

### What is the purpose of this plain language summary?

- The purpose of this plain language summary is to help you understand the findings from recent research.
- The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence.

### What is diffuse large B-cell lymphoma (DLBCL)?

- **Non-Hodgkin lymphoma** is a blood cancer that affects the lymph nodes. This type of cancer makes up about 4% of all new cancer cases in the United States.
- Nearly 90% of non-Hodgkin lymphoma cases affect a type of white blood cell called **B cells**, which are part of the body's natural defense against infection.
  - » DLBCL is the most common and aggressive non-Hodgkin lymphoma.
- B cells produce proteins called antibodies. These antibodies signal to the **immune system** to destroy and eliminate unwanted **pathogens**.
- DLBCL speeds up the rate at which B cells grow and divide so that the cells no longer develop or function as they should. Compared with healthy B cells, these abnormal B cells are larger and gather in lymph nodes or organs, causing painless lumps or swelling.
- The symptoms of DLBCL depend on how big the lumps and swellings are and where they are in the body. Common DLBCL symptoms include fever, night sweats, and unexplained weight loss.
- About 6 in 10 patients who have newly diagnosed DLBCL can be treated successfully with initial treatment.
- However, about 4 in 10 patients have a disease that either does not respond to or comes back after treatment. DLBCL that does not respond to or comes back after treatment is difficult to manage, with few treatment options available.

**Non-Hodgkin lymphoma:** A specific cancer of the **lymph nodes** that starts in the immune system's white blood cells, which are cells that help prevent infections.

**Lymph nodes:** Organs of the immune system located throughout the body that store lymphocytes (a type of white blood cell) and filter pathogens, such as viruses and bacteria.

**B cells:** A type of white blood cell that makes antibodies to fight infections.

**Immune system:** A network of organs, cells, and proteins that defends the body against infection while protecting the body's own cells.

**Pathogens:** Organisms or agents that enter the body and cause disease to its host.

**Antibody-drug conjugate:** An antibody that is linked to a powerful chemotherapy drug. When it enters the cancer cell, the toxic part is released, causing cell death.

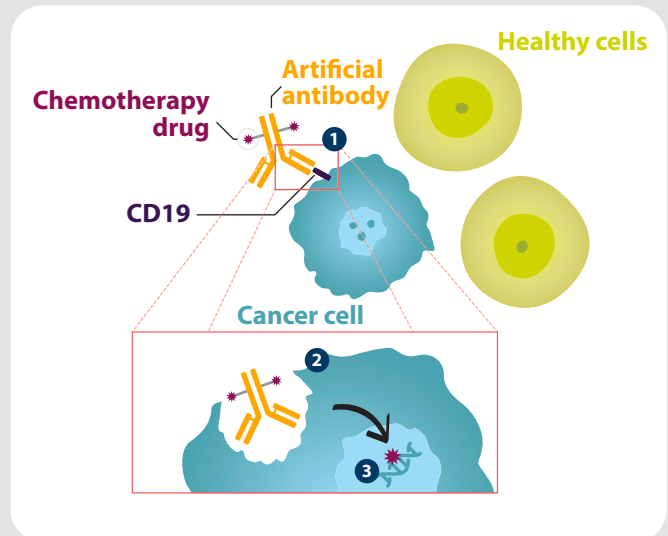
**Target:** Component of the body that a medication works on to produce a beneficial effect.

**Side effects:** Any unintended change to the body caused by the given medication.

## What is Lonca, and how does it work?

• Lonca is a type of therapy known as an **antibody–drug conjugate**. It was approved by the US Food and Drug Administration (FDA) in 2021 for use in patients with DLBCL after 2 or more lines of unsuccessful treatment.

- 1 The antibody is designed to attach or “anchor” to the **target** (for example, a particular protein on the surface of cancer cells). Lonca works by targeting a protein commonly found on DLBCL cells called CD19.
  - 2 When the antibody is attached to the cancer cell, the whole antibody–drug conjugate is taken inside the cancer cell, and the chemotherapy drug is released.
  - 3 The chemotherapy drug of the Lonca antibody–drug conjugate binds to the DNA of the cancer cell, causing it to die.
- » This targeted approach means that a powerful chemotherapy drug can be delivered to the cancer cells with minimal harm to normal cells. This may lead to fewer **side effects** from the cancer treatment.



## Why was the clinical study conducted?

- There are standard treatments that doctors often use first in patients with DLBCL, and these are known as first-line therapies.
- First-line therapies may stop working over time in some patients, so other therapies are needed that either have a different target or work in a different way than first-line therapies.
- While the number of treatment options for DLBCL is increasing, not all patients are eligible for, **able to access** easily, or **able to tolerate** the side effects associated with some or all of these therapies.
- For patients with DLBCL that does not respond to, gets worse, or comes back after treatment, there remains an unmet need for more treatments that are easily accessible, have long-term benefits, and have controllable side effects.
- The overall goal of the LOTIS-2 study was to evaluate how effective Lonca is at treating patients with DLBCL after they had received 2 or more prior treatments.

**Able to access:** Have insurance for or can afford to pay for treatment and live near a hospital that can provide the treatment.

**Able to tolerate:** Be able to take a medication without having to stop or delay treatment due to side effects.

## What was the purpose of this study?

**The researchers wanted to answer the following questions:**

- Did the lymphoma shrink partially or completely after receiving Lonca?
- For how long did the lymphoma shrink partially or completely before growing back again?
- How many participants had their lymphoma shrink completely?
- How long did the participants live after receiving Lonca?
- How long did the participants live before their lymphoma got worse?
- What were the most common side effects? Were any of the side effects severe (critical but not life-threatening)?

**How did the researchers determine how many participants' lymphoma improved after receiving Lonca?**

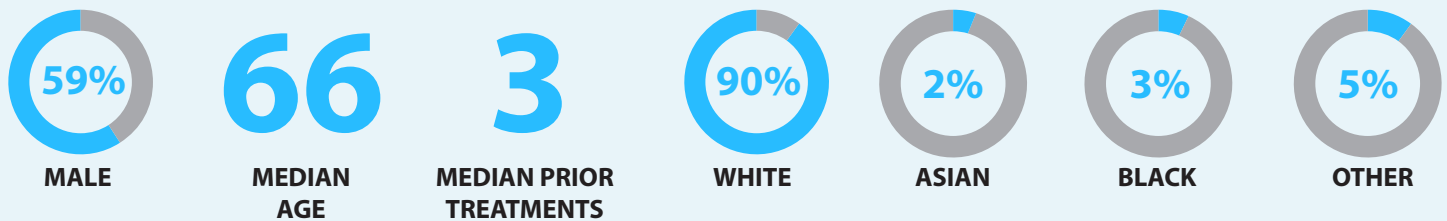
- To answer this question, the researchers measured participants' tumors before and after treatment using a computerized tomography scan, also called a CT scan.
- » The researchers considered tumors that shrunk by more than 50% to be partially shrunk. Tumors that disappeared entirely were considered to be completely shrunk.

## Who took part in this study?

Participants from the United States, the United Kingdom, Italy, and Switzerland could enroll in this study if they met the following criteria:

- Were 18 years or older
- Had DLBCL that did not respond or came back after 2 or more prior treatments
- Had lymphoma that was visible and could be measured by CT scans
- Had an **Eastern Cooperative Oncology Group (ECOG) performance status** of 0 to 2

**145 participants** entered the study, and these participants had the following characteristics:



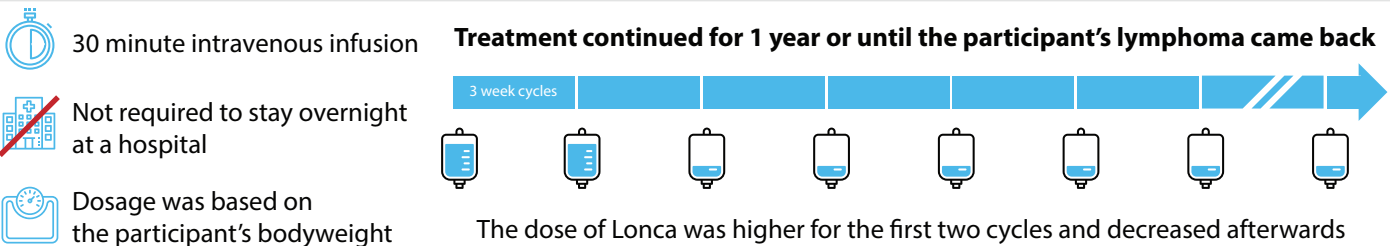
### Eastern Cooperative Oncology Group (ECOG) performance status:

A scoring system that estimates a person's ability to perform tasks and daily activities. A score of 0 indicates a fully active person, a score of 1 indicates that a person can perform daily activities and work that does not require strenuous physical effort, and a score of 2 indicates that a person is capable of self-care but unable to work.

**Median:** The middle value in a set of numbers, with half of the numbers above that value and half of the numbers below that value.

## What treatment did participants receive, what dose was given, and how was it administered?

- LOTIS-2 was an open-label, single-arm study, meaning that Lonca was the only drug included in the study and that both physicians and participants knew what drug the participant was receiving.
- Participants received Lonca in an **outpatient clinic** on the first day of every treatment cycle (each treatment cycle lasted 3 weeks) as a 30-minute intravenous infusion, meaning that the drug was given through the participant's vein.



- Participants received treatment with Lonca for up to 1 year. Lonca treatment was stopped early for participants who had unacceptable side effects and for participants whose lymphoma grew or came back.

» Participants whose disease shrank partially or completely were allowed to stay on treatment for longer than 1 year.

- Once participants stopped receiving Lonca, they continued to be seen by their doctor every 12 weeks for the first year after treatment and then every 6 months for up to 3 years or until their lymphoma worsened.
- Data from all participants who received at least 1 dose of Lonca were included in the study.

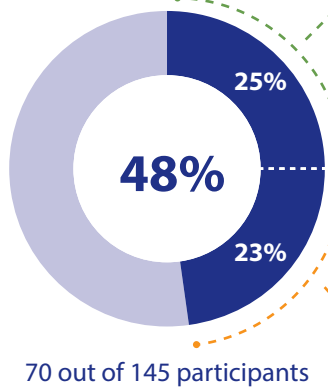
**During the study, participants received the following care:**

- Participants were checked by their doctors for a median time of 7.8 months.
  - » Participants whose disease shrank completely were checked for longer, a median of 35 months.
- Participants received a median of 3 cycles of Lonca treatment.

**Outpatient clinic:** A doctor's office or medical clinic that provides medical treatment or services in a single day without requiring the patient to stay overnight.

## What were the overall results?

Participants whose lymphoma shrank partially or completely



**Participants whose lymphoma shrank completely**  
36 out of 145 participants

Of this 25%, participants who remained lymphoma-free for

**1 YEAR**  
44% (16/36)

**2 YEARS**  
31% (11/36)

**Participants whose lymphoma partially shrank**  
34 out of 145 participants

- The median time needed for the lymphoma to shrink partially or completely was 41 days.
- The median time needed for the lymphoma to completely shrink was 47 days.

## For how long did the lymphoma shrink partially or completely before growing back again?

- For participants whose lymphoma shrank partially or completely, the effects of Lonca lasted a median of 13.4 months.
- Among the 25% of participants whose lymphoma shrank completely, the median length of time the response to Lonca lasted was not reached, meaning that at least half of the participants in this group had not yet experienced progression of their lymphoma at the time the data was analyzed. Participants were checked by their doctor for a median of 7.8 months after starting Lonca treatment.

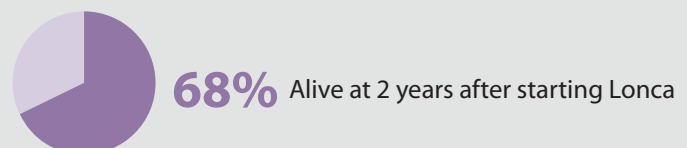


## How long did participants live after starting treatment?

- **Participants lived for a median of 9.5 months after starting Lonca treatment.**
- In the group whose disease shrank completely, the median length of time that participants lived after starting Lonca treatment was not reached by the time the data was analyzed. Participants were checked by their doctor for a median of 7.8 months after starting Lonca treatment.



**Among participants whose lymphoma shrank completely but might have had their lymphoma come back afterwards**

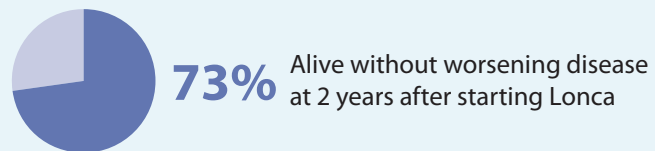
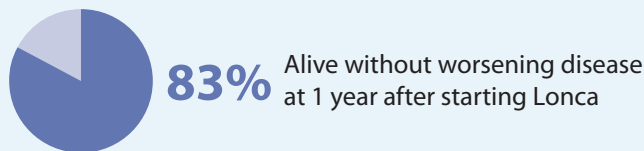


## How long did participants live with their lymphoma before it got worse?

- **Participants lived for a median of 4.9 months from the start of Lonca treatment without their disease getting worse.**
- In the group whose disease shrank completely, the median length of time that they lived without their lymphoma coming back was not reached by the time the data was analyzed. Participants were checked by their doctor for a median of 7.8 months after starting Lonca treatment.



### Among participants whose lymphoma shrank completely but might have had their lymphoma come back afterwards



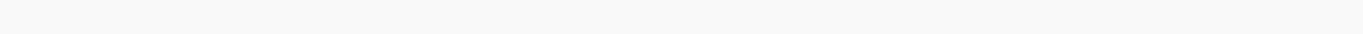
## How long did the response to treatment last after Lonca treatment was stopped?

- Some participants whose disease shrank completely did not have their lymphoma return even after treatment with Lonca had stopped. These participants did not require additional anticancer treatment for a median of **6.1 months**.

Participants whose disease shrank completely & were disease free for at least **1 year** did not require additional anticancer treatment for a median of **24.8 months**

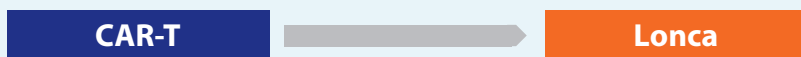


Participants whose disease shrank completely & were disease free for at least **2 years** did not require additional anticancer treatment for a median of **27.7 months**



## How are previous and future therapies impacted by treatment with Lonca?

- The researchers wanted to know if previous treatments might affect the response to treatment with Lonca.
- This is because after a treatment has failed, the disease can become **resistant**, such that future treatments that have the same target may not cause the cancer to shrink or disappear.
- A common treatment is **CAR-T therapy**.



- In this study, 14 participants had previously received CAR-T therapy.
  - » Six (43%) participants who had previously received CAR-T therapy had lymphoma responses to Lonca treatment, meaning that prior treatment with CAR-T therapy did not affect the ability of the lymphoma to later respond to Lonca.

**Resistant:** The ability of organisms or cells to resist the effects of medications that normally are effective against them.

**CAR-T therapy:** A way to get immune cells called T cells (a type of white blood cell) to fight cancer by modifying them in a laboratory so that they can find their target on cancer cells and destroy the cancer cells.

**Lonca**

**CAR-T**

- Researchers also wanted to know if treatment with Lonca would prevent the later use of CAR-T therapy that has the same target. In other words, for participants whose lymphoma came back or got worse after treatment with Lonca, would the lymphoma respond to other treatments that also have the same target?
  - » After treatment with Lonca, 16 (11%) participants went on to receive CAR-T therapy.
    - Of those 16 participants, 9 (56%) participants' disease responded to their CAR-T therapy, with 8 (50%) of these participants' lymphoma shrinking completely for at least some period of time. The LOTIS-2 study was not designed to follow these participants beyond this point.

**Lonca**

**Stem cell transplant**

- Lastly, researchers wanted to know if treatment with Lonca would prevent a later **stem cell transplant**, another common treatment for DLBCL.
  - » Twelve (8%) participants had a stem cell transplant after Lonca treatment. Their lymphoma shrank completely after transplant in 4 (80%) of the 5 participants with available data.
  - » This means receiving Lonca as a treatment for DLBCL does not prevent participants from later receiving a stem cell transplant and getting positive treatment results.

**Stem cell transplant:** A procedure that replaces damaged blood cells with a transplant, also called a bone marrow transplant.

## What are the side effects of Lonca?

- Side effects are rated according to their severity into 1 of 5 grades.

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild effects	Moderate effects	Severe effects	Life-threatening effects	Death
Does not affect daily activities or need to be treated.	Affects daily activities and may need to be treated.	Affects daily activities and may put participants in the hospital.	Side effects are life-threatening and require urgent management.	Side effects lead to death.

- Most participants (99%) in the study had at least 1 side effect of any grade.
  - » The most common side effects were the following:



**42%**

**Abnormal liver tests**  
(increased gamma-glutamyl transferase)



**40%**

**Decreased white blood cells**  
(neutropenia)



**33%**

**Decreased platelets**  
(thrombocytopenia)

- The percent of participants with more severe (at least grade 3) side effects was 74%.
  - » The most common severe side effects were the following:



**26%**

**Decreased white blood cells**  
(neutropenia)



**18%**

**Decreased platelets**  
(thrombocytopenia)



**17%**

**Abnormal liver tests**  
(increased gamma-glutamyl transferase)



**10%**

**Decreased red blood cells**  
(anemia)

- Side effects associated with the chemotherapy part of the Lonca antibody–drug conjugate include skin-related reactions, such as rash and sensitivity to light; swelling in the arms, legs, or an individual spot (**peripheral** or **localized edema**); fluid around the lungs (**pleural effusion**); increased levels of certain liver **enzymes**; and decreased white blood cells (**neutropenia**), decreased **platelets** (thrombocytopenia), and decreased red blood cells (**anemia**). These side effects were generally controllable by participants taking a drug called dexamethasone before and after receiving Lonca.
- Skin-related side effects were generally controllable by participants minimizing or avoiding exposure to sunlight.
- For edema and effusion, the recommendation was to take a medication known as a diuretic to help reduce fluid buildup.
- In some cases, reducing or delaying the Lonca dose was necessary to alleviate the side effects.
- The percentage of participants whose treatment was stopped due to side effects was 25%.
  - » The most common side effects that resulted in participants needing to stop taking Lonca were the following:
    - Abnormal liver tests (**increased gamma-glutamyl transferase**) (12%)
    - Swelling in the arms or legs (**peripheral edema**) (3%)
    - Swelling in an individual spot (**localized edema**) (2%)
    - Fluid around the lungs (**pleural effusion**) (2%)
- Of the participants with side effects, 8 (6%) participants died during the study. However, none of the deaths were considered to be due to treatment with Lonca.

**Peripheral edema:** Swelling caused by the accumulation of fluid in the arms and legs.

**Localized edema:** Swelling caused by the accumulation of fluid at a specific location.

**Pleural effusion:** Accumulation of fluid around the lungs in the **pleural cavity**.

**Pleural cavity:** The fluid-filled space that surrounds each lung.

**Enzyme:** A protein that helps speed up metabolism or the chemical reactions in our body. Some enzymes build up substances, while some enzymes break down substances.

**Neutropenia:** A low level of neutrophils, a type of white blood cell that can help fight infection, in the blood.

**Platelets:** A component of the blood that helps blood clots form.

**Anemia:** A condition that develops when your blood produces a lower-than-normal amount of healthy red blood cells. It means your body does not get enough oxygen-rich blood, and the lack of oxygen can make you feel tired or weak.

**Increased gamma-glutamyl transferase:** An increase in a type of enzyme found in the liver.

## What do the results of this study mean?

- The results from the LOTIS-2 study summarized in this article supported approvals in the United States, the European Union, and the United Kingdom for the treatment of DLBCL with Lonca in patients whose disease did not respond or came back after 2 or more previous treatments.
- The LOTIS-2 study in participants with DLBCL who had at least 2 previous treatments demonstrated the following results:
  - » Seventy out of 145 participants treated with Lonca had their lymphoma either partially or completely shrink.
  - » One in 4 participants had their lymphoma shrink completely.
  - » Participants lived for a median of 9.5 months after starting Lonca treatment and for a median of 4.9 months without their lymphoma getting worse.
  - » For participants whose disease responded to Lonca, the response was relatively quick at a median of 41 days.
  - » A subset of participants in the study had long-term responses to Lonca, and they were able to remain off treatment for at least 2 years, which may have had positive impacts on their quality of life.
  - » Treatment with Lonca did not prevent participants from going on to be treated with other common treatments for DLBCL if their lymphoma did not go away completely, including treatments with the same target. These treatments can result in the partial or

complete shrinkage of the lymphoma, and participants who later received CAR-T or stem cell transplant had promising responses to those treatments. However, these results are based on small subgroups.

- » The most common side effects were typically controllable.
- It should be noted that this article presents the results of 1 clinical trial, and these results should not be assumed to be the same in other groups of patients or types of cancer.
- The LOTIS-2 study included a small number of Black/African American participants and Hispanic participants. Further studies could be conducted to confirm how Lonca works in these populations.
- Patient-reported outcome measures, which can be a much more accurate indicator of the impact and severity of side effects and other study-related factors on participants' quality of life, have been reported in another manuscript for LOTIS-2.

## Where can readers find more information on this clinical study?

The full title of the original presentation published online in August 2023 in *Haematologica* is 'Loncastuximab tesirine in relapsed/refractory diffuse large B-cell lymphoma: Long-term efficacy and safety from the phase II LOTIS-2 study', and is free to access.

You can read the full text for the original publication at: <https://haematologica.org/article/view/haematol.2023.283459>.

You can read a manuscript that discusses patient-reported outcomes at: [https://www.clinical-lymphoma-myeloma-leukemia.com/article/S2152-2650\(21\)02031-0/fulltext](https://www.clinical-lymphoma-myeloma-leukemia.com/article/S2152-2650(21)02031-0/fulltext).

You can read more about the LOTIS-2 study by entering the number NCT03589469 into the search field at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or visiting <https://www.clinicaltrials.gov/study/NCT03589469>.

If you were a study participant and have questions about the results of this study, please speak with the doctor or staff at your study center.

### Educational resources

- Read more about non-Hodgkin lymphoma at: <https://www.cancer.net/cancer-types/lymphoma-non-hodgkin>.
- Read more about types of B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL), at: <https://www.cancer.org/cancer/types/non-hodgkin-lymphoma/about/b-cell-lymphoma.html>.
- Learn about the National Comprehensive Cancer Network clinical practice guidelines for patients with DLBCL in the 2024 NCCN guidance for patients at: <https://www.nccn.org/patients/guidelines/content/PDF/nhl-diffuse-patient.pdf>.
- Read more about DLBCL at: <https://lymphoma-action.org.uk/types-lymphoma-non-hodgkin-lymphoma/diffuse-large-b-cell-lymphoma>.

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### Declaration of interests

Mehdi Hamadani has received research funding from ADC Therapeutics SA and Spectrum Pharmaceuticals; he has been a consultant with AbbVie, ADC Therapeutics SA, BMS, Caribou, CRISPR, Gamida Cell, Genmab, Incyte Corporation, Kadmon, Kite, Legend Biotech, MorphoSys, Novartis, Omeros, and Seagen; has speakers bureau memberships for ADC Therapeutics SA, AstraZeneca, BeiGene, Kite, and Sanofi Genzyme; and participated on data monitoring committees for Genentech and Myeloid Therapeutics. Paolo F. Caimi has received research funding from AbbVie, ADC Therapeutics SA, and Genentech; he was on the advisory board for ADC Therapeutics SA, Amgen, BeiGene, Bristol Myers Squibb (BMS), Genentech, Kite, MEI Pharmaceuticals, and Novartis. Brian Hess has been a consultant with ADC Therapeutics, AstraZeneca, and BMS; has speakers bureau membership for BMS. John Radford has received research funding from Takeda; he has been a consultant or advisor for ADC Therapeutics, BMS, Kite Pharma, Novartis, and Takeda; has speaker bureau memberships for ADC Therapeutics, Seattle Genetics, and Takeda; current stockholder at ADC Therapeutics and AstraZeneca (spouse); provided expert testimony for and received honoraria from ADC Therapeutics and Takeda. Melhem Solh has been a consultant or advisor for ADC Therapeutics and Genentech; has speaker bureau memberships for BMS, GSK, and Sanofi. Pier Luigi Zinzani has been a consultant for EUSA Pharma, MSD, Sanofi, and Verastem; he has participated in advisory committees for ADC Therapeutics and Sandoz; he has been on the speakers bureau or advisory committees for BMS, Celltrion, EUSA Pharma, Gilead, Janssen-Cilag, Kyowa Kirin, MDS, Roche, Servier, Takeda, TG Therapeutics, and Varastem. Luqiang Wang and Zhiying Cindy Xu were employed and a current stockholders at ADC Therapeutics SA at the time of the study. Carmelo Carlo-Stella has received research funding from ADC Therapeutics SA, Roche, and Sanofi and has received honoraria from ADC Therapeutics SA, AstraZeneca, BMS, Incyte, Janssen Oncology, and Takeda; he has been a consultant with Sanofi; has been on the board of directors, speakers bureau, or advisory committee for ADC Therapeutics SA, BMS, Celgene, Karyopharm, Roche, and Sanofi. The authors have no other relevant affiliations, financial involvement, or competing interests with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

### Reviewer disclosures

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