24-month (24M) effectiveness and safety profile of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in treatment-naïve and treatment-experienced people living with HIV in the BICSTaR study

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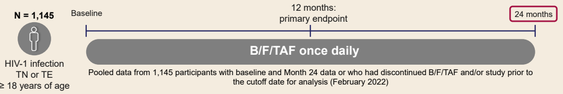
Introduction

- B/F/TAF is a guideline-recommended single tablet regimen for the treatment of HIV-1 infection that supports long-term treatment success in people living with HIV[1]
- BICSTaR is a large, ongoing, multi-country, prospective, observational study that has enrolled over 2,380 ARV treatment-naïve (TN) and treatment-experienced (TE) people in Europe, Canada, Israel, Japan, Taiwan, South Korea and Singapore

Methods

- This analysis included data collected up to February 2022 and during the COVID-19 pandemic. **Pooled 24-month effectiveness and safety** data are presented for 1,145 people receiving B/F/TAF in routine clinical care across **Europe** (France, Germany, Ireland, Italy, the Netherlands, Spain and UK), **Canada, Japan** and **Israel**
- **Virological and immunological outcomes, weight changes, DRAEs** and **patient-reported outcomes** (SF-36: PCS/MCS, HIV-SI and HIVTSQ score and change) were collected. Parametric and non-parametric statistical tests were performed to compare subgroups, as appropriate, based on data distribution and subgroup size being > 20
- **Predictors of weight increase > 10%** from baseline to 24 months were identified using **logistic regression models**. Clinical and demographic variables were included based on a backward selection procedure at a significance level of 0.05. Sex, age and race were included in the model regardless of significance

Study Design



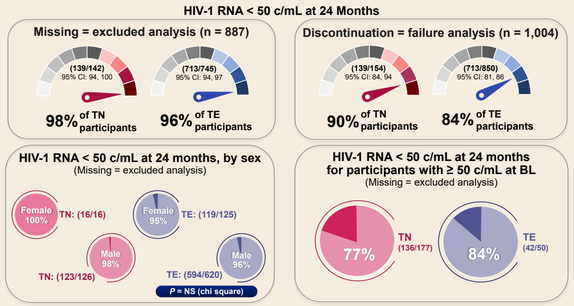
References: 1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf (accessed Nov 15, 2022); 2. HIVTSQ Recommendations for Use. Available at https://www.healthpsychologyresearch.com/sites/default/files/guidelines/HIVTSQ%20Summary_rev.11.8.15.pdf (accessed Nov 15, 2022)

Abbreviations: AE, adverse event; aOR, adjusted odds ratio; BL, baseline; CI, confidence interval; DRAE, drug-related adverse event; HIV-SI, HIV-Symptom Index; HIVTSQ, HIV Treatment Satisfaction Questionnaire; M, month; MCS, mental component summary; mut., mutations; NA, not available; NS, not significant; OR, odds ratio; PCS, physical component summary; TE, treatment-experienced; TN, treatment-naïve

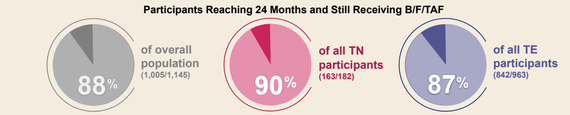
Acknowledgments: We thank all study participants and participating study sites. The BICSTaR study is sponsored by Gilead Sciences. Medical writing support was provided by Emma McConnell, PhD, and Olivia Morris, PhD (Aspire Scientific Ltd), and funded by Gilead.

Results

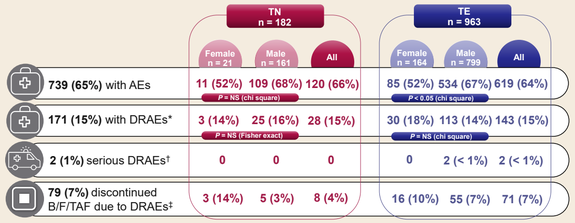
Effectiveness



Persistence



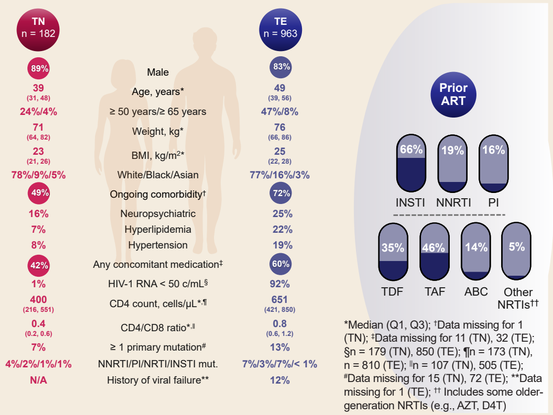
Key Safety Data Through 24 Months



*Most commonly weight increase (4%), depression (1%) and headache (1%); †Percentage of serious AEs that are drug related; ‡Most commonly weight increase (2%)

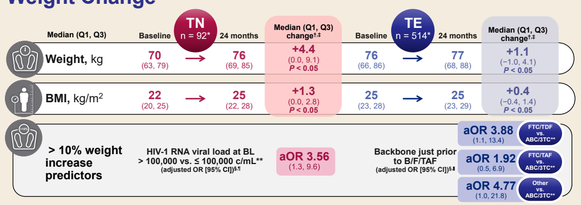
Disclosures: BICSTaR is sponsored by Gilead (GS-EU-380-4472/GS-CA-380-4574/GS-IL-380-5335). MGD: consulting/advisor fees for AbbVie, Janssen, MSD, ViiV, Gilead, Janssen, Pfizer; grants from AbbVie, Janssen, MSD, ViiV, Gilead, Janssen; MW: consulting/advisor fees for Gilead; OR: board membership and consulting/advisor fees for Gilead, MSD, ViiV; AW: consulting/advisor fees for AstraZeneca, Gilead, Merck, Moderna, Pfizer, ViiV; funding/grants from AbbVie, Gilead, Merck, ViiV; ES: nothing to disclose; JSL: nothing to disclose; BvW: consulting/advisor fees, payment for lectures from Gilead, ViiV; grants from Gilead; AM: consulting/advisor fees, grants, payment for lectures from Gilead, Janssen, MSD; payment for development of educational presentations from Gilead, MSD; YY: consulting/advisor fees for ViiV; payment for lectures from Gilead, Janssen, ViiV; payment for manuscript preparation from MSD; GDP: consulting/advisor fees, grants, from Gilead, Merck, ViiV; AM, TC, DT, MH, CLG: employees of Gilead and own shares in Gilead.

Participants



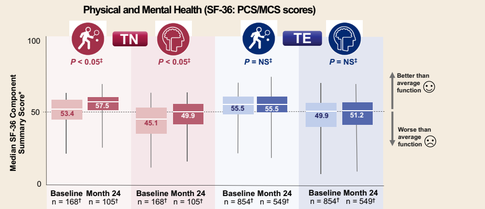
*Median (Q1, Q3); †Data missing for 1 (TN); ‡Data missing for 11 (TN), 32 (TE); §n = 179 (TN), 850 (TE); ¶n = 173 (TN), n = 810 (TE); ‖n = 107 (TN), 505 (TE); #Data missing for 15 (TN), 72 (TE); **Data missing for 1 (TE); †† Includes some older-generation NRTIs (e.g., AZT, D4T)

Weight Change

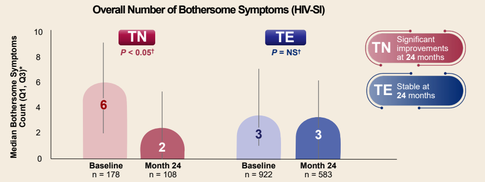


*Restricted population with weight and BMI data available at baseline and 24 months; †Sign test (H0 median = 0); ‡Changes calculated for each individual participant and the median of individual changes then calculated; §P < 0.05 adjusting for age, sex, race (Black vs. other); ¶Global P-value from logistic model (87 participants); ‖Global P-value from logistic model (497 participants); **Denotes the reference

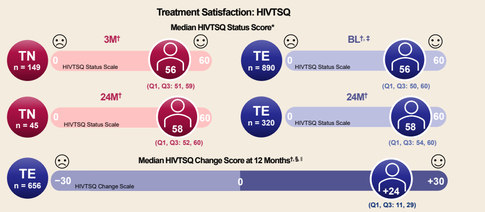
Patient-Reported Outcomes



Box plot represents median (Q1, Q3) values. *Scores are standardized to a mean of 50: > 50 represents better than average function; †From participants with data available at this timepoint; ‡Signed rank test (H0 median = 0) assessment due to the issue of recall bias. Change total score at 24M +22 (Q1, Q3: 7, 29 [n = 289])[2]



*Overall bothersome count indicates the number of bothersome symptoms and ranges from 0 to 20; †Sign test (H0 median = 0)



*Treatment satisfaction total score ranges from 0 to 60. The higher the score, the greater the satisfaction with treatment; †From participants with data available at this timepoint; ‡Baseline reflects assessment of satisfaction with ART taken immediately prior to B/F/TAF; §Treatment satisfaction (change) total score ranges from −30 to 30. The higher the score, the greater the improvement in satisfaction with treatment; ‖12M is the recommended timepoint for the latest assessment due to the issue of recall bias. Change total score at 24M +22 (Q1, Q3: 7, 29 [n = 289])[2]

Conclusions

- Effectiveness and persistence remained high in people receiving B/F/TAF for 24 months in this real-world study that included follow-up during the COVID-19 pandemic
- B/F/TAF was generally well tolerated through 24 months, with improvements in patient-reported outcomes that were significant in TN participants
- These real-world data continue to support the use of B/F/TAF in both newly diagnosed people and in people changing their current regimen

Presented at Infectious Disease Society Ireland Conference 2023, 18-19 May 2023, Dublin, Ireland