12-MONTH OUTCOMES OF DOVATO (DTG + 3TC) IN ART-NAIVE AND PRE-TREATED PLHIV IN GERMANY: REAL-WORLD DATA FROM THE GERMAN URBAN COHORT

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DOVATO is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhiitor class, or lamivudine

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Background

- The URBAN cohort study (initiated in 11/2018) provides prospective real-world data regarding the effectiveness, safety, metabolic outcomes, and patient-reported outcomes (PROs) associated with DOVATO (DTG + 3TC) in people living with HIV (PLHIV) either as two-pill or – after availability in 7/2019 – as one-pill regimen
- Here we present the month 12 (M12) outcomes

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Methods

- URBAN is a prospective, non-interventional, 3 year German cohort study in adult ART-naïve and pre-treated PLHIV receiving DTG/3TC in accordance with the label
- Inclusion criteria for the M12 analysis set were a documented M12 follow-up (visit window 9–15 months) or discontinuation prior to M12
- M12 viral suppression was defined as HIV-RNA <50 c/mL in visit window (9–15 months) or 50–200 c/mL with subsequent HIV-RNA <50 c/mL (excluding missing data/loss-to-follow-up)
- Persistence on DTG/3TC was estimated using Kaplan-Meier analysis
- Adverse drug reactions (ADRs) were coded by MedDRA (Medical Dictionary for Regulatory Activities) using system organ class (SOC) and preferred terms (PT)
- PRO measures included the HIV Symptom Distress Module [HIV-SDM] and the HIV Treatment Satisfaction Questionnaire [status version; HIV-TSQs]

Study Population

- Overall, 367 patients were enrolled across 19 study centers in the URBAN cohort
- At data-cut, 364 PLHIV were eligible for M12 analysis, 91.5% pre-treated, 93.4% men, median age 47.0 years
- 181 patients (49.7%) started on the two-pill regimen; 165/181 patients (91.2%) were switched to the one-pill regimen by M12

Table 1. Baseline Characteristics	ART-naïve (N=31)	Pre-treated (N=333)
Sex, male, n (%) [N]	30 (96.7) [31]	310 (93.1) [333]
Age, years, median (interquartile range; IQR) [N] Age ≥50 years, n (%)	35 (26–42) [31] 5 (16.1)	49 (39–55) [333] 155 (46.5)
Body weight, kg, median (IQR) [N]	68 (65–82) [30]	79 (70–90) [236]
BMI, kg/m^2, median (IQR) [N]	23 (21–25) [30]	25 (23–28) [236]
HIV-1 RNA, c/mL, median (IQR) [N] HIV-1 RNA >100,000 c/mL, n (%) HIV-1 RNA <50 c/mL, n (%)	37,200 (5,100–70,700) [31] 3 (9.7) 0 (0.0)	19 (0–39) [330] 1 (0.3) 319 (96.7)
CD4 T-cell count, cells/µL, median (IQR) [N]	456 (328–664) [31]	748 (550–940) [329]
History of AIDS (CDC C), n (%) [N]	0 (0) [31]	42 (12.6) [333]
Time since HIV diagnosis, years (median, IQR) [N]	0 (0–0) [31]	10 (5–16) [330]
Time on ART, years (median, IQR) [N]	n.a.	7 (4–13) [301]
Prevalence of comorbidities (as defines by disease categories in the eCRF), n (%) [N]	10 (32.3) [31]	189 (56.8) [333]
Most common comorbidities (>10%), n (%) Hypertension Depression Lipid disorders Chronic kidney disease	 1 (3.2) 3 (9.7) 1 (3.2) 0 (0.0)	 82 (24.6) 62 (18.6) 41 (12.3) 40 (12.0)

IQR, interquartile range; CDC, Centers for Disease Control and Prevention; n.a., not applicable.

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ART Prior to Switch to DTG + 3TC in Pre-Treated Patients

- The median duration on ART before DTG + 3TC was 7.0 years (IQR: 4.0–13.0)
- 32.7% had a history of ≥3 ART changes

Table 2a. Treatment switches prior to DTG + 3TC	N (%); N=333
No modifications	56 (16.8)
1–2 modifications	142 (42.6)
3–5 modifications	83 (24.9)
>5 modifications	26 (7.8)
Unknown	26 (7.8)

Table 2b. Previous ART prior to DTG + 3TC (in >5%)*	N (%); N=333
DTG/3TC/ABC	148 (44.4)
DTG + FTC/TAF	42 (12.6)
BIC/FTC/TAF	24 (7.2)
DTG + FTC/TDF	20 (6.0)
EVG/COBI/FTC/TAF	17 (5.1)

3TC, lamivudine; ABC, abacavir; BIC, bictegravir; COBI, cobicistat; DTG, dolutegravir; EVG, elvitegravir; FTC; emtricitabine; RPV, rilpivirine.
*in pre-treated PLHIV.

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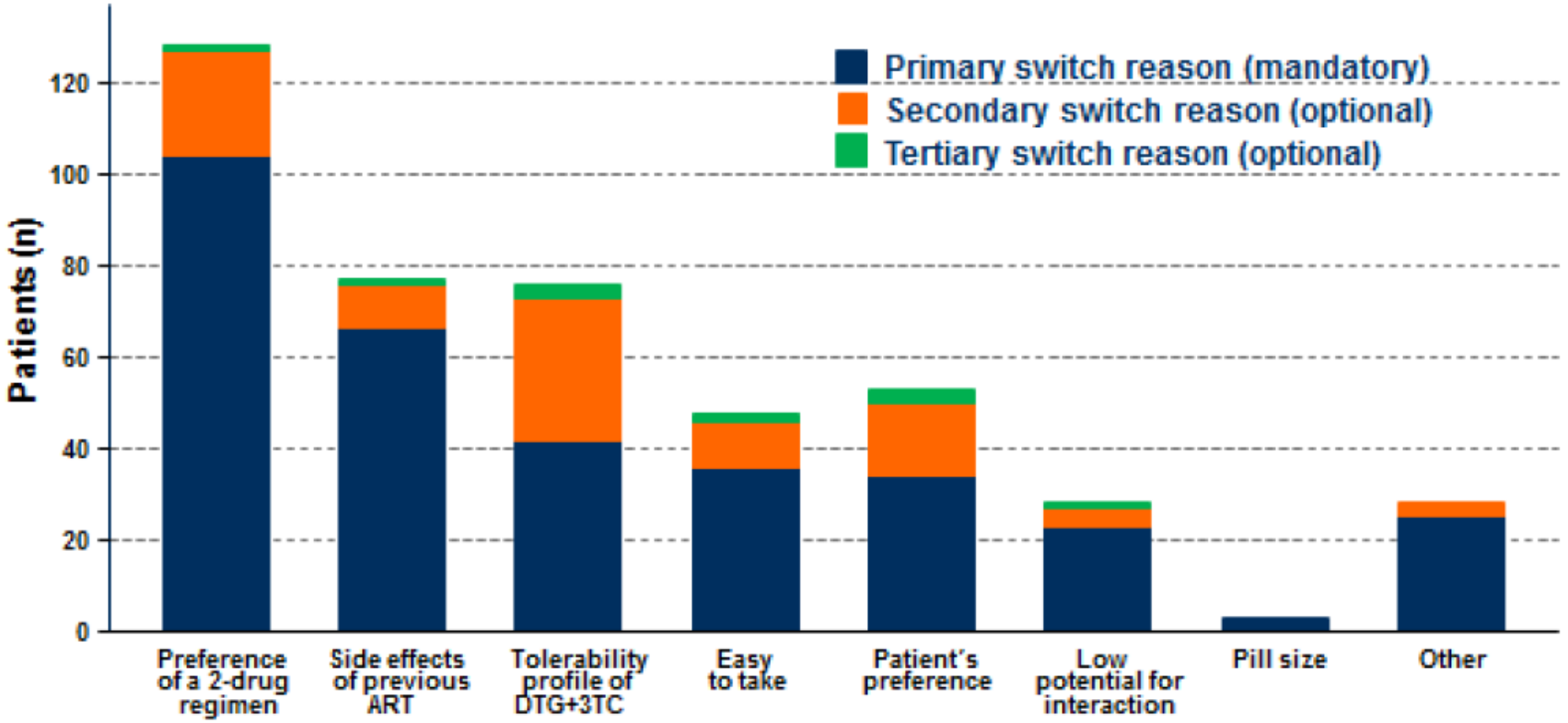
Primary, Secondary and Tertiary Reasons for Switch to DTG + 3TC

- Primary reasons for use of DTG + 3TC (in >15%) were ‘preference of a 2-drug regimen (2DR)’ (31.2%) and ‘side effects of previous ART’ (19.8%) in pre-treated patients, and ‘preference of a 2DR’ (45.2%) and ‘easiness to take’ (16.1%) in ART-naïve patients



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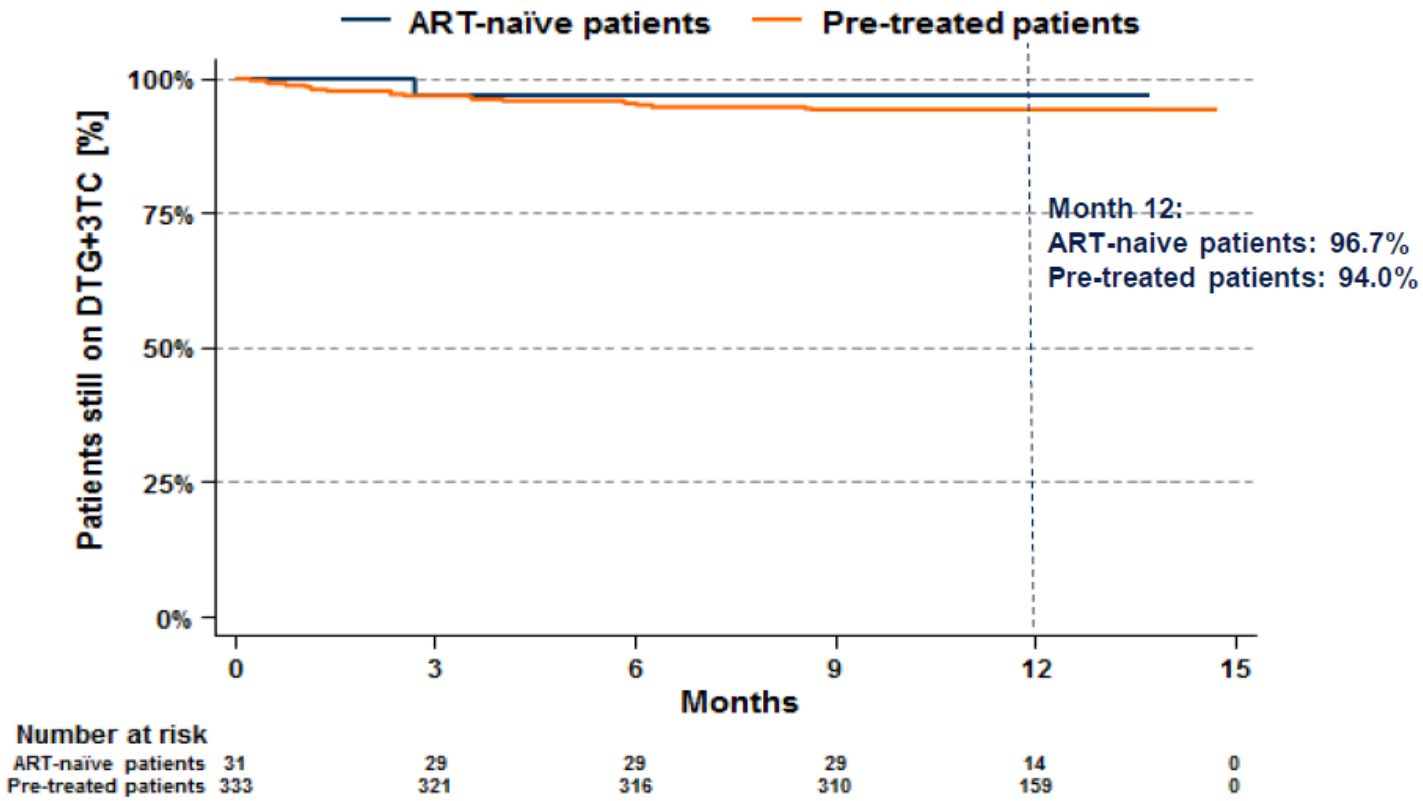
Persistence on DTG + 3TC (Kaplan-Meier Analysis)

- Persistence on DTG + 3TC through M12 was 94.2%
- 21 patients discontinued DTG + 3TC (5.8%), 3 patients were lost-to-follow-up and one patient withdrew consent
- Reasons for discontinuation were ADRs (n=11 patients [3.0%]), patient wish (n=6 [1.6%]), virologic reasons (n=3 [0.8] all pre-treated) and doctor's decision (n=1 [0.3%])



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Safety and Effectiveness

- Median weight change from baseline was +1.4 kg (IQR, -1.0–4.0; n=122) in pre-treated, and +2.0 kg (IQR, 1.0–6.0; n=15) in ART-naive PLHIV
- Until data-cut, 23 ADRs (grades 1–2, none serious) were reported in 18 PLHIV (4.9%)
- Most common ADRs (>1 event) were depression (n=3), sleep disorders (n=2) and headache (n=2)
- Viral suppression rate at M12 was 92.9% for pre-treated and 93.3% for ART-naïve PLHIV
- Overall, 3 patients were discontinued due to virologic reasons (at investigator's discretion, while HIV-RNA was <200 c/mL)
- No treatment-emergent resistance was reported (resistance testing was available in 7 participants)

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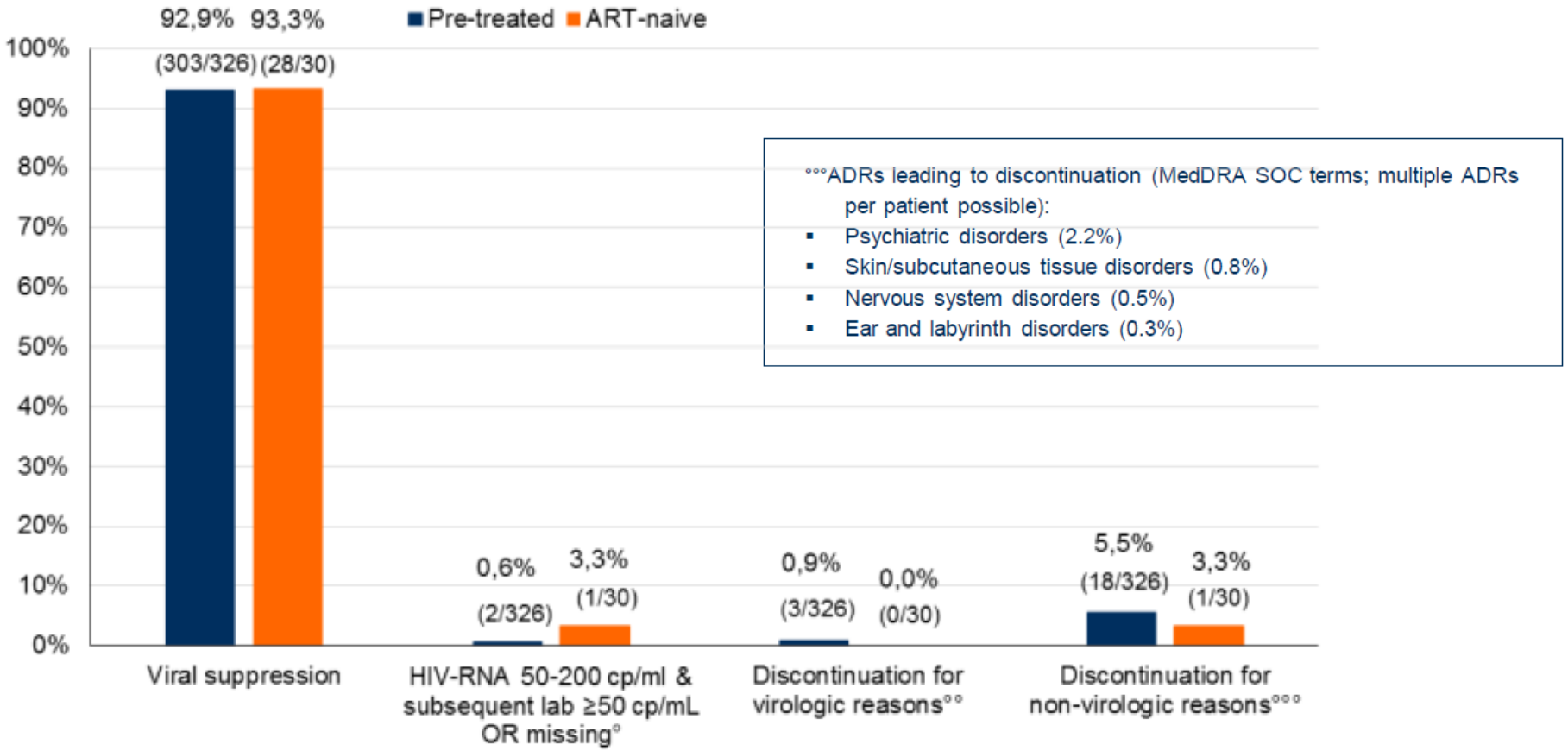
Virologic Outcomes at Month 12



Effectiveness set: N=356; n=8/364 with missing data; °incl. N=1 with subsequent lab (57 and 50 c/mL), n=2 with missing subsequent lab; °°at investigator's discretion with HIV-RNA <200 c/mL; °°°most common reasons (in >1% of patients) were adverse drug reactions (ADRs) (3.0%, n=11), and patient decisions (1.9%, n=7).

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Patient Reported Outcomes

- For pre-treated PLHIV completing questionnaires at baseline and M12, PROs changed statistically significantly: the median total HIV-SDM score decreased from 12.0 (IQR, 4.0–22.0) to 8.0 (3.0–18.0; p<0.001); HIV-TSQs score increased from 56.0 (51.0–60.0) to 59.0 (56.0–60.0; p<0.001)

Table 3. Patient Reported Outcomes	**Pre-treated** N	**Baseline** Total score; median (IQR)	**Month 12** Total score; median (IQR)	**Month 12** Change from baseline median (IQR)	**P-value** Wilcoxon-sign-rank test
HIV-SDM^	211	12.0 (4.0–22.0)	8.0 (3.0–18.0)	-2.0 (-7.0–+2.0)	<0.001
HIV-TSQs*	202	56.0 (51.0–60.0)	59.0 (56.0–60.0)	+1.0 (0.0–+6.0)	<0.001

^HIV-SDM: 20 items, range of total score 0–80; negative changes indicate score improvement.
*HIV-TSQs: range of total score 0–60; positive changes indicate score improvement.
Due to small sample size, PROs in ART-naïve PLHIV were not alayzed for statistically significant differences from baseline; the median total HIV-SDM score decreased from 8.5 (IQR 1.0–22.0) to 7.0 (1.0–16.0; n=14). The median HIV-TSQs at month 12 was 58.0 (55.0–60.0; n=15).

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Conclusions

- DOVATO use in a real-world setting showed high virologic suppression rates after one year with low numbers of discontinuations for virologic reasons (0.8%) and 0 cases of resistance development
- In pre-treated PLHIV, who made up the majority of the URBAN cohort, symptom distress and treatment satisfaction improved significantly

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