

Population Pharmacokinetics, Antidrug Antibodies and Exposure-Response of VH3810109 (N6LS) in Virologically Suppressed Adults Living With HIV From the Phase 2b EMBRACE Study

A. Yin Edwards,¹ Thijs Zweers,¹ Kathryn Brown,¹ Jan Losos,² Peter Leone,² Paul Wannamaker,² Margaret Gartland,² Rulan Griesel,³ Yash Gandhi⁴

¹Certara, Radnor, PA, USA; ²ViiV Healthcare, Durham, NC, USA; ³ViiV Healthcare, London, UK; ⁴GSK, Collegeville, PA, USA

Background

The EMBRACE study looks at a new HIV-1 treatment for adults with an undetectable viral load on successful antiretroviral therapy. It tests an antibody called VH3810109 (also known as N6LS) which works by attaching to a key part of the virus and stopping it from getting into human cells. The aim is to offer a treatment that doesn't need to be taken as often as current medicines, and to find out if the way the virus reacts to this antibody at the start affects how well the treatment works in the long run.

What treatment was studied here?

The focus is on N6LS, an antibody designed to treat HIV-1 over a long period. It's given in this study every 4 months and paired with cabotegravir given monthly, creating a 2-drug approach to managing HIV. N6LS was given as a shot under the skin or in the vein and cabotegravir was given as a shot into the buttocks.

What was the purpose of this study?

The analysis results here are part of a larger study that looked at how effective N6LS is and what side effects it may cause in adults who were already getting treatment for HIV and their HIV was well-controlled. The goal of this analysis was to see how the body handles N6LS and how the amount of N6LS in the body affected its effectiveness and side effects. Researchers want to understand how the drug behaves in the body, what might affect how people's bodies react to the medicine, and whether antidrug antibodies develop. Antidrug antibodies can develop when the body's defense system notices the "foreign" antibody and attempts to remove it from the body.

Who took part in the study and how was the treatment studied?

The study involved 125 adults aged 18-70 who had stable HIV levels and a healthy immune system. They were split into 3 groups: some received N6LS through a shot into the vein, others got it as a shot under the skin, and some continued with regular HIV pills. The study lasted 6 months and focused on how well the treatments kept HIV suppressed and how safe they were.

What are the research findings?

Most participants in the study maintained suppressed HIV levels with N6LS treatment. However a few people had increases in HIV levels compared with levels before entering the study despite treatment. Those who had more of the drug in their system generally did better, although the amount of N6LS in the body by itself wasn't the only reason the drug didn't keep HIV suppressed in some people. The amount of drug in the body wasn't affected much by a person's weight, suggesting that giving doses based on how much someone weighs isn't necessary. Antidrug antibodies were rare and didn't affect the drug's effectiveness or side effects, and reactions at the injection site where the drug was given were not linked to the amount of drug in the body.

What does this mean for people with HIV?

For those living with HIV, this study shows that N6LS could be a promising treatment, helping keep HIV suppressed with fewer doses. The treatment led to few side effects, which might make it easier for people to stick to their treatment.

Conclusions

The EMBRACE study shows that N6LS could be a good option for HIV management, potentially leading to simpler treatment plans and better health outcomes for people with HIV.

Disclaimer

This content was acquired following an unsolicited medical information enquiry by a healthcare professional. Always consult the product information for your country, before prescribing a ViiV medicine. ViiV does not recommend the use of our medicines outside the terms of their license. In some cases, the scientific Information requested and downloaded may relate to the use of our medicine(s) outside of their license.