**Effectiveness, persistence and safety of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/TAF), rilpivirine/F/TAF (R/F/TAF) or F/TAF + another 3rd agent in HIV-1+ patients over 24 months – Results from the German TAFNES cohort**

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**Background**

The prospective TAFNES cohort study evaluates the effectiveness and safety of F/TAF-based single-tablet regimens (STRs) (with boosted elvitegravir or rilpivirine) or F/TAF-based multi-tablet regimens in people living with HIV (PLWH) in clinical routine in Germany. Minimising side effects and optimizing long-term tolerability of ART together with sustained viral suppression over time are essential requirements for achieving healthy ageing in PLWH. Here we present the data from the TAFNES cohort after 24 months of follow-up.

**Methods**

**Inclusion criteria**

- All patients who participated in the analysis population who had been treated with F/TAF in the German TAFNES cohort study. The specific SMPCs and the specific SMPCs related to F/TAF-based STR codes with MedData Preferred Terms (PT).

**Study drug persistence**

- Kaplan-Meier estimates; loss to follow-up is censored.
- Virolologic effectiveness (HIV-RNA<50 cp/mL; discontinuation failure, loss to follow-up and missing-excluded).

**Incident serious and non-serious adverse drug reactions (ADRs) and SADR related to F/TAF or F/TAF-based STR codes with MedData Preferred Terms (PT).

**Results**

**Study population**

N=767 patients (TN: 301, TE: 466) were included in the analysis population: 318 patients received E/C/TAF, 192 R/F/TAF and 257 F/TAF-3rd agent (52% dolutegravir [DTG], 11% nevirapine [NN]), 10% darunavir/ritonavir [DRV]). 9% ritonavir [R] and 18% other or unspecified antiretroviral agents were present.

**Virologic effectiveness at month 24**

Overall virologic effectiveness was 74% (479/643) for E/C/TAF 83% (219/264), R/F/TAF 79% (127/160) and F/TAF-3rd agent 59% (130/220) (Figure 2 and Table 4).

**Safety**

By MD2, in 30 patients (3.9%). ADRs were the documented reason for study and/or study drug discontinuation, including 2 patients with virologic failure as documented ADR and 7 patients without further specification or documented ADR (Tables 3 and 5). Overall, 55 ADRs were reported including 3 serious adverse drug reactions (SADRs) in 61% of patients (n=43) (Table 5).

**Conclusions**

The non-interventional TAFNES cohort analyzed clinical routine use of F/TAF-based HIV-1 therapies in n=767 PLWH in Germany. The final data cut after 24 months of follow-up demonstrates:

- High persistence of F/TAF-based ART: 87% E/C/TAF, 85% R/F/TAF, 68% F/TAF-3rd agent.
- Prolonged virologic effectiveness: 83% E/C/TAF, 79% R/F/TAF, 59% F/TAF-3rd agent – with only 16% of discontinuations due to virologic failure. Study drug discontinuation due to therapy simplification was common in the F/TAF-3rd agent group, impacting the effectiveness result for this group.
- Low number of discontinuations due to ADRs: 3.9% of patients. Overall discontinuations were dominated by loss-to-follow-up and simplification in this cohort.

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1) Patients with NRTI and/or NNRTI resistance mutations not related to the F/TAF combination (excluding major NRTI resistance) were included.
2) Discontinuation due to virologic failure (V2) is defined according to the IAS guidelines.
3) 71 (11) patients were not evaluable for adverse drug reactions (ADRs) due to lack of information.

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