

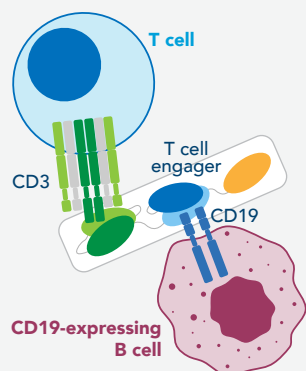
# A Study of CLN-978, a CD19-directed T Cell Engager, in People with Systemic Lupus Erythematosus

## Investigating a Potential New Treatment for Lupus

In this Phase 1 clinical trial, researchers are studying the **T cell engager, CLN-978**, as a potential treatment for people with active moderate to severe systemic lupus erythematosus (SLE) and have not responded well to at least two previous treatments.

CLN-978 is being studied in this clinical trial to evaluate its potential effects on lupus disease activity and the immune system, as well as any risks of the drug in people living with SLE. 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.

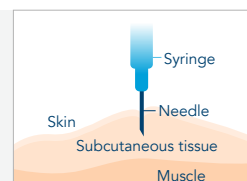
B cells are another type of immune cell that usually help fight infections. Sometimes, B cells can make proteins that cause diseases like SLE.

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 SLE 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 with active SLE who are between 18 and 70 years old who have:



been diagnosed with SLE for at least six months



a Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) score of eight or greater



had an inadequate response to at least two treatments, with one of the two being a biologic therapy or immunosuppressive therapy



tested positive for certain lupus-related antibodies

**Those with active, severe central nervous system disease are not eligible to participate.**

\*Additional eligibility requirements will apply, and only a study doctor can determine eligibility to participate. For additional information, please see ClinicalTrials.gov ([NCT06613360](https://clinicaltrials.gov/ct2/show/study/NCT06613360)).

## What Should Participants Expect?



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

### Before treatment begins:

- Participants will attend one screening visit 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:

- 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:

- After receiving CLN-978 treatment, participants will attend follow-up visits to check on their health on the following schedule:
  - weekly for the first four weeks
  - approximately monthly for the next five months
  - approximately every other month for the next five months
- These visits will include procedures such as physical exams and blood sample collections.

### Long-term follow-up (optional):

- There is an additional follow-up period of 48 weeks 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:



### Systemic Lupus Erythematosus:

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



### Rheumatoid Arthritis:

Clinical trial sites are in Europe



### Sjögren's Disease:

Clinical trial sites are in the U.S.

### Contact

If you are interested in learning more about this clinical trial, please talk to your healthcare provider, visit [ClinicalTrials.gov](https://ClinicalTrials.gov) (NCT06613360), or scan the QR code.



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

