



Katherine L. Nelson,¹ Laure Dupont-Benjamin,² Justine Boles,³ Emilie Elliot,⁴ Dainielle Fox,¹ Apinya Vutikullird,⁵ Amber Mottola,⁵ Kim Fletcher,⁶ Kehui Wang,⁷ Suryakant Somvanshi,⁸ Richard Grove,⁶ Rebecca Borsi,¹ Nanlesta Pilgrim,¹ Piotr Budnik,³ Jean van Wyk,³ Harmony P. Garges,⁷ Kimberley Brown¹

¹ViiV Healthcare, Durham, NC, USA; ²ViiV Healthcare, Rueil-Malmaison, France; ³ViiV Healthcare, London, UK; ⁴ViiV Healthcare, Madrid, Spain; ⁵Ark Clinical Research, Long Beach, CA, USA; ⁶GSK, London, UK; ⁷GSK, Durham, NC, USA; ⁸GSK, GCC, Bengaluru, India

Key Takeaways

- Participants had a better overall injection experience with a single dose of long-acting cabotegravir (CAB LA) than long-acting lenacapavir (LEN LA) through 6 months, with participants consistently reporting CAB LA as more comfortable and less disruptive to their daily lives
- Healthcare professionals (HCPs) reported a positive administration experience, finding CAB LA less difficult to administer and associated with less noticeable injection site reactions (ISRs) than LEN LA
- Visible ISRs differed between LAIs, with fewer ISR events and shorter ISR duration observed with CAB LA compared with LEN LA through 6 months of follow-up

Plain Language Summary

- 6 months after receiving 1 dose each of 2 long-acting injectables, cabotegravir (CAB LA) and lenacapavir (LEN LA), most participants shared they had a more positive experience with CAB LA than LEN LA
- Participants experienced fewer visible injection site reactions with CAB LA compared with LEN LA

Introduction

- Initial patient and healthcare professional (HCP) experience with long-acting injectables (LAIs) is a key differentiator that may influence LAI selection and persistence¹⁻⁴
- Prior CLARITY findings showed that after a single dose of each LAI, administered sequentially, ISRs were less frequent, visible, and shorter term with CAB LA versus LEN LA, a difference that persisted through up to 6 months^{5,6}
- Here, we report participant and HCP experiences with each LAI up to Day 190 (6 months)

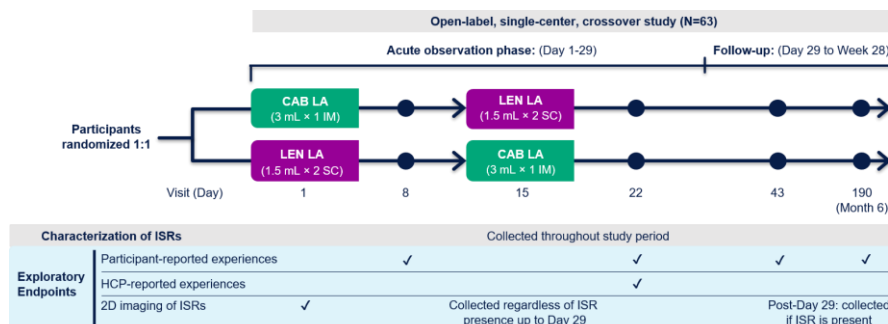
Methods

- CLARITY compared a single dose each of CAB LA (1 intramuscular gluteal injection) and LEN LA (2 subcutaneous abdominal injections) in people without HIV (Figure 1). Primary results have previously been reported^{5,6}
- Participants were adults aged ≥18 years without HIV, and with BMI 18-32 kg/m². Exclusion criteria included any important comorbidities/infections and substance use

Secondary and Exploratory Endpoints

- Participant surveys were completed on Days 8, 22, 43, and 190 (Figure 1)
- HCP surveys were completed at Day 22 to understand experiences with each injection type
- Investigators reported ISR incidence, severity, and duration of ISRs post-injection using the Division of AIDS (DAIDS) criteria
- 2D imaging was performed on all injection sites during planned study visits for 2 weeks post-injection, regardless of ISR occurrence; visible ISRs were imaged at subsequent visits until resolution

Figure 1. Study Design



Results

Participant and HCP Baseline Demographics

- 63 participants (33% female, 38% Hispanic or Latine, and 29% Black or African American) were enrolled
- Four HCPs (1 each self-identified as a physician, nurse, medical assistant, and other) completed the HCP questionnaire

THE PARTICIPANT INJECTION EXPERIENCE

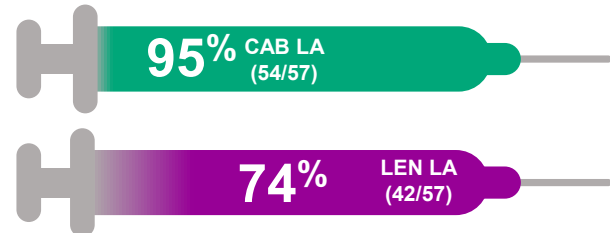
Post-injection Outcomes 7 Days After Each Injection (Day 8 and/or Day 22)

- Participants reported a more comfortable, easy, and positive experience with CAB LA vs LEN LA

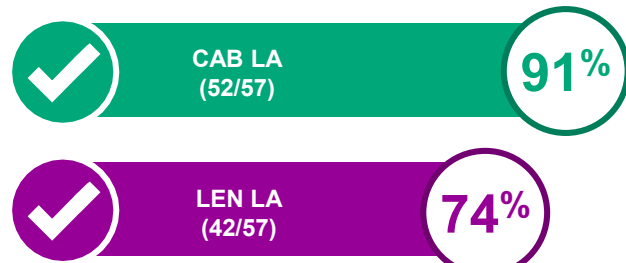
I felt comfortable during the injection process



Receiving the injection was easy



I had a good overall experience with the injection



It took less than 1 minute from start to finish to receive the actual injection(s)^a



I was able to return to my usual daily activities^b immediately after injection appointment



Month 6 Visit Outcomes

- Most participants (72%, 43/60) felt positive about the CAB LA injection compared with 42% (25/60) for LEN LA injections

^aInjections took 1-3 minutes for 28% (16/57; CAB LA) and 56% (32/57; LEN LA) of participants; 4-5 minutes for 2% (1/57; CAB LA) and 12% (7/57; LEN LA); and over 5 minutes for 0% (0/57; CAB LA) and 4% (2/57; LEN LA). ^bExamples of daily activities included going back to work, social events, exercise, and driving.

ERYTHEMA AND HYPERPIGMENTATION EVENTS

- Erythema and hyperpigmentation occurred less frequently with CAB LA vs LEN LA (Table)
- Hyperpigmentation events were shorter lasting with CAB LA vs LEN LA (median [IQR], 29 [15-93] vs 78 [29-127] days), with 0 events ongoing at Month 6 with CAB LA vs 27% with LEN LA
- Erythema duration was comparable between arms

Table. Summary of Erythema and Hyperpigmentation Events Through Month 6

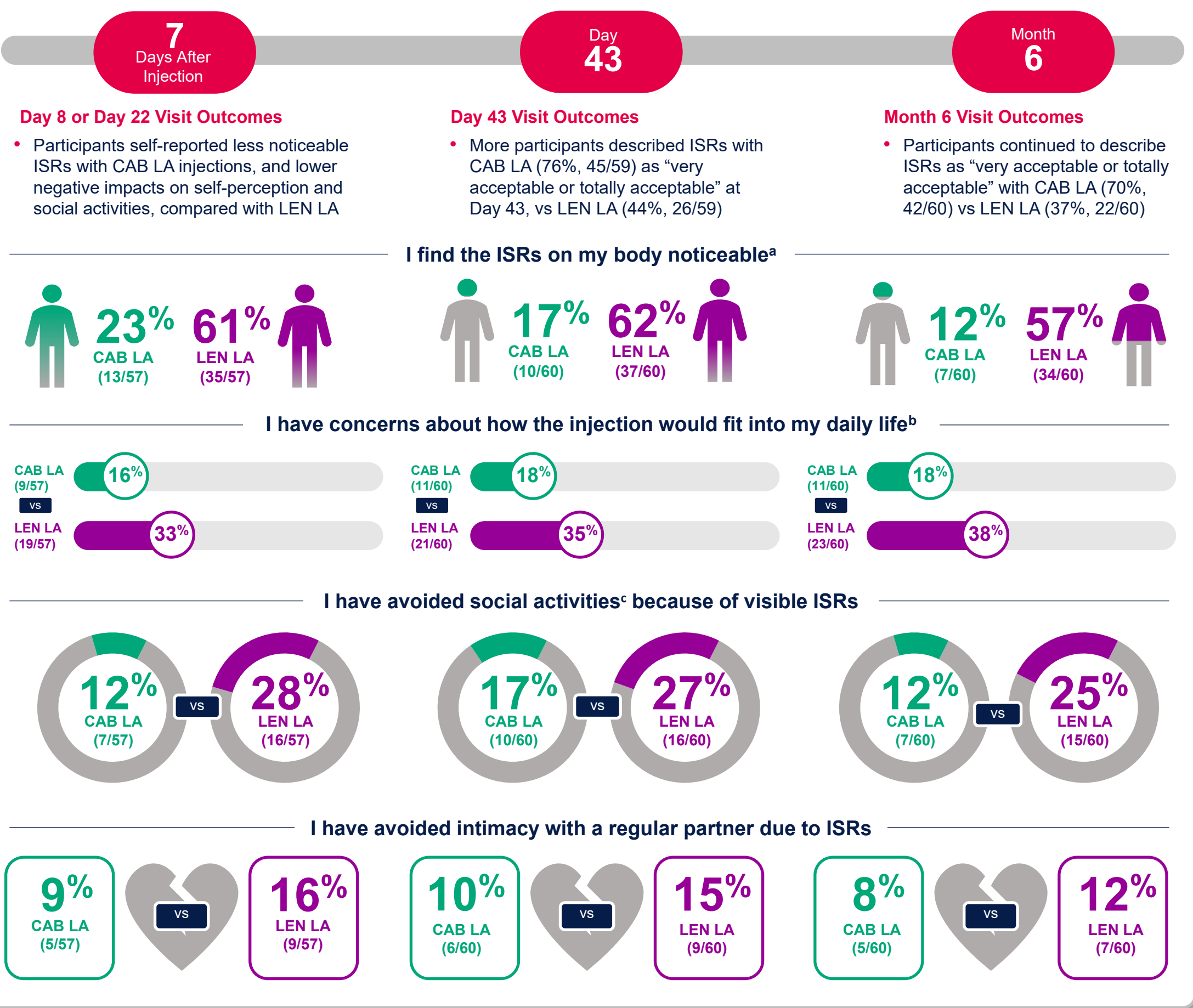
ISR Parameter	CAB LA (n=61)	LEN LA (n=62)
Erythema		
Events, n	7	54
Grade, n (%)		
Grade 1	4 (57)	44 (82)
Grade 2	3 (43)	9 (17)
Grade 3	0	1 (2)
Duration, days, median (IQR)	8 (6-17)	9.5 (5-14)
Maximum surface area, cm ² , median (IQR)	18.4 (12.6-33.0)	13.7 (9.2-22.5)
Hyperpigmentation		
Events, n	5	59
Grade, n (%)		
Grade 1	5 (100)	59 (100)
Duration, days, median (IQR)	29 (15-93)	78 (29-127)
Events ongoing at Day 190, n (%)	0 (0)	16 (27)
Maximum surface area, cm ² , median (IQR)	18.0 (0.8-18.8)	8.8 (4.0-20.0)

Representative Case of Erythema and Hyperpigmentation in 1 Participant Over Time



*Images were only collected for visible ISRs after Day 29.

IMPACT OF ISRs ON PARTICIPANTS



^aIncludes participants who answered "very noticeable" and "noticeable." ^bIf it was one of the options a participant could use to prevent an illness. ^cExamples of social activities provided to participants included swimming, wearing certain clothes, and sex.

THE HCP INJECTION EXPERIENCE

- Overall, HCPs reported greater ease during administration of CAB LA vs LEN LA at Day 22
- 3/4 reported CAB LA required less time to administer than LEN LA
- No HCPs reported having difficulty with administering or managing participants receiving CAB LA, whereas 3/4 had difficulty with LEN LA administration and 2/4 had difficulty managing participants on LEN LA
- Less HCPs described participants' ISRs as noticeable after CAB LA injections (2/4) than after LEN LA injections (4/4)

Conclusions

- Visible ISRs occurred less frequently with CAB LA compared with LEN LA through 6 months of follow-up
- Erythema was shorter lasting with both CAB LA and LEN LA, while hyperpigmentation persisted for a longer duration with LEN LA (27% of events still ongoing at Month 6 vs 0 events with CAB LA)
- In the 6 months following a single dose each of CAB LA and LEN LA, more participants reported noticeable ISRs and avoidance of social activities or intimacy related to LEN LA vs CAB LA injections
- Most participants described CAB LA injections as shorter (<1 minute), easier, and a "good" overall experience than LEN LA injections. HCPs reported that CAB LA was faster and easier to administer than LEN LA
- These results contribute to our understanding of the injection experience with LAIs and how these experiences may influence an individual's willingness to receive or continue an LAI regimen

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.