BIC-TAF-FTC vs. DTG-ABC-3TC as Initial Therapy

GS-380-1489

BIC-TAF-FTC versus DTG-ABC-3TC as Initial Therapy
GS-380-1489: Design

GS-1489: Study Design

- **Background**: Randomized, double-blind, active-controlled, phase 3 study evaluating the efficacy and safety of bictegravir-tenofovir alafenamide-emtricitabine versus dolutegravir-abacavir-lamivudine for treatment-naïve individuals
- **Inclusion Criteria**
  - Age ≥18
  - Antiretroviral-naïve (or ≤10 days of treatment)
  - HIV RNA ≥500 copies/mL
  - eGFR ≥50 mL/min
  - HLA B*5701 negative
  - No chronic HBV infection
- **Regimens**
  - Bictegravir-TAF-FTC (50/200/25 mg)
  - Dolutegravir-ABC-3TC (50/600/300 mg)

Bictegravir-TAF-FTC
(n = 314)

Dolutegravir-ABC-3TC
(n = 315)

Source: Gallant J, et al. Lancet. 2017;390:2063-72.

BIC-TAF-FTC versus DTG-ABC-3TC as Initial Therapy
GS-380-1489: Baseline Characteristics

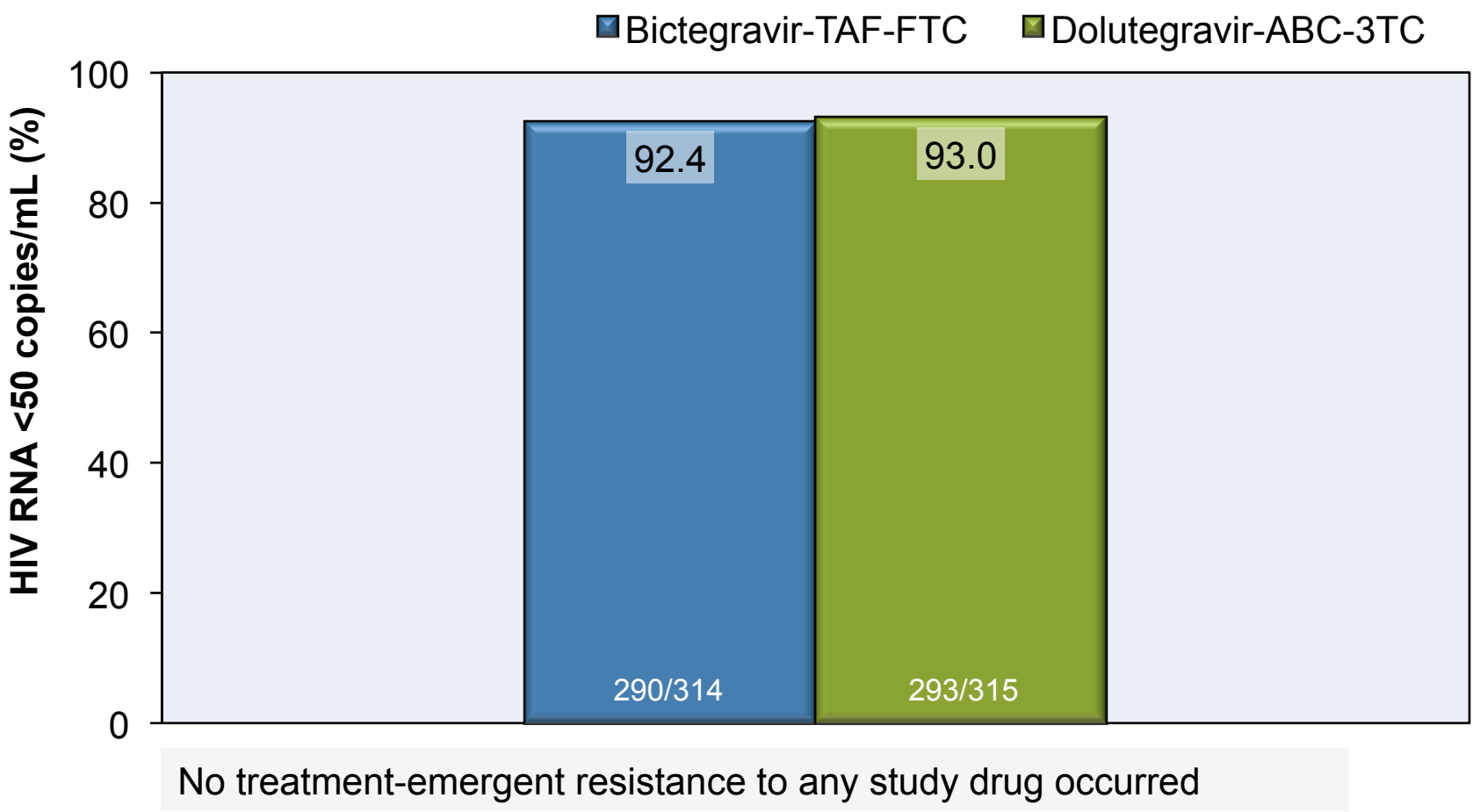
Study 1489 Baseline Characteristics		
Characteristic	**BIC-TAF-FTC (n = 314)**	**DTG + TAF-FTC (n = 315)**
Median age, years (range)	31 (18-71)	32 (18-68)
Male, %	91	90
Black or African descent, %	36	36
HIV RNA >100,000 copies/mL, %	17	16
CD4 count <200 cells/mm^3, %	11	10
Median CrCl, mL/min	125.9	123.0

Abbreviations: CrCl = creatinine clearance

Source: Gallant J, et al. Lancet. 2017;390:2063-72.

BIC-TAF-FTC versus DTG-ABC-3TC as Initial Therapy
GS-380-1489: Results

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



No treatment-emergent resistance to any study drug occurred

Source: Gallant J, et al. Lancet. 2017;390:2063-72.

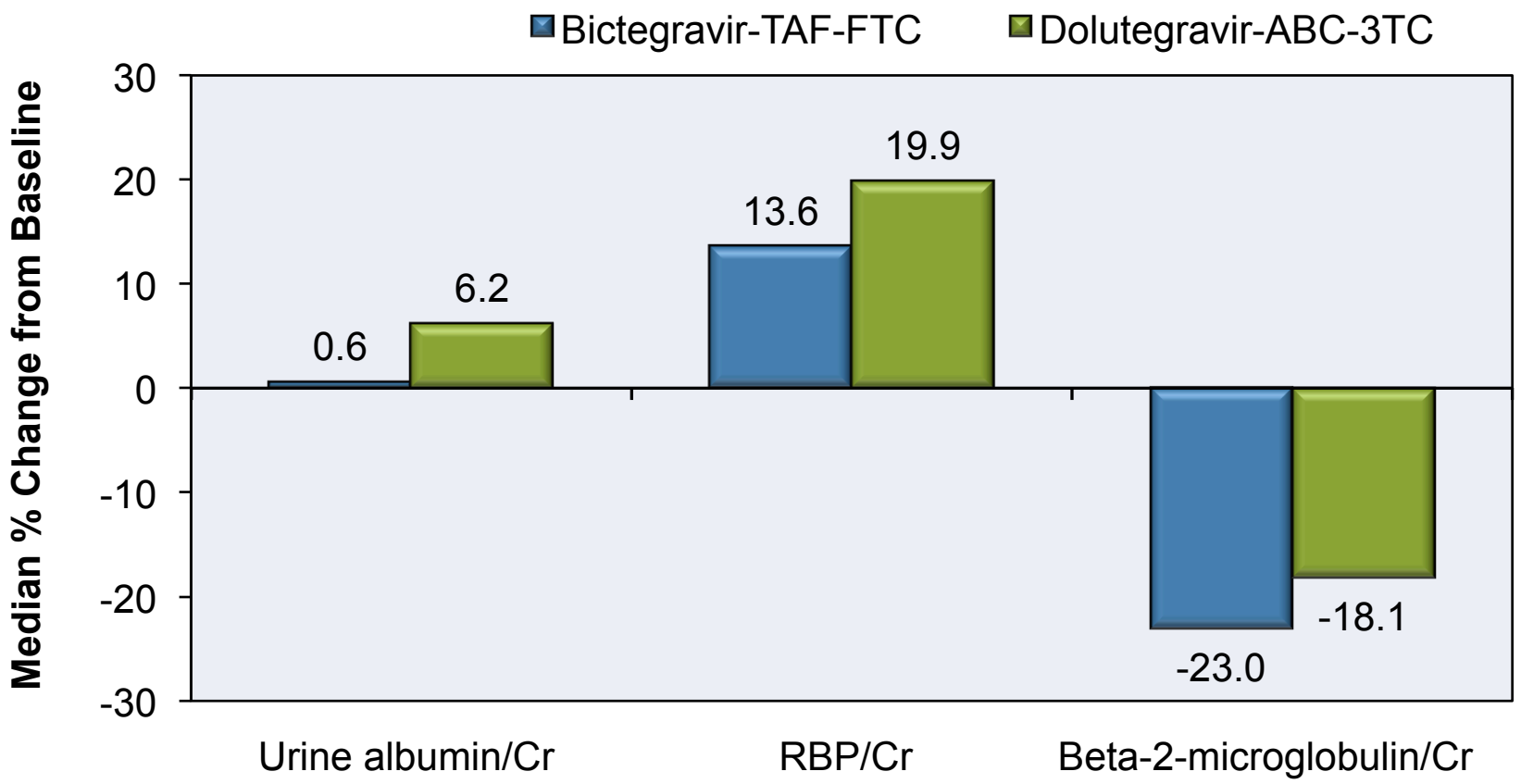
BIC-TAF-FTC versus DTG-ABC-3TC as Initial Therapy
GS-380-1489: Results

Treatment Emergent Adverse Events in Study 1489 (AE's >5%) Through Week 48		
	BIC-TAF-FTC (n = 314)	**DTG-ABC-3TC** (n = 315)
Diarrhea, %	13	13
Headache, %	11	14
Nausea, %	10	23
Fatigue, %	6	9
Arthralgia, %	4	6
Insomnia, %	4	6
Change in eGFR (mL/min)	-10.5	-10.8

Source: Gallant J, et al. Lancet. 2017;390:2063-72.

BIC-TAF-FTC versus DTG-ABC-3TC for Initial Therapy
Study 380-1489: Results

Change in Markers of Proximal Tubulopathy at 48 Weeks



Source: Gallant J, et al. Lancet. 2017;390:2063-72.

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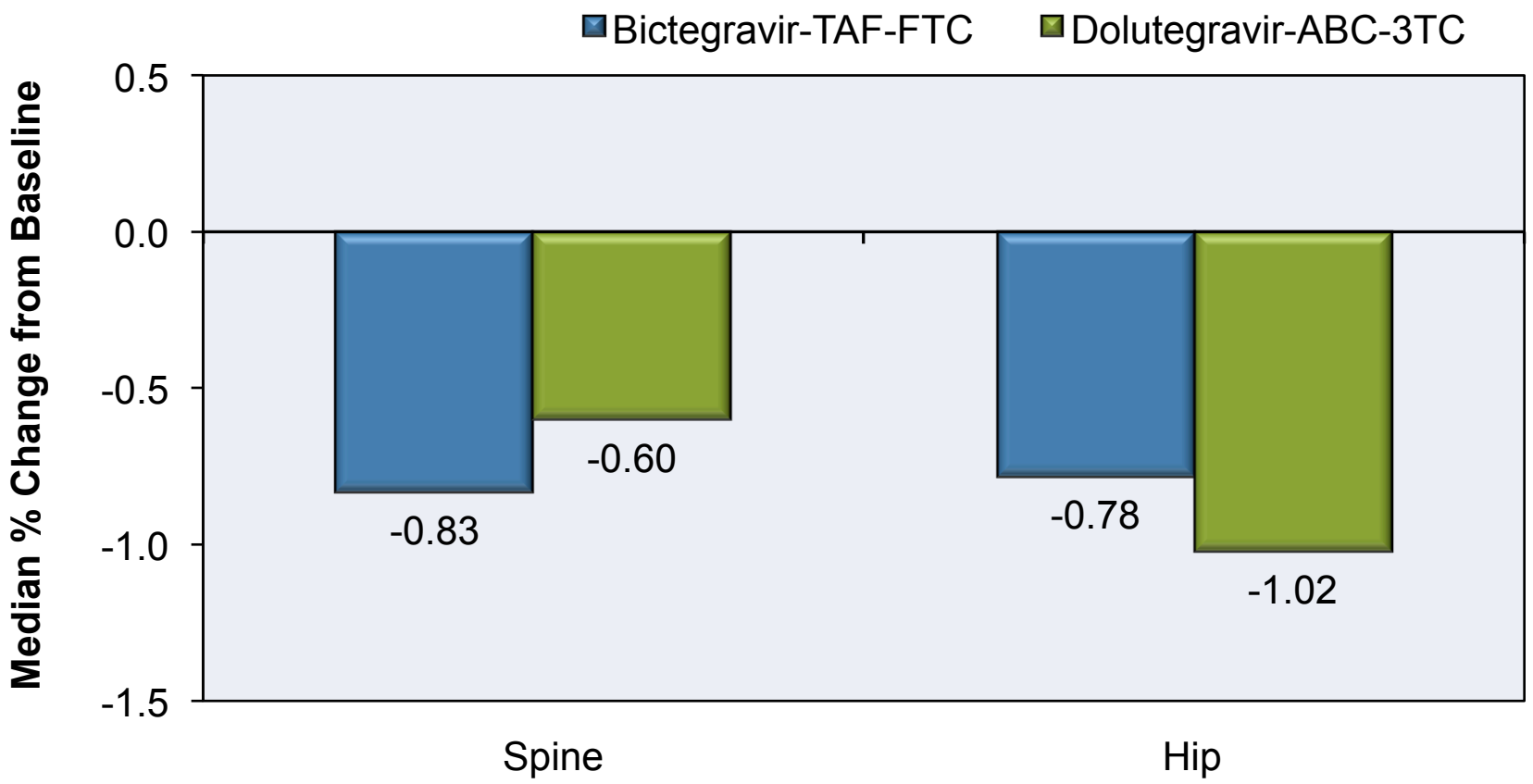
BIC-TAF-FTC versus DTG-ABC-3TC for Initial Therapy
GS-380-1489: Results

Change in Bone Mineral Density at 48 Weeks



Source: Gallant J, et al. Lancet. 2017;390:2063-72.

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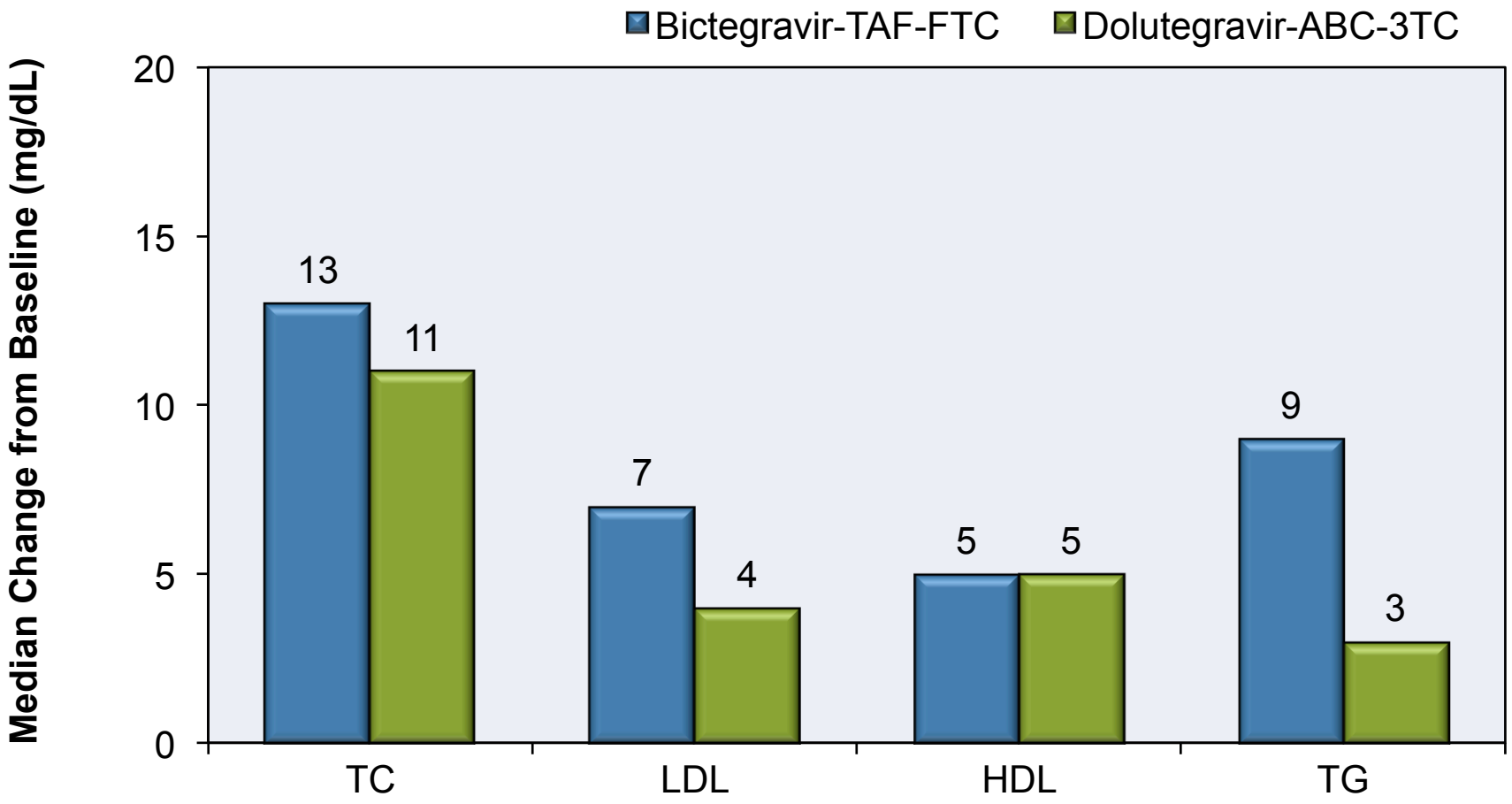
BIC-TAF-FTC versus DTG-ABC-3TC for Initial Therapy
GS-380-1489: Results

Change Lipids at 48 Weeks



Source: Gallant J, et al. Lancet. 2017;390:2063-72.

BIC-TAF-FTC versus DTG-ABC-3TC for Initial Therapy
GS-380-1489: Conclusions

Interpretation: "At 48 weeks, coformulated bictegravir, emtricitabine, and tenofovir alafenamide achieved virological suppression in 92% of previously untreated adults and was non-inferior to coformulated dolutegravir, abacavir, and lamivudine, with no treatment-emergent resistance. Bictegravir, emtricitabine, and tenofovir alafenamide was safe and well tolerated with better gastrointestinal tolerability than dolutegravir, abacavir, and lamivudine. Because coformulated bictegravir, emtricitabine, and tenofovir alafenamide does not require HLA B*5701 testing and provides guideline-recommended treatment for individuals co-infected with HIV and hepatitis B, this regimen might lend itself to rapid or same-day initiation of therapy in the clinical setting."

Source: Gallant J, et al. Lancet. 2017;390:2063-72.

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.

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AETC AIDS Education & Training Center Program
National Coordinating Resource Center