Presence, Severity, Interference With Usual and Daily Life Activities and Bothersomeness of Injection Site Reactions With Cabotegravir vs Lenacapavir: Insights From Participant Reported Outcomes in the CLARITY Study

LB30

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Key Takeaways

- In the CLARITY study, a single dose of long-acting cabotegravir (CAB LA) demonstrated a more favorable injection site reaction (ISR) profile (lower presence, severity, duration, and interference) than a single dose of long-acting lenacapavir
- The more favorable ISR profile of CAB LA compared with LEN LA was demonstrated immediately post-injection, through 6 months of follow-up
- These results highlight the need for personalized discussions, including the impact and severity of ISRs, during selection of long-acting injectables (LAIs)

Plain Language Summary

- The CLARITY study examined how participants experienced injection site reactions (ISRs) from long-acting cabotegravir (CAB LA) and long-acting lenacapavir (LEN LA)
- After receiving CAB LA, participants were less likely to report feeling very bothered by ISRs, less often reported that ISRs interfered with their daily activities, and reported that they experienced less severe and shorter-lasting visible ISRs than after receiving LEN LA
- These findings highlight meaningful differences in the injection site reaction experience of CAB LA and LEN LA injections, and underscore the importance of personalized discussions between patients and their healthcare providers when selecting a long-acting injectable PrEP option for HIV prevention

Introduction

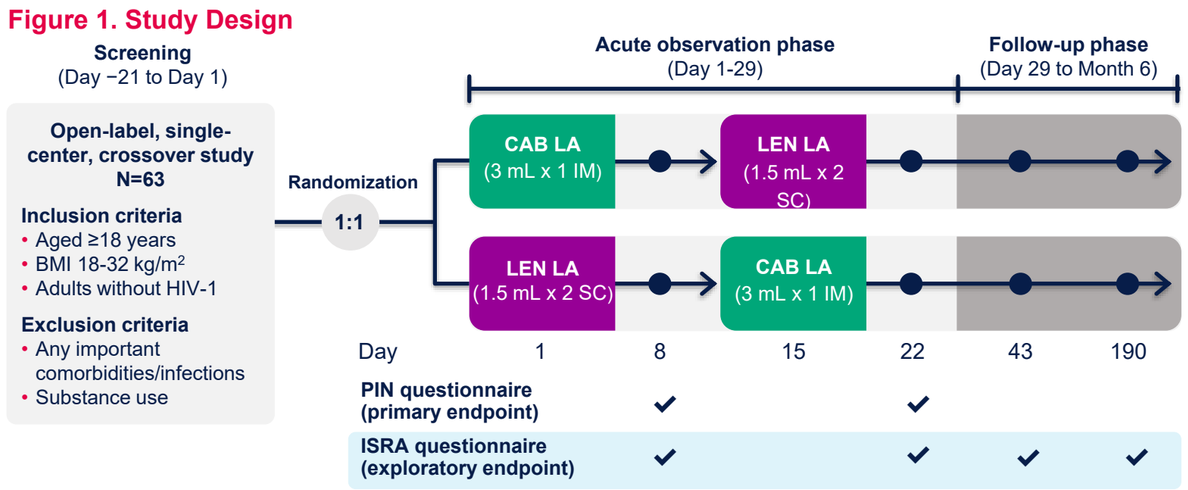
- Injection experience is a key determinant of adherence, acceptability, and persistence with LAIs for HIV prevention. Therefore, experience with ISRs and their impact on daily activities are critical drivers of overall satisfaction and preferences[1]
- ISRs are common with LAIs and may influence willingness to continue[2-5]
- Experience data from people who use PrEP provides essential insight into intervention burden, preferences, and real-world acceptability of LAIs; can help identify barriers to sustained use of injectables; and can support both the development and selection of more person-centered HIV prevention strategies
- The ISR assessment (ISRA) questionnaire was designed for this study to assess the presence, frequency, severity, interference, and bother of LAI-associated visible ISRs to capture participant experiences with CAB LA and LEN LA injections

Methods

Study Design

- CLARITY (NCT06970223) is an open-label, randomized crossover study designed to compare injection experiences between a single dose each of CAB LA, administered intramuscularly, and LEN LA, administered subcutaneously (Figure 1)[6]
- The primary endpoint was defined as the proportion of participants reporting "very acceptable or totally acceptable" local reactions and pain at Day 8 and Day 22 (ie, 7 days after each injection) using the Perception of Injection (PIN) questionnaire, adapted from the validated Vaccinees' PIN questionnaire[7,8]

Figure 1. Study Design



Assessment of Participant-Reported Injection Experience

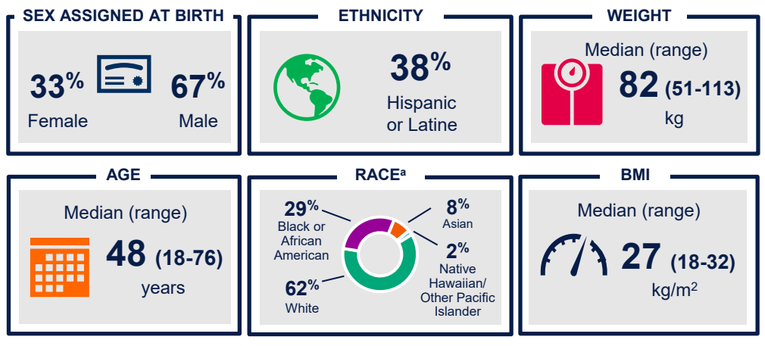
- Participant-reported injection experiences were assessed using the ISRA questionnaire, a 13-item patient-reported outcome measure designed to evaluate individuals' experience of ISRs associated with LAIs. It captures the self-reported occurrence of ISRs, including nodules, swelling, redness, and hyperpigmentation
  - For individuals experiencing ISRs, the tool further assesses perceived severity, asking participants to rate the intensity of their symptoms and the impact of ISRs on daily life, including the extent to which reactions disrupt normal activities over a recent recall period (ie, the past 7 days)
  - The questionnaire also includes an overall assessment of how bothersome these reactions are, providing a comprehensive measure of the overall burden of ISRs on patient comfort and daily functioning
- This analysis presents ISRA data at Day 8 and Day 22 (reflecting early post–cross-over injection experience), and Day 190 (representing the most mature available data point at 6 months post-injections)

Results

Participant Baseline Characteristics

- A diverse group of 63 participants (33% female, 38% Hispanic or Latine, and 29% Black or African American) were enrolled (Figure 2)
- Participants completed ISRA questionnaires after CAB LA injection at Days 8 and 22 (n=61), and Day 190 (n=60), and after LEN LA injection at Days 8 and 22 (n=59), and Day 190 (n=60)

Figure 2. Key Participant Baseline Characteristics

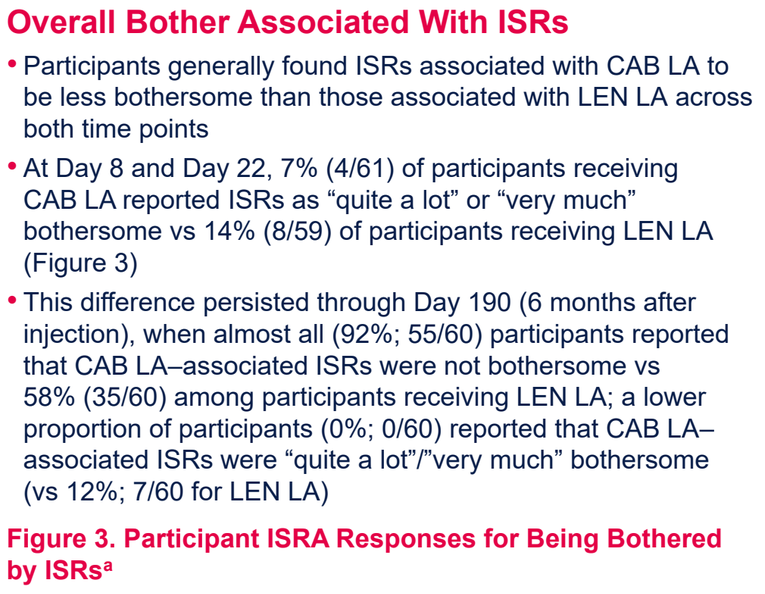


[a]Percentages add up to over 100% due to rounding of individual categories.

Overall Bother Associated With ISRs

- Participants generally found ISRs associated with CAB LA to be less bothersome than those associated with LEN LA across both time points
- At Day 8 and Day 22, 7% (4/61) of participants receiving CAB LA reported ISRs as "quite a lot" or "very much" bothersome vs 14% (8/59) of participants receiving LEN LA (Figure 3)
- This difference persisted through Day 190 (6 months after injection), when almost all (92%; 55/60) participants reported that CAB LA–associated ISRs were not bothersome vs 58% (35/60) among participants receiving LEN LA; a lower proportion of participants (0%; 0/60) reported that CAB LA–associated ISRs were "quite a lot"/"very much" bothersome (vs 12%; 7/60 for LEN LA)

Figure 3. Participant ISRA Responses for Being Bothered by ISRs[a]

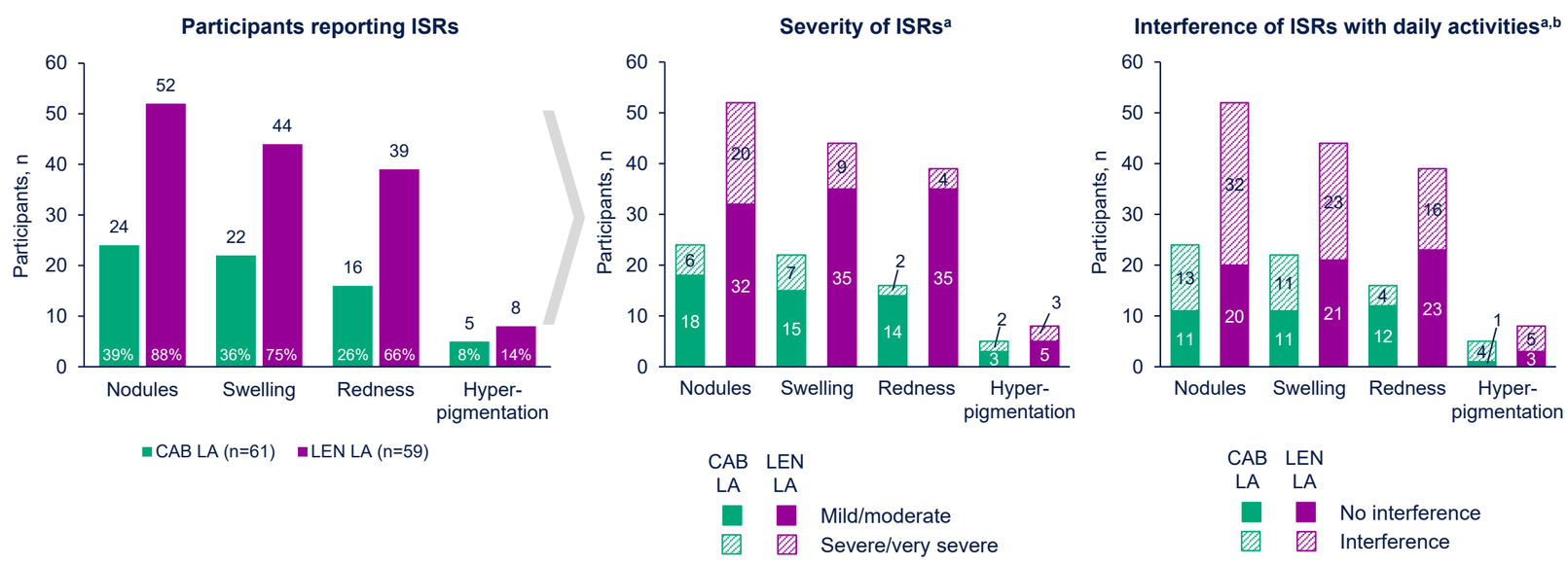


[a]Response categories were "quite a lot," "very much," "a little bit," "somewhat," and "not at all" and are grouped as indicated in the legend.

Days 8 and 22

- At Days 8 and 22, fewer participants reported that they experienced ISRs after the CAB LA injection than the LEN LA injections, with nodules as the most frequently reported ISR (in 39% [24/61] vs 88% [52/59] with CAB LA and LEN LA injections, respectively; Figure 4)
  - Among participants reporting nodules, 25% (6/24) and 38% (20/52) rated them as "severe" or "very severe" with CAB LA and LEN LA injection, respectively
  - Participants also reported that nodules interfered with daily activities (54% [13/24] with CAB LA and 62% [32/52] with LEN LA)
- Results from 7 days after each injection indicate that CAB LA injection is associated with a lower ISR burden than LEN LA

Figure 4. Participant ISRA Responses at Days 8 and 22

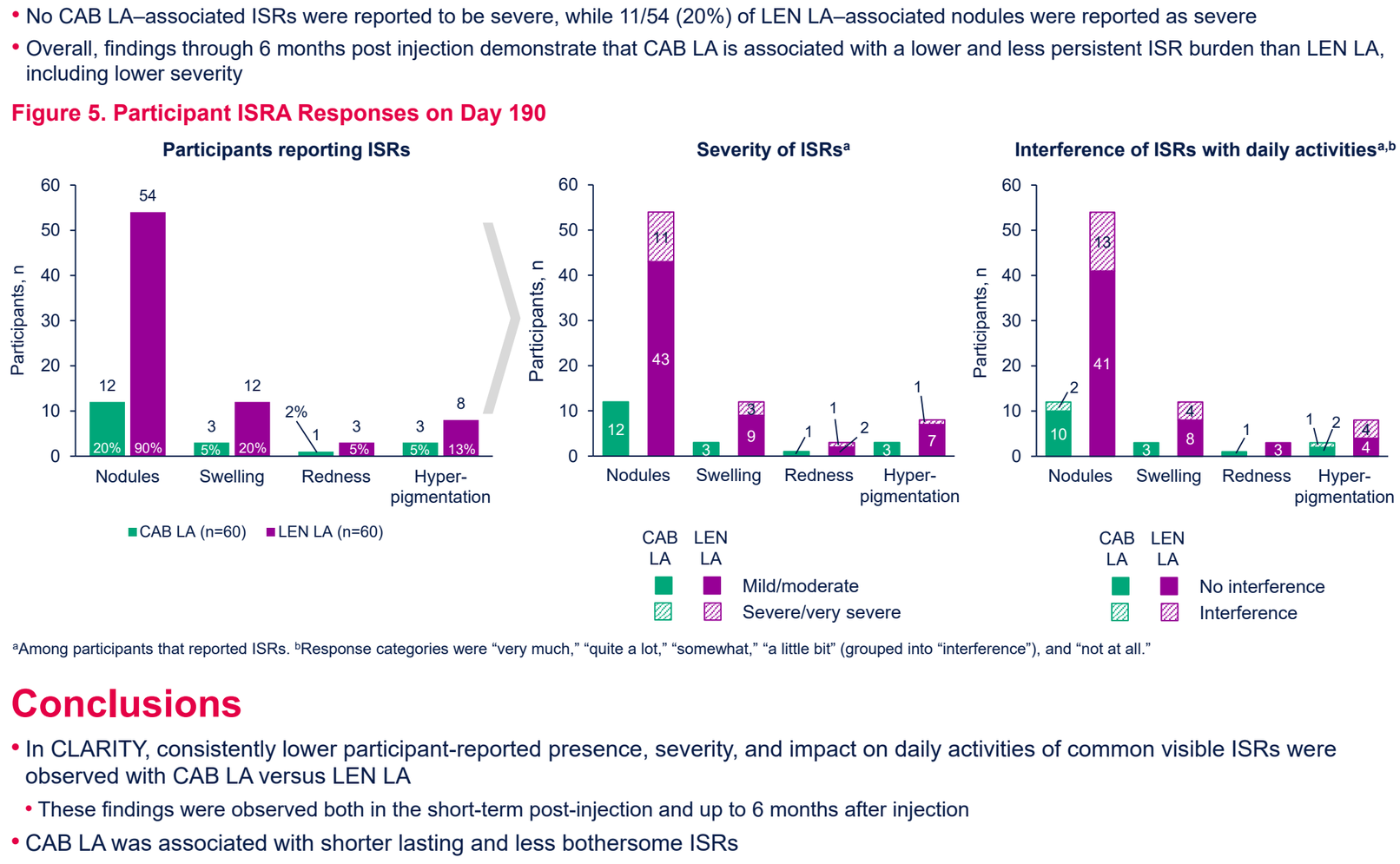


[a]Among participants that reported ISRs. [b]Response categories were "very much," "quite a lot," "somewhat," "a little bit" (grouped into "interference"), and "not at all" (defined as "no interference").

Day 190

- At Day 190 (6 months after injection), only 20% (12/60) of participants continued to report nodules after the CAB LA injection vs 90% (54/60) after LEN LA injections (Figure 5)
- No CAB LA–associated ISRs were reported to be severe, while 11/54 (20%) of LEN LA–associated nodules were reported as severe
- Overall, findings through 6 months post injection demonstrate that CAB LA is associated with a lower and less persistent ISR burden than LEN LA, including lower severity

Figure 5. Participant ISRA Responses on Day 190



[a]Among participants that reported ISRs. [b]Response categories were "very much," "quite a lot," "somewhat," "a little bit" (grouped into "interference"), and "not at all."

Conclusions

- In CLARITY, consistently lower participant-reported presence, severity, and impact on daily activities of common visible ISRs were observed with CAB LA versus LEN LA
  - These findings were observed both in the short-term post-injection and up to 6 months after injection
- CAB LA was associated with shorter lasting and less bothersome ISRs
  - In particular, 20% (CAB LA) vs 90% (LEN LA) of participants continued to report nodules at Day 190
- These results complement previously presented clinical assessments from the CLARITY study,[6,9] and emphasize the value of ISRA in capturing participant-reported outcomes to supplement clinical assessments made by healthcare providers
  - Results of the ISRA questionnaire also corroborate the CLARITY implementation science results presented in AIDS 2026 Poster #WEPEC177[10]
- These findings highlight participant experiences with LAIs and can be used to inform personalized patient-provider discussions including severity and impact of ISRs when selecting a regimen aligned with individual preferences

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References: 1. Ramgopal et al. *Lancet HIV*. 2023;10:e566-577. **2.** Maggi et al. *J Antimicrob Chemother*. 2004;53:678-681. **3.** van 't Klooster et al. *Antimicrob Agents Chemother*. 2010;54:2042-2050. **4.** Kelley et al. *N Engl J Med*. 2025;392:1261-1276. **5.** Landovitz et al. *N Engl J Med*. 2021;385:595-608. **6.** Boles et al. EACS 2025; Paris, France. Poster MeP20.4.LB. **7.** Chevat et al. *Health Qual Life Outcomes*. 2009;7:21. **8.** Chounta et al. *Adv Ther*. 2023;40:5300-5314. **9.** Fox et al. CROI 2026; Denver, CO. Poster 988. **10.** Nelson et al. AIDS 2026; Rio de Janeiro, Brazil. Poster WEPEC177.

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