Evaluation of VH3810109 (N6LS) and Cabotegravir Long-Acting, Dual-Modality Injections for HIV Treatment: People With HIV and Staff Perspectives

Cassidy A. Gutner,[1] Chelsea Macfarlane,[1] Viviana Wilches,[2] David Dorey,[3] Peter Leone,[1] Paul Wannamaker,[1] Jennifer N. Hill,[4] Owen Cooper,[5] Pavol Kral,[6] Margaret Gartland,[1] Christina Donatti,[7] Michael Warwick-Sanders,[8] Riccardo D'Agostino,[8] Rulan Griesel,[7] Jan Losos[1]

[1]ViiV Healthcare, Durham, NC, USA; [2]GSK, Collegeville, PA, USA; [3]GSK, Mississauga, Ontario, Canada; [4]IQVIA, Durham, NC, USA; [5]IQVIA, London, UK; [6]IQVIA, Bratislava, Slovakia; [7]ViiV Healthcare, London, UK; [8]GSK, London, UK

eP131

Please scan the QR code for a copy of the poster and additional resources

Key Takeaways

- **In this implementation science sub-study of the EMBRACE trial, most people with HIV found VH3810109 (N6LS) given every 4 months (Q4M) acceptable regardless of administration route, preferred infusions over injections or daily pills, and reported feeling "free" and "healthier"**
- **People with HIV reported increased treatment satisfaction, minimal concerns regarding Q4M administration, and multiple benefits with clinic visits, with interview responses mirroring positive questionnaire responses**
- **Most staff participants found dual-modality (infusion + injection) treatment acceptable and were comfortable administering N6LS Q4M**

Purpose

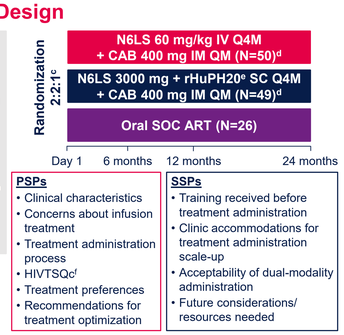
- Effective HIV therapy is evolving, with long-acting (LA) and ultra-long-acting (ULA) formulations that offer convenient, sustainable solutions to improve quality of life and adherence for people with HIV[1]
- As ART shifts from daily oral to LA and ULA formulations, understanding the preferences of people with HIV and healthcare staff becomes crucial for successful adoption
- VH3810109 (N6LS) is a broadly neutralizing CD4-binding site antibody in development for ULA HIV-1 treatment[2]
  - In the phase 2b EMBRACE study, N6LS Q4M + monthly CAB LA maintained viral suppression in a high proportion of adults with baseline N6LS sensitivity at Month 6
- Here, we present perspectives from people with HIV (patient study participants [PSPs]) and staff study participants (SSPs), using a mixed-methods assessment from EMBRACE

Methods

- Of 125 PSPs enrolled, only those who received N6LS Q4M administered intravenously (IV; N=50) or subcutaneously (SC) with recombinant human hyaluronidase (rHuPH20; N=49) + monthly CAB LA IM were included in this sub-study
  - The 26 PSPs who received oral standard-of-care (SOC) ART did not participate in this analysis

EMBRACE Study Design

Key eligibility criteria
- Aged 18-70 y
- ≥2 HIV-1 RNA <50 c/mL in the 12 mo before screening
- No prior ART switch for VF
- CD4+ cell count ≥350 cells/mm^3
- On stable ART for ≥6 mo
- No active HBV co-infection[a]
- Phenotypic sensitivity to N6LS (IC_{90} ≤2.0 µg/mL and MPI >98%)[b]



HBcAb, hepatitis B core antibody; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HIVTSQc, HIV Treatment Satisfaction Questionnaire, change version; IC_{90}, 90% inhibitory concentration; MPI, maximum percent inhibition; VF, virologic failure. [a]Individuals positive for HBsAg or negative for HBsAg but positive for HBcAb with detectable HBV DNA were excluded. [b]Performed using the PhenoSense® mAb DNA assay (Monogram Biosciences, South San Francisco, CA) using peripheral blood mononuclear cell samples obtained at screening. [c]Stratified by N6LS IC_{90} > or ≤1.0 µg/mL. [d]CAB 600 mg IM loading dose on Day 1. [e]rHuPH20 sourced from Halozyme Therapeutics, Inc (San Diego, CA). [f]Total score ranges from −33 to 33, with higher scores representing greater treatment satisfaction.

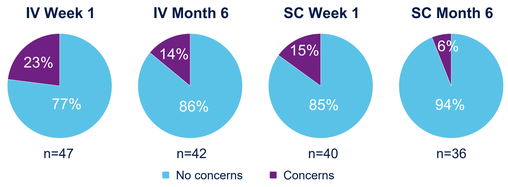
- 97 PSPs completed questionnaires at Week 1 and Month 6; a subset (n=30) completed interviews at Month 6
- SSPs completed questionnaires (n=42) and interviews (n=25) at Month 6

Results

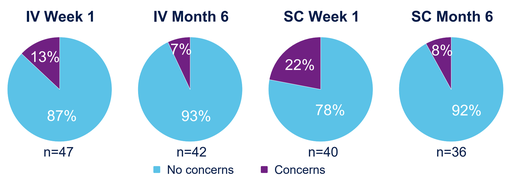
- Most PSPs identified as cisgender male (83%) and White (64%); mean age was 50.8 years, and mean time since HIV diagnosis was 14.8 years

Both IV and SC Administration of N6LS Q4M Were Associated With Minimal Concerns

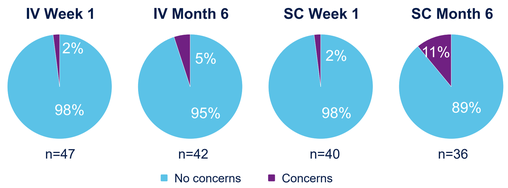
≥86% of PSPs reported no concerns with viral load suppression at Month 6



≥92% of PSPs were not concerned about side effects at Month 6



≥89% of PSPs reported no concerns with managing pain or soreness at Month 6



PSPs Found N6LS Q4M Administration Somewhat to Very Acceptable

At Month 6, 90% of PSPs found N6LS Q4M administration somewhat to very acceptable regardless of administration route

"Convenience, and again, that there is no pain. There are no marks…"
– SC participant

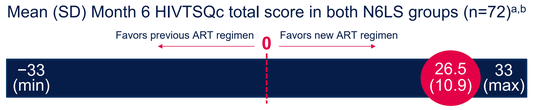
"Because it's better than, like I said, it's better to take the shot every 4 months instead of having to go there to pick up medication every month, pills every month."
– SC participant

"Actually, it's easier… I don't have to remember to carry anything with me. I don't have to remember to take it at a certain time. I don't have to remember a whole lot of anything."
– SC participant

Treatment Satisfaction Increased With N6LS Q4M

PSPs reported improvement in treatment satisfaction at Month 6 (26.5-point increase from baseline)

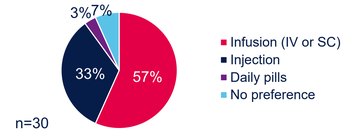
Mean (SD) Month 6 HIVTSQc total score in both N6LS groups (n=72)[a,b]



[a]Higher scores indicate greater satisfaction, with a score of 0 indicating no change. [b]Mean (SD) total score: N6LS IV, 26.5 (11.4); N6LS SC, 26.5 (10.4).

PSPs Preferred Infusions Over Injections or Daily Pills

PSP-reported treatment preference



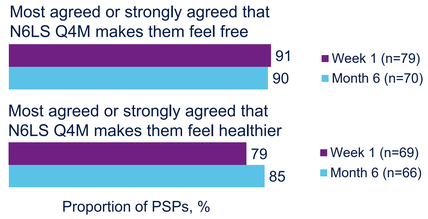
"…it's better to take the shot every 4 months instead of having to go there to pick up…pills every month."
– SC participant

- PSPs reported that infusions were more comfortable and less painful than injections, and they appreciated the less frequent administration compared with daily pills

N6LS Q4M Was Associated With Feeling Free and Healthier

"It's a long-term medication, so you forget about HIV for 4 months…"
– SC participant

"I just think it's amazing. It really has changed my whole outlook on my HIV status and the way that I'm receiving care."
– SC participant

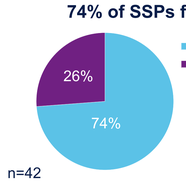


In Interviews, PSPs Discussed Multiple Benefits With Clinic Visit Frequency

While dual-modality (infusion + injection) treatment required periodic clinic visits, PSPs reported benefits with visit frequency (IV: n=12, 80%; SC: n=9, 60%)

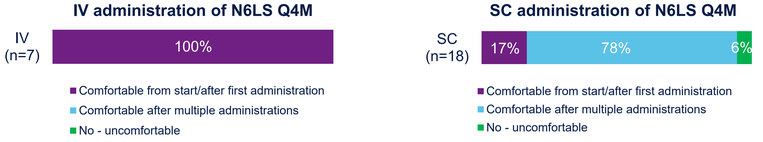
SSPs Found Administering N6LS Q4M Acceptable

74% of SSPs found dual-modality (infusion + injection) treatment acceptable



"That's fine. It's easy. I don't see an issue. I mean, the main issue is the infusions, but including the intramuscular injection, that I don't think it adds too much to the process because the injection is quick and easy, so it's doable."
– Physician

Qualitative Interviews Demonstrated Comfort With IV Administration From the First Administration



"The IV infusion was very straightforward. I mean, you just insert this needle and put just the pump infusion rate. It goes very smooth."
– Nurse

"I would say very comfortable. Our nurse was very comfortable with that. The [SC], I would still put very comfortable, maybe at [an] eight out of ten because it was brand new to him also. The nurse also wasn't very concerned with the directions on administering the [SC]."
– Study research coordinator

- When asked at Month 6, 48% of SSPs preferred SC administration due to ease and timing but needed more up-front training

PSPs Found N6LS Q4M Treatment Straightforward and Convenient

Treatment process

PSPs in the IV and SC groups reported a straightforward process, feeling comfortable, developing positive relationships with clinic staff, and indicating that the treatment process takes time

"Generally, good. The clinical staff, super. They always keep me informed. They explain everything to me. They are always very attentive. There is good communication. All in all, fantastic."
– IV participant

Treatment convenience

All PSPs interviewed (n=30 [100%]) reported that they would recommend the treatment to others, with most (n=22 [73%]) citing convenience compared with taking pills

"Absolutely, yes. For people who have access to medicine, and who have to take a treatment…this is very useful."
– IV participant

"I would certainly recommend it. Because so far it's working for me. So I think it can work for other people as well."
– SC participant

Conclusions

- Dual-modality treatment (N6LS infusion + CAB injection) was well received by PSPs and SSPs, with PSPs reporting higher satisfaction and SSPs comfortable with administration
- LA and ULA treatment options have the potential to transform the lives of people with HIV, as they reported feeling "healthier" and "free" with longer intervals between treatments, improving both psychological well-being and practical aspects of daily life
- Both PSPs and SSPs found IV and SC administration acceptable; having multiple administration routes could enable tailoring treatments to suit both individual preferences and clinic capabilities in the future
- For additional data on N6LS, please see Oral presentation PS09.1 and Posters eP127 and MeP10.1[3-5]

Acknowledgments: This study was funded by ViiV Healthcare. The authors would like to thank the study participants, the investigators and site staff, and the ViiV Healthcare and GSK study team members. Editorial assistance and graphic design support for this poster were provided under the direction of the authors by Fingerpaint Medical and funded by ViiV Healthcare.

References: 1. Nachega et al. *Lancet HIV*. 2023;10:e332-e342. **2.** Taiwo et al. CROI 2025; San Francisco, CA. Oral presentation 203. **3.** Griesel et al. EACS 2025; Paris, France. Oral presentation PS09.1. **4.** Gartland et al. EACS 2025; Paris, France. Poster eP127. **5.** Edwards et al. EACS 2025; Paris, France. Poster MeP10.1.

Presenting author: Cassidy A. Gutner; cassidy.x.gutner@viivhealthcare.com

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.