Positive Experiences of Healthcare Staff With Administration of Twice-Yearly Intravenous Lotivibart for HIV-1 Treatment in the EMBRACE Study

P046

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Key Takeaways

- **Data from EMBRACE Part 2 demonstrate strong enthusiasm for LVB administered IV 2 times a year among healthcare staff, reflecting high interest in LA regimens with extended dosing intervals**
- **Similar to 3-times-a-year dosing, healthcare staff reported positive overall experiences with administration of IV LVB 2 times a year, with early challenges described as logistical considerations rather than barriers to acceptability**
- **Healthcare staff viewed freedom from daily pills and extended dosing intervals as potential quality-of-life benefits of 2-times-a-year LVB, highlighting the patient-centered value of less frequent LA treatment**

Plain Language Summary

- In this study, healthcare staff involved in giving lotivibart (an HIV medicine in development) as an infusion into a vein 2 times a year to people with HIV were interviewed about their experiences
- Healthcare staff were enthusiastic about lotivibart given 2 times a year and felt positive overall about their experience giving it as an infusion into a vein
- Many healthcare staff believed that receiving lotivibart treatment only 2 times a year and avoiding daily pills could improve quality of life for people with HIV and reduce the impact of HIV treatment on everyday life

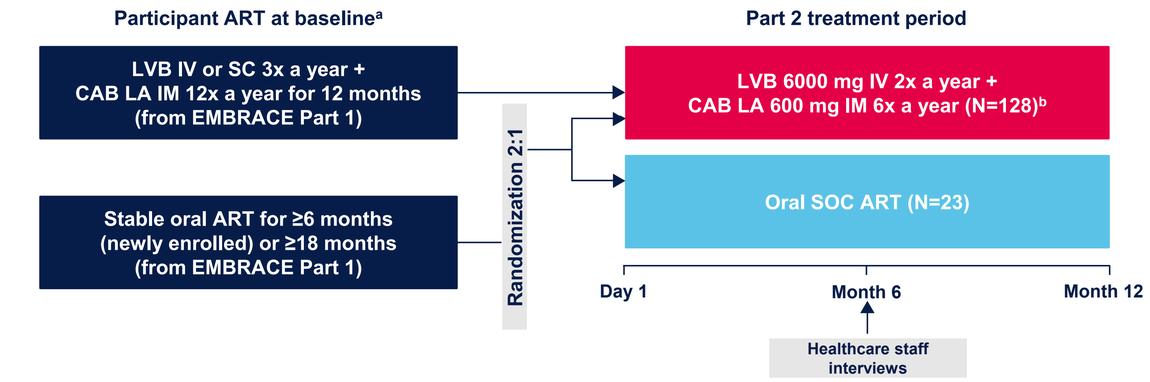
Introduction

- As long-acting (LA) HIV treatment options expand to include clinic-based injections or infusions, clinic capacity, workflow, and administration requirements remain important implementation considerations[1,2]
- Extending dosing intervals to 2 or 3 times a year may reduce treatment frequency and burden for people with HIV.[3] However, the operational implications and healthcare staff experiences with administering a twice-yearly intravenous (IV) LA regimen have not been evaluated
- Lotivibart (LVB) is a broadly neutralizing antibody in development for LA treatment of HIV-1[4]
- EMBRACE Part 1 evaluated 3-times-yearly IV or subcutaneous LVB plus monthly intramuscular (IM) cabotegravir (CAB) LA.[4] Healthcare staff generally reported acceptable experiences with LVB administration 3 times a year[5]
- EMBRACE Part 2 is the first evaluation of IV LVB administered twice yearly in combination with IM CAB LA 6 times yearly. We qualitatively explored healthcare staff experiences with administering IV LVB and their perceptions of its potential implementation and participant benefit

Methods

- EMBRACE Part 2 included adults with virologic suppression and phenotypic sensitivity to LVB who were either:
  - Receiving LVB IV or subcutaneously 3 times a year in Part 1 and switched to LVB IV 2 times a year + CAB LA 6 times a year
  - On stable oral antiretroviral therapy (ART) for ≥6 months (newly enrolled) or ≥18 months (from Part 1) and were randomized 2:1 to receive LVB IV 2 times a year + CAB LA 6 times a year or continue oral standard-of-care ART

EMBRACE Part 2 Study Design



ART, antiretroviral therapy; CAB, cabotegravir; FTR, fostemsavir; IC_{90}, 90% inhibitory concentration; IM, intramuscular; IV, intravenous; LA, long acting; LVB, lotivibart; SC, subcutaneous; SOC, standard of care. [a]Key inclusion/exclusion criteria for enrollment in EMBRACE Parts 1 and 2 included age 18-70 years; HIV-1 RNA <50 c/mL at screening and in ≥2 measurements in the 12 months before screening; on stable oral ART (excluding CAB or FTR) for ≥6 months; phenotypic sensitivity to LVB based on IC_{90} ≤2 µg/mL and maximum percent inhibition >98% (using the Monogram PhenoSense® monoclonal antibody DNA assay on samples obtained at screening); and no prior ART switch due to virologic failure (HIV-1 RNA ≥200 c/mL). [b]Participants initiating LVB + CAB LA received CAB LA 600 mg IM on Day 1, Month 1, Month 2, and every 2 months thereafter.

- Semi-structured qualitative interviews were conducted at Month 6 with a subset of EMBRACE study staff from US sites administering LVB
  - Staff included both LVB administrators and individuals responsible for oversight of administration
- Interview responses were thematically coded and analyzed descriptively
- Themes reflect what staff discussed during interviews; absence of a theme should not be interpreted as disagreement or endorsement of the opposite view

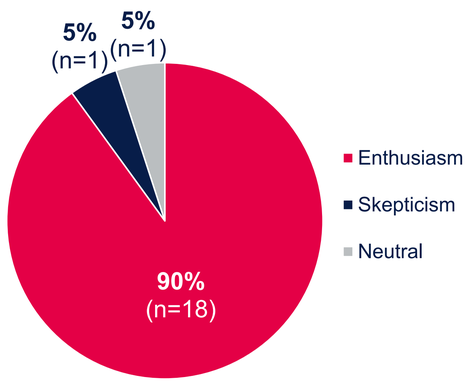
Results

- 21 healthcare staff completed interviews at Month 6

Strong Enthusiasm for Twice-Yearly LVB

- Most (90% [18/20]) healthcare staff felt enthusiastic about twice-yearly LVB
- The potential for longer dosing intervals with LA injectable treatment contributed to the positive initial reactions reported

Initial thoughts toward twice-yearly LVB[a]



*"**I was thrilled**….[Participants] always ask like, 'Oh, when is my next time? How many times?...' What I've seen is…**it's very convenient to have a treatment that can work for longer and [with fewer] visits.…It's more convenience that helps with the burden of remembering every single day.**…. I've seen good feedback of just having a good option that can give them treatment and maintain them in [a] non-detectable state for longer…"*

– Site manager

[a]Percentages are based on the total number of staff surveyed (n=20).

Positive Overall Experiences With Twice-Yearly IV LVB Administration, Despite Logistical Challenges in a Study Setting

- Many healthcare staff reported positive overall experiences with administration of IV LVB

"So far, touch wood, it's been going really, really well. The participants haven't had complaints. Even when we've had a smidgen of equipment issues, the participants themselves have been incredible and just go with the flow. From their perspective, they really like the study and the administration overall."

– Sub-investigator

- Interviews asked about any challenges or benefits related to the administration process

Challenges of IV LVB administration

52% (11/21) Identified IV infusion preparation as complex **in the study setting**

Benefits of IV LVB administration

73% (8/11) Reported participants were receptive to the dual-modality (IV+IM) regimen

  - Challenges related to IV LVB administration were viewed as logistical considerations rather than factors affecting acceptability
  - Many staff emphasized that workflow impacts were manageable with planning and appropriate resource allocation

- Comparisons with existing LA IM regimens were discussed by 15 staff, and 40% (n=6) reported no major differences in overall participant experience between regimens

Staff Perceived Reduced Daily Treatment Burden and Potential Adherence Benefits With Twice-Yearly LVB

- Healthcare staff described several perceived participant benefits of twice-yearly LVB treatment, including less frequent clinic visits and reduced day-to-day treatment burden, which were viewed as positive for participants' quality of life

Discussion of staff-perceived participant benefits of twice-yearly LVB[a]

62% (13/21) **Discussed not taking daily pills**

57% (12/21) **Discussed positive views on extended dosing intervals**

43% (9/21) **Discussed preference for fewer clinic visits**

[a]Percentages indicate the proportion of interviews in which each theme was mentioned.

"I think the biggest compliment is that [participants] no longer have to take pills.…This kind of just frees up that mind space like, 'I don't have to think about it. I just know I have an appointment.' They don't have to be reminded every day that they have HIV, and being able to come in less often is much better for their mental health and day-to-day life."

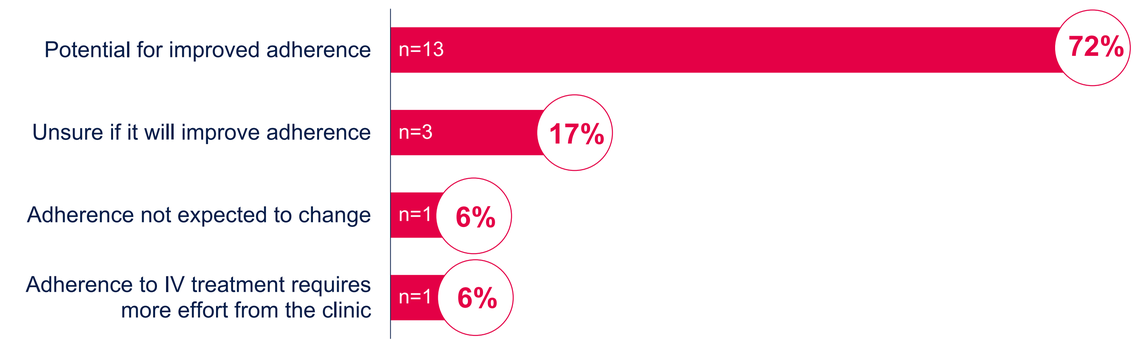
– Study coordinator

"[Participants] really like the treatment because they don't have to worry about pills anymore. They come in, get their infusion, and they're done for 6 months. From their point of view, it removes a big burden from their daily life, and they're very receptive to the combination of injections and infusions."

– Registered nurse coordinator

- 72% (13/18) of staff perceived that administration of IV LVB 2 times a year could support adherence by removing the requirement of daily oral ART

Adherence with twice-yearly LVB compared with daily oral ART[a]



"....People miss a day [of oral therapy] here and there, unfortunately, on occasion just with life.…Sometimes they miss more than just a day, and so the adherence is better because it's an infusion that is planned, scheduled out. They come in. They complete it, and they know their next time."

– Clinical research coordinator

"….We've never had a [participant] miss a single visit. Their adherence to the regimen has been very, very, very good and very consistent."

– Clinical research coordinator

[a]Percentages are based on the total number of staff surveyed (n=18).

Conclusions

- Healthcare staff reported positive initial reactions toward twice-yearly LVB, with 90% describing themselves as enthusiastic about twice-yearly LVB
- Similar to administration of LVB 3 times a year,[5] healthcare staff reported positive overall experiences administering IV LVB 2 times a year
- Early challenges with IV LVB administration were primarily logistical and viewed as manageable with planning
- Healthcare staff perceived avoidance of daily pills, extended dosing intervals, and less frequent clinic visits as potential benefits for participants that may reduce day-to-day treatment burden
- These findings highlight the potential patient-centered value of LA regimens dosed just 2 or 3 times a year, while underscoring the importance of considering clinic operational needs during implementation

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