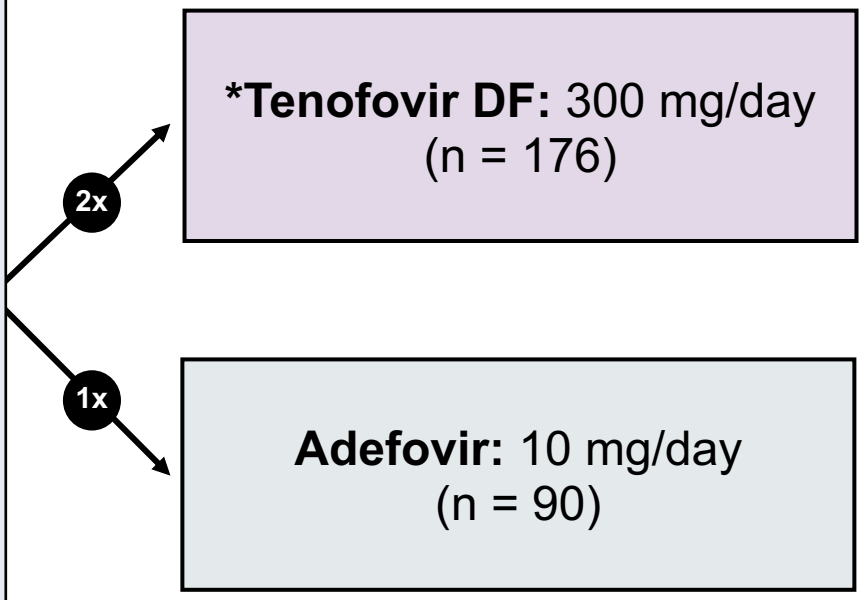
Tenofovir DF versus Adefovir in Chronic HBV Study 103: HBeAg-Positive

*Published in tandem with Study 102

Tenofovir DF versus Adefovir HBeAg-POSITIVE Participants: Study 103 Design

103: Study Design

- **Background**: Randomized, double-blind, controlled, phase 3 study to compare tenofovir DF versus adefovir for the treatment of HBeAg-positive adults with chronic HBV
- **Key Inclusion Criteria**
  - Age 18-69 years
  - HBeAg-positive (≥6 months)
  - ALT 2-10 x upper limit of normal
  - HBV DNA >1 million copies/mL
  - CrCl ≥70 mL/min
  - Knodell necroinflammation score ≥3
  - Compensated liver disease



*Stratified by 1:1 by ALT elevation (<4X ULN versus ≥4X ULN)

Source: Marcellin P, et al. N Engl J Med. 2008;359:2442-55.

Tenofovir DF versus Adefovir Study 103: HBeAg-Positive

Baseline Characteristic	Tenofovir DF (n = 176)	Adefovir (n = 90)
Age, mean (±SD), years	34 ±11	34 ±12
Male, no. (%)	119 (68)	64 (71)
Race, no. (%)		
White	92 (52)	46 (51)
Asian	64 (36)	32 (36)
Black	13 (7)	5 (6)
Other	7 (4)	7 (8)
Knodell inflammatory score, mean (±SD)	8.3 ±2.14	8.3 ±2.27
Knodell fibrosis score, mean (±SD)	2.3 ±1.23	2.4 ±1.19
Mean HBV DNA, $\log_{10}$ IU/mL (±SD)	8.64 ±1.076	8.88 ±0.930
Prior treatment with lamivudine or emtricitabine, no. (%)	8 (5)	1 (1)

Source: Marcellin P, et al. N Engl J Med. 2008;359:2442-55.

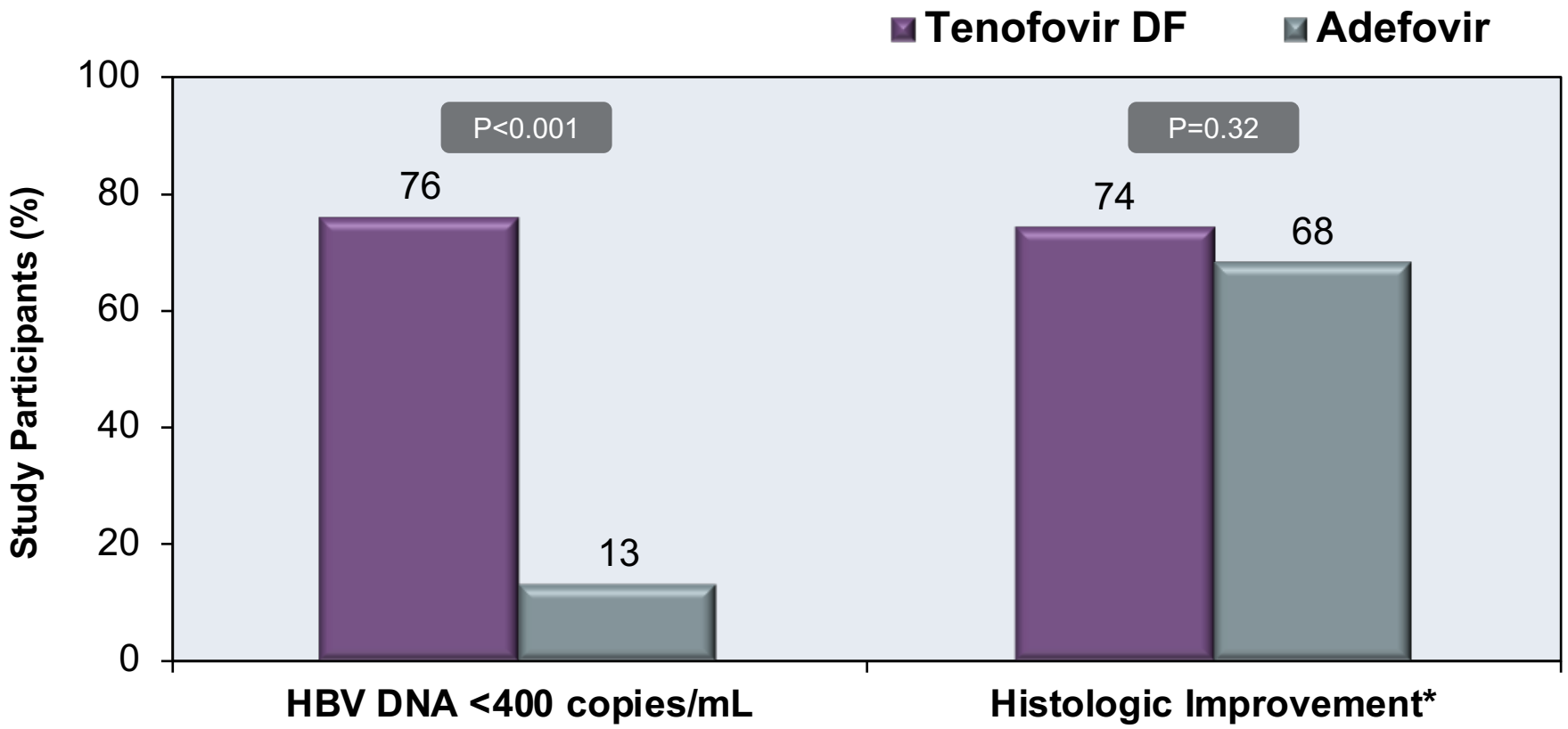
Tenofovir DF versus Adefovir Study 103: HBeAg-Positive

Baseline Characteristic	Tenofovir (n = 176)	Adefovir (n = 90)
Alanine aminotransferase, no. (%)		
<2 x upper limit of normal	39 (22)	16 (18)
2 to <5 x upper limit of normal	105 (60)	55 (61)
≥5 x upper limit of normal	32 (18)	19 (21)
Previous treatment with interferon, no. (%)	30 (17)	13 (14)
HBV genotype, no. (%)		
A	41 (24)	18 (20)
B	25 (14)	10 (11)
C	43 (25)	26 (30)
D	55 (32)	31 (35)
E, F, G, H	9 (5)	3 (3)
Other or unknown	3 (2)	2 (2)

Source: Marcellin P, et al. N Engl J Med. 2008;359:2442-55.

Tenofovir DF versus Adefovir
Study 103: HBeAg-Positive Results

HBeAg-Positive Participants: Week 48 Treatment Response

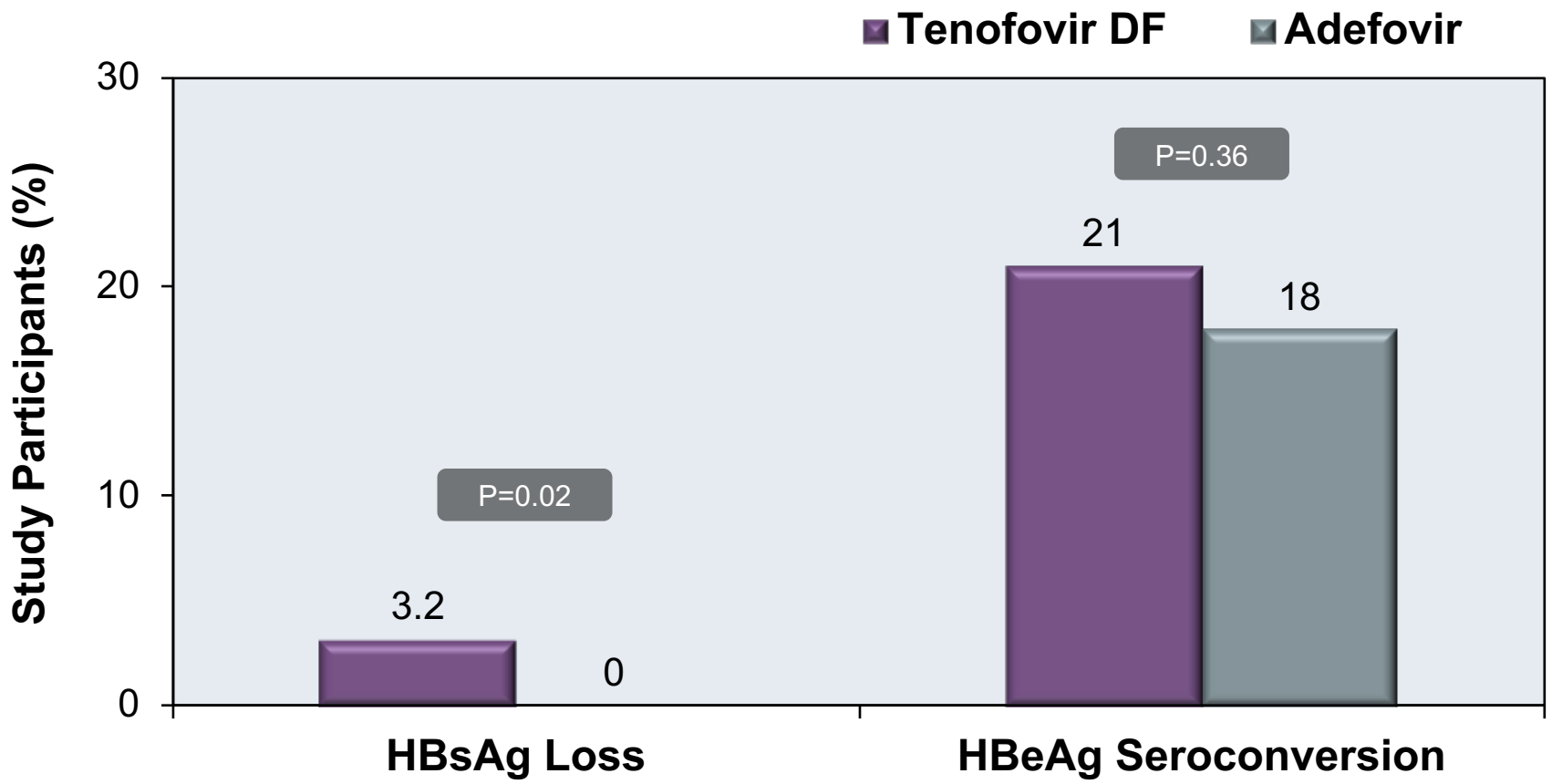


*Reduction of ≥2 points in the Knodell necroinflammatory score without an increase in fibrosis

Source: Marcellin P, et al. N Engl J Med. 2008;359:2442-55.

Tenofovir DF versus Adefovir
Study 103 Serologic Responses

HBeAg-Positive Participants: Week 48 Treatment Response



Source: Marcellin P, et al. N Engl J Med. 2008;359:2442-55.

Safety and Adverse Events
Study 102 (HBeAg-Negative) & 103 (HBeAg-Positive)

Conclusions: “Among patients with chronic HBV infection, tenofovir DF at a daily dose of 300 mg had superior antiviral efficacy with a similar safety profile as compared with adefovir dipivoxil at a daily dose of 10 mg through week 48.”

Source: Source: Marcellin P, et al. N Engl J Med. 2008;359:2442-55.