Patient-Reported Outcomes After 52 Weeks of Twice-Yearly Lenacapavir, Teropavimab, and Zinlirvimab

Poster #517

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Conclusions

- Participants had moderate-to-strong preferences for this first twice-yearly treatment over daily oral antiretroviral therapy (ART), consistent with the Week 26 patient-reported outcome (PRO) results[1]
- Participants reported increased treatment satisfaction and improved health-related quality-of-life (HRQoL) through Week 52 after switching to lenacapavir (LEN), teropavimab (TAB), and zinlirvimab (ZAB) from daily oral ART
- This analysis demonstrates that PRO improvements for people who switch to LEN, TAB, and ZAB are durable over 1 year of treatment

Plain Language Summary

- Lenacapavir is a medicine approved to treat HIV in people who have already tried lots of other HIV medicines and is given as two injections under the skin; teropavimab and zinlirvimab are new medicines given as an infusion (a drip into a vein) being tested to treat HIV
- Lenacapavir, teropavimab, and zinlirvimab can be given together every 6 months and are being tested together in a study with participants who already have very low levels of HIV in their blood to see if the levels stay low on treatment. The study also asked participants their opinions on this twice-yearly injection after switching from daily HIV pills (called patient-reported outcomes)
  - One year after switching to lenacapavir, teropavimab, and zinlirvimab, many participants said they preferred lenacapavir, teropavimab, and zinlirvimab given twice yearly over their usual daily oral HIV treatment, were less likely to forget to take treatment, and felt happier about this treatment and everyday life

Background

- ART with less frequent dosing intervals may offer advantages over daily oral therapy, such as increased adherence and reduced pill fatigue, for some people with HIV-1[2]
- LEN is an HIV-1 capsid inhibitor that is approved for the treatment of multidrug-resistant HIV-1 and for HIV-1 pre-exposure prophylaxis, and can be administered subcutaneously twice-yearly[3,4]
- TAB and ZAB are broadly neutralizing antibodies (bNAb) with extended half-lives that also allow for twice-yearly intravenous dosing[5]
  - TAB targets the gp120 CD4-binding site while ZAB targets the V3 glycan on the HIV-1 envelope
- In a Phase 2 open-label study (NCT05729568), the combination of LEN, TAB, and ZAB maintained high rates of virologic suppression (HIV-1 RNA <50 copies/mL) in people with HIV-1 that is susceptible to both bNAbs at Week 26 and Week 52 by US Food and Drug Administration Snapshot Algorithm[6]
- At Week 26, participants who switched at baseline from daily oral ART to twice-yearly LEN, TAB, and ZAB reported improved treatment satisfaction and quality of life (QoL)[1]

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Objective

- To describe Week 52 PROs for treatment preference, treatment satisfaction, and HRQoL in participants who switched at baseline from daily oral ART to twice-yearly LEN, TAB, and ZAB in the ongoing Phase 2 study[a]

[a]Participants who did not receive LEN, TAB, and ZAB were not included in the analysis.

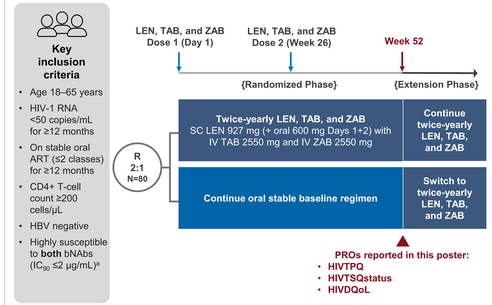
Methods

- In this open-label study, eligible virologically suppressed adults (≥12 months on ART) with HIV-1 meeting susceptibility criteria to both bNAbs (IC_{50} ≤2 µg/mL) were randomized 2:1 to switch to twice-yearly LEN, TAB, and ZAB, or to continue baseline daily oral ART[7] (**Figure 1**)

PRO assessments

- Exploratory PROs (electronic questionnaires) assessed at Week 52 included:
  - HIV Treatment Preference Questionnaire (HIVTPQ; measures preferences for switching from oral ART to LEN, TAB, and ZAB)
  - HIV Treatment Satisfaction Questionnaire – Status (HIVTSQstatus); evaluates treatment satisfaction at a specific time point (Week 52)
  - HIV Dependent Quality of Life (HIVDQoL) Questionnaire
- Complete-case analysis for LEN, TAB, and ZAB participants who completed baseline, Week 26, and Week 52 questionnaires was used for the HIVTPQ, HIVTSQstatus, and HIVDQoL Questionnaire
- Analyses were conducted using descriptive statistics, with Wilcoxon signed-rank tests applied to continuous data

Figure 1. Study Design[7]



[a]By PhenoSense® mAb Assay (Monogram Biosciences).
ART, antiretroviral therapy; bNAb, broadly neutralizing antibody; HBV, hepatitis B virus; HIVDQoL, HIV Dependent Quality of Life; HIVTPQ, HIV Treatment Preference Questionnaire; HIVTSQstatus, HIV Treatment Satisfaction Questionnaire – Status; IC_{50}, 50% inhibitory concentration; IV, intravenous; LEN, lenacapavir; PRO, patient-reported outcome; R, randomized; SC, subcutaneous; TAB, teropavimab; ZAB, zinlirvimab.

Results

Participants

- In total, 80 participants were randomized and dosed; 53 received LEN, TAB, and ZAB, and 27 continued their daily oral stable baseline ART
- At Week 26, 49/53 participants received a second dose of LEN, TAB, and ZAB and were followed up on treatment to Week 52
- A total of 42/49 participants who were followed up to Week 52 completed ≥1 of 3 PRO questionnaires at baseline, Week 26, and Week 52
  - Of the 42 questionnaire respondents, 81.0% were male, 52.4% White, 90.5% from the US, and median (range) age was 45 (20–65) years (**Table 1**)

Results

Table 1. Baseline Characteristics

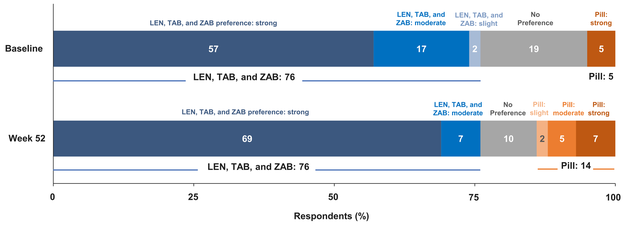
	LEN, TAB, and ZAB (n=53)	Questionnaire Respondents (n=42)
Median (range) age, years	46 (20–65)	45 (20–65)
Sex at birth, n (%)		
Male	45 (84.9)	34 (81.0)
Female	8 (15.1)	8 (19.0)
Gender identity, n (%)		
Cisgender	50 (94.3)	41 (97.6)
Prefer not to say	3 (5.7)	1 (2.4)
Race, n (%)		
Black	21 (39.6)	17 (40.5)
White	28 (52.8)	22 (52.4)
Other	4 (7.5)	3 (7.1)
Ethnicity, n (%)		
Hispanic or Latine	13 (24.5)	11 (26.2)
Not Hispanic or Latine	40 (75.5)	31 (73.8)
Mean (SD) body mass index, kg/m²	30.9 (7.4)	31.2 (7.6)
Region, n (%)		
United States	48 (90.6)	38 (90.5)

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

HIV Treatment Preference Questionnaire (HIVTPQ)

- At Week 52, 32/42 (76%) participants receiving LEN, TAB, and ZAB preferred this regimen over daily oral ART (HIVTPQ: strong preference, n=29 [69%]; moderate preference, n=3 [7%]) (**Figure 2**)

Figure 2. HIVTPQ Results on Treatment Preference at Baseline and Week 52 (n=42)

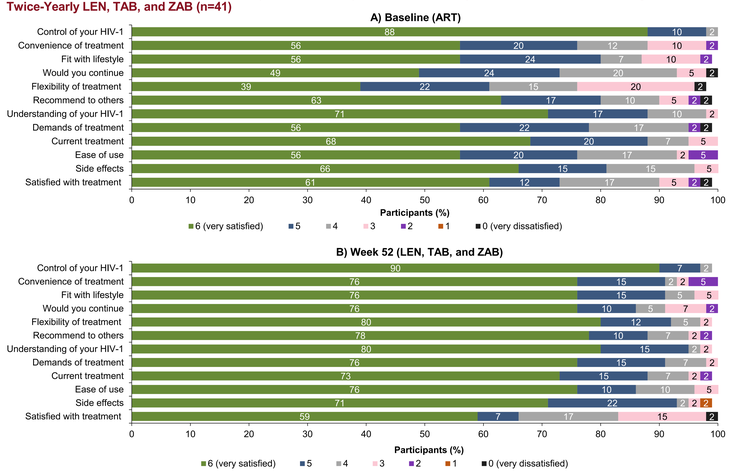


Data are from complete-case analyses which included all randomized participants who received ≥1 dose of LEN, TAB, and ZAB with evaluable HIVTPQ data at baseline, Week 26, and Week 52 (n=42).
HIVTPQ, HIV Treatment Preference Questionnaire; LEN, lenacapavir; TAB, teropavimab; ZAB, zinlirvimab.

HIV Treatment Satisfaction Questionnaire – Status (HIVTSQstatus)

- Mean (SD) HIVTSQstatus score increased from 58 (8) at baseline to 62 (8) at Week 52 (n=41; mean [SD] change from baseline, 4 [11.0]; nominal *p*-value, 0.03), indicating an increase in treatment satisfaction with LEN, TAB, and ZAB after switching from daily oral ART
- Compared with scores for ART at baseline (**Figure 3A**), the proportion of participants on LEN, TAB, and ZAB who felt "very satisfied" increased at Week 52 in 11 of the 12 questionnaire concepts (**Figure 3B**)
- Questionnaire concepts for which the greatest proportion of LEN, TAB, and ZAB participants felt "very satisfied" at Week 52 were 'control' of their HIV-1 (37/41; 90%), 'flexibility' of treatment (33/41; 80%), and 'understanding' of their HIV-1 (33/41; 80%) (**Figure 3B**)

Figure 3. HIVTSQstatus Scores by Topic at A) Baseline and B) Week 52 for Participants Who Switched From Daily Oral ART to Twice-Yearly LEN, TAB, and ZAB (n=41)



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 baseline, Week 26, and Week 52 (n=41).
ART, antiretroviral therapy; HIVTSQstatus, HIV Treatment Satisfaction Questionnaire – Status; LEN, lenacapavir; TAB, teropavimab; ZAB, zinlirvimab.

HIVDQoL Questionnaire

- At baseline and Week 52, respectively, a total of 34/37 (92%) and 36/37 (97%) participants who switched from oral ART to LEN, TAB, and ZAB reported good–excellent HRQoL, and 6/37 (16%) and 14/37 (38%) reported excellent HRQoL
- After switching from oral ART to LEN, TAB, and ZAB at baseline, HIVDQoL scores improved from baseline to Week 52 in most QoL domains (15/26 domains) (**Figure 4**)
- A decline in QoL was observed in one domain: "Others fuss or worry about me", with the mean weighted impact score from baseline to Week 52 indicating "a little more [fuss or worry]" (**Figure 4**)
- Overall, 25/26 domains reflected an improved/neutral change from baseline at Week 52

Figure 4. Change From Baseline to Week 52 in the HIVDQoL Questionnaire Individual Domain Measurements for Participants Who Switched From Daily Oral ART to Twice-Yearly LEN, TAB, and ZAB (n=37)

Improvement in QoL | No change in QoL | Decline in QoL

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 52 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 baseline, Week 26, and Week 52 (n=37).
ART, antiretroviral therapy; HIVDQoL, HIV Dependent Quality of Life; LEN, lenacapavir; QoL, quality of life; TAB, teropavimab; ZAB, zinlirvimab.

Limitations

- The study group may not be representative of the broader HIV-1 population which may impact generalizability of these findings
  - Individuals who elected to participate in this study may have exhibited more favorable baseline attitudes toward long-acting injectable HIV-1 treatment compared with the general population; however, the proportion of 'strong' HIVTPQ preference scores for LEN, TAB, and ZAB increased from baseline to Week 52
- This analysis focuses only on those who switched to LEN, TAB, and ZAB at baseline and this poster does not present a comparison with those who continued their baseline daily oral ART from baseline to Week 52