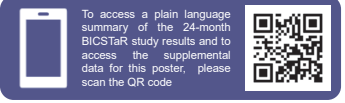


# Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) for the Treatment of People Living With HIV: 24-Month Analyses by Age, Race, Sex, Adherence and Late Diagnosis in a Multi-Country Cohort Study

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## Introduction

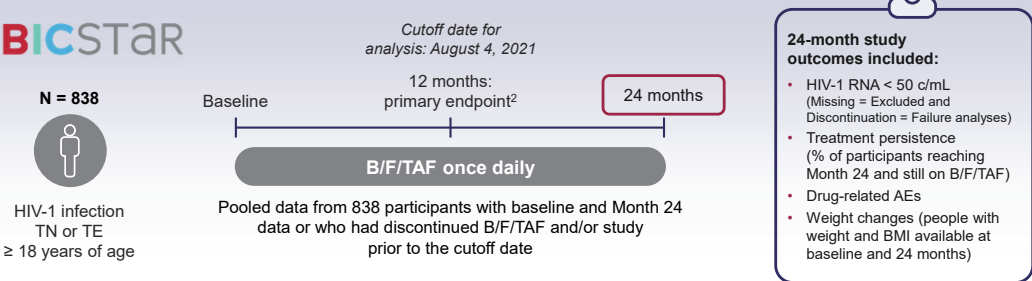
- B/F/TAF is a guideline-recommended single-tablet regimen for the treatment of HIV-1 infection that can contribute to long-term treatment success in people living with HIV<sup>1</sup>
- BICSTAR is a large, ongoing, multi-country, prospective, observational study that has enrolled 2,380 ARV treatment-naïve (TN) and treatment-experienced (TE) people in Europe (France, Germany, Ireland, Italy, the Netherlands, Spain, UK), Canada, Israel, Japan, Taiwan, South Korea and Singapore

## Methods

- In this planned analysis with a data cutoff of August 4, 2021, **pooled 24-month effectiveness and safety** data are presented for people receiving B/F/TAF in routine clinical care from France, Germany, Ireland, Italy, the Netherlands, Spain, UK, Canada and Israel
- We describe data both in the overall population and in key groups related to sex, age, race, treatment adherence level, late diagnosis and prior use of TDF (for weight only)\*

\*With exception of individuals with a late diagnosis, key group analyses were restricted to the TE participants due to the small numbers in the TN group

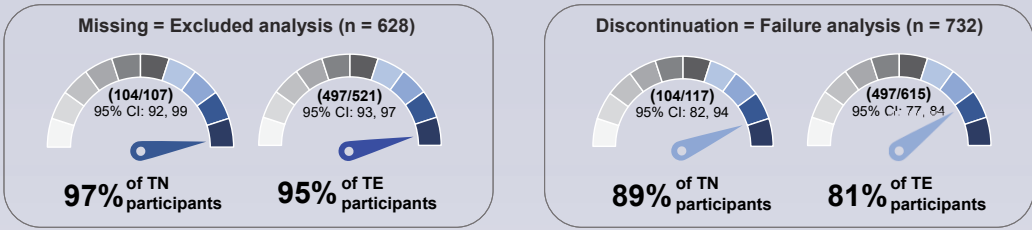
## Study Design



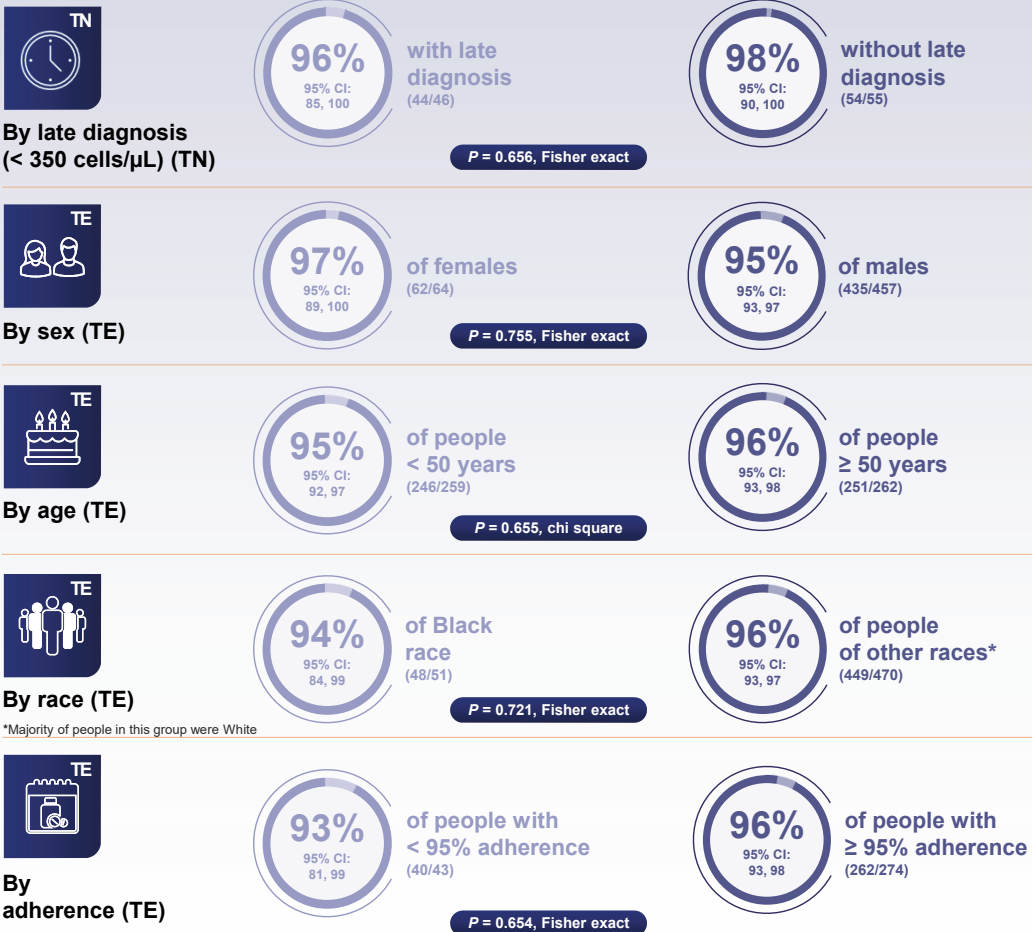
## Conclusions

- B/F/TAF showed high effectiveness and persistence after 24 months in a cohort of people living with HIV in routine clinical care
- Together with clinical trial data, these real-world data continue to support the broad use of B/F/TAF in both treatment-naïve and treatment-experienced individuals

## Effectiveness: % HIV-1 RNA < 50 c/mL at 24 Months – Overall Population



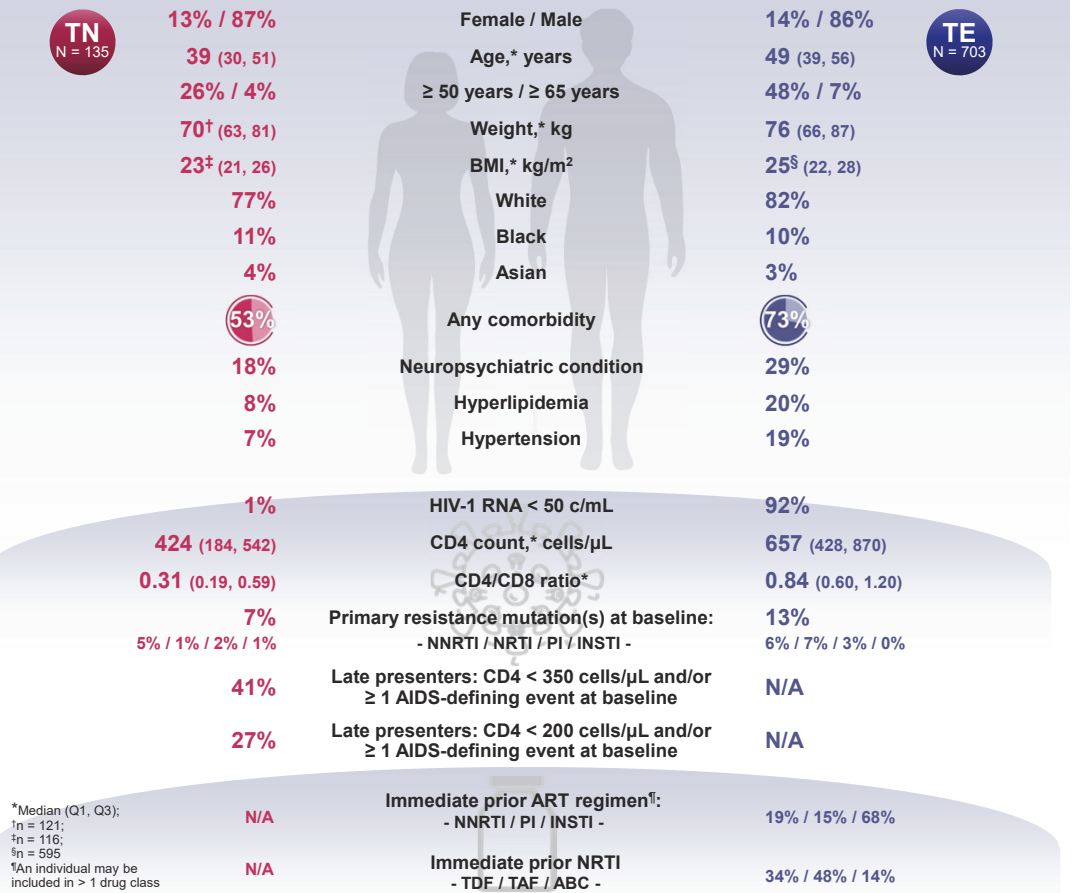
## Effectiveness: % HIV-1 RNA < 50 c/mL at 24 Months – Key Groups



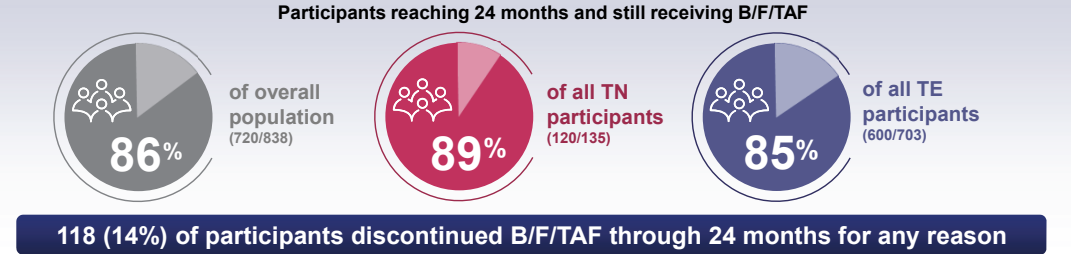
## Change from Baseline in CD4 Cell Count at 24 Months – Overall Population



## Baseline Characteristics



## Persistence



## Key Safety Data Through 24 Months

Overall population (N = 838)	By sex (TE)		By age (TE)	
	Female (n = 96)	Male (n = 607)	< 50 y (n = 369)	≥ 50 y (n = 334)
128 (15%)* with DRAE(s)	15 (16%)	89 (15%)	61 (17%)	43 (13%)
2† (< 1%) serious DRAEs	0	2 (< 1%)	1 (< 1%)	1 (< 1%)
62 (7%)‡ discontinued B/F/TAF due to DRAEs§	9 (9%)	45 (7%)	31 (8%)	23 (7%)

\*TN: 18% (24/135), TE: 15% (104/703); †Both in the TE group; ‡TN: 6% (8/135), TE: 8% (54/703); §Most commonly weight increase (3%) and depression (1%); ¶Chi square and Fisher exact tests for the difference between groups: the null hypothesis was that there were equal proportions in the two groups

## Weight (kg) – Overall and Key Groups

	Median (Q1, Q3) Baseline	TN (N = 75)*	24 months	Median change†	TE (N = 376)*	24 months	Median change†
Overall	69 (63, 80)	→	75 (68, 84)	+4.3† (0, 9)	76 (67, 87)	→	77 (69, 89)
By baseline CD4	68 (63, 72)	→	73 (70, 83)	+6.6† (1.4, 10.0)	70 (62, 80)	→	79 (67, 84)
By sex	65 (59, 74)	→	65 (58, 78)	+0.5 (-1.6, 3.0)	78 (69, 88)	→	79 (70, 90)
By age	76 (66, 86)	→	77 (68, 88)	+1.5† (-0.9, 4.7)	77 (68, 87)	→	78 (70, 89)
By race	72 (65, 85)	→	74 (66, 86)	+0.9 (-1.0, 4.3)	77 (67, 87)	→	78 (69, 89)
By prior TDF	77 (67, 87)	→	78 (69, 90)	+1.0† (-1.0, 4.5)	74 (67, 86)	→	77 (68, 88)

\*Population with weight and BMI data available at baseline and 24 months; †Calculated as changes from baseline to 24 months for each individual participant; ‡People of other races, of which the majority were White; §Non-parametric test null hypothesis was that there were equal median changes in the two subgroups; ¶P < 0.05 for change from baseline in group using the sign test (null hypothesis that there was zero change from baseline)