Investigational

BIC-TAF-FTC vs. DTG + TAF-FTC as Initial Therapy

GS-1490

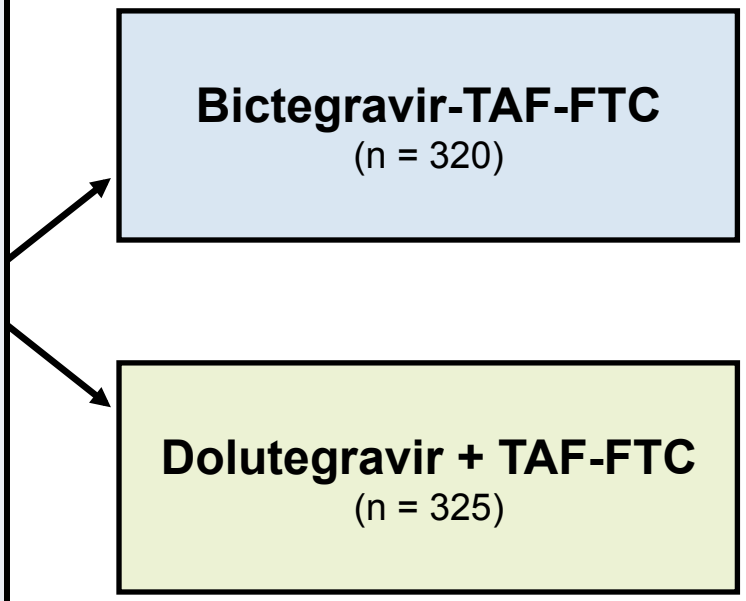
National HIV Curriculum

BIC-TAF-FTC vs. DTG + TAF-FTC as Initial Therapy

GS-1490: Design

GS-1490: Study Design

- **Background**: Randomized, double-blind, active-controlled, phase 3 study evaluating the efficacy and safety of bictegravir-tenofovir alafenamide-emtricitabine versus dolutegravir plus tenofovir alafenamide-emtricitabine for treatment-naïve individuals
- **Inclusion Criteria**
  - Age ≥18
  - Antiretroviral-naïve (or ≤10 days of treatment)
  - HIV RNA ≥500 copies/mL
  - eGFR ≥30 mL/min
- **Regimens**
  - Bictegravir-TAF-FTC (50/200/25 mg)
  - Dolutegravir (50 mg) + TAF-FTC (200/25 mg)



Source: Sax PE, et al. Lancet. 2017;390:2073-82.

Investigational

BIC-TAF-FTC vs. DTG + TAF-FTC as Initial Therapy
GS-1490: Baseline Characteristics

Study 1490 Baseline Characteristics		
Characteristic	**BIC-TAF-FTC (n = 320)**	**DTG + TAF-FTC (n = 325)**
Median age, years (range)	33 (27-46)	34 (27-46)
Male, %	88	89
Black or African descent, %	30	31
HIV RNA >100,000 copies/mL, %	21	17
CD4 count <200 cells/mm^3, %	14	10
HBV coinfection, %	3	2
HCV coinfection, %	2	2
Median CrCl, mL/min	120.4	120.6

Abbreviations: CrCl = creatinine clearance

Source: Sax PE, et al. Lancet. 2017;390:2073-82.

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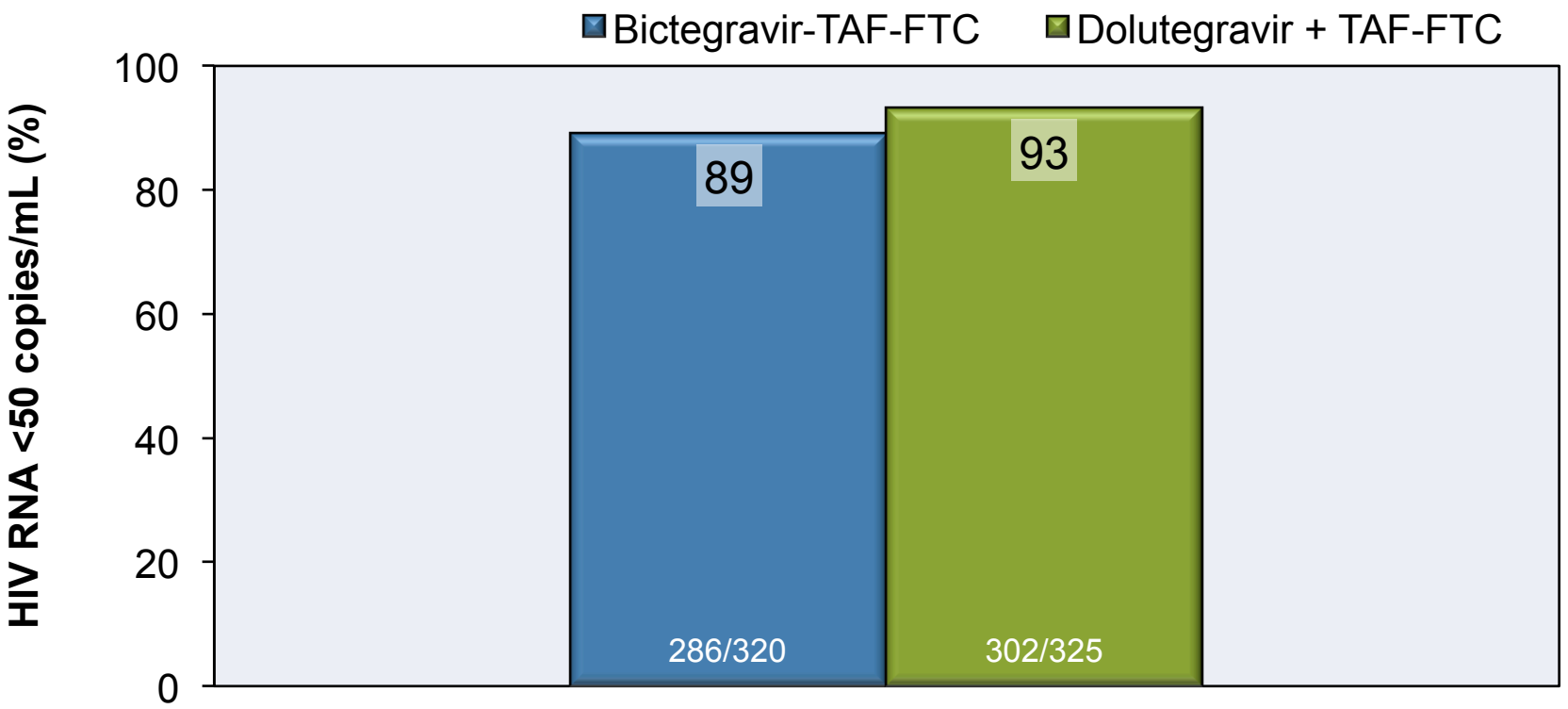
BIC-TAF-FTC vs. DTG + TAF-FTC as Initial Therapy

GS-1490: Results

Week 48 Virologic Response (Intention-to-Treat Analysis)



No participant discontinued due to lack of efficacy in either arm
No treatment-emergent resistance to any study drug occurred

Source: Sax PE, et al. Lancet. 2017;390:2073-82.

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BIC-TAF-FTC vs. DTG + TAF-FTC as Initial Therapy
GS-1490: Results

Treatment Emergent Adverse Events in Study 1490 (AE's >5%) Through Week 48		
	BIC-TAF-FTC (n = 320)	**DTG + TAF-FTC** (n = 325)
Headache, %	13	12
Diarrhea, %	12	12
Nausea, %	8	9
Fatigue, %	6	8
Arthralgia, %	5	3
Insomnia, %	5	4
Change in eGFR	-7.3 mL/min	-10.8 mL/min
Abbreviations: eGFR = estimated glomerular filtration		

Source: Sax PE, et al. Lancet. 2017;390:2073-82.

Investigational

BIC-TAF-FTC vs. DTG + TAF-FTC as Initial Therapy
GS-1490: Conclusions

Interpretation: "At 48 weeks, virological suppression with the bictegravir regimen was achieved and was non-inferior to the dolutegravir regimen in previously untreated adults. There was no emergent resistance to either regimen. The fixed-dose combination of bictegravir, emtricitabine, and tenofovir alafenamide was safe and well tolerated compared with the dolutegravir regimen."

Source: Sax PE, et al. Lancet. 2017;390:2073-82.

Acknowledgment

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The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

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AETC AIDS Education & Training Center Program
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