

Bictegravir versus Dolutegravir, each with TAF-FTC
GS-141-1475

Bictegravir versus Dolutegravir, each with TAF-FTC

GS-141-1475: Design

Study Design

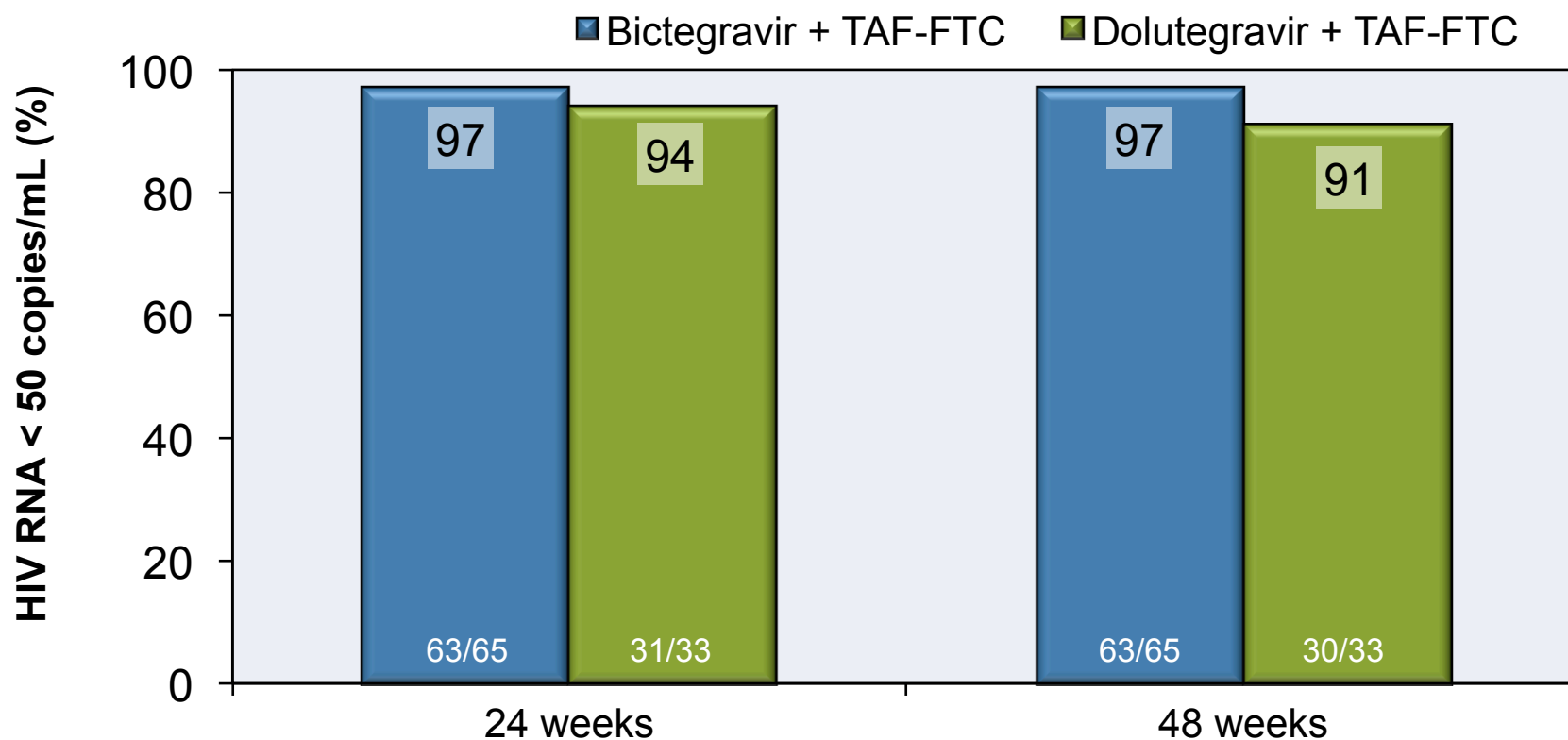
- **Background:** Randomized, double-blind, placebo controlled, phase 2 study evaluating the efficacy and safety of bictegravir versus dolutegravir as part of antiretroviral therapy for treatment-naïve individuals
- **Inclusion Criteria**
 - Age \geq 18
 - Antiretroviral-naïve
 - CD4 count >200 cells/mm³
 - HIV RNA $\geq 1,000$ copies/mL
 - eGFR >70 mL/min
 - Genotypic sensitivity to TAF and FTC
 - No hepatitis B or C
 - Not pregnant
 - No AIDS-defining condition within 30 days

**Bictegravir 75 mg QD
+ TAF-FTC**
(n = 65)

**Dolutegravir 50 mg QD
+ TAF-FTC**
(n = 33)

Bictegravir versus Dolutegravir, each with TAF-FTC GS-141-1475: Results

Week 24 and 48: Virologic Response by FDA Snapshot Analysis



Bictegravir versus Dolutegravir, each with TAF-FTC GS-141-1475: Adverse Effects

Most frequent adverse events in either study group

	Bictegravir + TAF-FTC (n = 65)	Dolutegravir + TAF-FTC (n = 33)
Any adverse event	55 (85%)	22 (67%)
Diarrhea	8 (12%)	4 (12%)
Nausea	5 (8%)	4 (12%)
Arthralgia	4 (6%)	2 (6%)
Fatigue	4 (6%)	2 (6%)
Headache	5 (8%)	1 (3%)

No serious treatment-related adverse events occurred in either arm. 1 participant (with history of atopic dermatitis) in the bictegravir arm discontinued due to urticaria.

Bictegravir versus Dolutegravir, each with TAF-FTC GS-141-1475: Laboratory Abnormalities

Most frequent laboratory abnormalities in either study group

	Bictegravir + TAF-FTC (n = 65)	Dolutegravir + TAF-FTC (n = 33)
Any laboratory abnormality	28 (44%)	15 (47%)
Creatinine kinase elevation	8 (13%)	3 (9%)
AST elevation	6 (9%)	1 (3%)
Fasting glucose elevation	5 (8%)	4 (13%)
ALT elevation	4 (6%)	0 (0%)
LDL elevation	4 (6%)	3 (9%)
Amylase elevation	3 (5%)	2 (6%)

Median decrease from baseline in estimated creatinine clearance: 7.0 mL/min in the bictegravir arm and 11.3 mL/min in the dolutegravir arm.

Bictegravir versus Dolutegravir, each with TAF-FTC GS-141-1475: Virologic Rebound and Resistance

Participants with Viral Rebound Meeting Protocol-Defined Criteria for Genotype Resistance Testing

	Study arm	Resistance detected
Participant 1	Bictegravir + TAF-FTC	None
Participant 2	Dolutegravir + TAF-FTC	None
Participant 3	Dolutegravir + TAF-FTC	T97A*

*This participant discontinued the study at week 48 due to non-adherence.

Bictegravir versus Dolutegravir, each with TAF-FTC GS-141-1475: Conclusions

Interpretation: “Bictegravir plus emtricitabine and tenofovir alafenamide and dolutegravir plus emtricitabine and tenofovir alafenamide both showed high efficacy up to 24 weeks. Both treatments were well tolerated. Administration of bictegravir, a novel, potent, once-daily INSTI designed to improve on existing INSTI options with the backbone of emtricitabine and tenofovir alafenamide, might provide an advantage to patients.”

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.

