

Satisfaction, Preference, and Health-Related Quality of Life Changes Using HIV-Specific Patient-Reported Outcome Measures With a Novel, Twice-Yearly Administered HIV-1 Treatment Regimen

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Conclusions

- Participants in an ongoing Phase 2 study (NCT05729568) who switched from daily oral antiretroviral therapy (ART) to twice-yearly lenacapavir (LEN), teropavimab (TAB), and zinlirvimab (ZAB) reported at Week 26:
 - Improved treatment satisfaction and quality of life (QoL)
 - A moderate-to-strong preference for LEN, TAB, and ZAB over daily oral ART
- Upcoming analyses from this study will evaluate patient-reported outcomes (PRO) through Week 52 to provide longer-term data

Plain Language Summary

- Lenacapavir is a medicine given as an injection approved for the treatment of HIV in people who have tried many different HIV medicines, some of which no longer work well for them
- Teropavimab and zinlirvimab are new medicines given as an infusion (a drip into a vein) being tested to help treat HIV
- Lenacapavir, teropavimab, and zinlirvimab can all be given once every six months instead of most HIV treatments that involve taking pills every day
- These three medicines are being tested together in a study with participants who already have no or very low levels of HIV in their blood (called viral suppression)
 - Most participants in the study still had viral suppression six months after treatment with lenacapavir, teropavimab, and zinlirvimab
- The study also asked participants about their experiences after switching from daily HIV pills to lenacapavir, teropavimab, and zinlirvimab (called patient reported outcomes)
 - This included how they felt, how satisfied they were with the treatment, and which treatment they preferred
- Six months after switching to lenacapavir, teropavimab, and zinlirvimab, participants said they:
 - Had more positive feelings about treatment and everyday life
 - Liked lenacapavir, teropavimab, and zinlirvimab more than their usual daily oral HIV treatment

Introduction

- LEN is an HIV-1 capsid inhibitor which can be administered subcutaneously (SC) twice yearly and is approved for the treatment of multidrug-resistant HIV-1¹
- TAB and ZAB are broadly neutralizing antibodies (bNAb) with extended half-lives administered as infusions,² currently under investigation as a twice-yearly combination treatment with LEN for people with HIV-1 (PWH) who are virologically suppressed
- In an ongoing, Phase 2, open-label study (NCT05729568), 1/53 (1.9%) PWH who switched from daily oral ART to twice-yearly LEN, TAB, and ZAB had virological failure (HIV-1 RNA ≥50 copies/mL) by FDA Snapshot Algorithm at the Week 26 primary endpoint, which was comparable with the standard-of-care comparator group³
- PROs provide an assessment of the impact of HIV-1 treatment and care on participants’ QoL⁴
 - In this study, participants were also asked how satisfied they were with their treatment and whether they preferred LEN, TAB, and ZAB over their usual daily oral ART
- PRO data from the ongoing Phase 2 study of LEN, TAB, and ZAB provide the first indication of treatment satisfaction and QoL associated with a twice-yearly treatment regimen for HIV-1

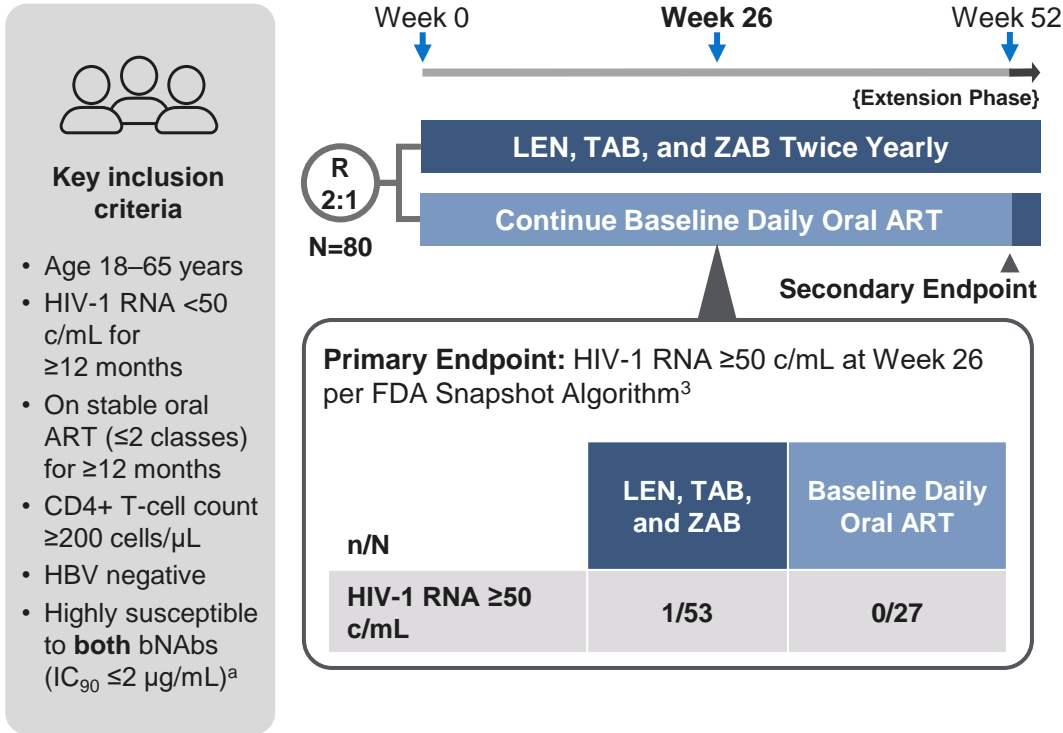
Objective(s)

- To describe Week 26 PROs for participants switching from daily oral ART to twice-yearly LEN, TAB, and ZAB from the ongoing Phase 2 study

Methods

- Virologically suppressed PWH (≥12 months on ART) with HIV-1 highly susceptible to both bNAbs were enrolled
 - Participants were randomized 2:1 to SC LEN 927 mg (with LEN oral loading) plus intravenous TAB 2550 mg and ZAB 2550 mg twice yearly, or to continue baseline daily oral ART (**Figure 1**)

Figure 1. Study Design



^aBy PhenoSense® mAb Assay (Monogram Biosciences).
ART, antiretroviral therapy; bNAb, broadly neutralizing antibody; c/mL, copies/mL;
FDA, Food and Drug Administration; HBV, hepatitis B virus; IC₉₀, 90% inhibitory concentration;
LEN, lenacapavir; R, randomized; TAB, teropavimab; ZAB, zinlirvimab.

PRO assessments

- PRO assessments included:
 - HIV Treatment Satisfaction Questionnaire – Status (HIVTSQstatus) and – Change (HIVTSQchange); which measure treatment satisfaction at a specific time point and changes in treatment satisfaction after switching regimens, respectively
 - HIV Treatment Preference Questionnaire (HIVTPQ; evaluates treatment preferences between regimens)
 - and HIV Dependent Quality of Life (HIVDQoL) Questionnaire
- Exploratory analyses were conducted for participants who switched from daily oral ART to LEN, TAB, and ZAB using descriptive statistics and complete-case analysis
 - Complete-case analysis was used for the HIVTSQstatus, HIVTPQ, and HIVDQoL Questionnaire; changes in individual measures were calculated for participants with complete data at baseline and Week 26
- Participants with missing data were included in the percentage denominator for HIVTSQchange

Results

Baseline characteristics

- Overall, 80 participants were randomized and dosed; 53 received LEN, TAB, and ZAB, and 27 continued their baseline daily oral ART
- Baseline characteristics of participants switching from daily oral ART to LEN, TAB, and ZAB are shown in **Table 1**

Results cont.

Table 1. Baseline Characteristics

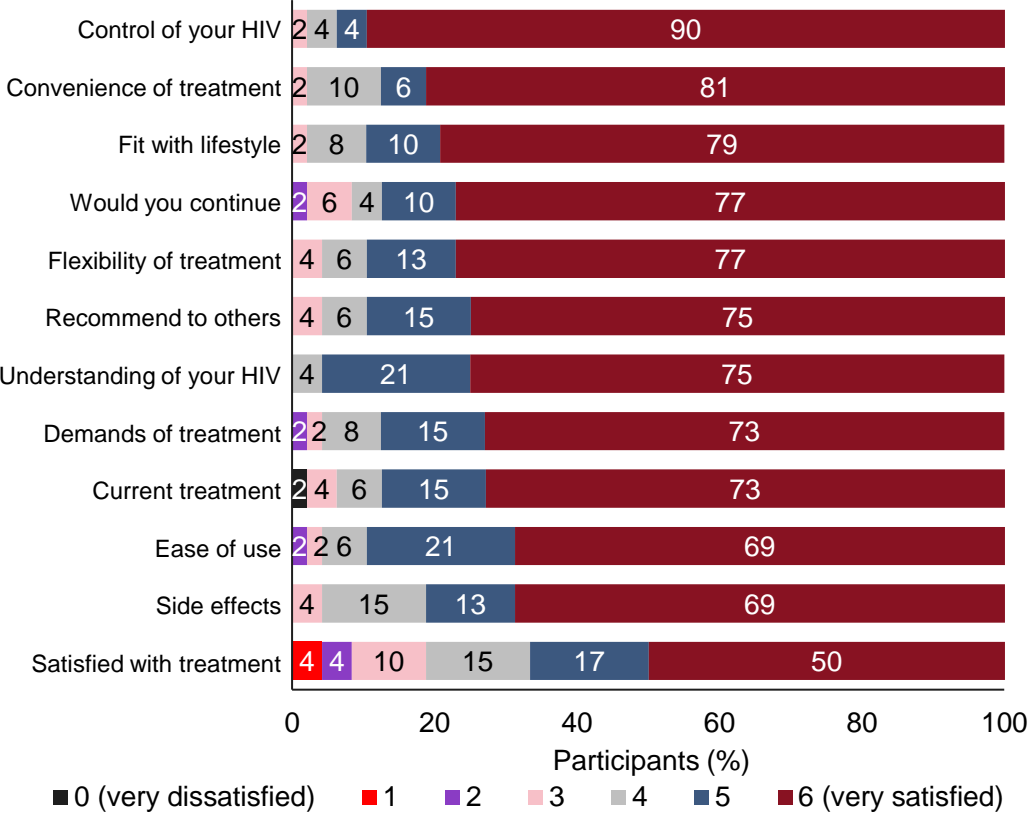
	LEN, TAB, and ZAB (n=53)
Median (range) age, years	46 (20–65)
Aged ≤24 years, n (%)	7 (13.2)
Sex at birth, n (%)	
Male	45 (84.9)
Female	8 (15.1)
Gender identity, n (%)	
Cisgender	50 (94.3)
Prefer not to say	3 (5.7)
Race, n (%)	
Asian	1 (1.9)
Black	21 (39.6)
White	28 (52.8)
Other	3 (5.7)
Ethnicity, n (%)	
Hispanic or Latino	13 (24.5)
Not Hispanic or Latino	40 (75.5)
Mean (SD) body mass index, kg/m ²	30.9 (7.37)
Region, n (%)	
United States	48 (90.6)

LEN, lenacapavir; TAB, teropavimab; ZAB, zinlirvimab.

HIV Treatment Satisfaction Questionnaire – Status (HIVTSQstatus)

- Mean (SD) HIVTSQstatus score increased from 58 (7.7) at baseline to 61 (7.3) at Week 26, indicating a positive change in treatment satisfaction over daily oral ART
 - The questionnaire topics for which most participants felt “very satisfied” were control of your HIV (43/48; 90%), convenience of treatment (39/48; 81%), and fit with lifestyle (38/48; 79%) (**Figure 2**)

Figure 2. HIVTSQstatus Scores by Topic at Week 26 for Participants Who Switched From Daily Oral ART to Twice-Yearly LEN, TAB, and ZAB

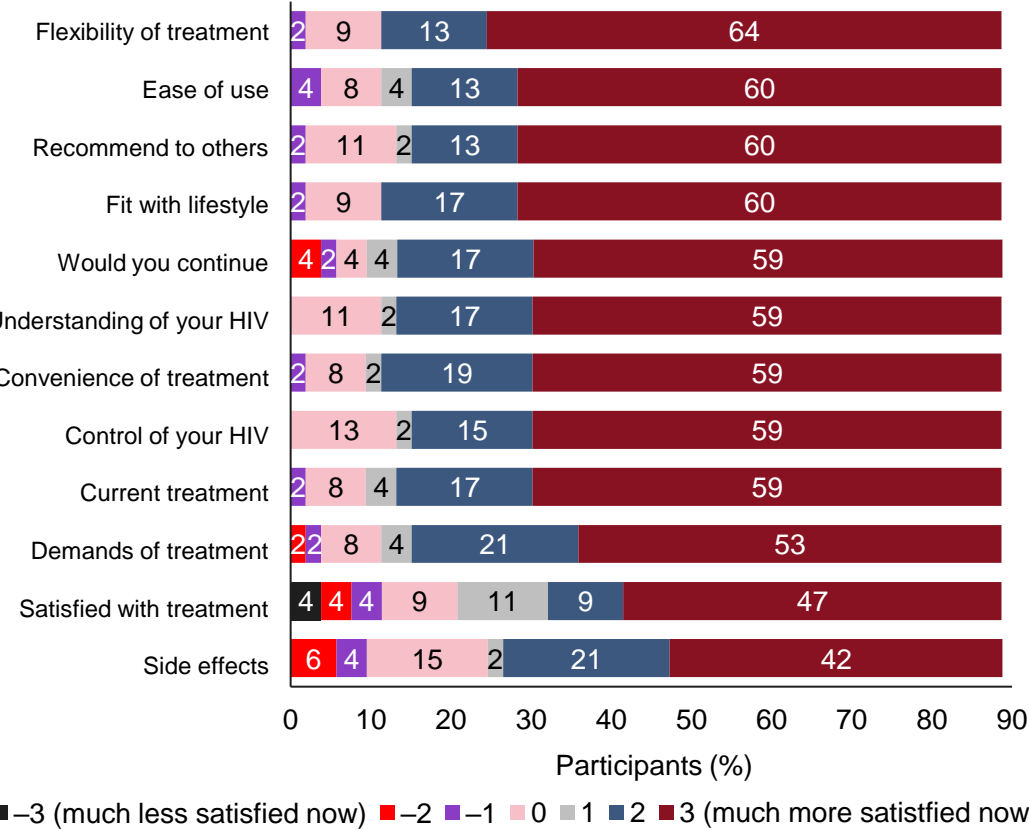


Data are from complete-case analyses which included all randomized participants who received ≥1 dose of LEN, TAB, and ZAB with evaluable HIVTSQstatus data at both baseline and Week 26.
ART, antiretroviral therapy; HIVTSQstatus, HIV Treatment Satisfaction Questionnaire – Status; LEN, lenacapavir; TAB, teropavimab; ZAB, zinlirvimab.

HIV Treatment Satisfaction Questionnaire – Change (HIVTSQchange)

- Week 26 HIVTSQchange mean (SD) score was 25 (10.6), indicating improved satisfaction over baseline daily oral ART
 - The questionnaire topics for which most participants felt “much more satisfied now” were flexibility of treatment (34/53; 64%), ease of use (32/53; 60%), recommend to others (32/53; 60%), and fit with lifestyle (32/53; 60%) (**Figure 3**)

Figure 3. HIVTSQchange Scores by Topic at Week 26 for Participants Who Switched From Daily Oral ART to Twice-Yearly LEN, TAB, and ZAB

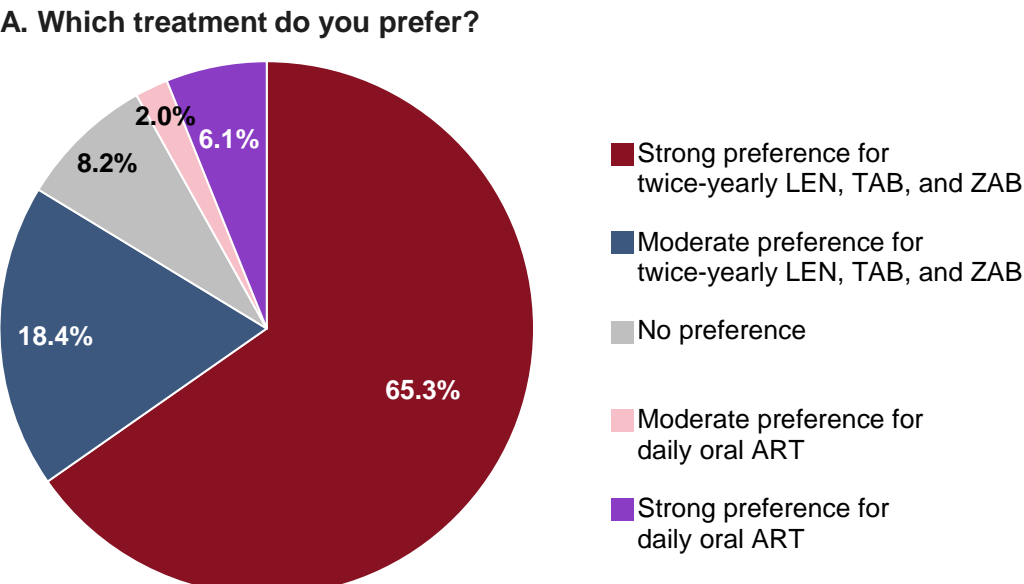


Six (11%) participants had missing data and were included in the percentage denominator.
ART, antiretroviral therapy; HIVTSQchange, HIV Treatment Satisfaction Questionnaire – Change; LEN, lenacapavir; TAB, teropavimab; ZAB, zinlirvimab.

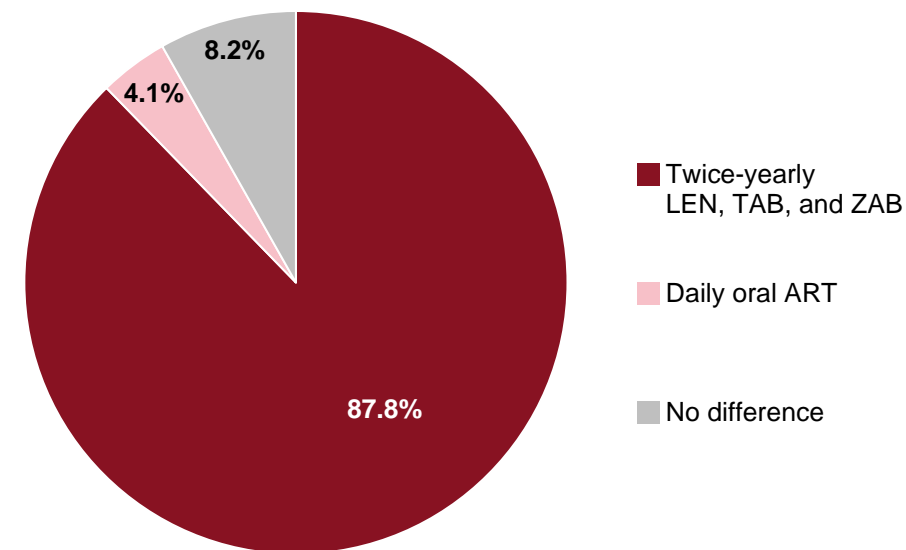
HIV Treatment Preference Questionnaire (HIVTPQ)

- At Week 26, 41/49 (83.7%) participants reported a preference for LEN, TAB, and ZAB (strong, n=32; moderate, n=9; **Figure 4A**) over daily oral ART
- A total of 43/49 (87.8%) participants indicated twice-yearly LEN, TAB, and ZAB would improve adherence compared with daily oral ART (**Figure 4B**)

Figure 4. HIVTPQ Results on Treatment Preference (A) and Which Treatment Would be Easier to Take Without Missing a Dose (B)



B. Which treatment would be easier to take without missing a dose?



Data are from complete-case analyses which included all randomized participants who received ≥1 dose of LEN, TAB, and ZAB with evaluable HIVTPQ data at both baseline and Week 26.
ART, antiretroviral therapy; HIVTPQ, HIV Treatment Preference Questionnaire; LEN, lenacapavir; TAB, teropavimab; ZAB, zinlirvimab.

HIV Dependent Quality of Life (HIVDQoL) Questionnaire

- HIVDQoL scores increased from baseline to Week 26 in the majority of QoL domains (19/26 domains) for PWH who switched to LEN, TAB, and ZAB (**Figure 5**)
- A decline in QoL was observed in one QoL domain, “Others fuss or worry about me”
 - It should be considered that the sample size was small, there were potential inter-item correlations, and heatmaps have a descriptive nature; overall, 25/26 domains reflected a positive/neutral sentiment
- At baseline, 42/45 (93.3%) participants who switched to LEN, TAB, and ZAB reported positive (good–excellent) QoL, with 11/45 (24.4%) reporting excellent QoL
- At Week 26, 44/45 (97.8%) participants who switched to LEN, TAB, and ZAB reported positive (good–excellent) QoL, with 17/45 (37.8%) reporting excellent QoL

Figure 5. Change From Baseline to Week 26 in the HIVDQoL Questionnaire Individual Domain Measurements for Participants Who Switched From Daily Oral ART to Twice-Yearly LEN, TAB, and ZAB

Leisure	Friends and social life	Stigma	Freedom to drink
Work	Dates	Concealment from others	Spiritual/religious life
Holiday	Close relationships	Feelings about the future	Feelings about the past
Getting out and about	Sex life	Financial situation	Having children or more children
Long journeys	Physical appearance	Dependency on others	Sleep
Physical	Self-confidence	Others fuss or worry about me	Family life
	Motivation to do things	Freedom to eat	

Improvement, no change, and decline in QoL were defined as the numerical mean change from baseline to Week 26 in weighted impact scores of >0, 0, and <0, respectively, for each of the 26 domains.
Data are from complete-case analyses which included all randomized participants who received ≥1 dose of LEN, TAB, and ZAB with evaluable HIVDQoL at both baseline and Week 26.
ART, antiretroviral therapy; HIVDQoL, HIV Dependent Quality of Life; LEN, lenacapavir; QoL, quality of life; TAB, teropavimab; ZAB, zinlirvimab.

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Conflict of Interest Disclosure: **Aditya Gaur:** Gilead Sciences, Inc. (grants), Viiv Healthcare (grants/webinar panelist/advisor).
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