National HIV Curriculum

# Bictegravir-Tenofovir alafenamide-Emtricitabine (*Biktarvy*)

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# Bictegravir-Tenofovir alafenamide-Emtricitabine


Bictegravir-Tenofovir alafenamide-Emtricitabine

| 50 mg | 25 mg | 200 mg |
|---|---|---|
| INSTI | NRTI | NRTI |

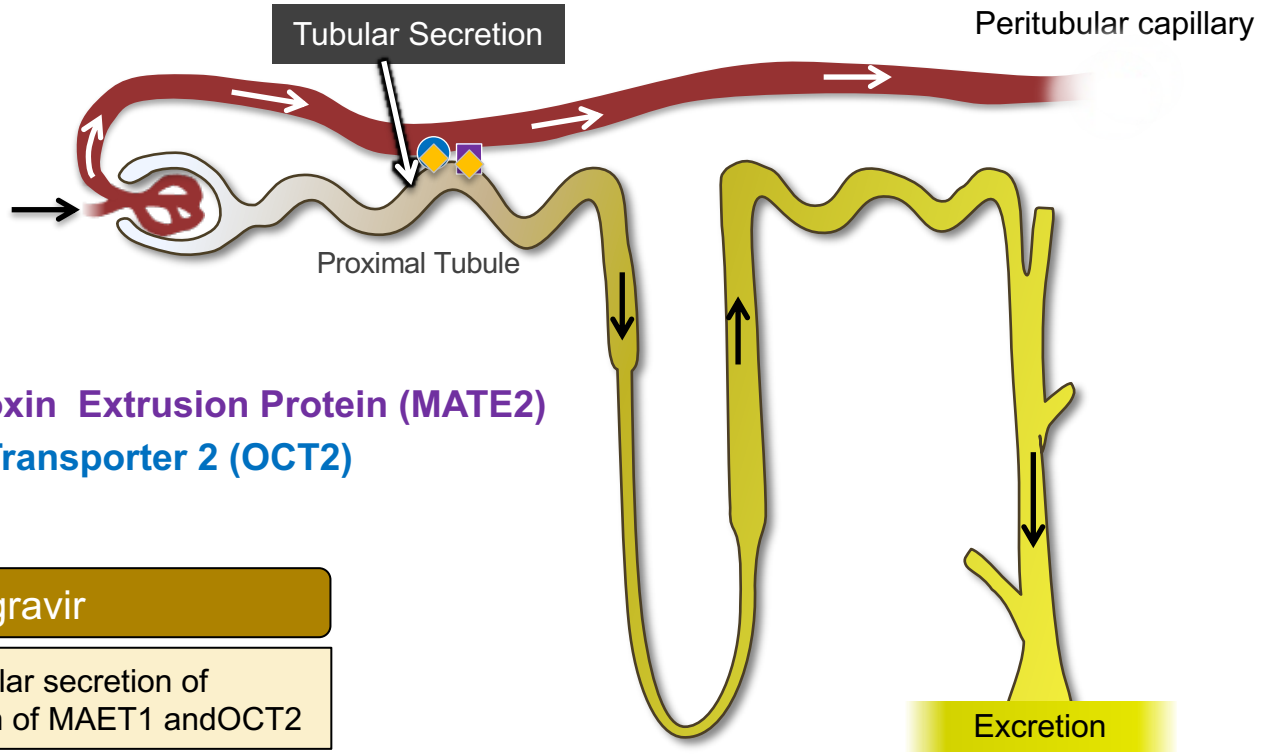
Dose: 1 tablet once daily with or without food

# Bictegravir-Tenofovir alafenamide-Emtricitabine

- **With Renal Impairment:** do not initiate if estimated CrCl <30 mL/min
- **Pregnancy**: insufficient data
- **Common Adverse Events (≥5%)**
  - Diarrhea (6%)
  - Nausea (5%)
  - Headache (5%)
- **Drug-Drug Interactions**
  - Avoid: rifamycins, dofetilide, carbamazepine, phenytoin, St. John's wort
  - Consider: metformin, cation-containing compounds

Source: Bictegravir-Tenofovir alafenamide-Emtricitabine. Prescribing Information.

# Bictegravir and Inhibition of Tubular Secretion of Creatinine




- **Multidrug and Toxin Extrusion Protein (MATE2)**
- **Organic Cation Transporter 2 (OCT2)**
- **Bictegravir**

**Bictegravir**

Decreases tubular secretion of creatinine via inhibition of MAET1 andOCT2

Illustration: David H. Spach, MD

# Bictegravir-Tenofovir alafenamide-Emtricitabine
# Summary of Key Phase 3 Studies

- **Trials in in Treatment-Naïve Adults**
  - GS-380-1489: BIC-TAF-FTC vs. DTG-ABC-3TC
  - GS-380-1490: BIC-TAF-FTC vs. DTG + TAF-FTC
- **Trials in Adults with Virologic Suppression**
  - GS-380-1844: Switch to BIC-TAF-FTC vs. continue DTG-ABC-3TC
  - GS-380-1878: Switch to BIC-TAF-FTC vs. continue boosted PI + NRTIs
  - GS-380-1961: Switch to BIC-TAF-FTC for women
  - GS-380-4030: Switch to BIC-TAF-FTC vs. DTG + TAF-FTC
  - BAAVE2020: Switch to BIC-TAF-FTC for Black Americans

**Abbreviations**: BIC-TAF-FTC = bictegravir-tenofovir alafenamide-emtricitabine; DTG-ABC-3TC =dolutegravir-abacavir-lamivudine; PI = protease inhibitor; NRTIs = nucleoside reverse transcriptase inhibitors

## Bictegravir-Tenofovir alafenamide-Emtricitabine

# Trials in Treatment Treatment-Naïve Adults

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

# GS-380-1489: Week 48 Results

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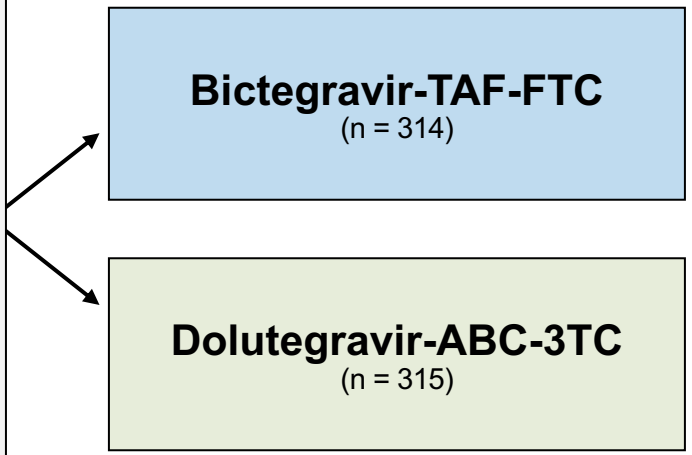
# Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Design

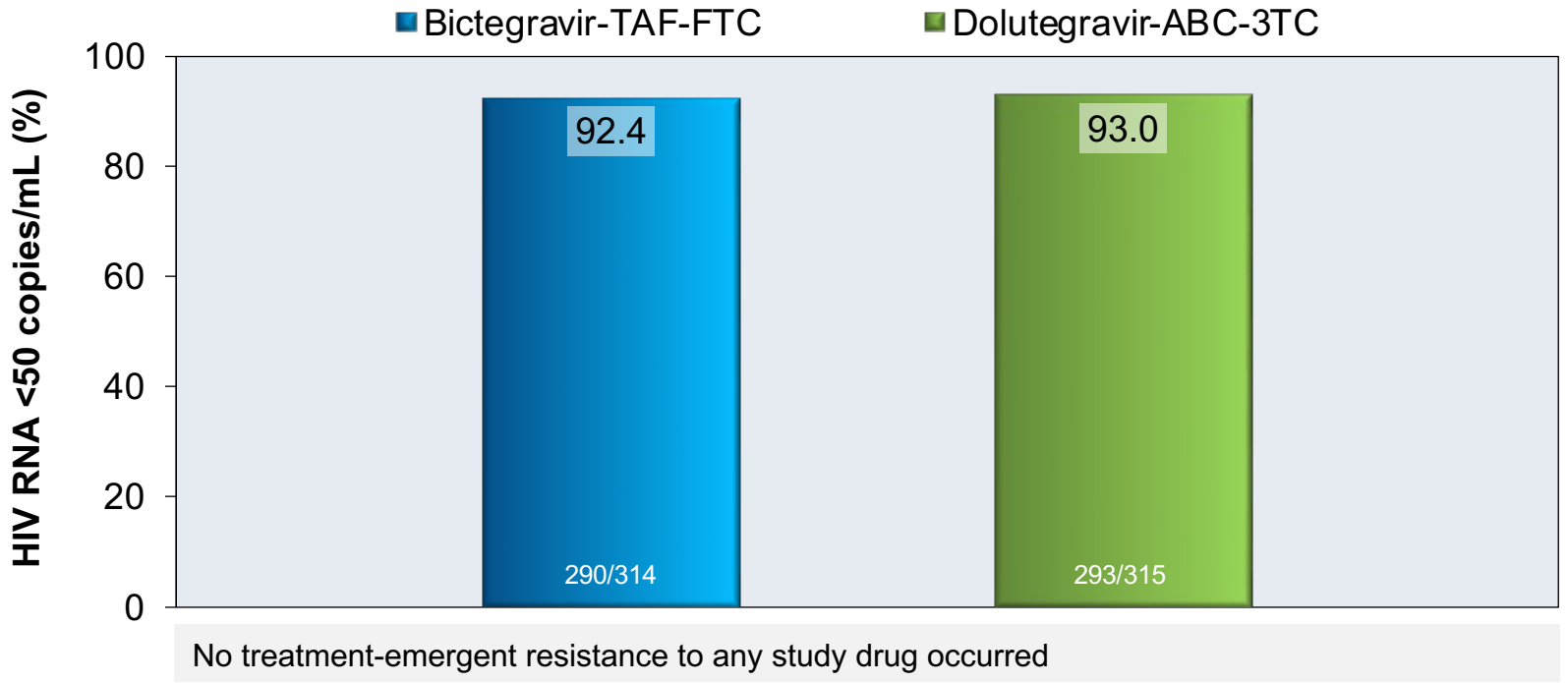
- **Design**
  - Randomized, double-blind, active-controlled, phase 3 study evaluating the efficacy and safety of bictegravir-tenofovir alafenamide-emtricitabine versus dolutegravir-abacavir-lamivudine for treatment-naïve adults with HIV
- **Including Criteria**
  - Age ≥18 years
  - Antiretroviral-naïve (or ≤10 days of treatment)
  - HIV RNA ≥500 copies/mL
  - eGFR ≥50 mL/min
  - HLA B*5701 negative
  - No chronic HBV infection




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

# Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Week 48 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.

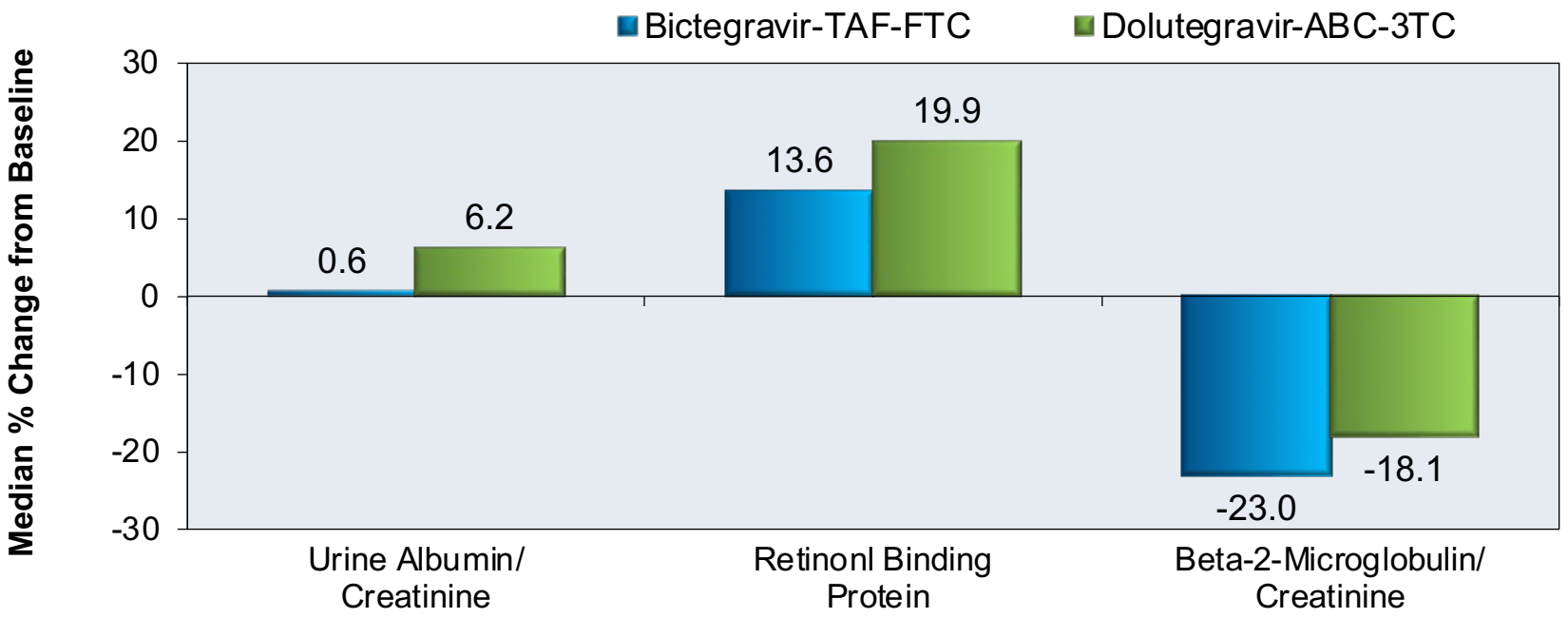
# Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Adverse Effects

| Treatment Emergent Adverse Events (AE's >5%) Through Week 48 | | |
|---|---|---|
| **Adverse Effect** | **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.

# Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy
# GS-380-1489: Adverse Effects

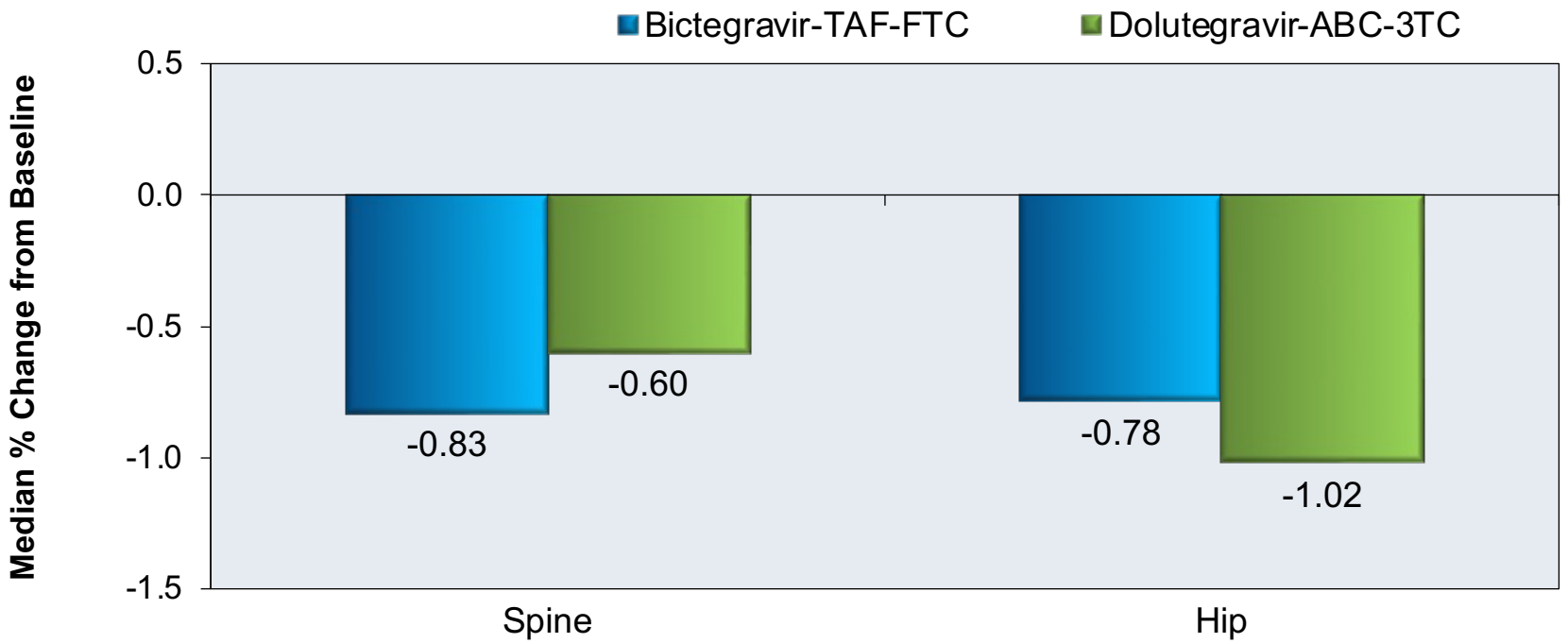
## Change in Markers of Proximal Tubulopathy at 48 Weeks




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

# Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Adverse Effects

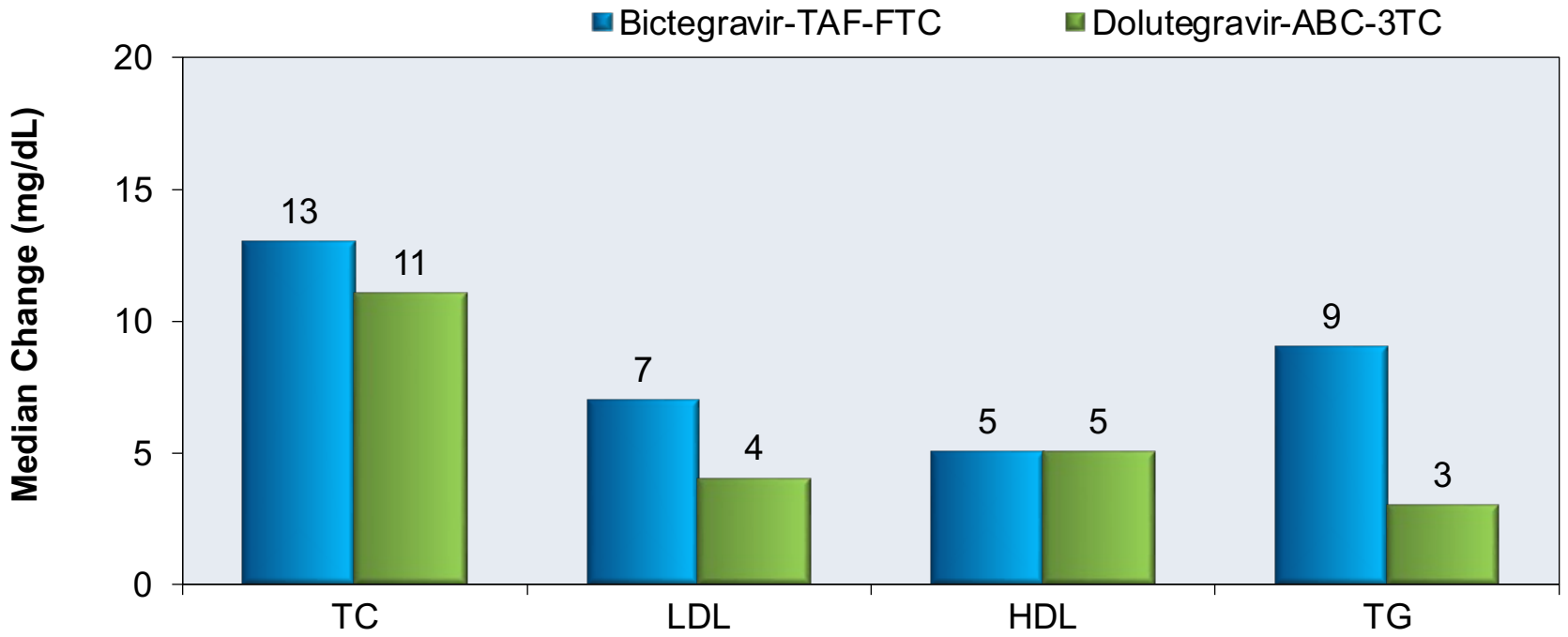
## Change in Bone Mineral Density at 48 Weeks




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

# Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as Initial Therapy GS-380-1489: Results

## Change in Lipids at 48 Weeks




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

# Bictegravir-TAF-FTC versus Dolutegravir-ABC-3TC as 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.”

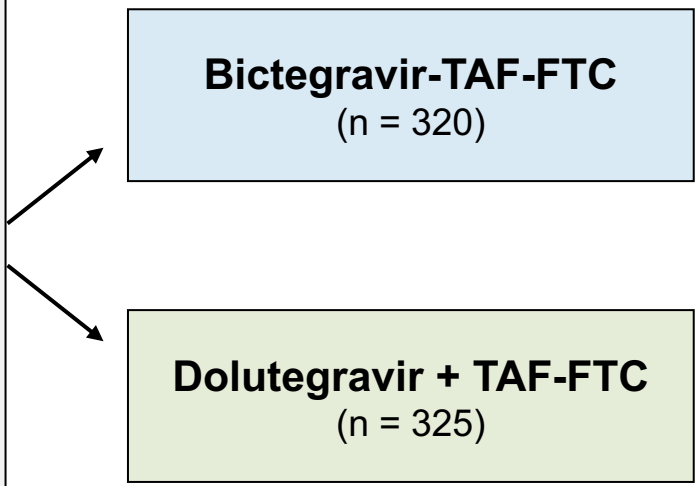
Source: Gallant J, et al. Lancet. 2017;390:2063-72.

BIC-TAF-FTC versus DTG + TAF-FTC as Initial Therapy

# GS-380-1490: Week 48 Results

# Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1490: Design

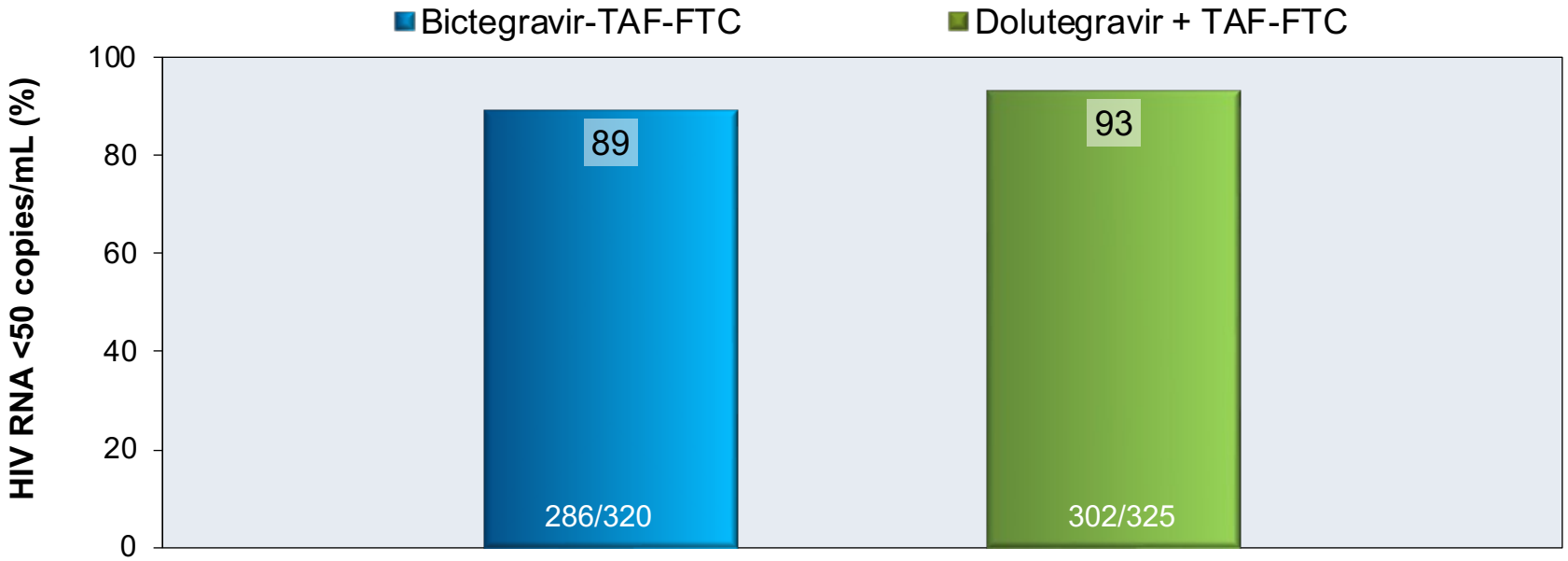
- **Design**
  - Randomized, double-blind, active-controlled, phase 3 study comparing bictegravir-tenofovir alafenamide-emtricitabine versus dolutegravir plus tenofovir alafenamide-emtricitabine as initial therapy
- **Inclusion Criteria**
  - Age ≥18 years
  - Antiretroviral-naïve (or ≤10 days of treatment)
  - HIV RNA ≥500 copies/mL
  - eGFR ≥30 mL/min




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

# Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1490: Week 48 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.

# Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1490: Adverse Events

| Treatment Emergent Adverse Events (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.

# Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1490: Conclusion

**Interpretation**: “These week 96 data support bictegravir, emtricitabine, and tenofovir alafenamide as a safe, well tolerated, and durable treatment for people living with chronic HIV.”

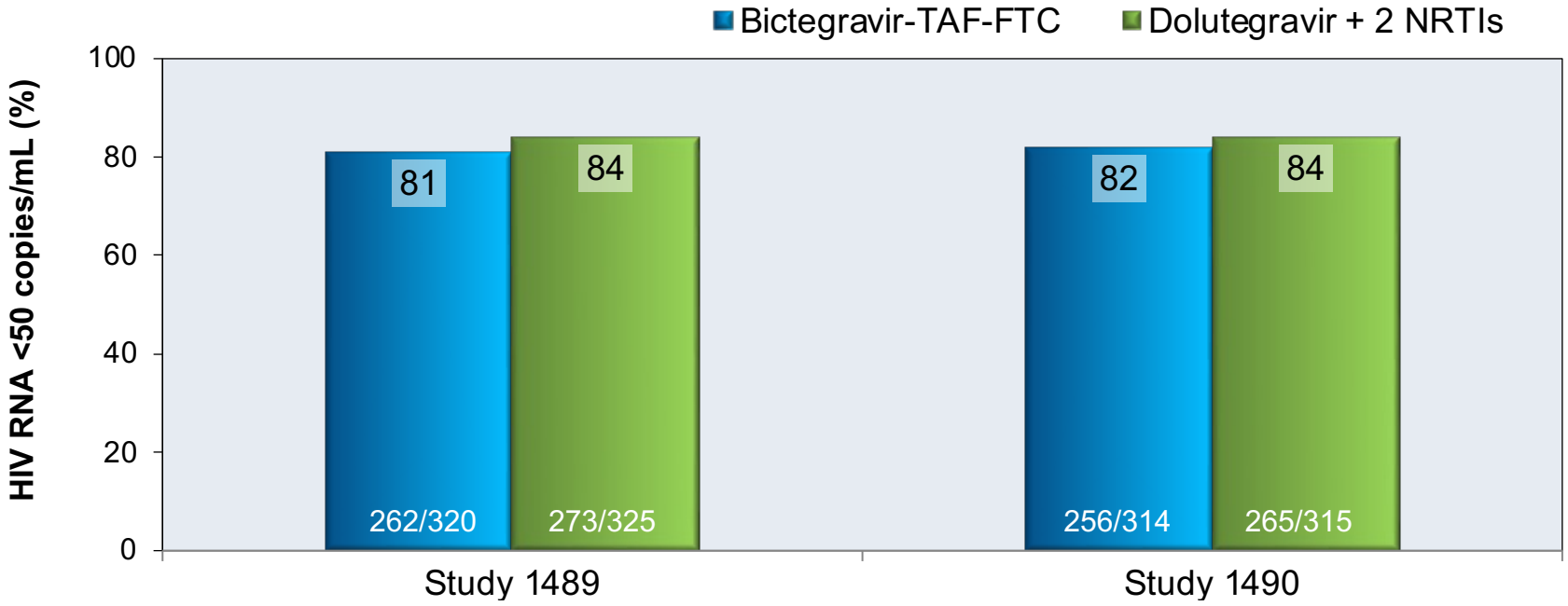
Source: Sax PE, et al. Lancet. 2017;390:2073-82.

BIC-TAF-FTC versus DTG + 2 NRTIs as Initial Therapy

# GS-380-1489 & 1490: Week 144 Results

# Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1489 & 1490: Week 144 Results

## Week 144 Virologic Response (Intention-to-Treat Analysis)

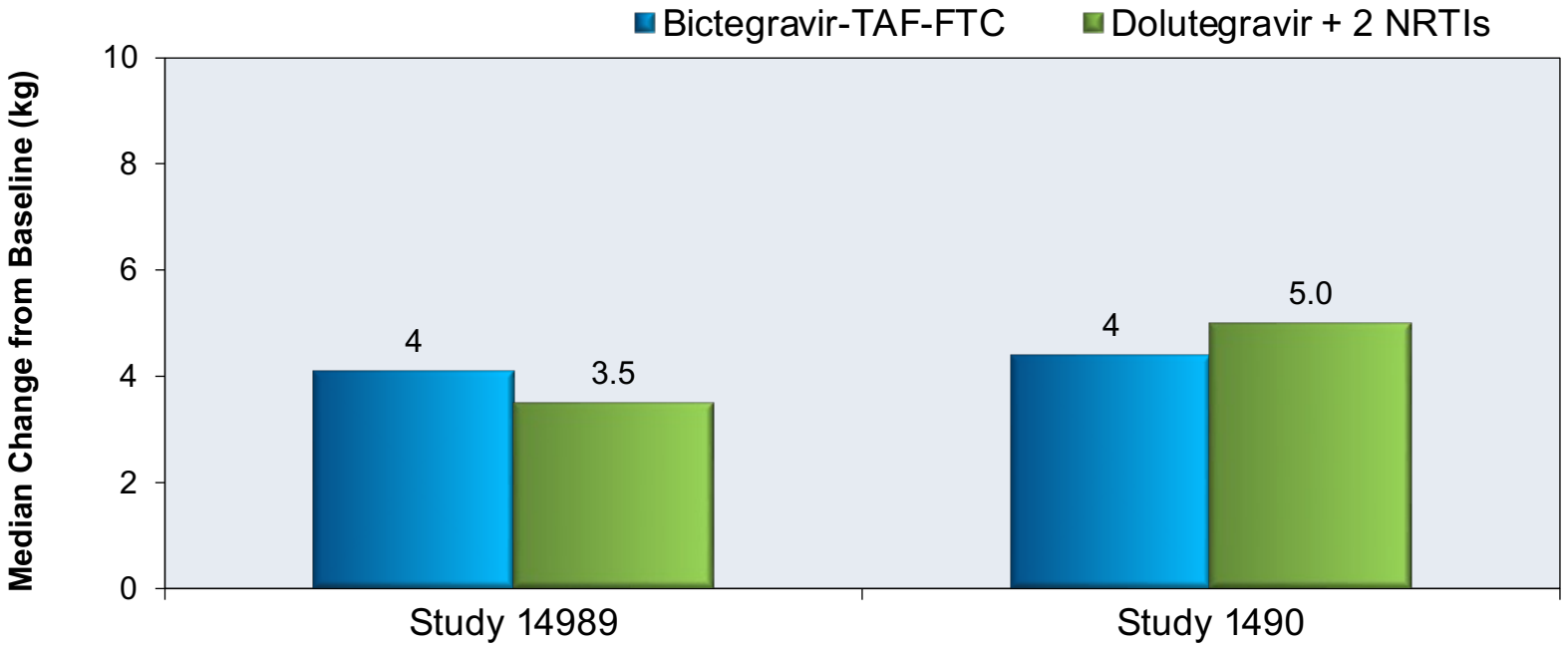



No treatment-emergent resistance to any study drug occurred

Source: Orkin C et al. Lancet HIV. 2020;7:e389-e400.

# Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1489 & 1490 (Week 144): Results

## Week 144 Change in Weight from Baseline




Source: Orkin C et al. Lancet HIV. 2020;7:e389-e400.

# Bictegravir-TAF-FTC versus Dolutegravir + TAF-FTC as Initial Therapy GS-380-1489 & 1490 (Week 144): Conclusion

**Interpretation**: “These long-term data support the use of bictegravir, emtricitabine, and tenofovir alafenamide as a safe, well tolerated, and durable treatment for people with HIV, with no emergent resistance.”

Source: Orkin C et al. Lancet HIV. 2020;7:e389-e400.

## Bictegravir-Tenofovir alafenamide-Emtricitabine

# Switch Studies in Adults with Virologic Suppression

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Switch from DTG-ABC-3TC to BIC-TAF-FTC in Adults with Virologic Suppression

# GS-380-1844

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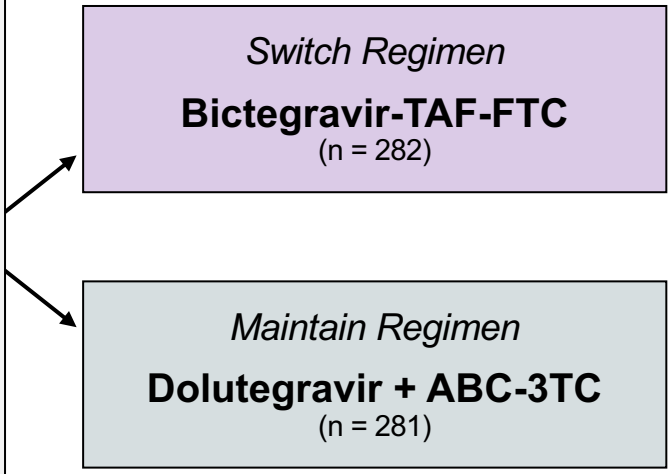
# Switch from DTG-ABC-3TC to BIC-TAF-FTC
# GS-380-1844: Design

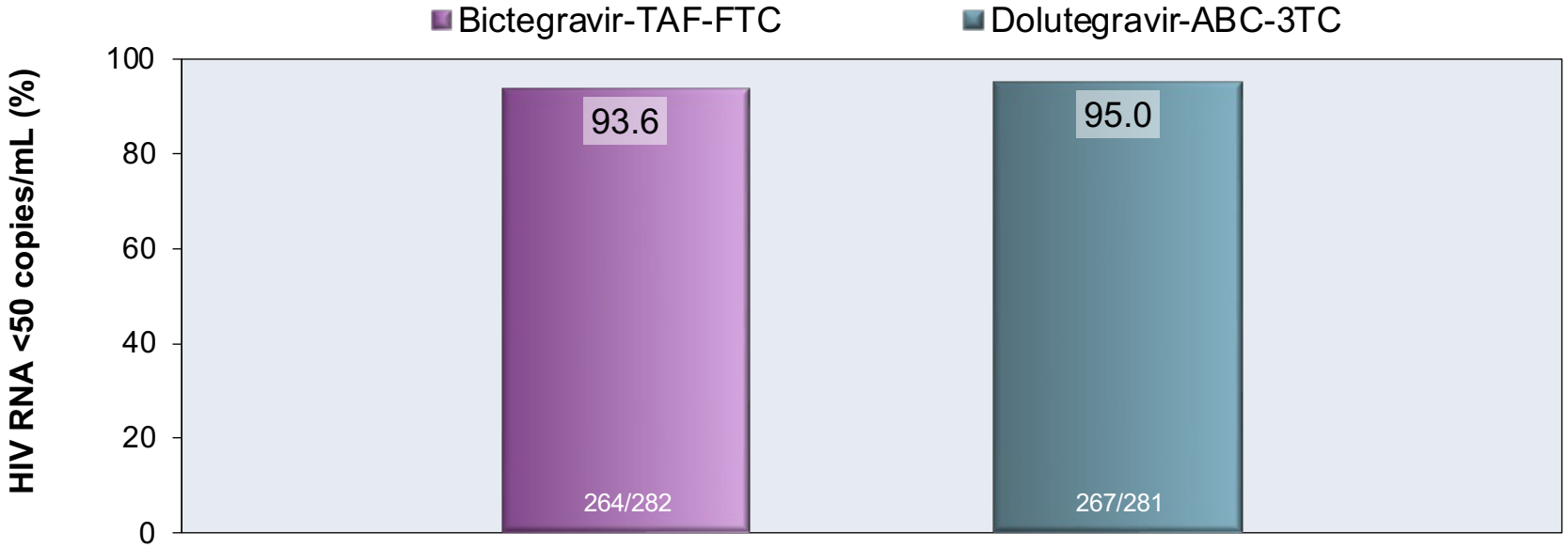
- **Background**: Randomized, phase 3, multicenter, double-blind, active-controlled study evaluating the efficacy and safety of switching adults with HIV and viral suppression to BIC-TAF-FTC versus continuing DTG-ABC-3TC
- **Inclusion Criteria**
  - Age ≥18 years
  - HIV RNA <50 copies/mL for at least 3 months
  - eGFR ≥50 mL/min for at least 3 months
  - No history of treatment failure
  - Taking DTG-ABC-3TC or DTG + ABC-3TC
  - No documented or suspected resistance to DTG, ABC, 3TC, FTC, or TAF
  - HCV infection allowed
  - HBV infection not allowed




Source: Molina JM, et al. Lancet HIV. 2018;5:e357-e365.

# Switch from DTG-ABC-3TC to BIC-TAF-FTC
# GS-380-1844: Results

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




At 48 weeks, proportion with HIV RNA ≥50 copies/mL not statistically different: 1% BIC vs <1% DTG
5 participants met criteria for virologic failure and resistance testing (3 BIC, 2 DTG); no resistance found

Source: Molina JM, et al. Lancet HIV. 2018;5:e357-e365.

# Switch from DTG-ABC-3TC to BIC-TAF-FTC GS-380-1844: Results

| Most Common Treatment-Related Adverse Events (AE's) by 48 Weeks | | |
|---|---|---|
| **Baseline Antiretroviral Medications** | **BIC-TAF-FTC** (n = 282) | **DTG-ABC-3TC** (n = 281) |
| AE's leading to study drug discontinuation | 2 | 1 |
| Headache, % | 2 | 3 |
| Diarrhea, % | 1 | 1 |
| Abnormal dreams, % | <1 | 2 |
| Fatigue, % | <1 | 1 |
| Nausea, % | 0 | 2 |
| Insomnia, % | 0 | 3 |

Source: Molina JM, et al. Lancet HIV. 2018;5:e357-e365.

# Switch from DTG-ABC-3TC to BIC-TAF-FTC GS-380-1844: Conclusions

**Interpretation**: “The fixed-dose combination of bictegravir, emtricitabine, and tenofovir alafenamide might provide a safe and efficacious option for ongoing treatment of HIV-1 infection.”

Source: Molina JM, et al. Lancet HIV. 2018;5:e357-e365.

Switch from Boosted PI + 2 NRTIs to BIC-TAF-FTC with Viral Suppression

# GS-380-1878

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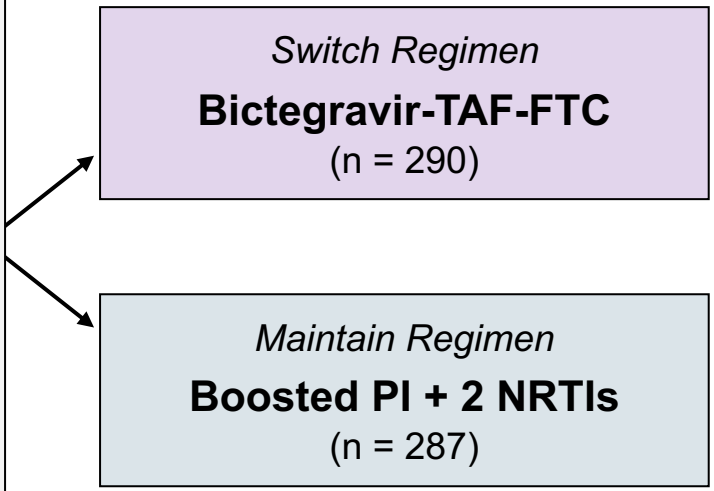
# Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC
# GS-380-1878: Design

- **Background**
  - Randomized, phase 3, multicenter, open-label switch study evaluating the efficacy and safety of switching adults with viral suppression taking a boosted PI plus 2 NRTIs to BIC-TAF-FTC
- **Inclusion Criteria**
  - Age ≥18 years
  - HIV RNA <50 copies/mL for ≥6 months
  - Taking stable antiretroviral regimen for ≥6 months
  - No history of virologic failure
  - No prior treatment with an INSTI
  - eGFR ≥50 mL/min
  - HBV and HCV allowed
  - Taking atazanavir or darunavir (each boosted by ritonavir or cobicistat) + TDF-FTC or ABC-3TC




Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

# Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC
# GS-380-1878: Baseline Characteristics

| Study GS-380-1878 Baseline Characteristics | | |
|---|---|---|
| **Characteristic** | **BIC-TAF-FTC** (n = 290) | **Boosted PI + 2 NRTIs** (n = 287) |
| Median age, years (range) | 48 | 47 |
| Male, % | 84 | 82 |
| Black or African descent, % | 27 | 25 |
| Hispanic/Latino, % | 21 | 16 |
| Median CD4, cells/mL | 617 | 626 |
| HBV coinfection, % | 8 | 6 |
| HCV coinfection, % | 5 | 5 |
| Median eGFR, mL/min | 107 | 105 |
| Baseline TDF-FTC, ABC-3TC, % | 84, 16 | 85, 15 |
| Baseline DRV, ATV, % | 57, 43 | 54, 46 |

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

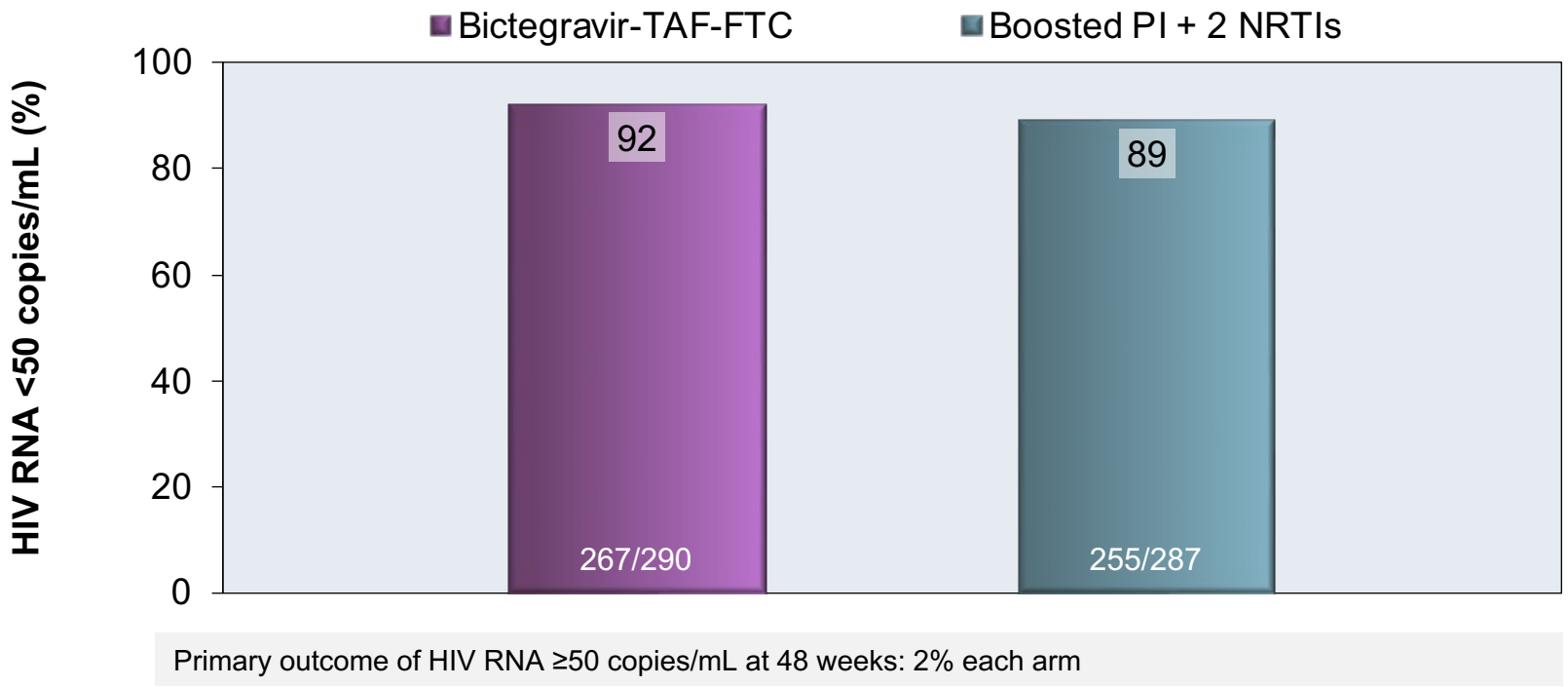
# Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Baseline Characteristics

| Study GS-380-1878 Baseline Antiretroviral Regimen | | |
|---|---|---|
| **Baseline Antiretroviral Medications** | **BIC-TAF-FTC** (n = 290) | **Boosted PI + 2 NRTIs** (n = 287) |
| **NRTI** | | |
| Tenofovir DF-emtricitabine, % | 84 | 85 |
| Abacavir-lamivudine, % | 16 | 15 |
| **Protease Inhibitor** | 21 | 16 |
| Darunavir, % | 57 | 54 |
| Atazanavir, % | 43 | 46 |

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

# Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Results

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




Primary outcome of HIV RNA ≥50 copies/mL at 48 weeks: 2% each arm

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

# Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Adverse Events

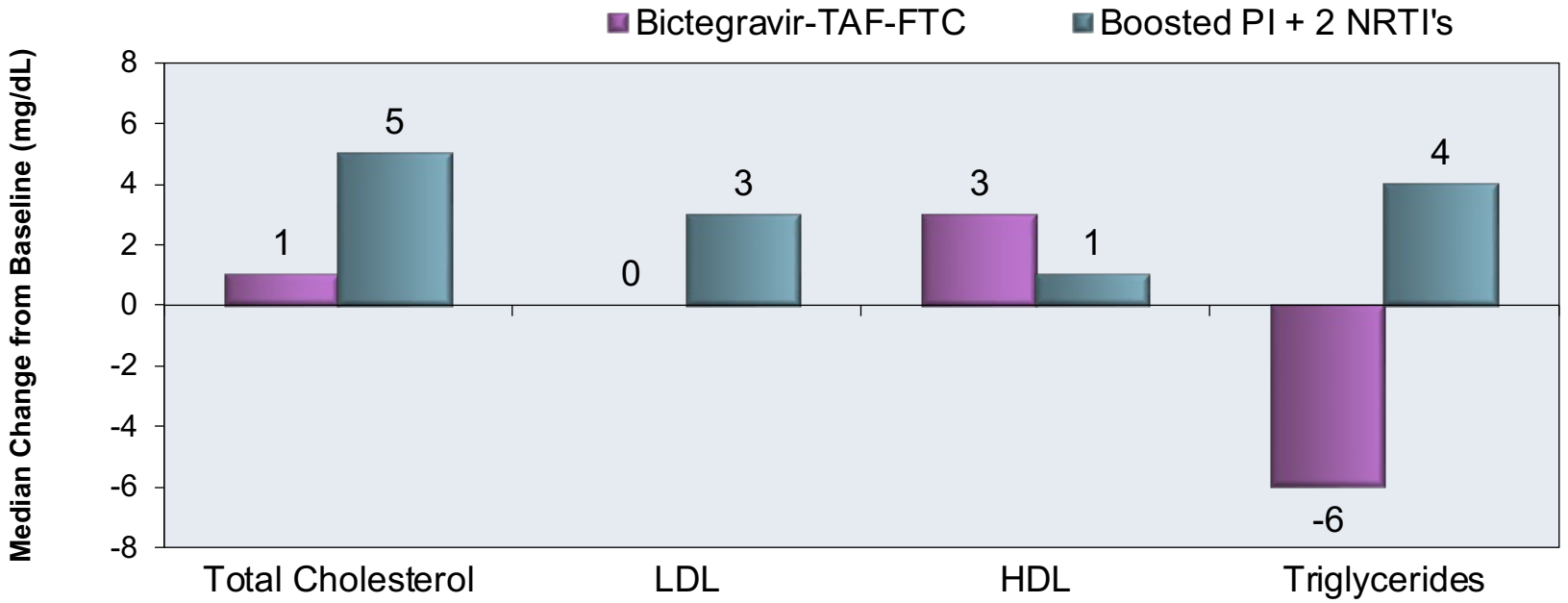
| Most Common Treatment-Related Adverse Events (AE's) Through 48 Weeks | | |
|---|---|---|
| | **BIC-TAF-FTC** (n = 290) | **Boosted PI + 2 NRTI's** (n = 287) |
| Headache, % | 12 | 4 |
| Diarrhea, % | 8 | 8 |
| Nasopharyngitis, % | 7 | 12 |
| URI, % | 7 | 8 |
| Back pain, % | 5 | 6 |
| Arthralgia, % | 4 | 5 |
| Change in eGFR | -4.3 mL/min | 0.2 mL/min |

Abbreviations: eGFR = estimated glomerular filtration

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

# Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Results

## Change in Lipids at 48 Weeks




Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

# Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Conclusions

**Interpretation**: “Fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide might be a safe and efficacious alternative to continued boosted protease inhibitor therapy in adults with HIV-1 infection.”

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

Switch to BIC-TAF-FTC in Women with Virologic Suppression

# GS-380-1961

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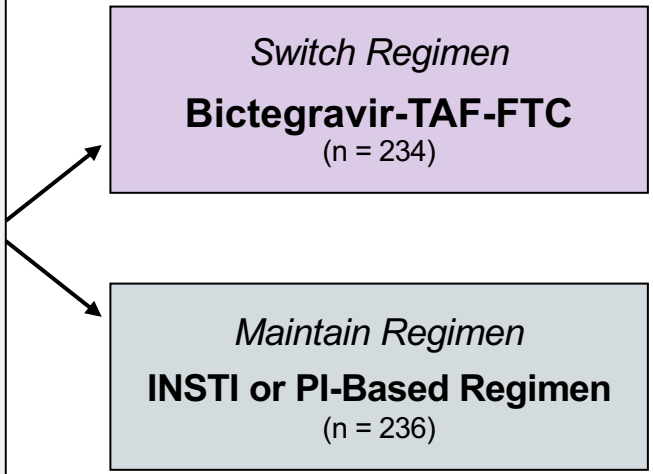
# Switch to BIC-TAF-FTC in Women with Virologic Suppression
# GS-380-1961: Design

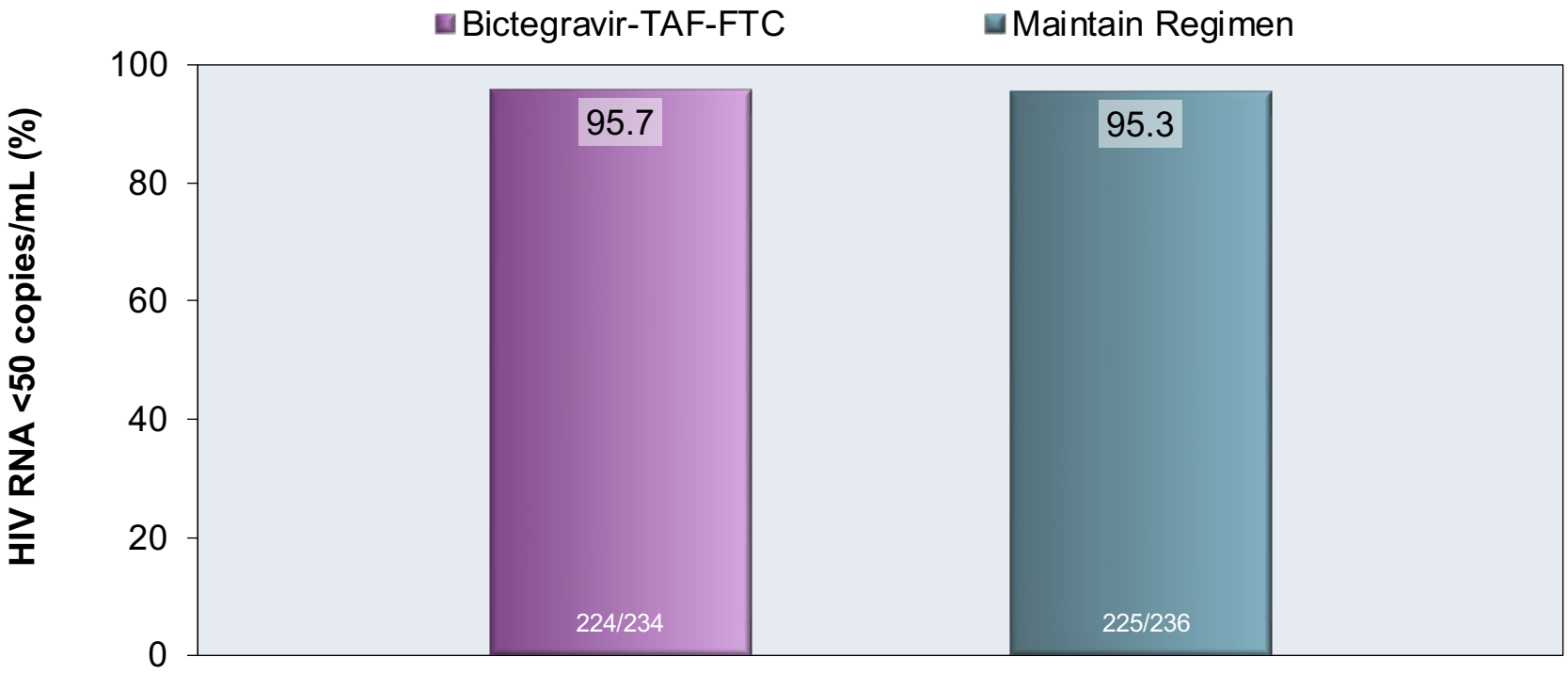
- **Background**: Randomized, phase 3, multicenter, open label, active-controlled study evaluating the efficacy and safety of switching women with HIV and viral suppression to BIC-TAF-FTC versus continuing their baseline regimen
- **Inclusion Criteria**
  - Women aged ≥18 years
  - HIV RNA <50 copies/mL for at least 12 weeks
  - *EVG/c/TAF/FTC, EVG/c/TDF/FTC, or ATV/r + TDF/FTC
  - eGFR >50 mL/min
  - No suspected resistance to study drugs
  - Using contraception if child-bearing potential
  - Chronic hepatitis B or C allowed




*Regimens: 53% EVG/c/TAF/FTC and 42% EVG/c/TDF/FTC

Source: Kityo C, et al. J Acquir Immune Defic Syndr. 2019;82:321-8.

# Switch to BIC-TAF-FTC in Women with Virologic Suppression
# GS-380-1961: Results by U.S. FDA Snapshot Algorithm




Source: Kityo C, et al. J Acquir Immune Defic Syndr. 2019;82:321-8.

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# Switch to BIC-TAF-FTC in Women with Virologic Suppression GS-380-1961: Conclusions

**Interpretation**: ““Fixed-dose combination bictegravir-emtricitabine-tenofovir alafenamide provides a safe and efficacious option for ongoing treatment of HIV in women. This study contributes important data on safety, tolerability, and outcomes of antiretroviral therapy among women living with HIV.”

Source: Kityo C, et al. J Acquir Immune Defic Syndr. 2019;82:321-8.

Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression

# GS-380-4030

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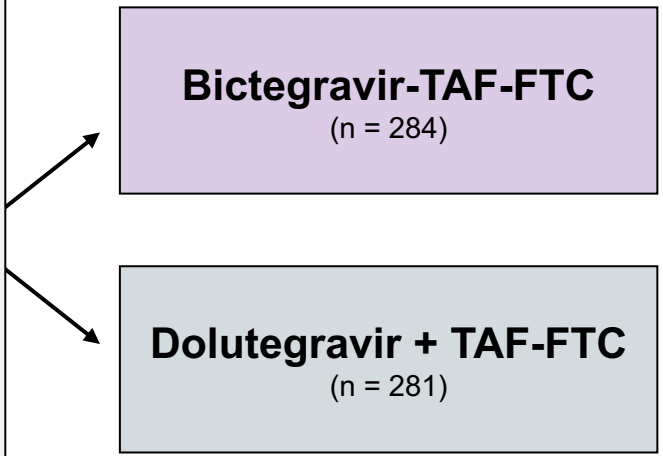
# Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression
# GS-380-4030: Design

- **Background**
  - Randomized, double-blind, switch study comparing the efficacy of switching adults with viral suppression (with or without documented or suspected NRTI resistance) taking DTG plus TAF-FTC or TDF-FTC to BIC-TAF-FTC versus DTG plus TAF-FTC
- **Inclusion Criteria**
  - Age ≥18 years
  - HIV RNA <50 copies/mL for 3 months if no resistance
  - HIV RNA <50 copies/mL for 6 months if NRTI resistance
  - Taking stable regimen of DTG plus TDF-FTC or TAF-FTC
  - eGFR ≥30 mL/min
  - Chronic HBV and HCV infection permitted
  - Documented or suspected NRTI resistance permitted
  - Excluded if integrase resistance or virologic failure on INSTI




Source: Sax PE, et al. Clin Infect Dis. 2021;73:e485-e493.

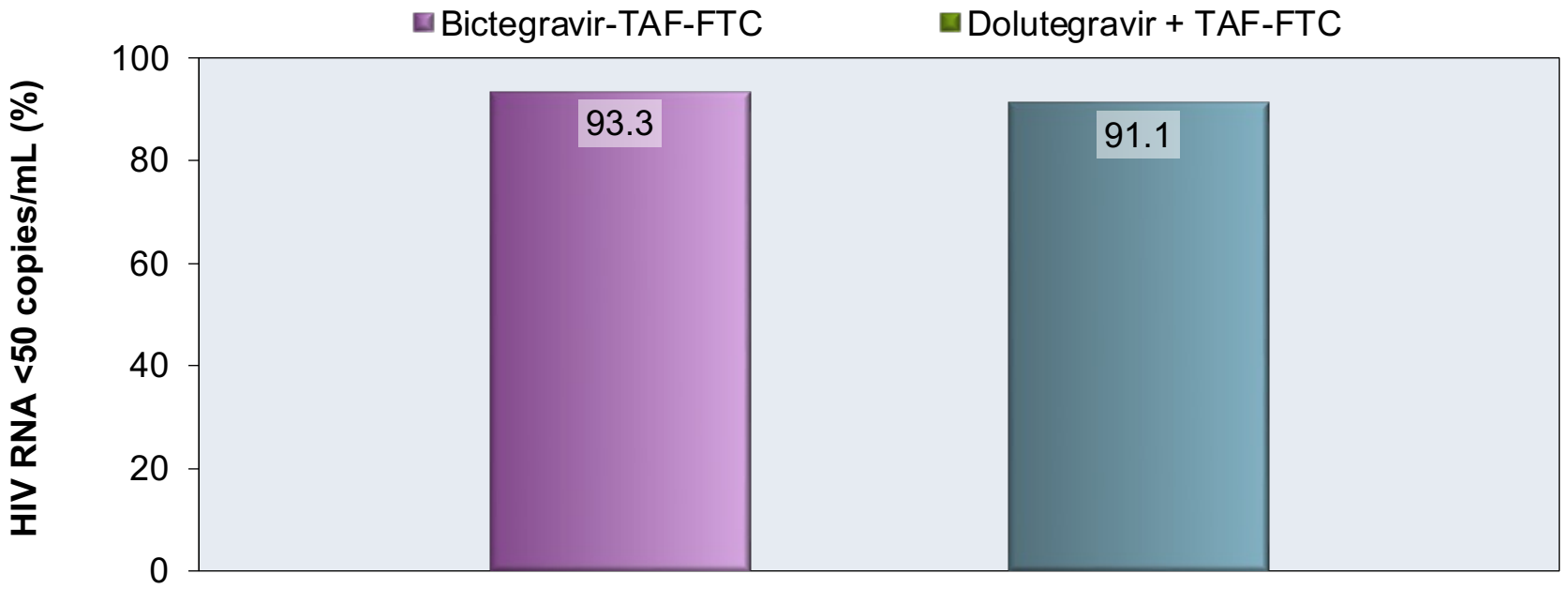
# Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression
## GS-380-4030: Baseline Characteristics

| Study GS-380-4030 Baseline Participant Demographics & Clinical Characteristics | | |
|---|---|---|
| **Baseline Characteristic** | **BIC-TAF-FTC** (n = 284) | **DTG + TAF-FTC** (n = 281) |
| Age, years, median (range) | 51 (22-79) | 50 (20-79) |
| Women, n (%) | 39 (14%) | 41 (15%) |
| Black, n (%) | 68 (24%) | 61 (22%) |
| Hispanic or Latino, n (%) | 61 (22%) | 49 (18%) |
| CD4 cell count, cells/μL, median (IQR) | 659 (486-885) | 642 (462-791) |
| TAF-FTC NRTI backbone, n (%) | 194 (68%) | 195 (69%) |
| K65R/E/N or ≥3 TAMs mutation(s), n (%) | 16 (6%) | 14 (5%) |
| Any other pattern of NRTI mutation(s), n (%) | 55 (19%) | 53 (19%) |
| No NRTI mutation, n (%) | 213 (75%) | 214 (76%) |

Source: Sax PE, et al. Clin Infect Dis. 2021;73:e485-e493.

# Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression GS-380-4030: Results

## Virologic Outcome at Week 48




Primary outcome of HIV RNA ≥50 copies/mL at 48 weeks: 0.4% BIC-TAF-FTC arm; 1.1% DTG + TAF-FTC arm

Source: Sax PE, et al. Clin Infect Dis. 2021;73:e485-e493.

# Switch to BIC-TAF-FTC or DTG + TAF-FTC in Adults with Virologic Suppression
# GS-380-4030: Conclusions

**Interpretation**: “The single-tablet regimen B/F/TAF is a safe, effective option for people virologically suppressed on DTG plus either F/TDF or F/TAF, including in individuals with preexisting resistance to NRTIs.”

Source: Sax PE, et al. Clin Infect Dis. 2021;73:e485-e493.

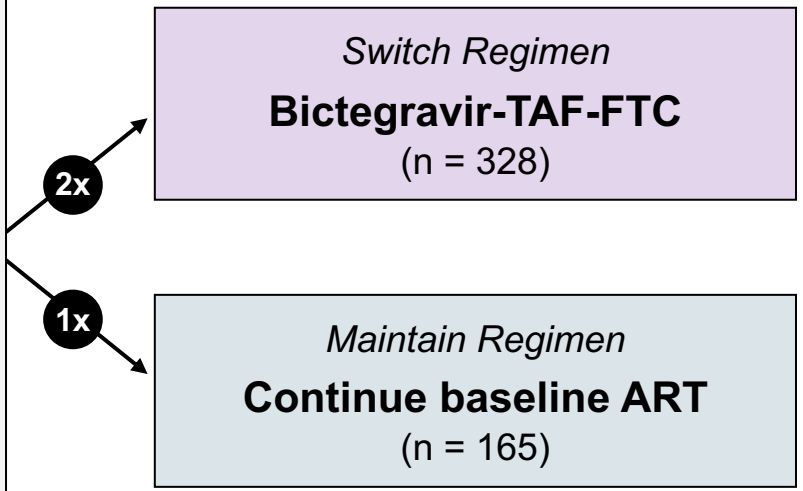
Switch to Bictegravir-Tenofovir alafenamide-Emtricitabine for Black Americans

# BRAAVE2020

National HIV Curriculum

# Switch to Bictegravir-TAF-FTC for Black Americans
# BRAAVE2020: Design

- **Background**
  - Randomized, phase 3, multicenter, open-label switch study evaluating the efficacy and safety of switching Black American adults with viral suppression to BIC-TAF-FTC, including individuals with a history of NRTI, NNRTI, and/or PI resistance
- **Inclusion Criteria**
  - Age ≥18 years
  - Self-described as Black, African American, or mixed race that includes Black
  - HIV RNA <50 copies/mL for ≥12 months
  - Taking stable antiretroviral regimen that includes 2 NRTIs plus 3rd agent for ≥6 months
  - eGFR ≥50 mL/min
  - No INSTI resistance; no K65R, T69ins, or ≥3TAMs




10% of all participants with M184V at baseline

Source: Hagins D, et al. JAIDS. 2021;88:86-95.

# Switch to Bictegravir-TAF-FTC for Black Americans
# BRAAVE2020: Baseline Characteristics

| BRAAVE2020 Baseline Participant Demographics & Clinical Characteristics | | |
|---|---|---|
| **Baseline Characteristic** | **BIC-TAF-FTC** (n = 328) | **Continue Baseline ART** (n = 165) |
| Age, years, median (range) | 49 (18-79) | 49 (19-70) |
| Female sex at birth, n (%) | 101 (31) | 55 (33) |
| Cisgender, n (%) | 317 (96) | 159 (96) |
| Hispanic or Latino, n (%) | 61 (22%) | 49 (18%) |
| CD4 cell count, cells/μL, median (IQR) | 747 (570-922) | 758 (494-969) |
| TAF-FTC NRTI backbone, n (%) | 224 (68) | 107 (65) |
| TDF-FTC NRTI backbone, n (%) | 56 (17) | 34 (21) |
| ABC-3TC NRTI backbone, n (%) | 44 (13) | 24 (15) |
| Other NRTI backbone, n (%) | 4 (1) | 0 |

Source: Hagins D et al. JAIDS. 2021;88:86-95.

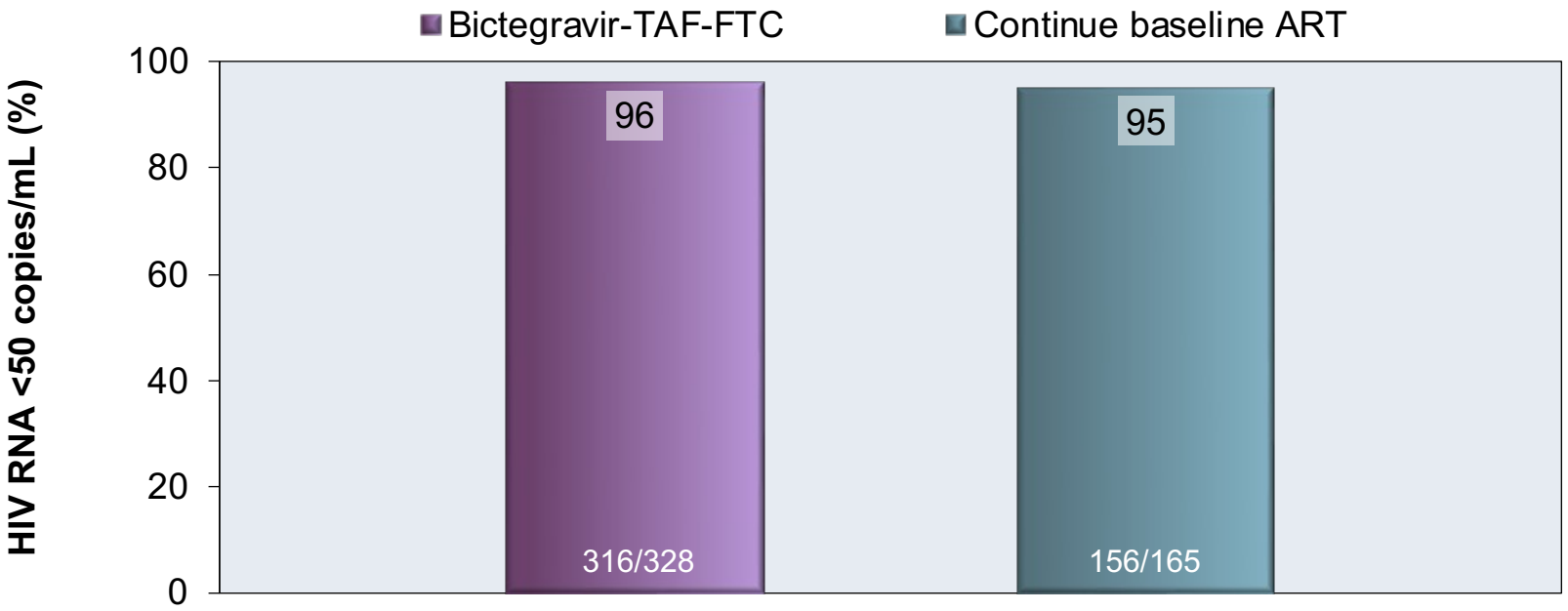
# Switch to Bictegravir-TAF-FTC for Black Americans
# BRAAVE2020: Baseline Characteristics

| BRAAVE2020 Baseline Participant Demographics & Clinical Characteristics | | |
|---|---|---|
| **Baseline Characteristic** | **BIC-TAF-FTC** (n = 328) | **Continue Baseline ART** (n = 165) |
| Baseline 3rd agent, n (%) | | |
| INSTI | 202 (61) | 99 (60) |
| NNRTI | 100 (30) | 51 (31) |
| PI | 30 (9) | 14 (9) |
| CCR5 antagonist | 0 | 1 (1) |
| Baseline ARV resistance, n (%) | | |
| NRTI resistance | 44 (13) | 26 (16) |
| M184V/I | 31 (9) | 20 (12) |
| NNRTI resistance | 70 (21) | 32 (19) |
| PI resistance | 36 (11) | 26 (16) |
| INSTI resistance | 8 (2) | 3(2) |

Source: Hagins D et al. JAIDS. 2021;88:86-95.

# Switch to Bictegravir-TAF-FTC for Black Americans
# BRAAVE2020: Results

## Week 24 Virologic Response (Intention-to-Treat Analysis)

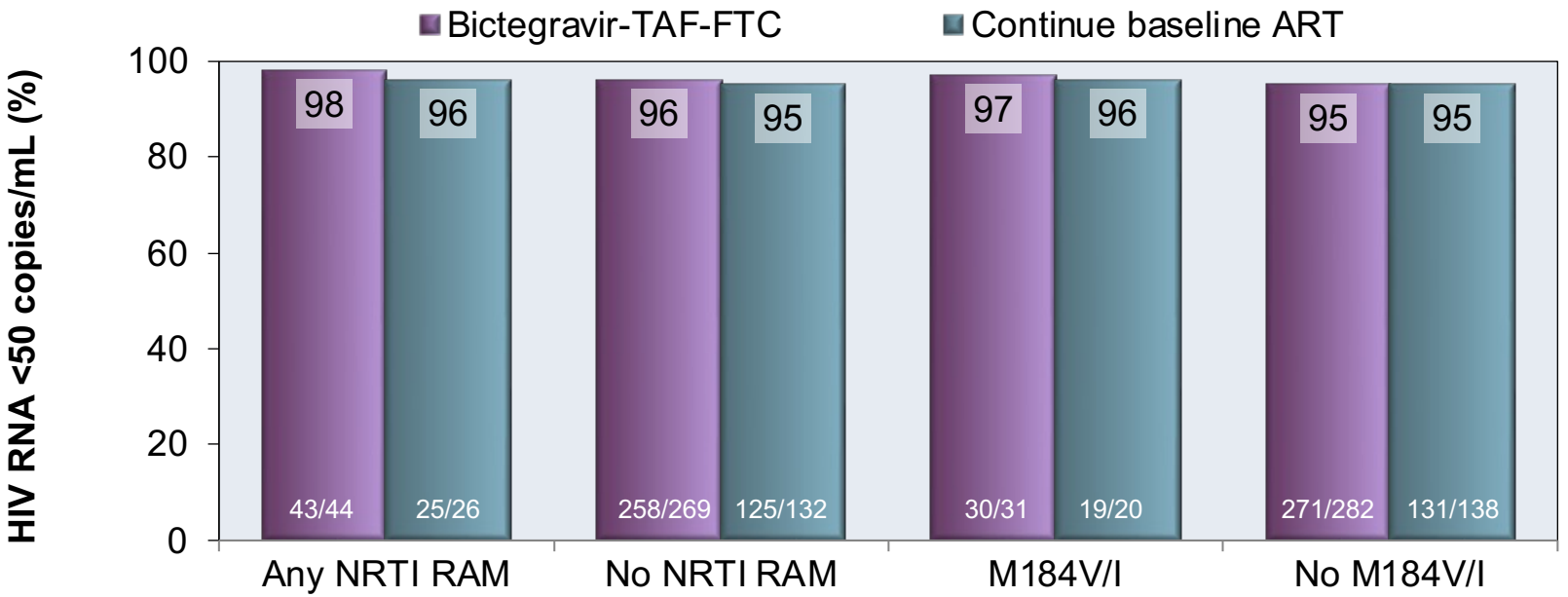



Primary outcome of HIV RNA ≥50 copies/mL at 24 weeks: 0.8% BIC-TAF-FTC arm; 1.6% continue baseline ART arm

Source: Hagins D et al. JAIDS. 2021;88:86-95.

# Switch to Bictegravir-TAF-FTC for Black Americans
# BRAAVE2020: Results

## Week 24 Virologic Response by Baseline Resistance (Intention-to-Treat Analysis)




RAM = resistance associated mutation

Source: Hagins D, et al. JAIDS. 2021;88:86-95.

# Switch to Bictegravir-TAF-FTC for Black Americans
# BRAAVE2020: Conclusions

**Conclusions**: “For Black Americans with HIV, switching to B/F/TAF was noninferior to continuing a variety of regimens, including those with pre-existing NRTI mutations.”

Source: Hagins D, et al. JAIDS. 2021;88:86-95.

# Acknowledgments

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AETC AIDS Education & Training Center Program

National HIV Curriculum

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