

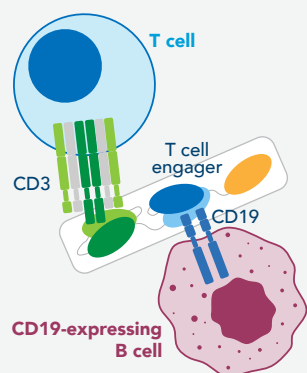
A Study of CLN-978, a CD19-directed T Cell Engager, in People with Sjögren's Disease

Investigating a Potential New Treatment for Sjögren's Disease

In this Phase 1b clinical trial, researchers are studying the **T cell engager, CLN-978**, as a potential treatment for people with active, moderate to severe Sjögren's disease.

The purpose of this study is to evaluate the safety, effects on the immune system, and effects on disease activity of CLN-978 in people living with Sjögren's disease. The trial will explore various doses of CLN-978.

What is a T Cell Engager?



In the body's immune system, there are special cells called T cells that find and destroy harmful cells.

T cell engagers are a type of treatment that works by guiding the body's own T cells to recognize and eliminate certain cells in the body.

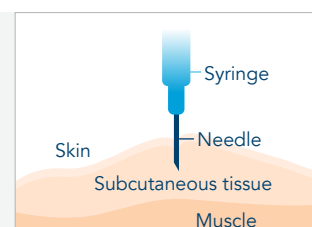
B cells are another type of immune cell that usually help fight infections. Sometimes, B cells can make proteins that cause diseases like Sjögren's disease.

CLN-978 is a T cell engager. It works by guiding T cells to find B cells. Each CLN-978 molecule sticks to a T cell and a B cell, which makes the T cell destroy the B cell.

CLN-978 is investigational and has not been approved by any health authority. It is being studied in a clinical trial to see if it works for treating Sjögren's disease and is safe.

How is CLN-978 Given?

CLN-978 is given as an injection under the skin called a subcutaneous injection. This provides flexible and convenient dosing.



Who Can Participate in the Clinical Trial?

The trial will enroll eligible people living with active, moderate to severe Sjögren's disease who have:



EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) score ≥ 5 (moderate to severe Sjögren's disease)



had an inadequate response to at least two treatments



tested positive for one or more Sjögren's-related antibodies

*Additional eligibility requirements will apply, and only a study doctor can determine eligibility to participate. For additional information, please see [ClinicalTrials.gov](https://clinicaltrials.gov) (**NCT07041099**) or visit euclinicaltrials.eu (**2025-521462-96-00**).

What Should Participants Expect?



Total participation time: Up to two years, after receiving the investigational therapy

Before treatment begins:

- Participants will attend one or more screening visits before the study treatment period begins.
- Certain tests and procedures will be done to make sure patients are eligible to participate in the study, such as blood sample collections and a physical exam.

Study treatment:

- Prior to CLN-978 treatment, one tissue biopsy will be performed.
- Following a subcutaneous (under the skin) injection of CLN-978, participants will be monitored for two days in an inpatient setting, such as a hospital. Participants may receive up to four weekly injections in total and will stay in the hospital for two days after at least the first two injections.
- All participants will receive CLN-978. No one in the study will receive a placebo. A placebo is a substance that does not have the active ingredient being studied.

Post-treatment follow-up:

- Participants will attend eight follow-up visits to check on their health for one year after receiving the investigational therapy (approximately one visit every one to two months). Eight weeks after CLN-978 is given, one tissue biopsy will be done.
- These visits will include procedures such as physical exams and blood sample collections.

Long-term follow-up (optional):

- There is an additional longer-term year-long follow-up period available to interested participants with four visits in total (every three months).

CLN-978 Clinical Development Program

CLN-978 will be studied worldwide for the treatment of autoimmune diseases where B cells play an integral role:



Sjögren's Disease:

Clinical trial sites are in the U.S.



Systemic Lupus Erythematosus:

Clinical trial sites are in the U.S., Europe, and Australia



Rheumatoid Arthritis:

Clinical trial sites are in Europe

Contact

If you are interested in learning more about this clinical trial, please talk to your healthcare provider, visit ClinicalTrials.gov (NCT07041099), visit euclinicaltrials.eu (2025-521462-96-00), or scan the relevant QR code.

CLN-978 is an investigational agent and has not been approved by the U.S. FDA or any other regulatory agency.

U.S.



EU

