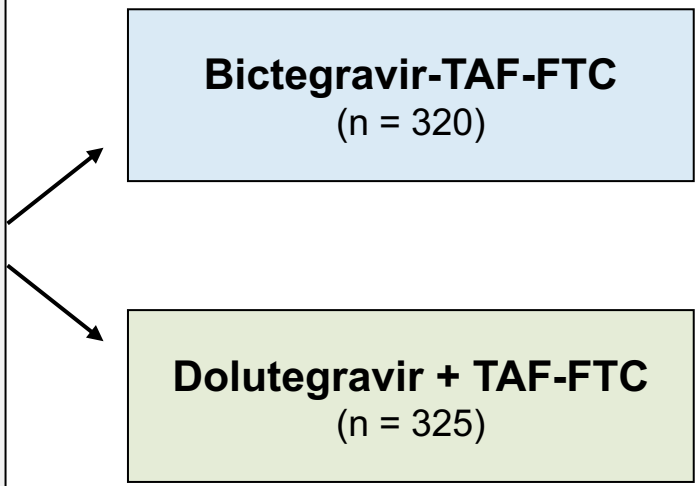
BIC-TAF-FTC versus DTG + TAF-FTC as Initial Therapy

GS-380-1490: Week 48 Results

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

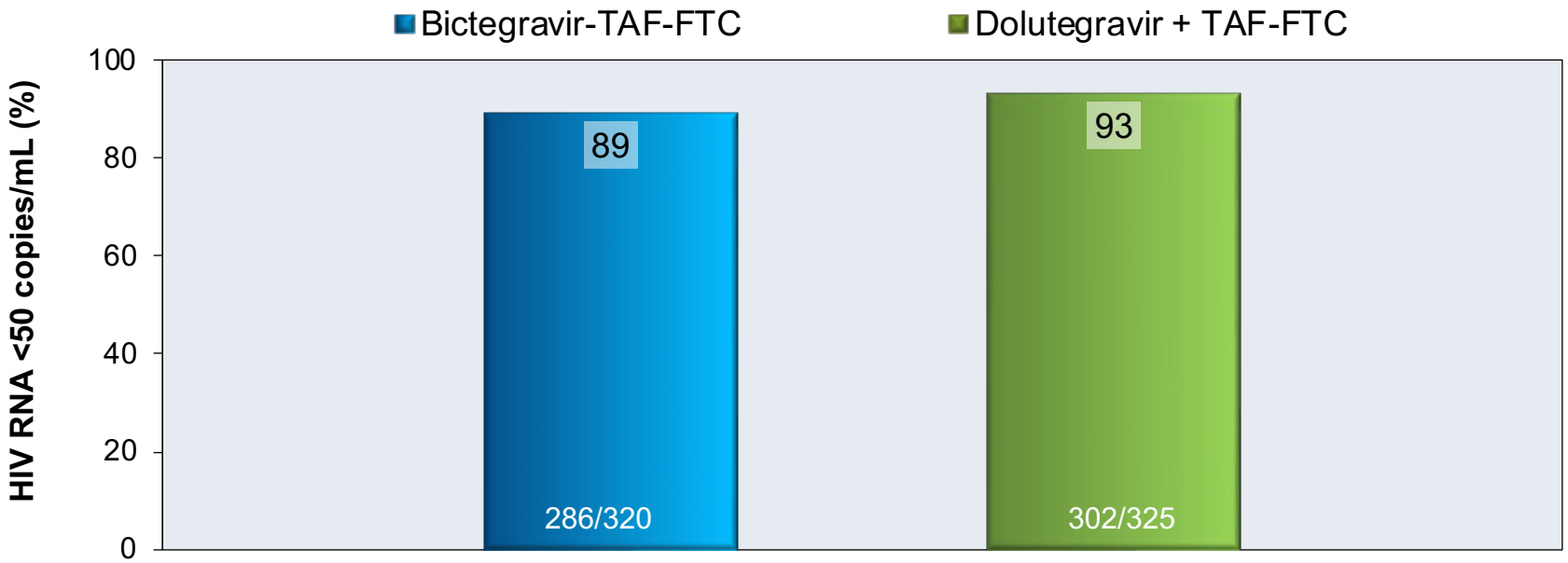
- **Design**
  - Randomized, double-blind, active-controlled, phase 3 study comparing bictegravir-tenofovir alafenamide-emtricitabine versus dolutegravir plus tenofovir alafenamide-emtricitabine as initial therapy
- **Inclusion Criteria**
  - Age ≥18 years
  - Antiretroviral-naïve (or ≤10 days of treatment)
  - 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.

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