Insights and Experiences from the CAPELLA Trial: Perspectives of Healthcare Professionals and Study Coordinators on Lenacapavir Use Amongst Heavily Treatment-Experienced People with HIV

Poster: eP.C1.060

Jarjieh Fang[1], Olga Boiko[2], Abigail N Herbst[1], Megan S Dunbar[3], Lauren Temme[3], Keith Dunn[3], Dylan Mezzio[3], Martin S Rhee[3], Michael Bogart[3], Bridget Gaglio[1], William R Lenderking[1]

[1]Evidera, Bethesda, Maryland, US; [2]Evidera, London, UK; [3]Gilead Sciences, Inc., Foster City, California, US

Key Findings

- Lenacapavir (LEN) is a HIV-1 capsid inhibitor approved for the treatment of heavily treatment-experienced (HTE) people with HIV-1 (PWH), based on the results of the Phase 2/3 CAPELLA study
- CAPELLA study investigator healthcare professionals (HCPs) and site study coordinators (SCs; a specialized researcher who supports the management and coordination of clinical research studies) in the US reported favorable perceptions of participants' experiences with LEN. Additionally, HCPs and SCs believed LEN would have a positive impact on clinical outcomes and quality of life (QoL) for HTE PWH in real-world practice
- Of the perceived barriers to real-world LEN use, HCPs believed factors such as cost and insurance would be the most important barriers in real-world practice once approved; however, this has not been validated in the real-world post-registration
- Overall, CAPELLA HCPs and SCs perceived LEN to be easy to implement into real-world practice

Conclusions

- This analysis showed that LEN has the potential to improve care for HTE PWH:
  - Overall, CAPELLA HCPs and SCs reported an increase in participant optimism and confidence, and reduced concerns post-LEN treatment. If an injection-site reaction (ISR) was experienced, most HCPs and SCs (96%) perceived participants as willing to continue LEN
  - Most HCPs and SCs recognized a strong potential for LEN to improve patient QoL and clinical outcomes, and believed LEN would be easy to integrate into real-world clinical practice
- This study highlights the importance of understanding HCPs' and SCs' experiences and participants' perspectives to support continued real-world use of LEN

Background

- Despite successful antiretrovirals (ARVs), new treatment options are urgently required for HTE PWH with limited treatment options to end the HIV-1 epidemic[1–3]
- LEN is a potent, first-in-class, long-acting HIV-1 capsid inhibitor that is administered subcutaneously every 6 months, following oral initiation dosing[4–6]
  - LEN is approved for the treatment of HTE PWH in combination with other ARVs in the EU, US, and other countries based on results from the ongoing Phase 2/3 CAPELLA study (NCT04150068); CAPELLA study design and enrollment criteria have been previously reported[5–8]
  - Through Week 52 of CAPELLA, 78% of participants who received LEN combined with an optimized background regimen (OBR) achieved virologic suppression (HIV-1 RNA <50 copies/mL)[8]

References: **1**. Temereanca A and Ruta *S. Front Microbiol*. 2023;14:1133407. **2**. Puertas MC, et al. *Lancet Microbiol*. 2020;1:e130–e135. **3**. Eisinger RW, et al. *Clin Infect Dis*. 2019;69:2212–2217. **4**. Link JO, et al. *Nature*. 2020;584:614–618. **5**. Lenacapavir Prescribing Information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215973s000lbl.pdf. (Accessed October 2023). **6**. Lenacapavir Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/sunlenca-epar-product-information_en.pdf. (Accessed October 2023). **7**. Segal-Maurer S, et al. *N Engl J Med*. 2022;386:1793–1803. **8**. Ogbuagu O, et al. *Lancet HIV*. 2023;10:e497–e505.

Acknowledgments: We extend our thanks to the CAPELLA participants, their families, and all participating investigators. This study was funded by Gilead Sciences, Inc. Medical writing support was provided by Rosemary A. Dalton, PhD, of Ashfield MedComms (Macclesfield, UK), an Inizio company, and funded by Gilead Sciences, Inc.

Disclosures: **JF**, **OB**, and **ANH** are all employees of Evidera, part of Thermo Fisher Scientific. **BG** and **WRL** are employees of Evidera, part of Thermo Fisher Scientific and are shareholders of Thermo Fisher Scientific. **MSD**, **LT**, **KD**, **DM**, **MR**, and **MB** are all employees and shareholders of Gilead Sciences, Inc.

Correspondence: megan.dunbar2@gilead.com

Background (continued)

- Understanding HCPs' and SCs' experiences of LEN in the CAPELLA study, and their perceptions of participants' experiences, is an important step in facilitating the implementation of LEN in real-world practice

Study Objectives

- To explore HCPs' and SCs' perspectives and insights from US CAPELLA sites of:
  - Participants' experiences with LEN
  - Potential impact of LEN on clinical and patient outcomes
  - Lessons for real-world practice

Methods

- An online, cross-sectional survey of US CAPELLA HCPs and SCs was conducted between March and September 2023
- Survey domains included:
  - HCPs' and SCs' experience of LEN administration
  - Strategies to support adherence to LEN and other ARVs included in the background regimen
  - Interpretation of participants' experiences of LEN
  - HCPs' and SCs' perceptions of integrating LEN into clinical practice
  - Perceived barriers and facilitators to real-world LEN use
- Data were summarized using descriptive statistics

Results

- Overall, 11 and 14 respondents were HCPs and SCs, respectively

LEN administration experience

- Among respondents, 1 (9%) HCP directly administered LEN injections to participants; the remainder had other care providers administer the LEN subcutaneous injections at their site

Adherence to LEN and OBR

- Most HCPs and SCs (19/25, 76%) reported ease of supporting participants' adherence to LEN
- While most HCPs' and SCs' responses were aligned, 6/14 (43%) SCs reported mixed difficulty when supporting adherence to OBR prior to LEN initiation, with the main barriers to adherence being pill burden, remembering to take medication, and busy lifestyles
- After LEN initiation, an improvement in OBR adherence was reported by 7/11 (64%) HCPs; the remaining HCPs perceived adherence to stay the same

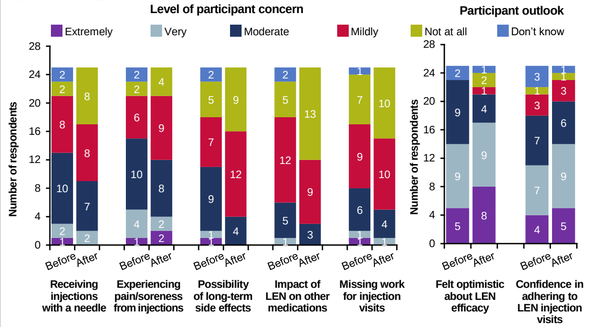
Interpretation of participants' experiences

- After starting LEN, most respondents perceived decreasing concerns among study participants (**Figure 1**)
  - HCPs did not perceive participants to be moderately to extremely concerned regarding long-term side effects, LEN affecting other medication, or missing work for injection visits
  - SCs perceived participants to be moderately concerned about long-term side effects (4/14, 29%), LEN affecting other medication (3/14, 21%), and missing work for injection visits (4/14 [29%] moderately concerned; 1/14 [7%] very concerned)
  - Overall, HCPs and SCs reported improved optimism about LEN efficacy and confidence in adhering to LEN injection visits after starting LEN

Results (continued)

Figure 1. Response frequencies of HCPs' and SCs' perceptions of participants expectations of LEN

Q: How do you think CAPELLA participants felt about LEN before versus after starting the medication? N=25

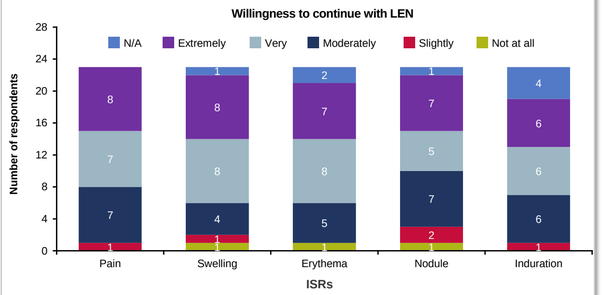


HCP, healthcare professional; LEN, lenacapavir; SC, study coordinator.

- Only one respondent (4%) considered participants to be unwilling to continue LEN following ISRs of swelling, erythema, or nodule (no respondents perceived participants to be unwilling to continue LEN following pain or induration) (**Figure 2**)

Figure 2. Response frequencies of HCPs' and SCs' perceptions of participants' willingness to continue LEN after ISRs

Q: How willing were participants to continue with LEN treatment after experiencing an ISR? N=23



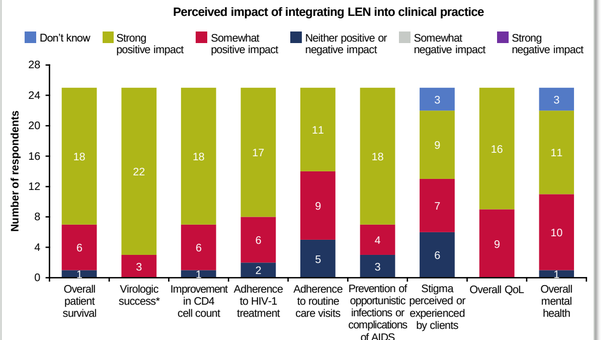
HCP, healthcare professional; ISR, injection-site reaction; LEN, lenacapavir; N/A, not applicable; SC, study coordinator.

Integration of LEN into clinical practice

- Of the 21 respondents with prior experience of administering intramuscular cabotegravir/rilpivirine, 13 (62%) perceived LEN to be as easy or easier to administer, and no respondents perceived LEN as more difficult to administer
- Most respondents considered LEN to be easier or as easy to integrate into clinical practice compared with other treatments for HTE PWH (13/25, 52%) and other injectable HIV-1 treatments (13/25, 52%)
- Respondents reported that LEN has strong potential to improve overall clinical outcomes and QoL of HTE PWH (**Figure 3**)
  - No respondents considered LEN to have any potential negative impacts

Figure 3. Response frequencies of HCPs' and SCs' perceptions of integrating LEN into clinical practice

Q: What impact will integrating LEN into real-world clinical practice have on the outcomes of HTE PWH? N=25



*i.e., HIV-1 RNA <50 copies/mL.HCP, healthcare professional; HTE, heavily treatment experienced; LEN, lenacapavir; PWH, people with HIV-1; QoL, quality of life; SC, study coordinator.

Barriers to real-world LEN use

- Prior to the approval of LEN in the US, most respondents (21/25, 84%) perceived system factors (e.g., insurance, cost) to be the most important potential barrier to regular real-world LEN use
  - Other potential barriers to real-world LEN use perceived by respondents (8% each) included individual client factors (e.g., lack of awareness or cognitive difficulties) and individual provider factors (e.g., resistance or lack of knowledge/skills)
  - No HCPs or SCs considered organizational/teamwork factors or logistic/operational factors as potential barriers

Limitations

- This study was conducted in a small sample size of HCPs and SCs, which may not represent the entire population
- Second hand or indirect feedback about participants' experiences may be inaccurate when not directly reported by the participants
- The system factors or insurance problems and cost being potential real-world barriers to LEN use have not been verified outside of the study setting by HTE PWH receiving LEN, or by payers

Presented at EACS: The 19th European AIDS Conference, October 18–21 2023, Warsaw, Poland