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Patient-reported outcomes (PROs) after 1 year of routine clinical practice with bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF): The BICStaR cohort

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Introduction and Objective

- The **BIC**tegravir **S**ingle **Ta**blet **R**egimen (BICSTaR) study is an ongoing, 2-year, multi-country, observational cohort study that plans to enrol at least 1400 PLWH who receive B/F/TAF in routine clinical practice
- In addition to evaluating the effectiveness and safety of B/F/TAF, patient-reported outcomes (PROs) are directly completed by participants to capture aspects of health status, such as mental/physical health, health-related quality of life (HRQoL), and treatment satisfaction
- We present preliminary PRO data that were prospectively collected in ART-naïve (TN) and ART-experienced (TE) participants after 12 months of receiving B/F/TAF as an initial or switch regimen

Methods

- This pre-specified, descriptive PRO analysis included a subset of participants from Germany, Canada, France, and the Netherlands who completed PRO questionnaires at both baseline and Month 12 ('PRO analysis population')
- PROs collected were:

Table 1. PRO tools

Domain	PRO tool	Visits	Evaluation
Quality of life (HRQoL) Mental (MCS) Physical (PCS)	SF-36	Baseline Month 12	Median SF-36 summary score
HIV ART-related symptoms*	HIV-SI	Baseline Month 12	% Participants reporting 'bothersome symptoms'
HIV treatment satisfaction (only TE)	HIVTSQs HIVTSQc	Baseline Month 12	Median total score change

*Symptoms were dichotomised into 'not bothersome' (scores of 0 or 1) or 'bothersome' (scores of 2, 3, or 4). The overall bothersome symptom count at baseline was generated by counting the number of individual symptoms scored as bothersome

ART, antiretroviral-treatment; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; HIVTSQc, HIV Treatment Satisfaction Questionnaire – change; HIVTSQs, HIV Treatment Satisfaction Questionnaire – status; HIV-SI, HIV Symptom Index; MCS, mental component score; PCS, physical component score; PLWH, people living with HIV; SF-36, 36-item Short Form Health Survey; TE, treatment-experienced; TN, treatment-naïve

Results

- Overall study population baseline characteristics are:

Table 2.

	TN, n=84	TE, n=429
Male, n (%)	76 (91)	392 (91)
Age, years, median (Q1–Q3) Age ≥50 years, n (%)	38 (29–48) 20 (24)	49 (40–56) 209 (49)
White, n (%)	71 (85)	387 (90)
Comorbidities None, n (%) 1–2, n (%) ≥3, n (%)	41 (49) 25 (30) 18 (21)	108 (25) 168 (39) 153 (36)
Neuropsychiatric disorder, n (%) Hyperlipidaemia, n (%) Hypertension, n (%)	16 (19) 7 (8) 5 (6)	122 (28) 87 (20) 87 (20)
Any comedication received, n (%)	35 (45)	256 (60)
HIV-1 RNA, $\log_{10}$ cp/mL, median (Q1, Q3) <50 cp/mL, n (%) >100,000 cp/mL, n (%)	4.77 (3.94, 5.18) 0 (0) 30/82 (37)	1.59 (1.28, 1.59) 362/393 (92) 2/393 (1)
CD4 count*, cells/µL, median (Q1, Q3) CD4 <200 cells/µL, % CD4 <350 cells/µL, %	427 (244, 581) 21 38	668 (455, 877) 4 14
CD4/CD8 ratio, median (Q1, Q3)	0.4 (0.3, 0.6)	0.8 (0.6, 1.2)

*Sample size of 78 for TN and 382 for TE
cp, copies; Q, quartile; TE, treatment-experienced; TN, treatment-naïve

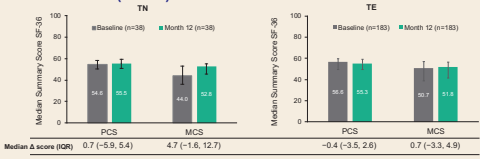
Table 3. PRO Analysis Population Baseline Characteristics

	Overall sample (N=513)		SF-36 (n=221)		HIV-SI (n=250)	
	TN n=84	TE n=429	TN n=38	TE n=183	TN n=43	TE n=207
Age (years), median age (Q1, Q3)	38 (29–48)	49 (40–56)	37 (30, 44)	48 (40, 55)	36 (29, 44)	49 (40, 55)
Age ≥50 years, n (%)	20 (24%)	209 (49%)	8 (21%)	79 (43%)	9 (21%)	96 (46%)
Male, n (%)	76 (91%)	392 (91%)	34 (90%)	170 (93%)	39 (91%)	194 (94%)
White, n (%)	71 (85%)	387 (90%)	33 (87%)	167 (91%)	37 (86%)	188 (91%)

- In the PRO analysis population, 221 and 250 PLWH completed the SF-36 and HIV-SI questionnaires, respectively, at both Baseline and Month 12
- The PRO analysis population was comparable to the overall study population in terms of age, gender, and ethnicity

Results Cont.

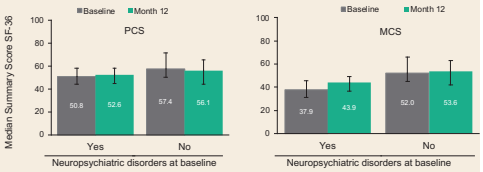
Figure 1. HRQoL SF-36 PCS and MCS at Baseline and Month 12 (n=221)



Error bars are IQR. PRO analysis population (n=221). SF-36 scale is 0–100, where higher scores indicate better quality of lifeSummary scores are standardised to a mean of 50, with >50 representing better than average and <50 poorer than average function
IQR, interquartile range; MCS, mental component score; PCS, physical component score; PRO, patient-reported outcomes; SF-36, 36-item Short Form Health Survey; TE, treatment-experienced; TN, treatment-naïve

- Physical component scores (PCS) were high at baseline in both TN and TE participants, and remained stable after 12 months.
- In TN participants, a numerically higher mental component score (MCS) was observed at 12 months; the score remained stable in TE participants

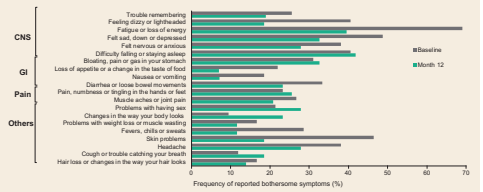
Figure 2. HRQoL SF-36 PCS and MCS at Baseline and Month 12 in All Participants by Presence of Neuropsychiatric Disorders at Baseline (n=221)



Error bars are IQR. PRO analysis population (n=221). SF-36 scale is 0–100, where higher scores indicate better quality of life
Summary scores are standardised to a mean of 50, with >50 representing better than average and <50 poorer than average function
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; IQR, interquartile range; MCS, mental component score; PCS, physical component score; SF-36, 36-item Short Form Health Survey

- In participants with neuropsychiatric disorders at baseline, a numerically higher mental health component score (MCS) was observed after 12 months on B/F/TAF

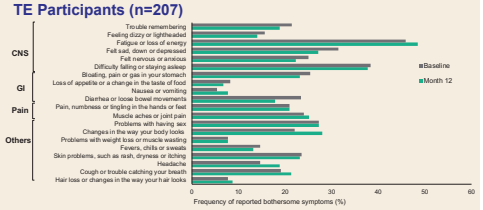
Figure 3. HIV-SI 'Bothersome' Symptoms* in TN Participants (n=43)



*Symptoms were dichotomised into 'not bothersome' (scores of 0 or 1) or 'bothersome' (scores of 2, 3, and 4), PRO analysis population (n=43)
CNS, central nervous system; GI, gastrointestinal; HIV-SI, HIV Symptom Index; IQR, interquartile range; TN, treatment-naïve

- For TN, the overall median bothersome symptom count at baseline was 6 (IQR 2, 9); this decreased to 3 (2, 7) at Month 12
- A trend towards a decrease in the frequency of CNS-related bothersome symptoms was observed in TN participants after 12 months

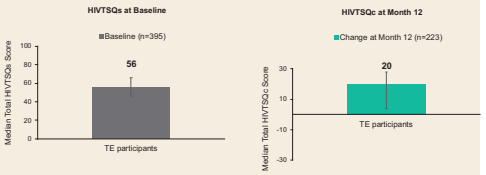
Figure 4. HIV-SI 'Bothersome' Symptoms* in TE Participants (n=207)



*Symptoms were dichotomised into 'not bothersome' (scores of 0 or 1) or 'bothersome' (scores of 2, 3, and 4)
CNS, central nervous system; GI, gastrointestinal; HIV-SI, HIV Symptom Index; IQR, interquartile range; TE, treatment-experienced

- For TE, t=he overall median bothersome symptom count at baseline was 3 (IQR 0, 6); this did not change at Month 12
- Overall, small numerical differences were observed in bothersome symptoms in TE participants at Month 12

Figure 5. HIVTSQs – HIV Treatment Satisfaction in TE participants



HIVTSQs score ranged 0 to 100, higher total scores indicate greater satisfaction with treatmentHIVTSQc score ranged from −30 to +30; positive total scores indicate improvement in satisfaction with study treatment
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; HIVTSQc, HIV Treatment Satisfaction Questionnaire – change; HIVTSQs, HIV Treatment Satisfaction Questionnaire – status; TE, treatment experienced

- Baseline HIVTSQs total score was high in TE participants with numerically higher scores observed following switch to B/F/TAF at Month 12, with an HIVTSQc median total score change of 20

Discussion

- HRQoL (SF-36)
  - In TN participants initiating ART with B/F/TAF, a numerical increase in the HRQoL mental component score was observed after 12 months, while the physical component remained stable
  - In TE participants, both mental and physical components remained stable and no changes were observed
- HIV ART-related symptoms (HIV-SI)
  - In TN participants, a trend towards a decrease in frequency of CNS-related bothersome symptoms was observed after 1 year on B/F/TAF
- Treatment satisfaction (HIVTSQs and HIVTSQc)
  - A numerical increase in treatment satisfaction was observed among participants who switched to B/F/TAF

Conclusions

- **These data support the favourable profile of B/F/TAF in a real-world setting using self-reported outcomes from treatment-naïve and treatment-experienced PLWH who had a high prevalence of comorbidities at baseline**

Disclosures

- **HK** has acted as a consultant for Gilead;
- **CS** has acted as consultant for AbbVie, Gilead, Hexal AG, Janssen-Cilag, MSD and received travel grants from Gilead, Janssen-Cilag and MSD;
- **MW** has acted as a board member for ViiV;
- **JB** has participated in advisory boards for Gilead, Merck and ViiV; and reports travel grants from Gilead and ViiV and speaker bureaus, speaker fees and consultancy for Gilead;
- **BT** has participated in advisory boards for Gilead, Merck and ViiV; and reports travel grants from Gilead and ViiV;
- **FB** reports travel grants from Gilead and ViiV and speaker bureaus, speaker fees and consultancy for Gilead, ViiV, Janssen, MSD;
- **CD** has participated in advisory boards for Gilead, and ViiV and reports travel grants from Merck, Gilead and ViiV and speaker fees and consultancy for Gilead and ViiV;
- **BvW** has nothing to disclose.
- **FM**, **HT**, **DT**, **ATC**, **AM**, and **RC** are employees and shareholders of Gilead.

Acknowledgments

We thank all study participants, study sites and investigators.

The BICStaR study is sponsored by Gilead Sciences

HIV-SI, HIV Symptom Index; PLWH, people living with HIV; Q, quartile; SF-36, 36-item Short Form Health Survey; TE, treatment-experienced; TN, treatment-naïve
ART, antiretroviral therapy; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CNS, central nervous system; HIVTSQc, HIV Treatment Satisfaction Questionnaire – change; HIVTSQs, HIV Treatment Satisfaction Questionnaire – status; HIV-SI, HIV Symptom Index; HRQoL, health-related quality of life; PLWH, people living with HIV; SF-36, 36-item Short Form Health Survey

Presented at DÖAK, 25-27 March 2021, München, Germany