O23: Table 1. Efficacy as determined by US FDA-defined Snapshot algorithm at W26

	LEN + TAB + ZAB 10 mg/kg (*n* = 14)	LEN + TAB + ZAB 30 mg/kg (*n* = 16)
HIV-1 RNA ≥50 copies/ml, *n* (% [95% CI])	3 (21.4 [4.7–50.8])	0 (0.0 [0.0–20.6])
HIV-1 RNA <50 copies/ml, *n* (% [95% CI])	11 (78.6 [49.2–95.3])	15 (93.8 [69.8–99.8])
No virological data in W26 window, *n* (%) (discontinued study drug due to other reasons[a] and last available HIV-1 RNA <50 copies/ml)	0	1[b] (6.3)

Abbreviations: AE, adverse event; LEN, lenacapavir; TAB, teropavimab; W, week; ZAB, zinlirvimab.
[a]Reasons other than AE/death or lack of efficacy (e.g. discontinued study drug due to investigator's discretion, participant decision, lost to follow-up, non-compliance with study drug, protocol violation, pregnancy or study terminated by sponsor). [b]Withdrew from the study after W12.

high dose, 30 mg/kg IV). Week 26 data for the primary cohort have been previously reported [1]. In this analysis, we assessed pooled virological outcomes (using US FDA Snapshot algorithm) and safety of both cohorts by treatment group through Week 26.

Results: Thirty-two participants were randomized; 31 received the complete study regimen; one restarted antiretroviral therapy due to a major protocol violation and was excluded from analyses. Participants were: 19% female, 22% Black and 31% Hispanic/Latinx. At baseline, median age was 48 years and mean CD4 count was 992 cells/μl. At week 26, 3/14 (21%) in the low dose, and 0/16 (0%) in the high dose group had HIV-1 RNA ≥50 copies/ml (Table 1). There were no serious adverse events (AEs) related to study drug; the most common AEs were injection site reactions related to subcutaneous LEN administration.

Conclusions: All participants who received LEN, TAB and high-dose ZAB maintained viral suppression with no difference in safety or tolerability between dose groups. These early phase results suggest that high treatment efficacy for the long-acting regimen of LEN, TAB and high-dose ZAB can be achieved when at least one antibody is highly active in people with HIV highly susceptible to one or both bNAbs.

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Antiretroviral Treatment Strategies

O24

Comparable efficacy and safety of dolutegravir/lamivudine to a three-drug regimen among ARV naive people living with HIV with CD4 <200/mm^3: the DOLCE study

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Background: Dolutegravir/lamivudine dual therapy (DTG/3TC) (DT) has demonstrated non-inferiority compared to triple therapy (TT) in the GEMINI trials. The population with fewer than 200 CD4 cells/mm^3 had a lower response rate, though this was not related to virological failure.

Materials and methods: DOLCE is a randomized, exploratory, open-label, multicentre study conducted in Argentina and Brazil, to assess the antiviral activity at week 48 of DTG/3TC among ART-naïve HIV participants with CD4 counts ≤200 cells/mm^3. Participants were randomly assigned in a 2:1 ratio to receive DTG/3TC single tablet regimen (STR) or DTG+TDF/XTC, stratified by country and by plasma viral load (pVL) at screening (> or ≤100,000 copies/ml). Primary endpoint: proportion of participants with pVL <50 copies/ml at week 48 (FDA Snapshot analysis for the intent-to-treat exposed [ITT-E] population). Efficacy and safety results at week 48 are reported. NCT04880395.

Results: Baseline characteristics were similar in both arms (*n* = 230): median age 35 years, 77% male, 48.3% heterosexual, median CD4 cell count 116 (IQR 53–188), median pVL 151,000 copies/ml (IQR 49,027–446,947); 43.4% had CD4 <100 cells/mm^3 and 69%, pVL >100,000 copies/ml. CDC stage C: 33%. At week 48, 82.2% in the DT (125/152) versus 80.5% (62/77) with TT achieved pVL <50 copies/ml, adjusted treatment difference 2% (95% CI −8.7, 12.8%) in the ITT-E analysis. Participants with baseline pVL >100,000 copies/ml showed 80.9% response in DT and 76.6% in TT, adjusted treatment difference: 5.1% (95% CI −10.1, 20.3%). Per-protocol analysis: 91.9% responded in the DT and 91.2% in the TT, adjusted treatment difference 1.8% (95% CI −6.3, 9.9%). No statistically significant differences were observed between arms in different analyses (Table 1). CD4 count change from baseline to week 48: +200 cells/mm^3 in DT, +177 cells/mm^3 in TT. Ten participants developed immune reconstitution inflammatory syndrome: DT: 6/153 (3.9%); TT: 4/77 (5.2%). Severe adverse events (*n* = 27) were reported: DT 17/153 (11.1%); TT: 10/77 (12.9%). No difference in safety parameters between arms was observed.

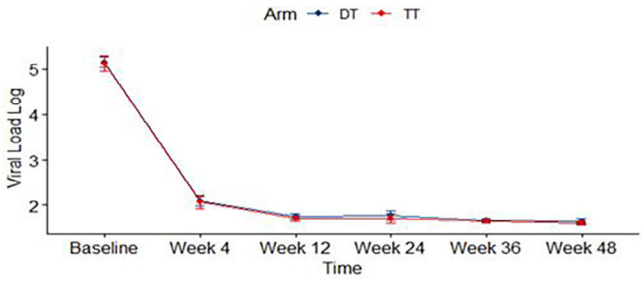
Conclusions: DTG/3TC achieved comparable results to triple therapy, meeting non-inferiority criteria in a severely immunosuppressed population with low CD4 counts and high viral load. pVL slope (Figure 1), time to viral suppression and CD4 recovery were also comparable between arms. Similar results were observed in patients with pVL >100,000 copies/ml. This study adds information regarding the efficacy and safety of dual therapy with DTG/3TC, regardless of baseline CD4 counts and viral load.

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O24: Table 1. Efficacy analysis. Primary outcome viral load <50 copies/ml at week 48

	Total	Dual therapy (DT)	Triple therapy (TT)	Adjusted risk difference (95% CI)	Non-inferiority *p*-value[a]
ITT-E (global *n* = 229; TT *n* = 77; DT *n* = 152) *n* (%) [95% CI]	187 (81.7%) [76–86%]	125 (82.2%) [75–88%]	62 (80.5%) [70–88%]	2.0% (−8.7, 12.8%)	0.016
ITT-E, baseline VL >100,000 copies/ml (global *n* = 141; TT *n* = 47; DT *n* = 94) *n* (%) [95% CI]	112 (79.4%) [72–86%]	76 (80.9%) [71–88%]	36 (76.6%) [62–87%]	5.1% (−10.1, 20.3%)	0.026
Per protocol (global *n* = 204; TT *n* = 68; DT *n* = 136) *n* (%) [95% CI]	187 (91.7%) [87–95%]	125 (91.9%) [86–96%]	62 (91.2%) [81–96%]	1.8% (−6.3, 9.9%)	0.005

[a]One-sided non-inferiority test, with a significance level of 0.05. This gives a confidence interval of 90% for the difference between treatment arms (a narrower CI than 95% CI). The non-inferiority margin (10%) is not included in the 90% CI, therefore, non-inferiority can be claimed. For the ITT-E, the CI is (−8.3, 11.7%); for the ITT-E, baseline VL >100,000 copies/ml, the CI is (−9.5, 18.0%); and in the per protocol analysis, the CI for the difference is (−7.2, 8.7%).



O24: Figure 1. Mean viral load log over time on DT and TT arms.

Infection Prevention

O25

Post-exposure prophylaxis with doxycycline (DoxyPEP) in a cohort of men who have sex with men (MSM) in high risk for sexually transmitted infections (STI): the PRIDOX study

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Background: Clinical trials have shown the high efficacy of doxycycline as STI post-exposure prophylaxis (DoxyPEP), but real-world data are limited. We aimed to analyse the impact of DoxyPEP on the incidence of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and syphilis (SPL) in a high-risk MSM cohort.

Materials and methods: PrEP users in follow-up at our clinic, meeting criteria of high risk for STI similar to the IPERGAY and DoxiPEP trials [1,2], were offered to be included in a DoxyPEP programme. PrEP users who started DoxyPEP between March 2023 and June 2024 are included in this analysis. The pre-DoxyPEP period was considered from the date starting PrEP to the date starting DoxyPEP, and the post-DoxyPEP period from DoxyPEP start to 30 June 2024, or DoxyPEP discontinuation. Subjects were tested at baseline, each visit, and when symptomatic for NG and CT by PCR in pharynx, rectum and urine, and serological tests for SPL; NG culture was also conducted. Additionally, microbiological cultures for multidrug-resistant bacteria were performed on nasal and rectal samples at DoxyPEP start and at 48 weeks. The incidence of the first episode of CT, NG and SPL was analysed and compared between periods using Cox proportional hazard models.

Results: Among 846 active PrEP users, 189 (22.3%) received DoxyPEP; all were MSM with a mean age of 39±8.9 years. Median follow-up was 464±346 days and 257±142 days for the pre-DoxyPEP and post-DoxyPEP periods. The incidence rates per 100 PY of the first episode for each STI in the pre- and post-DoxyPEP periods were: 31.8 and 8.53 (p = 0.0001) for CT, 41.7 and 26.6 (p = 0.0228) for NG, and 21.6 and 2.52 (p = 0.0001) for SPL. NG culture was positive in 33% of PCR-positive samples; 25% of isolates were tetracycline-resistant, similar to those not on DoxyPEP (42%; p = 0.2). DoxyPEP was discontinued in five (2.6%) participants (two adverse events, two due to reduced STI risk, one for medical reasons). Microbiological cultures for multidrug-resistant bacteria were available in 150 (79.8%) participants, with 16 (10.6%) positive at baseline and 13 (8.6%) at 48 weeks.

Conclusions: DoxyPEP was well accepted as part of routine PrEP care, significantly reducing STI incidence with good tolerance. Our data demonstrate the efficacy and safety of this strategy in a real-world setting. The impact of DoxyPEP on the emergence of multidrug-resistant germs or resistant NG has not been evident. However, its impact on bacterial resistance and microbiota requires further evaluation.

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O26

Both smallpox MVA vaccine and mpox infection produce potent immune response to mpox in people living with HIV

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