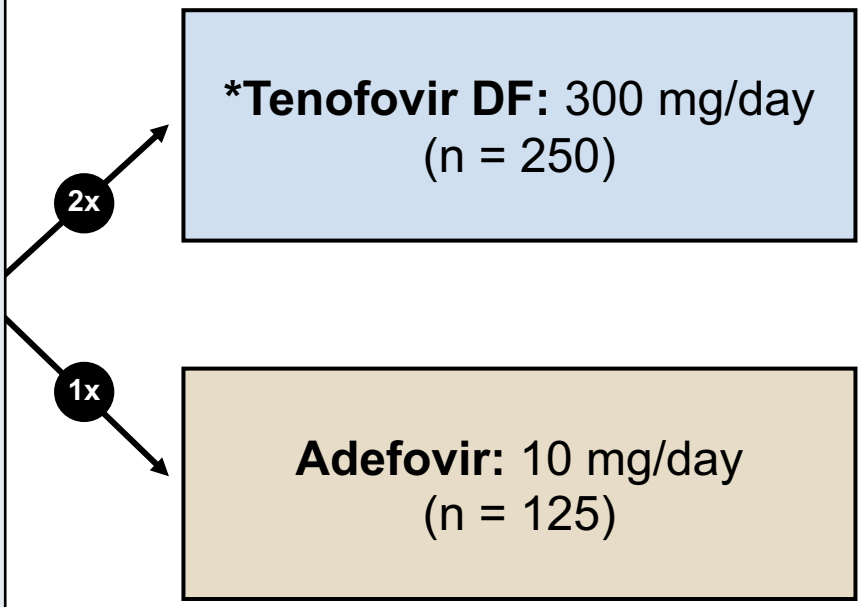
Tenofovir DF versus Adefovir in Chronic HBV
*Study 102: HBeAg-Negative

*Published in tandem with Study 103

Tenofovir DF versus Adefovir HBeAg-NEGATIVE Participants: Study 102 Design

102: Study Design

- **Background**: Randomized, double-blind, controlled, phase 3 study to compare tenofovir DF versus adefovir for the treatment of HBeAg-negative adults with chronic HBV
- **Key Inclusion Criteria**
  - Age 18-69 years
  - HBeAg-negative
  - ALT 1-10 x ULN
  - HBV DNA >100,000 copies/mL
  - CrCl ≥70 mL/min
  - Knodell necroinflammation score ≥3
  - Compensated liver disease



*Stratified by 1:1 by prior lamivudine or emtricitabine exposure (<12 weeks versus ≥12 weeks)

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

Tenofovir DF versus Adefovir
Study 102: HBeAg-Negative Participants

Baseline Characteristic	Tenofovir DF (n = 250)	Adefovir (n = 125)
Age, mean (±SD), years	44 ±10.6	43 ±10.0
Male, no. (%)	193 (77)	97 (78)
Race, no. (%)		
White	161 (64)	81 (65)
Asian	63 (25)	30 (24)
Black	8 (3)	4 (3)
Other	18 (7)	10 (8)
Knodell inflammatory score, mean (±SD)	7.8 ±2.44	7.9 ±2.18
Knodell fibrosis score, mean (±SD)	2.3 ±1.21	2.4 ±1.23
Mean HBV DNA, $\log_{10}$ IU/mL (±SD)	6.86 ±1.31	6.98 ±1.27
Prior treatment with lamivudine or emtricitabine, no. (%)	43 (17)	23 (18)

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

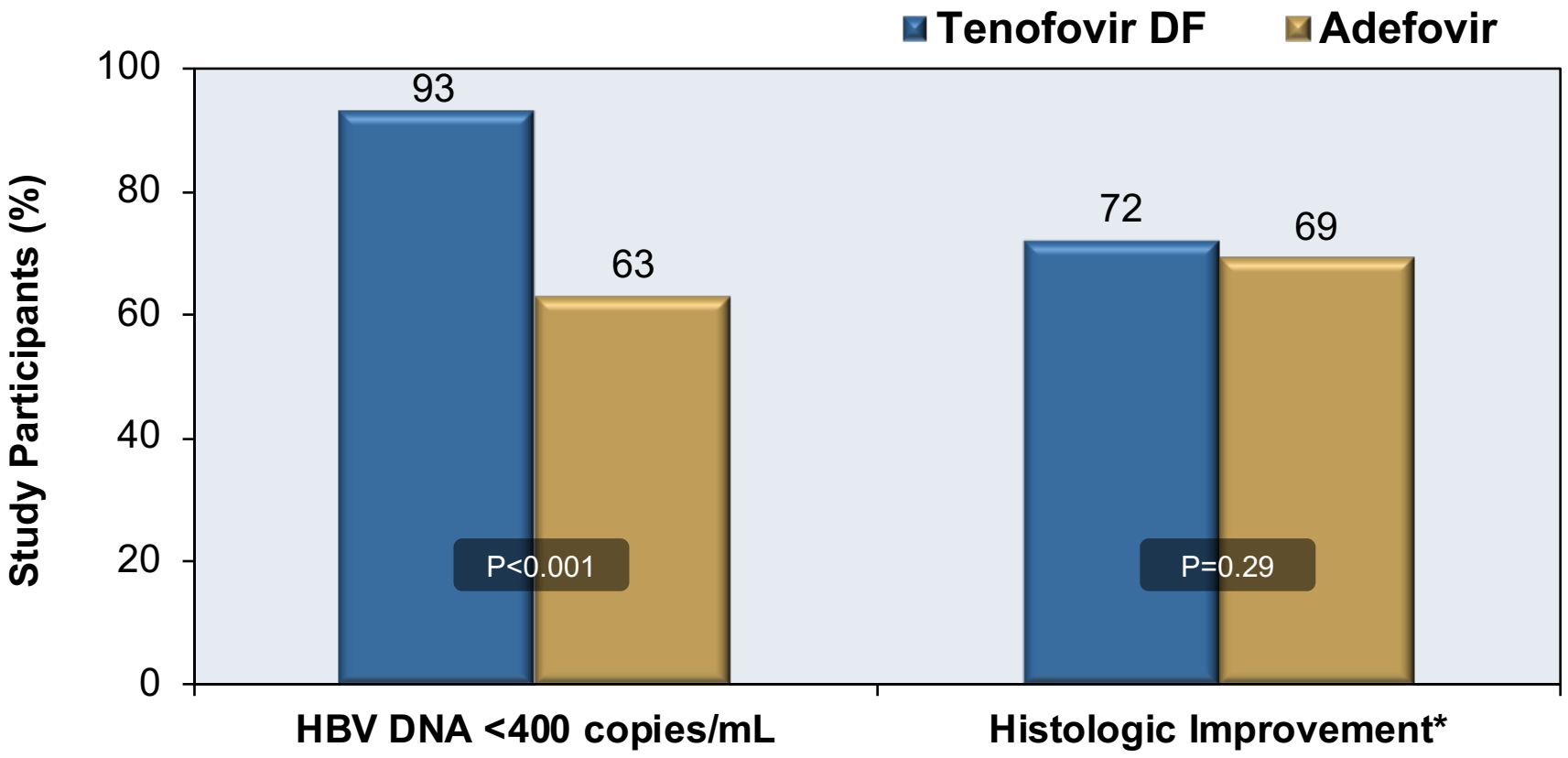
Tenofovir DF versus Adefovir Study 102: HBeAg-Negative

Baseline Characteristic	Tenofovir DF (n = 250)	Adefovir (n = 125)
Alanine aminotransferase, no. (%)		
<2 x upper limit of normal	95 (38)	38 (30)
2 to <5 x upper limit of normal	117 (47)	54 (43)
≥5 x upper limit of normal	38 (15)	33 (26)
Previous treatment with interferon, no. (%)	42 (17)	23 (18)
HBV genotype, no. (%)		
A	28 (12)	14 (11)
B	22 (9)	17 (14)
C	29 (12)	12 (10)
D	156 (64)	79 (63)
E, F, G, H	8 (3)	3 (2)
Other or unknown	7 (3)	0

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

Tenofovir DF versus Adefovir
Study 102: HBeAg-Negative Participants

HBeAg-Negative 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.

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