Participants Report Positive Experiences Switching From Subcutaneous to Intravenous Lotivibart (LVB, N6LS, VH3810109) and Cabotegravir Long-Acting Injections for HIV-1 Treatment in EMBRACE Study

WEPEB097

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Cassidy Gutner,[1] Christina Donatti,[2] Irina Kolobova,[1] Peter Leone,[1] Paul Wannamaker,[1] Owen Cooper,[3] Jennifer N. Hill,[4] Jack Brouwer,[5] Anne Luetkemeyer,[6] Gerald Pierone Jr,[7] Javier Morales-Ramirez,[8] Jan Losos[1]

[1]ViiV Healthcare, Durham, NC, USA; [2]ViiV Healthcare, London, UK; [3]IQVIA, London, UK; [4]IQVIA, New York, NY, USA; [5]IQVIA, Amsterdam, Netherlands; [6]University of California, San Francisco, CA, USA; [7]Whole Family Health Center, Vero Beach, FL, USA; [8]Clinical Research Puerto Rico Inc, San Juan, Puerto Rico

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Key Takeaways

- EMBRACE data show that people with HIV-1 seeking a change from daily pill burden are willing to adopt injectables given just 3 times per year
- Participants reported that a key benefit of SC LVB infusion was not having to take a pill every day and would recommend it to others for this reason
- The overwhelming majority (93%) of participants found that benefits of treatment with LVB + CAB LA outweighed disadvantages and were willing to continue, strongly endorsing regimens administered only a few times a year

Plain Language Summary

- In this study, people receiving lotivibart (an HIV medicine in development) were interviewed after switching from an injection under the skin to an infusion into a vein
- People felt positive about switching how they received lotivibart and preferred receiving it through a vein rather than as an injection under the skin
- Most people felt the benefits of lotivibart outweighed any downsides and said they would recommend it to other people with HIV-1

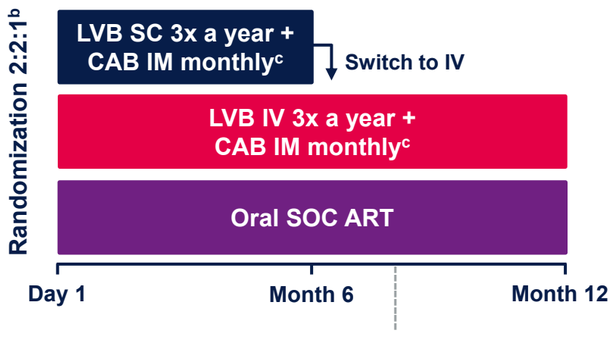
Introduction

- Long-acting (LA) regimens have emerged as an alternative to daily oral antiretroviral therapy (ART), with the potential to reduce pill burden and shift administration from self-managed daily pills to clinic-based injections or infusions[1,2]
- Successful integration of LA regimens into routine care depends not only on their efficacy and safety but also on the acceptability and real-world experience of people with HIV-1 across different modes of administration
- Lotivibart (LVB; formerly N6LS or VH3810109) is a broadly neutralizing antibody targeting the CD4 binding site in development as part of a complete LA regimen in combination with intramuscular (IM) cabotegravir (CAB) LA for the treatment of HIV-1[3]
- We assessed experiences and attitudes among participants who switched from daily ART to subcutaneous (SC) and then to intravenous (IV) infusion of LVB in Part 1 of the ongoing randomized, multicenter, phase 2b EMBRACE trial, which evaluated efficacy, safety, and tolerability of SC or IV LVB 3 times a year + monthly IM CAB LA

Methods

- In addition to evaluating clinical outcomes, the EMBRACE study included evaluation of participant experiences with different LVB administration modalities
  - Participants receiving SC LVB in Part 1 of EMBRACE were required by the study to switch to IV LVB
- Interviews were conducted with participants who switched from SC to IV LVB
  - Interviews were conducted approximately 2 months after participants received their first IV infusion following the switch

Study Design[a]



ART, antiretroviral therapy; BL, baseline; CAB, cabotegravir; FTR, fostemsavir; IC_{90}, 90% inhibitory concentration; IM, intramuscular; IV, intravenous; LA, long-acting; LVB, lotivibart; SC, subcutaneous; SoC, standard of care; VF, virologic failure. [a]At time of enrollment into EMBRACE Part 1, participants were aged 18-70 years with HIV-1 RNA <50 c/mL, were on stable oral ART (excluding CAB or FTR) for ≥6 months, had phenotypic sensitivity to LVB based on IC_{90} of ≤2 µg/mL and a maximum percent inhibition >98% (using the monogram PhenoSense® monoclonal antibody assay on samples obtained at a screening visit), and had no history of VF (HIV-1 RNA ≥200 c/mL). [b]Stratified by LVB IC_{90} > or ≤1.0 µg/mL. [c]CAB 600 mg IM loading dose on Day 1.

- Of 41 study participants who switched from SC to IV LVB, 29 (71%) completed switch interviews
- Interview questions assessed participants' SC to IV switch experiences and preferences, reasons for/against recommending SC infusion compared with previous oral ART, experiences with SC infusion, and benefits/disadvantages of treatment, which included using the Patient's Qualitative Assessment of Treatment version 2 (PQATv2)

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References: 1. Claborn et al. *Psychol Health Med*. 2015;20:255-265. **2.** Kerrigan et al. *PLoS One*. 2018;13:e0190487. **3.** Rolle et al. CROI 2026; Denver, CO. Oral presentation 178.

Results

- Of the 29 study participants who completed switch interviews, 83% (n=24) were male and 17% (n=5) were female

No Daily Pill Burden Was Main Advantage of SC Infusion Over Oral ART

- Participants were asked to compare SC LVB 3 times a year to their previous daily oral ART

Advantages of SC infusion vs oral ART

- **86%** (n=25) Not having to remember/take a daily pill
- **35%** (n=10) Ease of travel without pills
- **14%** (n=4) Does not interrupt daily routine

Emotional impact of SC infusion vs oral ART

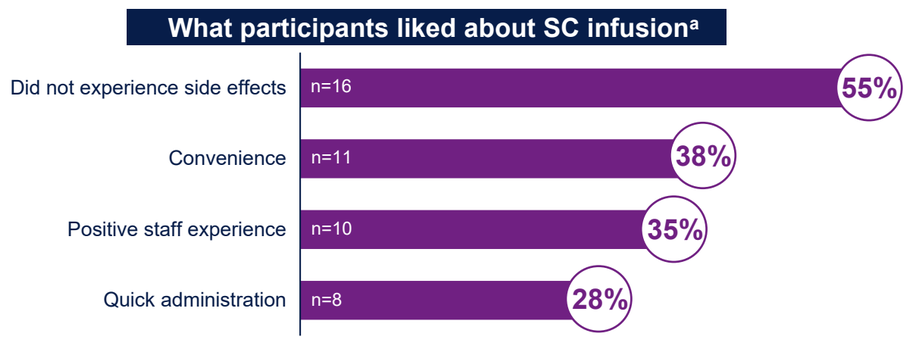
- **52%** (n=15) Relief of not having to remember to take pills daily
- **31%** (n=9) No emotional impact
- **17%** (n=5) Not a daily reminder of illness

- More than half (52% [n=15]) of participants reported no disadvantages (such as time commitment, physical discomfort at infusion site, and painful infusion) of SC LVB infusion compared with oral ART

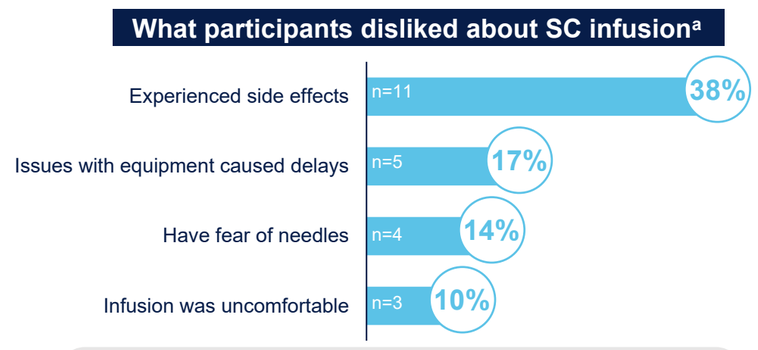
Side Effects of SC LVB: A Benefit for Over Half, a Barrier for Some

- Over half of participants cited no side effects as what they liked about SC LVB infusion, whereas approximately two-fifths reported side effects as a reason for disliking SC LVB infusion

What participants liked about SC infusion[a]



What participants disliked about SC infusion[a]



"The most beneficial thing for me would be not having to take daily medication—it's much easier, fewer complications, not having to remember it every day…"

"…every time I would get my little injection in my tummy…for about 1 day, my tummy would get kind of big and red. Then, by the next day, it would shrink down and everything was fine."

[a]Participants were allowed to provide multiple reasons; therefore, total values may exceed 100%.

Most Participants Would Recommend SC Infusion to Others

- The majority (83% [n=24]) of participants stated in interviews that they would recommend SC infusion 3 times a year to other people with HIV-1
- Top reasons for recommending SC infusion were not needing to take daily pills (48% [n=14]) and convenience (31% [n=9])

"You don't have to think about medication every single day. You only have to think about a single date that you have to return [to the clinic]."

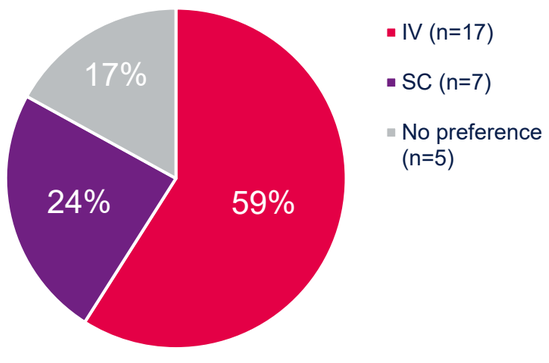
"It's 4 months that you don't have to be taking medication daily. That's a relief."

"I'm always traveling… With this, you don't have to worry about it."

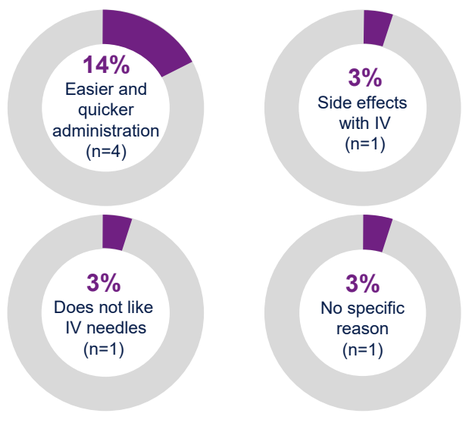
Over Half of Interviews Discussed a Preference for IV Administration

- Participants who received SC LVB were asked about their experience switching to IV administration for the remainder of the study

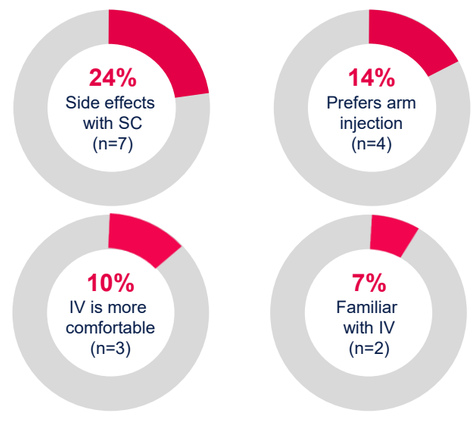
Study treatment preferences



Reasons for preferring to continue with SC



Reasons for preferring to switch to IV



"No problem at all. It was nice to only get poked once in the arm. They could do the blood draw and the intravenous treatment all in one, as opposed to we do the blood draw, then we have to go to the abdomen. That was nice and convenient."

"It virtually makes no difference. I mean, the intravenous [was] as pain-free as a subcutaneous was, getting the needle in for the IV, but that's minor."

Most Participants Discussed Willingness to Continue LVB + CAB LA in PQATv2 Interviews

- When participants shared their overall experience with LVB + CAB LA during the EMBRACE study via the PQATv2 questionnaire, 93% (n=27) reported that the benefits of this regimen outweighed the disadvantages
- Over half (55% [n=16]) of participants discussed no disadvantages
- Nearly all participants (97% [n=28]) reported they would be willing to continue using SC or IV LVB with IM CAB LA after the trial

Mean (SD) score for benefits of drug received during trial (n=29)[a]

Mean (SD) score for disadvantages of drug received during trial (n=29)[b]

[a]Participants were asked "on a scale of 0 to 10, how beneficial was the drug you received during this trial? (0 = Not beneficial at all, 10 = Extremely beneficial)" as part of the PQATv2. [b]Participants were asked "on a scale of 0 to 10, how disadvantageous was the drug you received during this trial? (0 = Not disadvantageous at all, 10 = Extremely disadvantageous)" as part of the PQATv2.

Conclusions

- In the EMBRACE switch interviews, participants overwhelmingly recommended LVB, reporting that its benefits outweighed any disadvantages; the vast majority expressed a willingness to continue using LVB treatment beyond the trial, driven by the freedom of a regimen administered only a few times a year
- Participants switching from SC to IV LVB highly valued the initial SC infusion phase, highlighting its convenience, lack of side effects, and most importantly the liberation from daily oral ART pill burden
- While most participants ultimately preferred IV administration, a subset (24%) favored SC administration
  - Rather than a "one-size-fits-all" model, this highlights that multiple non-oral routes of administration can accommodate individual lifestyle preferences and maximize real-world uptake

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

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