Experiences and Quality of Life with Long-Acting Lenacapavir from People with Multidrug-Resistant HIV-1 Enrolled in the Phase 2/3 CAPELLA Study

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Conclusions

- Following lenacapavir (LEN) initiation, the majority of CAPELLA participants reported positive experiences with LEN, including improved health status and quality of life (QoL)
- Injection site reactions (ISRs) were common with this twice-yearly subcutaneous (SC) injection; however, ISRs were mostly reported as not or only a little bothersome, and did not lead to discontinuation
- Participants reported increased adherence to their optimized background regimen (OBR) when LEN was part of their treatment regimen, motivated in part by improved virologic outcomes
- Experiences reported by CAPELLA participants aligned with reports by CAPELLA health care providers, study coordinators, and providers from the LEN individual patient use program about their perceptions of participant experiences
- These responses reflect a subset of participants enrolled in CAPELLA. Additional research is ongoing to further understand the personal experience of people using LEN
- The surveys and interview findings will inform strategies for the successful implementation of LEN-based, long-acting injectable therapy combinations

Plain Language Summary

- Lenacapavir is a medicine approved for the treatment of HIV in people who have previously received many different HIV medicines, and for whom many currently approved medicines no longer control HIV due to multidrug resistance
- Lenacapavir is given as an injection under the skin once every 6 months, with the first few doses of lenacapavir given as a pill, and is given along with other HIV medicines selected by a doctor (known as an optimized background regimen)
- Lenacapavir was approved based on positive results of the CAPELLA clinical trial
- Understanding how people felt when they took lenacapavir may help other people who need to start lenacapavir as part of their treatment, and their doctors. We asked people who took lenacapavir in the CAPELLA study to answer questions in order to learn about how they felt about taking lenacapavir
- After taking lenacapavir, most of the people who were surveyed felt good about taking lenacapavir
- Many people experienced "injection site reactions", which are side effects in the part of the body where the injection was given, such as pain, redness, swelling, or lumps under the skin. However, most people found that these side effects did not bother them, or only bothered them a little, and they did not want to stop taking lenacapavir because of these side effects
- The scheduled visits for injections were easy to go to, lenacapavir was easy to use, and people felt the medicine helped them feel better
- All the people who completed the questions wanted to continue taking lenacapavir

Background

- Despite the success of antiretroviral (ARV) therapies for the treatment of HIV-1, new treatment options with novel mechanisms of action are required to overcome pre-existing ARV resistance and achieve virologic suppression, halt progression to AIDS, and reduce morbidity and mortality in heavily treatment-experienced (HTE) people with multidrug-resistant HIV-1[1–3]
- LEN is a first-in-class, potent HIV-1 capsid inhibitor administered by SC injection once every 6 months (Q6M) following initial oral loading[4–6]
- LEN is approved in the EU, US, and other countries for the treatment of HIV-1 in people with HIV-1 (PWH) with HTE with multidrug resistance, in combination with other ARVs, based on results from the ongoing Phase 2/3 CAPELLA trial (NCT04150068)[5,6]
- In CAPELLA, 82% of participants with data were virologically suppressed (HIV-1 RNA <50 copies/mL) at Week 104 of receiving LEN combined with an OBR[7]
- US-based CAPELLA study coordinators, health care providers, and providers from the LEN individual patient use program have reported multiple positive characteristics of LEN based on their experiences with utilizing LEN in the clinical setting[8,9]
- Investigating the experiences of PWH who participated in CAPELLA can help facilitate the implementation of LEN in the real world

Objective

- To explore the experiences and self-reported QoL of CAPELLA participants' following LEN initiation captured via surveys and interviews

Methods

- CAPELLA, a Phase 2/3 multicenter study, assessed the efficacy and safety of Q6M SC LEN combined with an investigator-selected OBR in HTE PWH with multidrug-resistant HIV-1
  - Enrollment in CAPELLA occurred from November 2019 to January 2021
- Participants from the CAPELLA study in the US who received at least one LEN injection were recruited for a one-time web-based survey between December 2022 and November 2023
  - Survey data were summarized using descriptive statistics. No missing data were imputed or pro-rated
- One-on-one, 45- to 60-minute in-depth telephone or web-based interviews were conducted with a subset of the survey respondents using a semi-structured interview guide
  - Qualitative interview data were analyzed using ATLAS.ti® software
- Survey and interview domains included: experiences with LEN, QoL, ISRs, and ARV adherence

Results

Study Population

- Out of 72 CAPELLA participants, 42 were US participants, and 14 US participants completed the survey
  - A summary of survey-respondent demographic characteristics is shown in **Table 1**
- Of the 14 survey respondents, six participated in follow-up interviews

Demographics

Table 1. Summary of Participant Demographic Characteristics

	Survey Respondents (N=14)
Age (years)	
Mean (SD)	61.6 (5.2)
Range	52.2–70.7
Median (IQR)	61.9 (58.4–64.4)
Race[a], n (%)	
Black or African American	6 (43)
White/Caucasian	7 (50)
Other[b]	1 (7)
Ethnicity, n (%)	
Non-Hispanic	12 (86)
Hispanic	2 (14)
Gender identity, n (%)	
Cisgender male[c]	10 (71)
Cisgender female[d]	2 (14)
Other gender category	1 (7)
I prefer not to answer	1 (7)

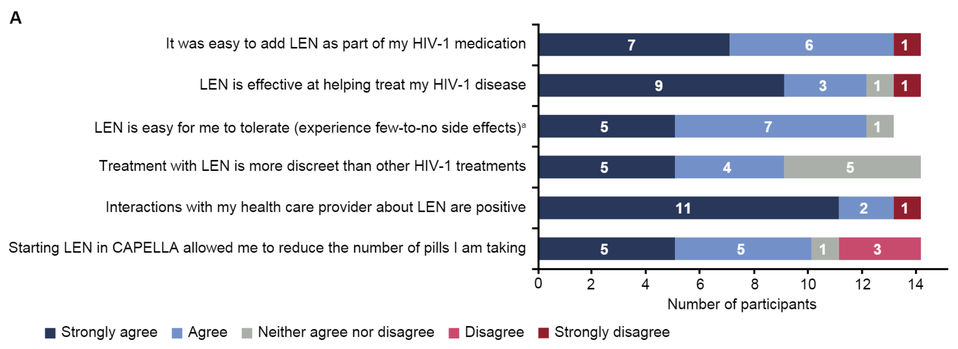
[a]Multiple responses allowed. [b]Identified as unspecified racial group. [c]Assigned male at birth and identifying as male. [d]Assigned female at birth and identifying as female.
IQR, interquartile ratio; SD, standard deviation.

Participant Experiences

- Survey participants reported mostly positive experiences with LEN (**Figure 1**)
  - ≥85% of participants agreed that it was easy to add LEN as part of their HIV-1 medication regimen (n=13/14), that LEN is effective in helping to treat their HIV-1 (n=12/14), and that interactions with their health care providers regarding LEN are positive (n=13/14)

Results (cont.)

Figure 1. CAPELLA Trial Participant LEN Experience A) Survey Results and B) Supporting Quotes from Interviews

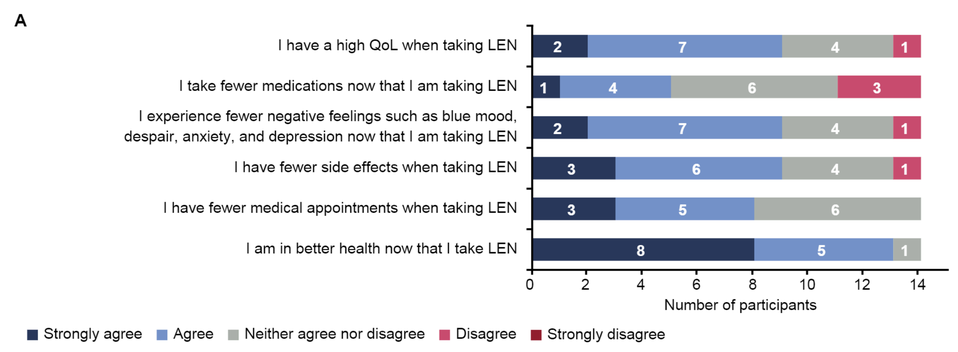


LEN, lenacapavir.
For quotes, extraneous words have been removed and replaced with "[…]". Care has been taken not to distort the meaning of any quotes.

Participant Health and QoL

- ≥85% of participants agreed (n=13/14) that they are in better health after starting LEN (**Figure 2**)
- The majority of participants also agreed that they have a high QoL when taking LEN, have experienced fewer negative emotions now that they are taking LEN, and have fewer side effects when taking LEN (n=9 each; **Figure 2A**)
- Interviewees frequently reported feeling optimistic and encouraged to continue their treatment progress, attributing an enhanced QoL to their use of LEN (**Figure 2B**)

Figure 2. CAPELLA Trial Participant Health and QoL A) Survey Results and B) Supporting Quotes from Interviews

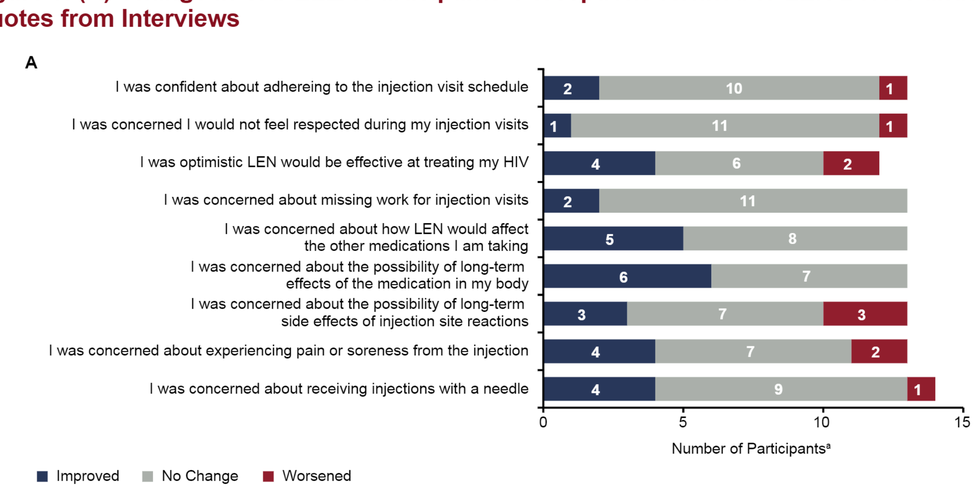


LEN, lenacapavi; QoL, quality of life.
For quotes, extraneous words have been removed and replaced with "[…]". Care has been taken not to distort the meaning of any quotes.

Participant Concerns

- The majority of survey participants reported an improvement or no change in their concerns regarding LEN, after receiving LEN injections compared to before receiving LEN (**Figure 3**)
- The concerns with the largest improvements following LEN initiation included those relating to long-term side effects, drug interactions, and efficacy

Figure 3. (A) Change in CAPELLA Participants' Perceptions Related to LEN Before and After Experience With LEN and (B) Supporting Quotes from Interviews



[a]Participants are only counted if they provided answers to the question for both 'before' and 'after' starting LEN.
LEN, lenacapavir.

ISRs

- All surveyed participants experienced some form of an ISR but were usually bothered either a little, or not at all, by ISRs
  - The most bothersome type of ISR were nodules or firm lumps that remained under the skin at the injection site (n=14), with three participants expressing that it didn't bother them, and three participants expressing that it bothered them more than a little
- ISRs were also considered very/extremely manageable by 10/14 participants, and no participants reported ISRs to be unmanageable
  - While 8/14 participants did not need anything to help manage an ISR, others used a warm compress (n=3), a cold compress (n=3), or an over-the-counter pain reliever (n=2)
- Survey findings were confirmed in interviews. For instance, one interviewee stated "The only reactions I had were the […] little sort of the bumps on either side of my navel where they did the injection, and […] for a couple of days, some itching."
- Every participant either disagreed or strongly disagreed that their experiences with injection site reactions would cause them to consider stopping LEN injections

LEN and OBR Adherence and Continuation

- Participants reported no, or few, difficulties with LEN adherence
  - 85% of participants (n=12/14) reported that time required for clinic visits and ability to travel to the clinic for visits were not difficult at all
- After starting LEN, the number of times participants reported missed doses of other HIV-1 medications decreased
  - Most participants (n=10/14) reported never/rarely missed doses of other ARVs pre-LEN initiation and this improved to all participants (n=14/14) reporting never/rarely missed doses post-initiation
  - Interviews revealed that improved adherence to oral medication was due in part to being encouraged by the positive outcomes associated with LEN
  - One interviewee stated: "…the fact that my lab results have been so good is great reinforcement to remember."
- All participants reported feeling motivated to continue taking LEN

References: **1**. Cutrell J, Jodlowski T, Bedimo R. *Ther Adv Infect Dis*. 2020;7:2049936120901395. **2**. US Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Updated February, 2024. (Accessed June, 2024). **3**. Gandhi RT, et al. *JAMA*. 2023;329:63–84. **4**. Link JO, et al. *Nature*. 2020;584:614–18. **5**. Sunlenca® Prescribing Information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215973s000lbl.pdf (Accessed May 2024).

6. Sunlenca® Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/sunlenca-epar-productinformation_en.pdf (Accessed May 2024). **7**. Ogbuagu O, et al. Presented at IDWeek, October 11–15 2023, Boston, MA, USA. **8**. Fang J, et al. Presented at the European Aids Conference 2023, October 18–21, 2023. Warsaw, Poland. **9**. Herbst AN, et al. Presented at the Internation AIDS Society Meeting, July 23–26, 2023. Brisbane, Australia.

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