Investigational

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

GS-1490

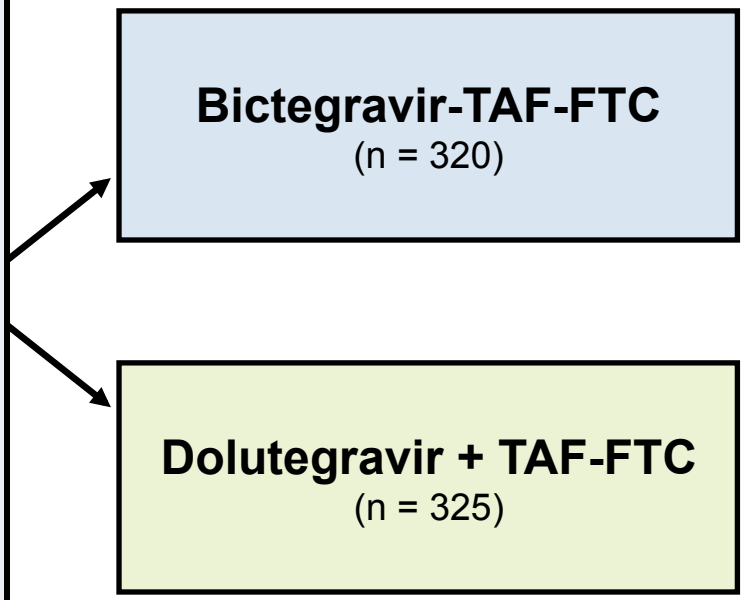
National HIV Curriculum

Investigational

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. IAS 2017, Paris. Abstract TUPDB0201LB.

Investigational

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

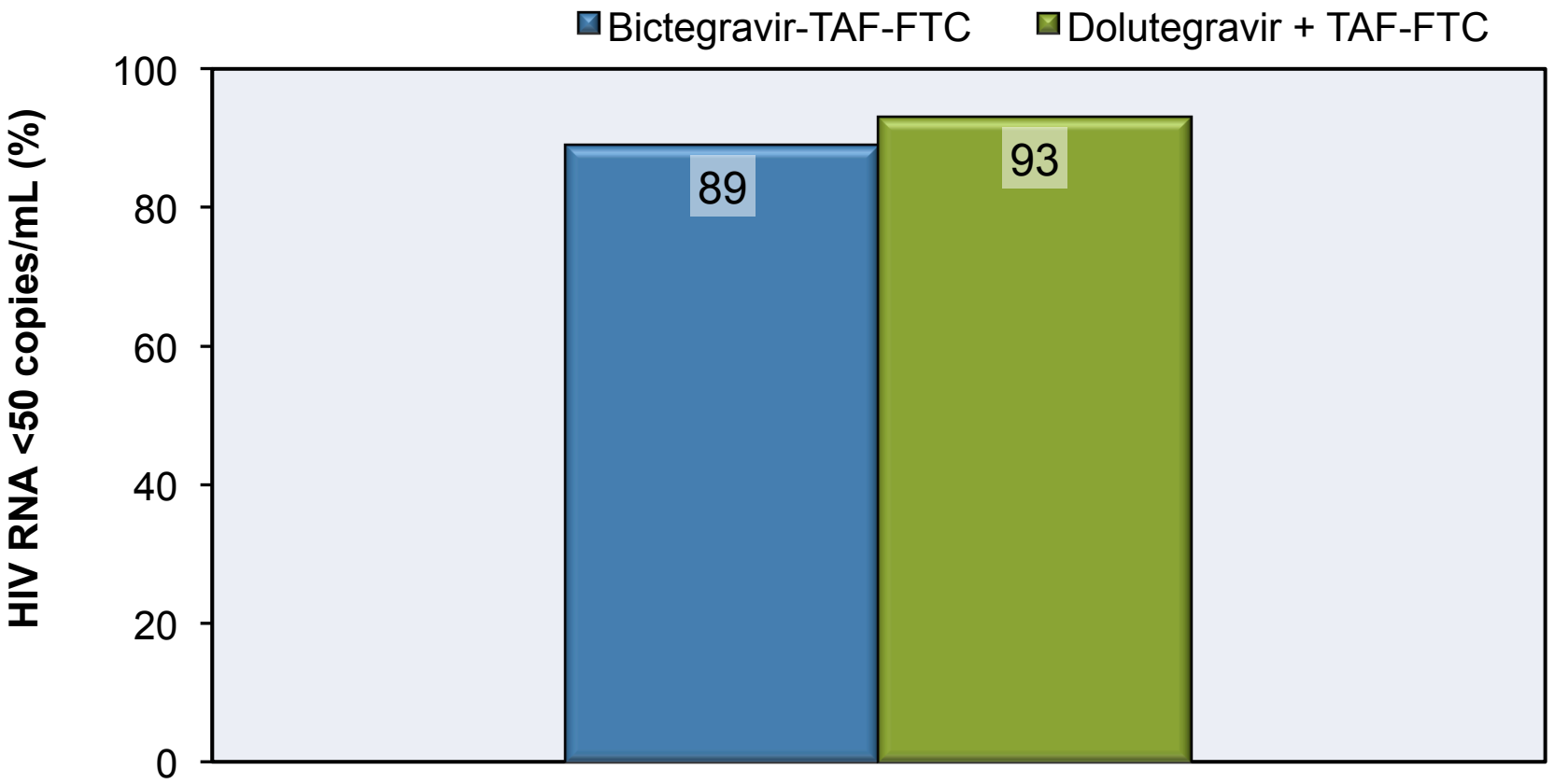
Study 1490 Baseline Characteristics		
Characteristic	**BIC-TAF-FTC (n = 320)**	**DTG + TAF-FTC (n = 325)**
Median age, y (range)	33 (18-71)	34 (18-77)
Male, %	88	88
Black or African descent, %	30	31
HIV RNA >100,000 copies/mL, %	21	17
CD4 count <200 cells/mL, %	14	10
HBV/HCV coinfection, %	3/2	2/2
Median eGFR, mL/min	120.4	120.6

Source: Sax PE, et al. IAS 2017, Paris. Abstract TUPDB0201LB.

Investigational

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

GS-1490: Results



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. IAS 2017, Paris. Abstract TUPDB0201LB.

Investigational

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		
	Bictegravir-TAF-FTC (n = 320)	**Dolutegravir + TAF-FTC** (n = 325)
Headache, %	12.5	12.3
Diarrhea, %	11.6	12.0
Nausea, %	7.8	8.9
Fatigue, %	5.9	8.0
Arthralgia, %	5.0	2.8
Insomnia, %	5.0	4.3
Change in eGFR	-7.3 mL/min	-10.3 mL/min

Abbreviations: eGFR = estimated glomerular filtration

Source: Sax PE, et al. IAS 2017, Paris. Abstract TUPDB0201LB.

Investigational

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

Conclusions: "After 48 weeks, bictegravir-tenofovir alafenamide-emtricitabine achieved virologic suppression in 89.4% of treatment- naïve adults and was noninferior to dolutegravir + tenofovir alafenamide-emtricitabine. Bictegravir-tenofovir alafenamide-emtricitabine was safe and well tolerated."

Source: Sax PE, et al. IAS 2017, Paris. Abstract TUPDB0201LB.

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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.

National HIV Curriculum

AETC AIDS Education & Training Center Program
National Coordinating Resource Center