HIV Drug Therapy GLASGOW 2020

P053

BICSTaR

Please see Poster #P046 for BICSTaR overall effectiveness and safety results

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

H Knechten[1], C Stephan[2], M Waizmann[3], J Brunetta[4], B Trottier[5], F Bonnet[6], C Duvivier[7], **B van Welzen**[8], F Mack[9], H Tossonian[10], D Thorpe[11], A Torres Cornejo[12], A Marongiu[11], R Curbelo[13]

[1]PZB (Practice Centre Blondelstrasse), Aachen, Germany; [2]University Hospital Frankfurt, Medical Clinic II, Frankfurt, Germany; [3]Praxis Waizmann, Leipzig, Germany; [4]Maple Leaf Medical Clinic, Toronto, Canada; [5]Clinique Médicale Urbaine du Quartier Latin, Montreal, Canada; [6]CHU de Bordeaux, Hôpital Saint-André and INSERM U1219, Université de Bordeaux, Bordeaux, France; [7]Centre d'Infectiologie Necker-Pasteur, APHP–Hôpital Necker–Enfants malades, Paris, France; [8]University Medical Centre, Utrecht, Netherlands; [9]Gilead Sciences GmbH, Munich, Germany; [10]Gilead Sciences Canada Inc, Ontario, Canada; [11]Gilead Sciences Ltd, London, UK; [12]Gilead Sciences, Amsterdam, Netherlands; [13]Gilead Sciences, Madrid, Spain

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.*

Background

- The **Bic**tegravir **S**ingle **T**ablet **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 prespecified, 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:

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

Please see Poster #P046 for further information on the overall baseline characteristics

Results: Overall Study Population Baseline Characteristics

	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[a], 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)

[a]Sample size of 78 for TN and 382 for TE

cp, copies; Q, quartile; TE, treatment experienced; TN, treatment naïve

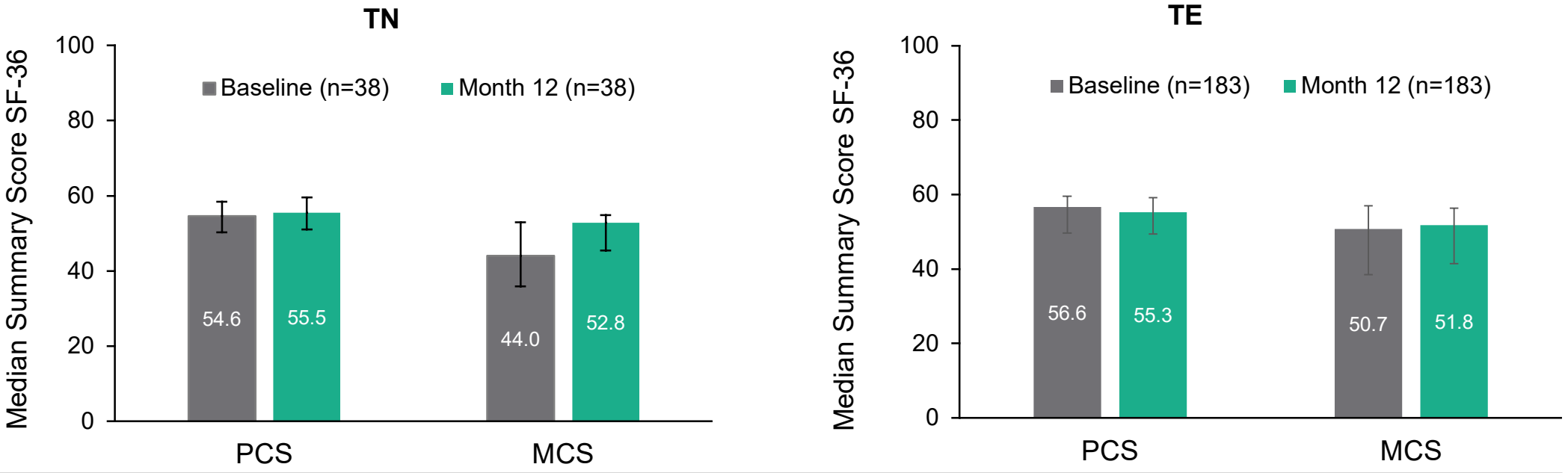
Results: PRO Analysis Population Baseline Characteristics

	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

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

Results: HRQoL SF-36 PCS and MCS at Baseline and Month 12 (n=221)



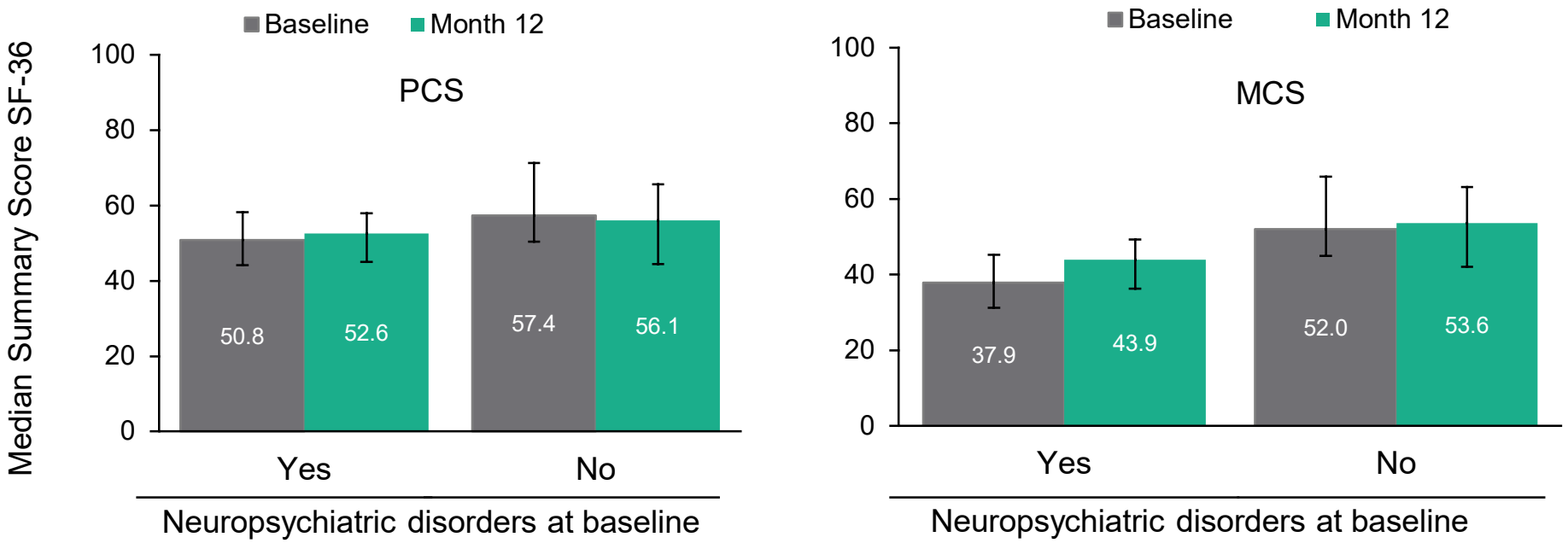
	TN		TE	
Median Δ score (IQR)	0.7 (−5.9, 5.4)	4.7 (−1.6, 12.7)	−0.4 (−3.5, 2.6)	0.7 (−3.3, 4.9)

- 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

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

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

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

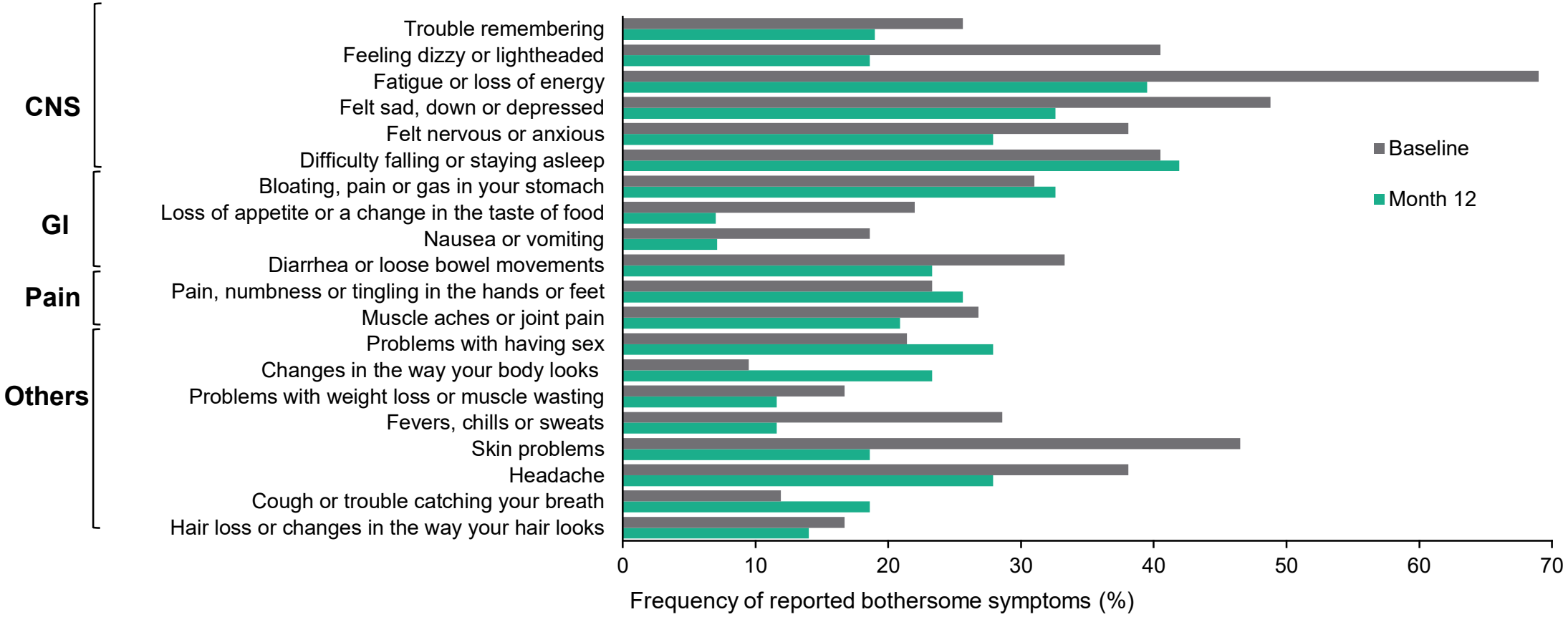


- In participants with neuropsychiatric disorders at baseline, a numerically higher mental health component score (MCS) was observed after 12 months on B/F/TAF

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

Results: HIV-SI ‘Bothersome’ Symptoms* in TN Participants (n=43)

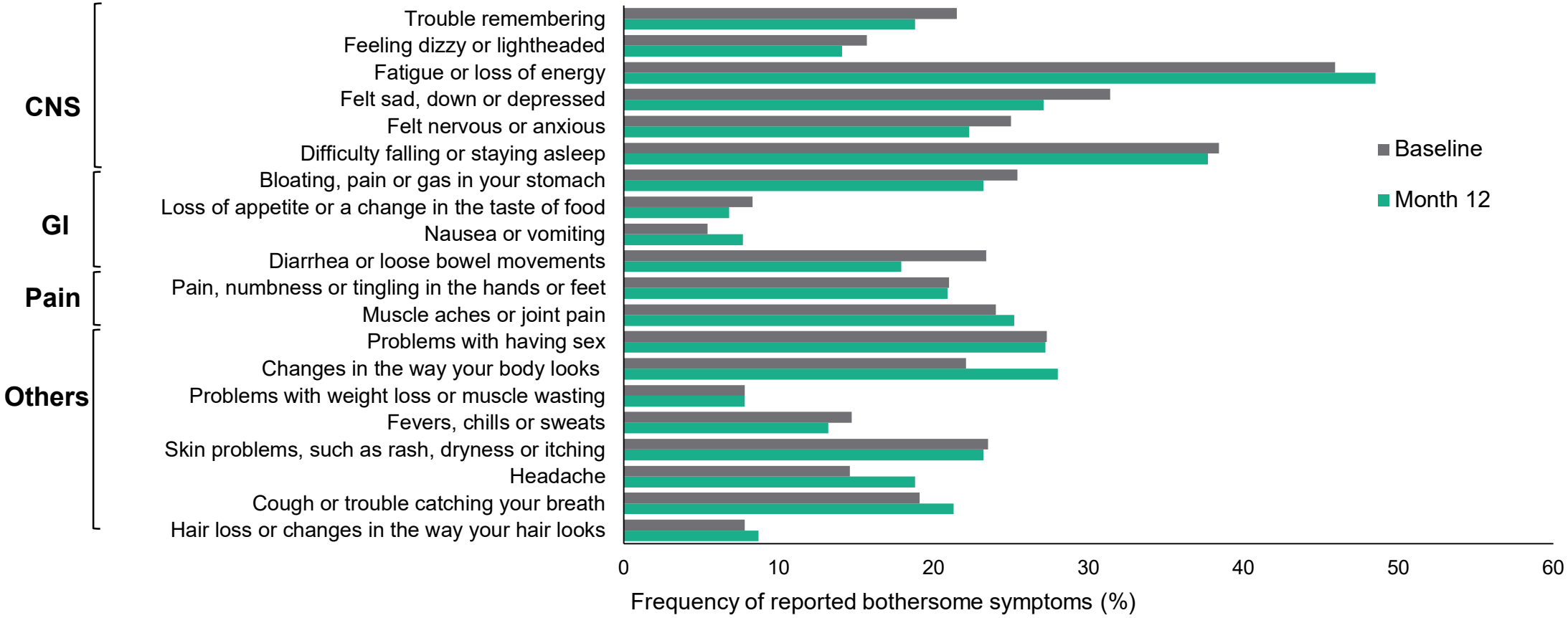


- The overall median bothersome symptom count at baseline was 6 (IQR 2, 9); this decreased to 3 (2, 7) at Month 12
- A trend towards a decrease in the frequency of CNS-related bothersome symptoms was observed in TN participants after 12 months

*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

Results: HIV-SI ‘Bothersome’ Symptoms* in TE Participants (n=207)

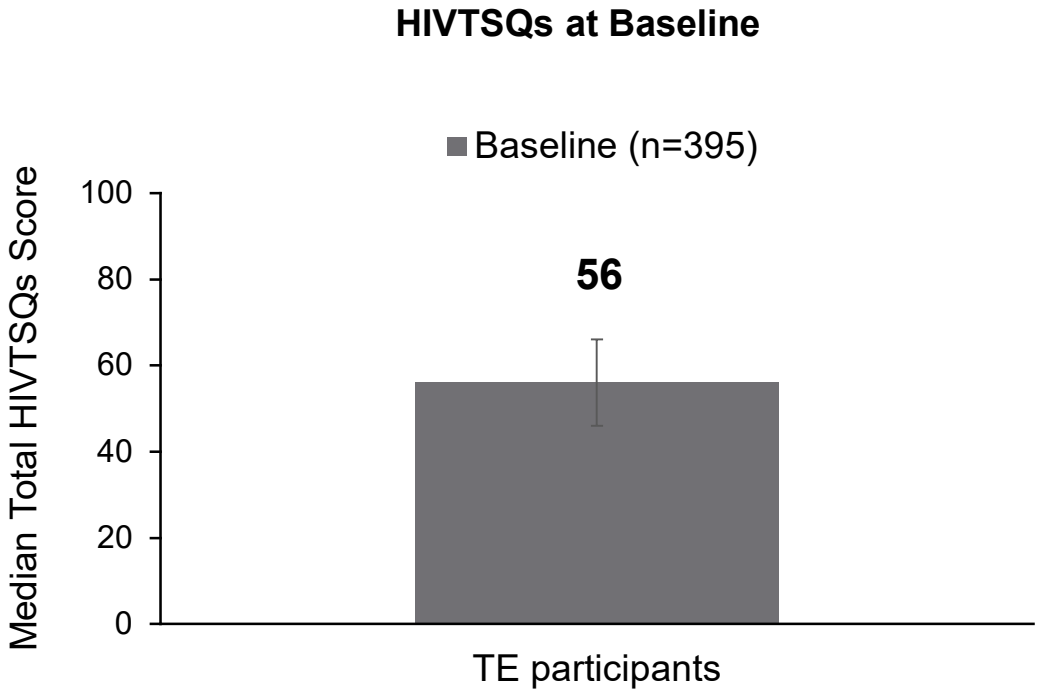


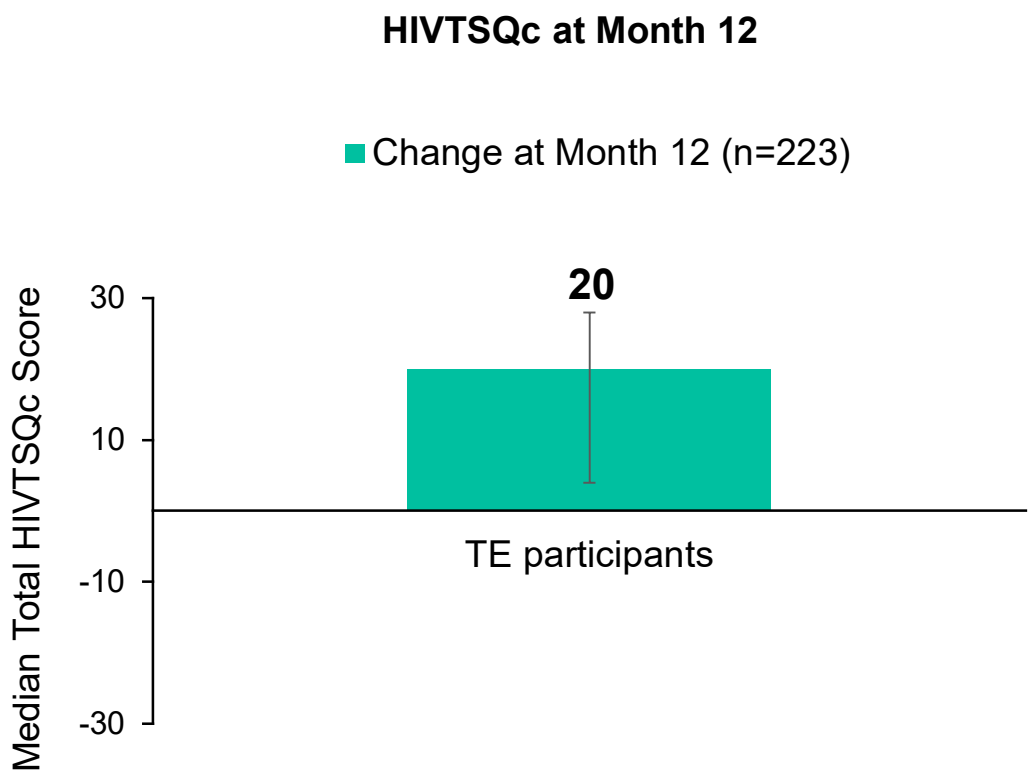
- The overall median bothersome symptom count at baseline was 3 (IQR 0, 6); this did not change at Month 12
- Overall, small numerical differences were observed in bothersome symptoms in TE participants at Month 12

*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

Results: HIVTSQs – HIV Treatment Satisfaction in TE participants





- 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

HIVTSQs score ranged 0 to 100, higher total scores indicate greater satisfaction with treatment
HIVTSQc 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

Conclusions

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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

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

Acknowledgement: We thank all study participants, study sites and investigators. The BICSTaR study is sponsored by Gilead Sciences

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