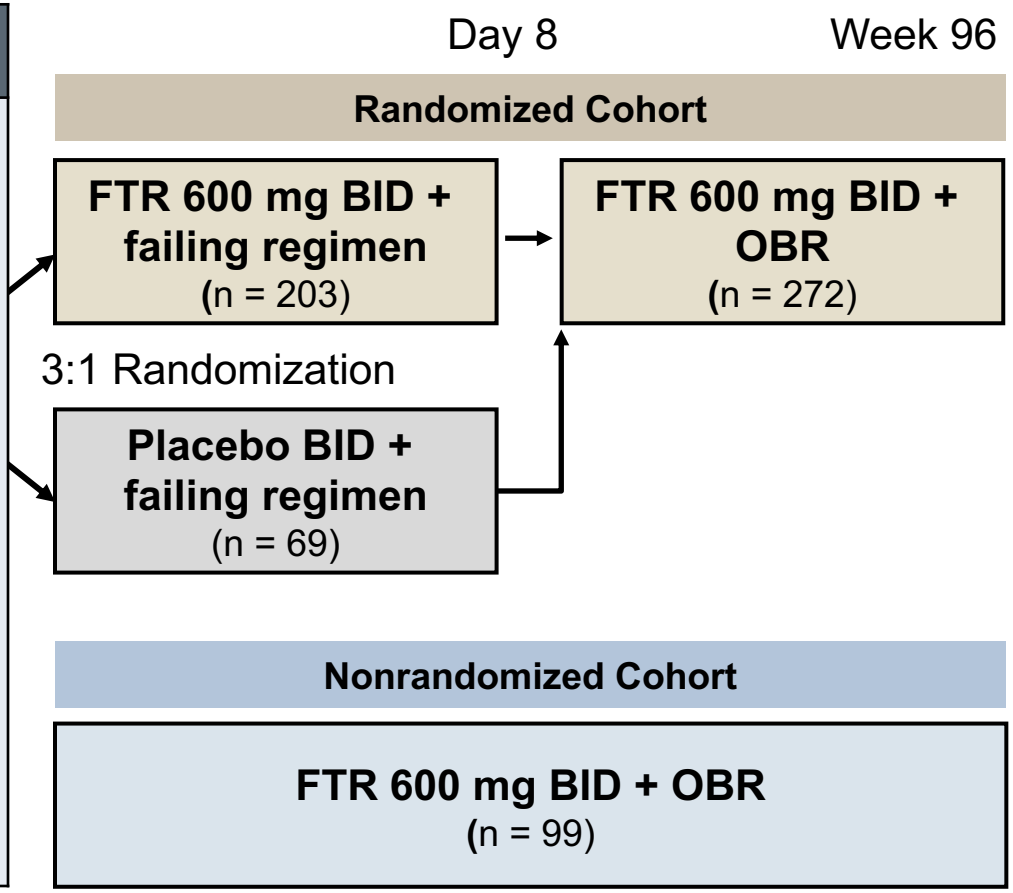
Fostemsavir in Treatment-Experienced Patients

BRIGHTE Study (Week 48 Data)

Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 48): Background

Study Design: BRIGHTE

- **Background**:
  - Phase 3, randomized, multicenter, placebo-controlled, non-inferiority trial evaluating attachment inhibitor fostemsavir (FTR) in salvage ART
- **Enrollment Criteria:**
  - Highly ART-experienced adults
  - Failing current ART regimen
  - HIV RNA >400 copies/mL
  - Multiclass ART resistance
  - At least one fully active agent
  - Unable to construct viable regimen



*Also a cohort with 0 remaining active agents; all given Fostemsavir 600 mg BID + OBR (n = 99)
*OBR = optimized background regimen

Source: Kozal M, et al. N Engl J Med. 2020;382:1232-43.

Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 48): Baseline Characteristics

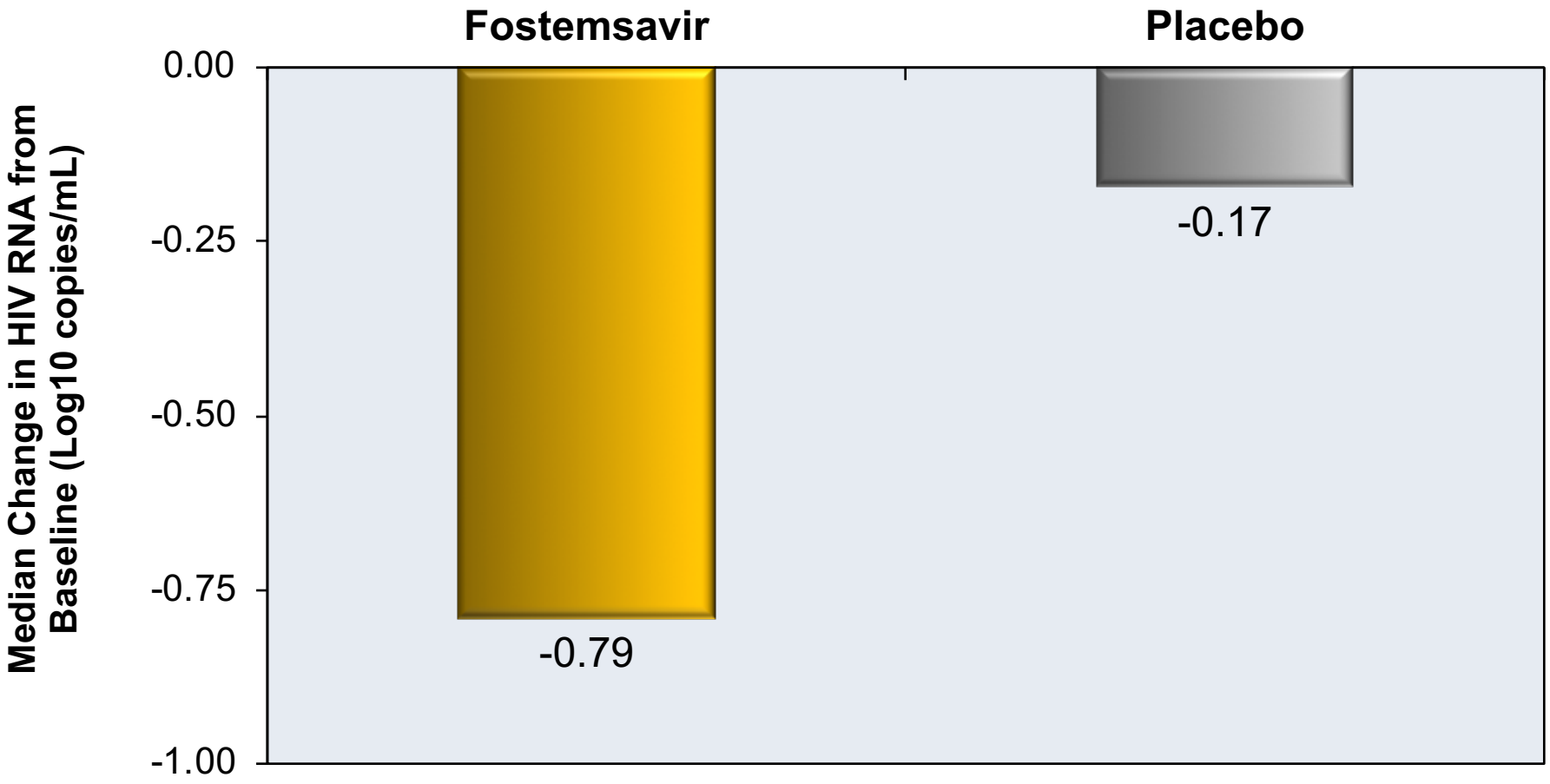
Baseline Characteristics	Randomized (n = 272)	Non-Randomized (n = 99)
Age, years, median (range)	48 (18-73)	50 (17-72)
Male sex, n (%)	200 (74)	89 (90)
White, n (%)	184 (68)	74 (74)
Black/African American, n (%)	60 (22)	23 (23)
HIV RNA 1,000-100,000 copies/mL, n (%)	161 (59)	75 (76)
HIV RNA >100,000 copies/mL, n (%)	80 (29)	15 (15)
CD4 count—cells/mm^3, median (range)	99 (0-1160)	41 (0-641)
2 fully active agents in OBR, %	42	0
1 fully active agent in OBR, %	52	19
0 fully active agents in OBR, %	6	81

*Most common ARV's in OBR: dolutegravir, darunavir, tenofovir DF, etravirine, maraviroc, enfuvirtide, ibalizumab

Source: Kozal M, et al. N Engl J Med. 2020;382:1232-43.

Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 48): Results

Baseline to Day 8 Change in HIV RNA Level



Source: Kozal M, et al. N Engl J Med. 2020;382:1232-43.

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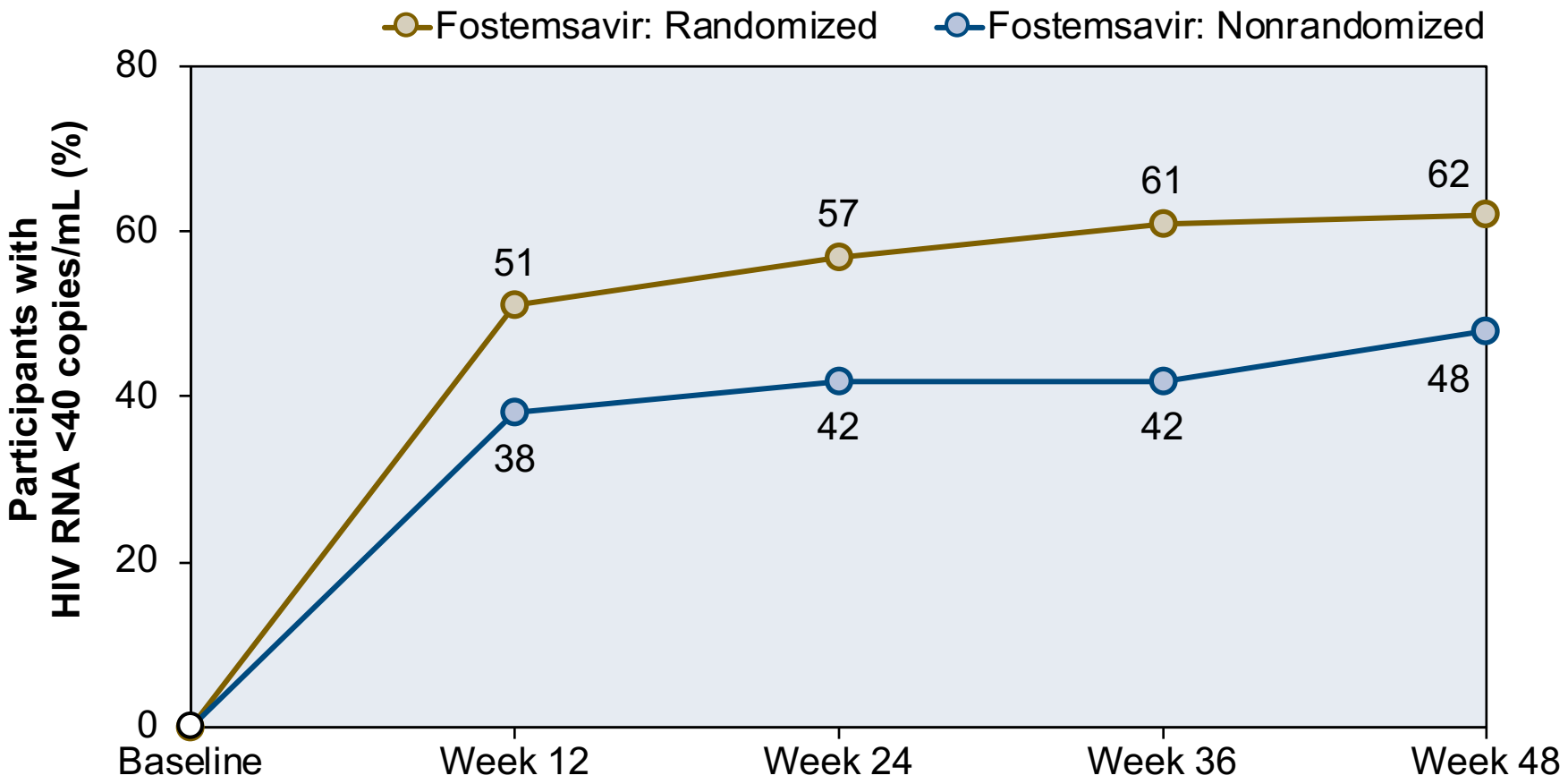
Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 48): Results

Virologic Response Through Week 48 (HIV RNA <40 copies/mL)



Source: Kozal M, et al. N Engl J Med. 2020;382:1232-43.

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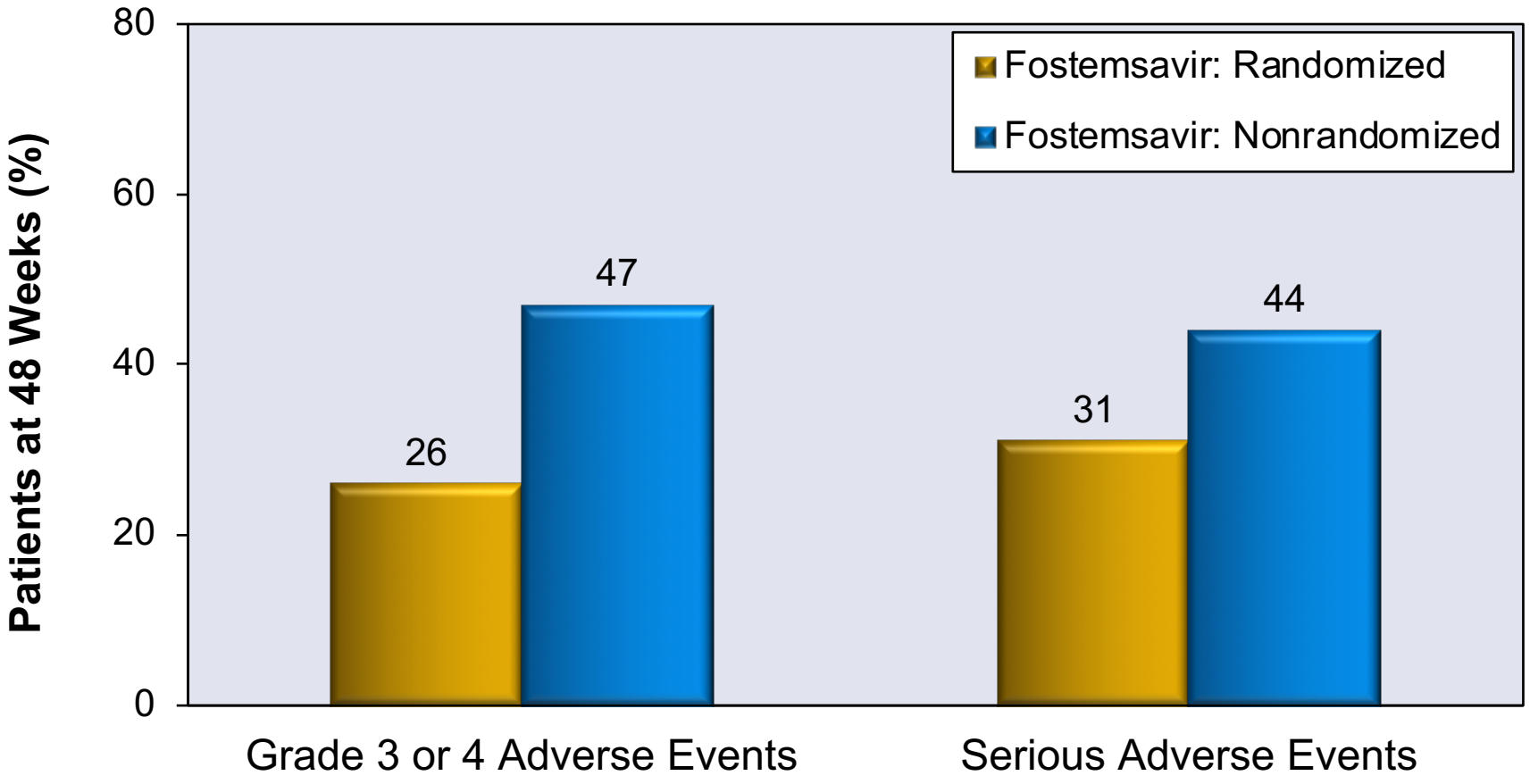
Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 48): Results

Adverse Events



Source: Kozal M, et al. N Engl J Med. 2020;382:1232-43.

Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 48): Conclusion

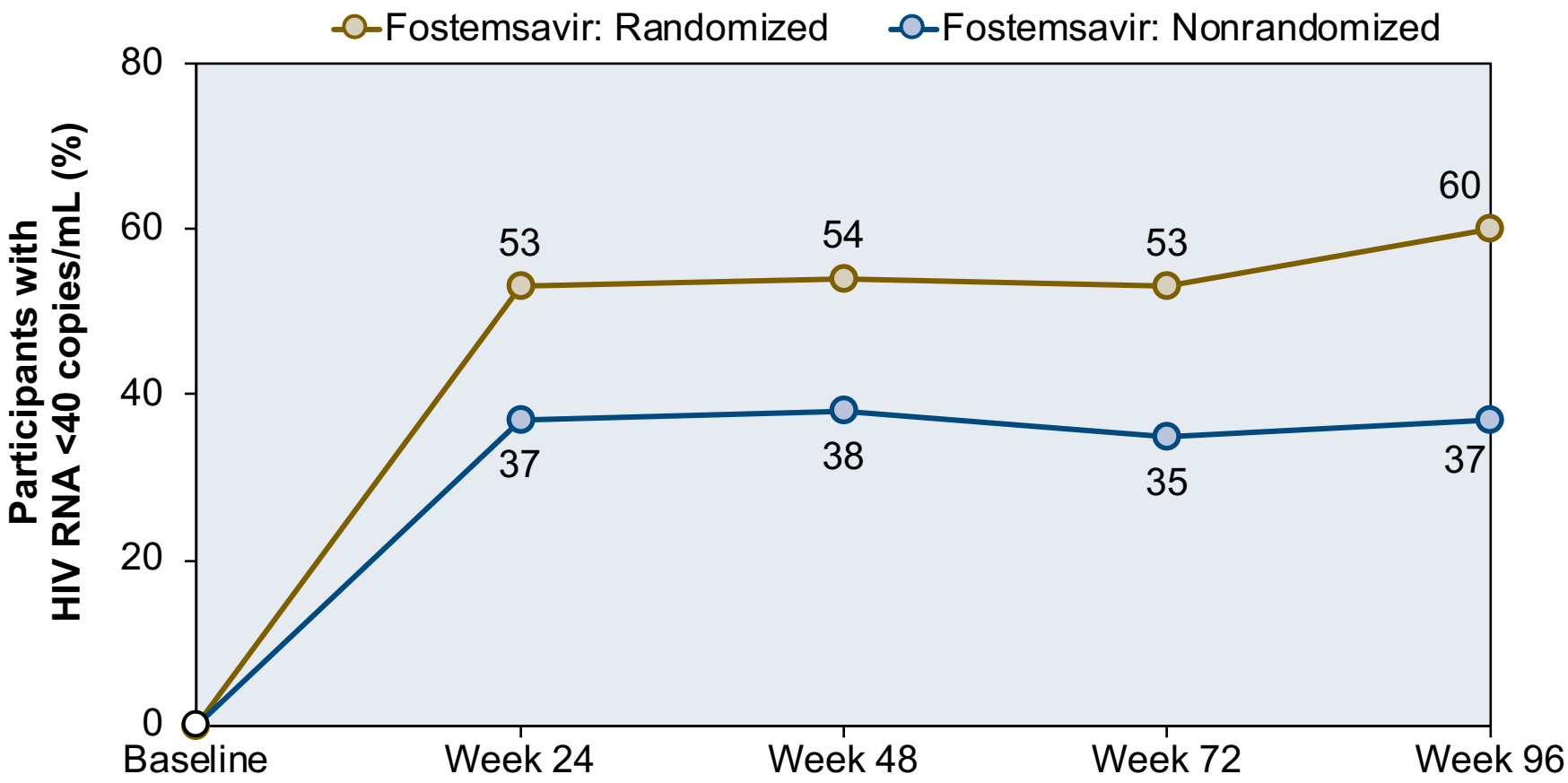
Conclusion: “In patients with multidrug-resistant HIV-1 infection with limited therapy options, those who received fostemsavir had a significantly greater decrease in the HIV-1 RNA level than those who received placebo during the first 8 days. Efficacy was sustained through 48 weeks.”

Source: Kozal M, et al. N Engl J Med. 2020;382:1232-43.

Fostemsavir in Treatment-Experienced Patients
BRIGHTE Study (Week 96 Data)

Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 96): Results

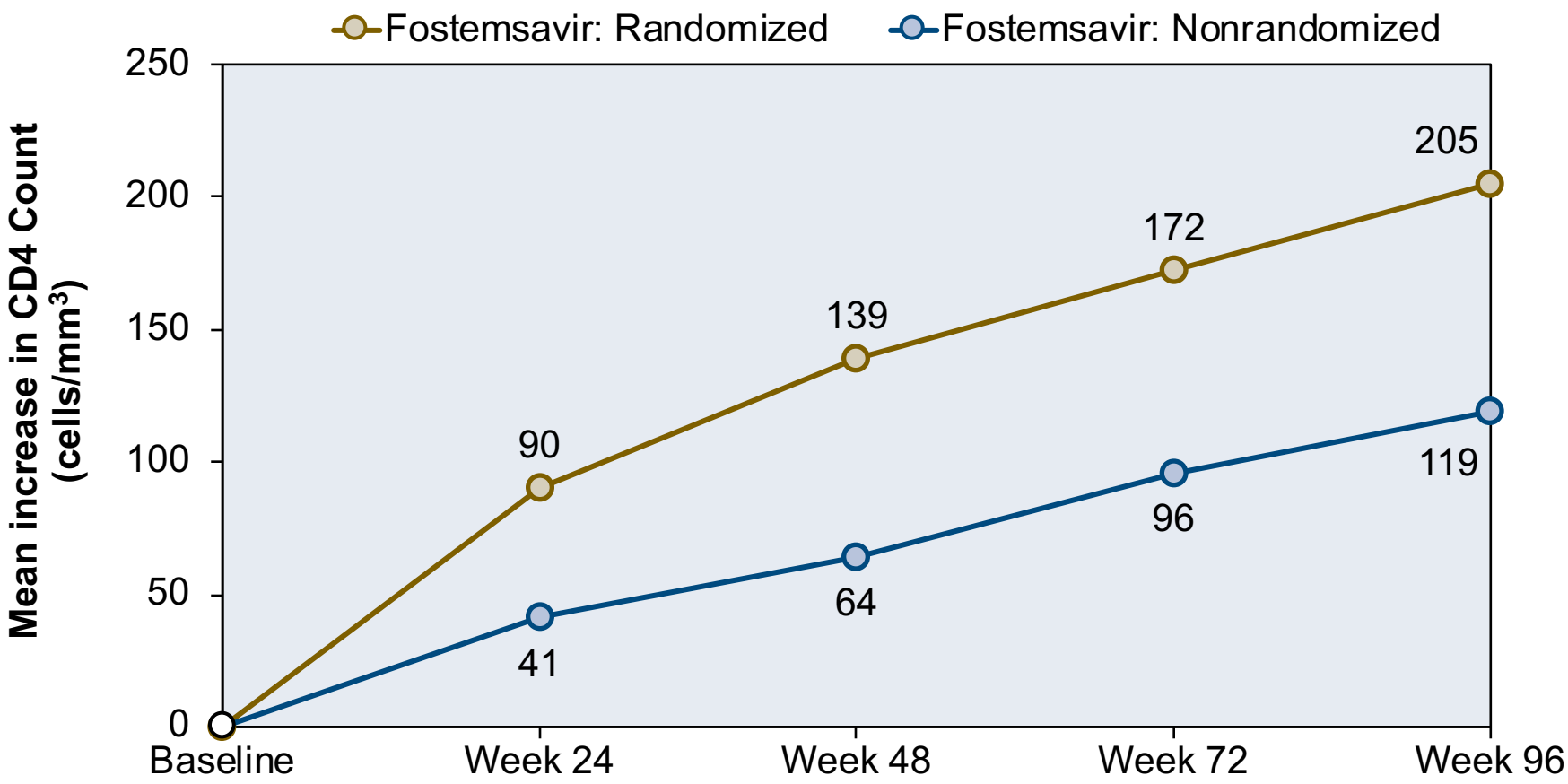
Virologic Response Through Week 96 (HIV RNA <40 copies/mL)



Source: Lataillade M, et al. Lancet HIV. 2020;7:e740-51.

Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 96): Results

Mean Change in CD4 T-Cell Count Through Week 96



Source: Lataillade M, et al. Lancet HIV. 2020;7:e740-51.

Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 96): Results

Adverse Events (AEs)	Randomized (n = 272)	Non-Randomized (n = 99)
Any AE, n (%)	249 (92)	98 (99)
Drug-related grade 2-4 AEs, n (%)	57 (21)	22 (22)
Nausea	9 (3)	5 (5)
Diarrhea	6 (2)	3 (3)
Headache	6 (2)	1 (1)
Vomiting	4 (1)	2 (2)
Fatigue	3 (1)	2 (2)
Asthenia	2 (<1)	2 (2)
Drug-related AE leading to discontinuation, n (%)	7 (3)	7 (3)
Drug-related serious AE, n (%)	9 (3)	3 (30)

Source: Lataillade M, et al. Lancet HIV. 2020;7:e740-51.

Fostemsavir (FTR) for Heavily Treatment Experienced BRIGHTE Study (Week 96): Conclusion

Interpretation: “In heavily treatment-experienced individuals with advanced HIV-1 disease and limited treatment options, fostemsavir-based antiretroviral regimens were generally well tolerated and showed a distinctive trend of increasing virological and immunological response rates through 96 weeks; these findings support fostemsavir as a treatment option for this vulnerable population.”

Source: Lataillade M, et al. Lancet HIV. 2020;7(11):e740-51.

Acknowledgment

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