3-YEAR OUTCOMES FOR DOLUTEGRAVIR (DTG) + LAMIVUDINE (3TC) IN ANTIRETROVIRAL THERAPY (ART)-NAIVE AND PRE-TREATED PEOPLE LIVING WITH HIV-1 IN GERMANY: REAL-WORLD DATA FROM THE GERMAN URBAN COHORT

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# Background:

The URBAN study provides real-world data on effectiveness, tolerability, metabolic parameters, and patient-reported outcomes (PROs) in people living with HIV-1 using DTG+3TC. We present 3-year results.

#### Methods:

URBAN is a prospective, non-interventional, multi-center, 3-year German cohort study in ART-naive and pre-treated individuals receiving DTG+3TC. The primary endpoint was proportion with virologic suppression (viral load [VL] <50 or 50-200 c/mL with subsequent VL <50 c/mL within 120 days; discontinuation = failure) at 3-year follow-up. Lipid and liver parameter changes were assessed. PROs were assessed via HIV Treatment Satisfaction Questionnaire, status version (HIV-TSQs) and HIV Symptom Distress Module (HIV-SDM).

### Results:

Of 366 individuals, median baseline age was 47 years; 93.2% were male. Overall, 332/366 (90.7%) individuals were eligible for the primary analysis (missing data [n=8] or lost to follow-up [n=26] excluded). In pre-treated individuals, median time on ART before switch to DTG+3TC was 7 years (interquartile range [IQR], 4-13; n=303), and 32.8% had a history of ≥3 ART switches. Three-year virologic suppression rates were 83.0% for pre-treated and 77.8% for ART-naive individuals. Overall, 6/332 (1.8%) individuals discontinued DTG+3TC for virologic reasons at investigator's discretion with VL ≥50 c/mL (n=5 pre-treated, n=1 ART-naive); no emergent resistance was reported. Median (IQR) weight change from baseline at Year 3 was 2.0 kg (−1.0, 6.0; n=131) in pre-treated and 5.0 kg (1.0-10.0; n=13) in ART-naive individuals. Lipid and liver parameter changes from baseline were minimal. Pre-treated individuals who completed baseline and Year 3 questionnaires had significantly increased HIV-TSQs scores: mean (standard deviation) change from baseline, 2.2 (8.9); *P*<0.0001. HIV-SDM scores remained stable.

# **Conclusion:**

At Year 3, high virologic suppression rates and few discontinuations for virologic reasons were observed with DTG+3TC; no emergent resistance was reported.

Treatment was well tolerated, with minimal lipid and liver parameter changes. Pretreated individuals reported significant improvements in treatment satisfaction.

#### **Disclosure of Interest Statement:**

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