BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE (B/F/TAF) IN ANTIRETROVIRAL TREATMENT-NAÏVE (TN) AND -EXPERIENCED (TE) PEOPLE WITH HIV (PWH): 3-YEAR EFFECTIVENESS AND SAFETY OUTCOMES IN THE BICSTAR OBSERVATIONAL COHORT

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Background:

BICSTaR is an ongoing, multinational, observational, 2-year cohort study evaluating real-world effectiveness and safety of B/F/TAF in PWH. Follow-up has recently been extended for a further 3 years in some countries. We assessed 3-year effectiveness and safety of B/F/TAF, including effectiveness in key groups of PWH.

Methods:

Data were pooled from people enrolled in Germany, France and Canada. Outcomes included virologic effectiveness (HIV-1 RNA <50 copies/mL; missing data=excluded [M=E] and discontinuation=failure [D=F]), persistence, drug-related adverse events (DRAEs) and laboratory parameters.

Results:

781 (122 TN/659 TE) PWH were included from the main study, of whom 449 (67 TN/382 TE) consented to the extension. Of the TE participants, 68%/18%/14% switched from INSTI-/NNRTI-/PI-based and 50%/34%/14% from TAF-/TDF-/ABC-based regimens, respectively. Baseline characteristics were similar between those not eligible for, and those consenting to, the extension.

Effectiveness was high at 3 years (M=E/D=F), 97%/76% in TN and 97%/78% in TE participants, with similar rates observed across key groups. Persistence was 88% during the main study and remained high (81%) for those with 3-year follow-up. There was no reported emergence of resistance to the components of B/F/TAF. DRAEs occurred in 10% (82/781), 2% (15/670) and <1% (1/444) of participants in Years 1, 2 and 3, respectively. Discontinuations due to DRAEs were few (7%). Overall, weight increase (4%) and depression (2%) were the most common DRAEs, leading to discontinuation in 2% and 1% of participants, respectively. Serious DRAEs were rare (0.3%; 2 TE participants with depression). Lipid parameters are shown in, and other key outcomes are listed in.

Conclusion:

B/F/TAF was associated with high levels of effectiveness at 3 years across all groups, with no emergence of resistance and no new or unexpected safety findings. These real-world data continue to support the broad use of B/F/TAF in clinical practice.

Disclosure of Interest Statement:

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