

# Promising results of Phase 1 drug trial for HIV patients

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Credit: University of Minnesota

A Phase 1 clinical trial conducted by University of Minnesota researchers has demonstrated the safety and efficacy of a novel immunotherapy drug in the treatment of human immunodeficiency virus (HIV). Results of the trial were published today in *Nature Medicine*.

"We are excited by the promise shown in this initial trial," said Tim

Schacker, MD, the study principal investigator and vice dean for research at the Medical School. "We hope to move this work into Phase II trials so that we can ultimately add a hopeful treatment for those living with HIV."

The trial involves a novel investigative drug—N-803—that has been studied in blood cancers and with other tumors. This is the first time the drug has been tested with HIV patients, moving beyond the [preclinical phase](#) of study.

This Phase 1 trial at the University enrolled 16 participants who were required to be on [antiretroviral therapy](#) (ART) for at least one year. Of enrollees, 11 completed the trial with minimal adverse effects, suggesting N-803 administration for HIV patients who are ART-suppressed is safe.

Although not a primary goal of the trial, participants using N-803 showed a significant decrease in HIV infected cells in the blood for a period of up to six months following treatment.

"What was exciting in this Phase 1 trial was that it actually showed a decrease in the number of HIV infected cells, suggesting this might eventually be part of a long-awaited HIV cure strategy," said Schacker.

The research team hopes the [drug](#) will go to Phase 2 [trials](#) in the near future.

**More information:** Jeffrey S. Miller et al, Safety and virologic impact of the IL-15 superagonist N-803 in people living with HIV: a phase 1 trial, *Nature Medicine* (2022). [DOI: 10.1038/s41591-021-01651-9](https://doi.org/10.1038/s41591-021-01651-9)

Provided by University of Minnesota

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