Heplisav-B vs Engerix-B in Healthy Adults, Aged 40-70 Years

HBV-16 Trial

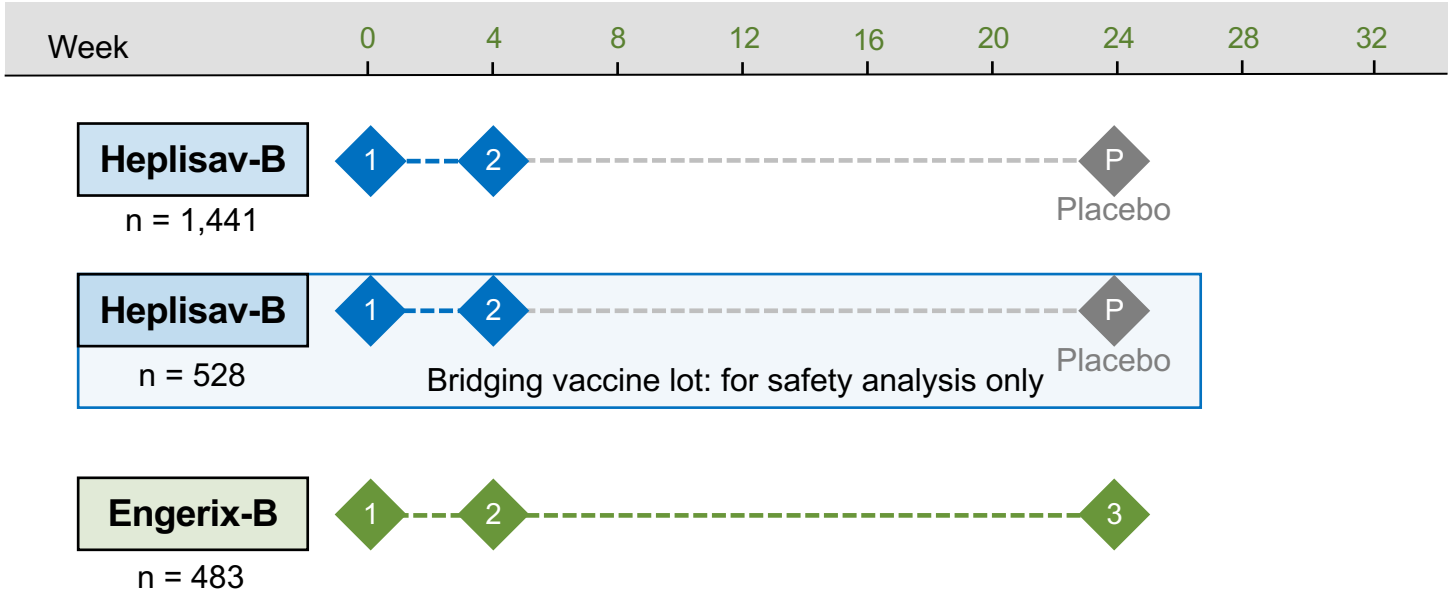
Heplisav-B Vaccine versus Engerix-B Vaccine in Healthy Adults Aged 40-70 Years HBV-16 Trial: Study Design

- **Design**
  - Phase 3 randomized observer-blinded controlled trial to compare the safety and efficacy of Heplisav-B versus Engerix B vaccines in healthy adults 40-70 years of age
- **Participants** n = 2,4520
  - Ages: 40-70 years
  - HBV vaccine naïve
  - Exclusions: HBV*, HIV, pregnancy or lactation, autoimmune or other clinically significant illness, immunosuppressed
- **Setting**
  - Multiple centers in United States & Canada
- **Study End-Point**
  - Seroprotection = anti-HBs level ≥10 mIU/mL

*Any positive test for HBsAg, anti-HBs, or anti-HB core

Source: Heyward WL, et al. Vaccine. 2013;31:5300-5.

Heplisav-B Vaccine versus Engerix-B Vaccine in Healthy Adults Aged 40-70 Years HBV-16 Trial: Design



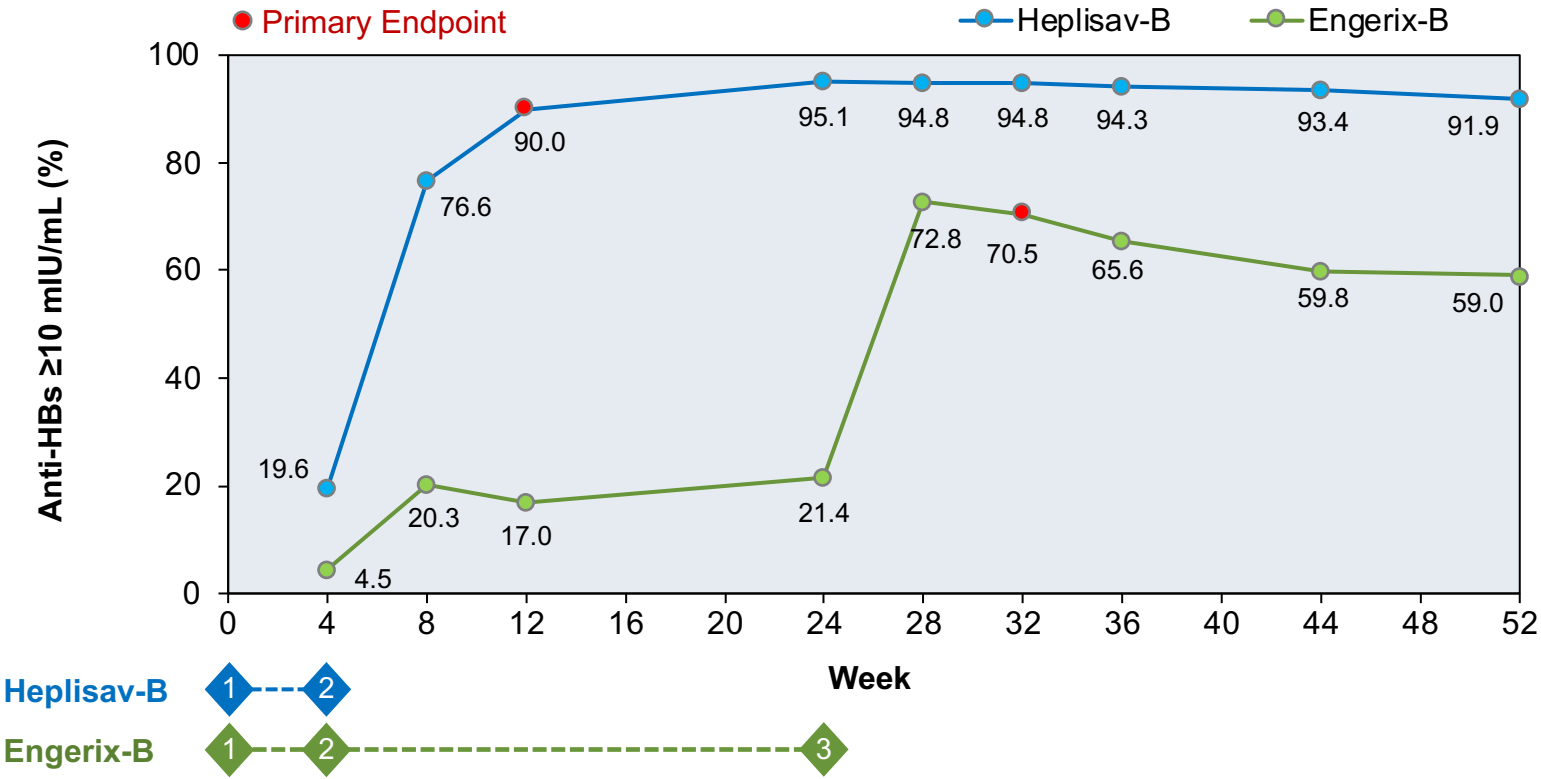
Vaccine Dosing

Heplisav-B: 0.5 mL dose of 3 mg 1018 adjuvant with 20 mcg recombinant HBsAg at week 0 and 4

Engerix-B: 1 mL dose of 20 mcg recombinant HBsAg with aluminum adjuvant at week 0, 4 and 24

Source: Heyward WL, et al. Vaccine. 2013;31:5300-5.

Heplisav-B Vaccine versus Engerix-B Vaccine in Healthy Adults Aged 40-70 Years HBV-16 Trial: Results



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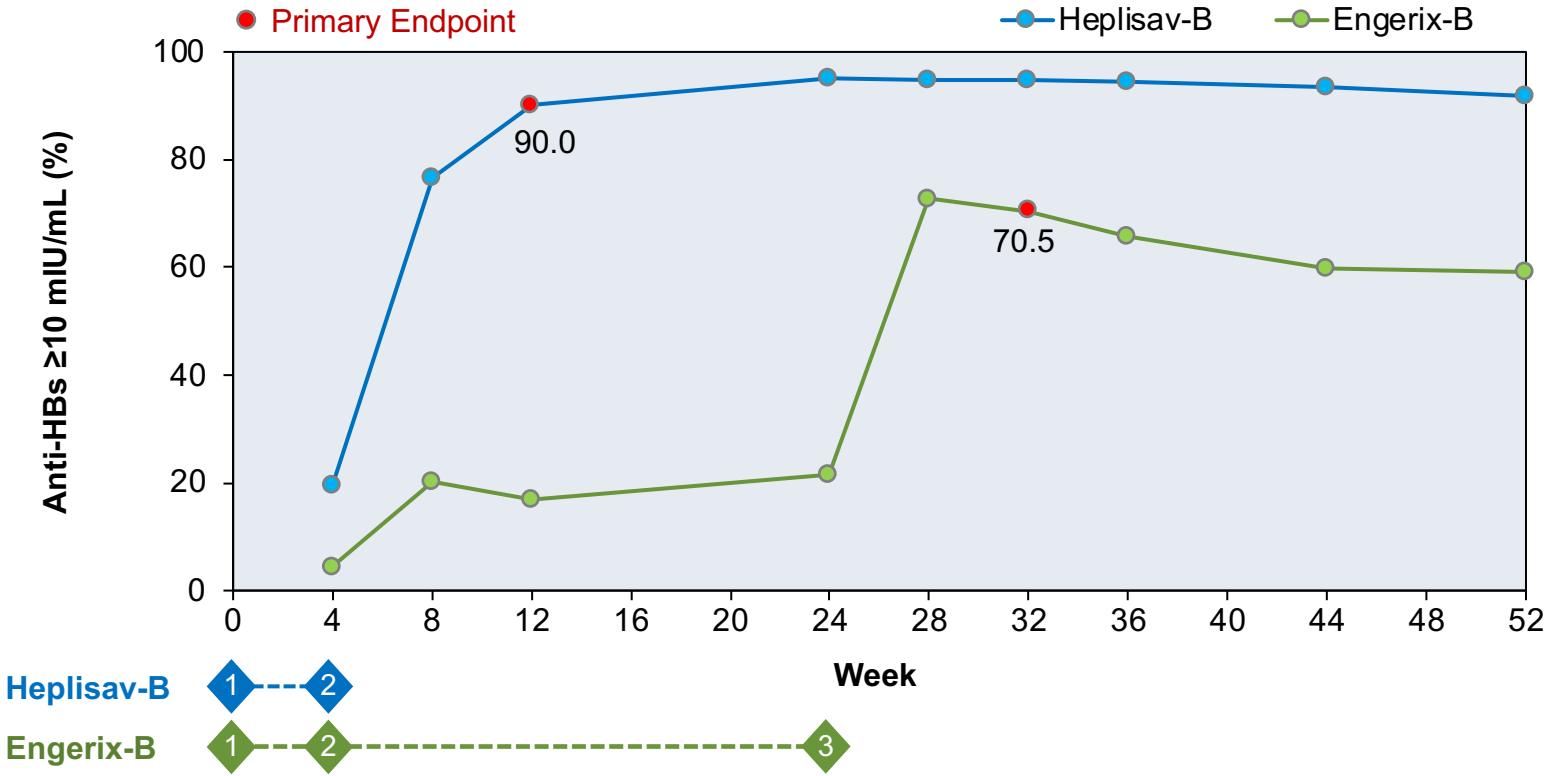

Source: Heyward WL, et al. Vaccine. 2013;31:5300-5.

Heplisav-B Vaccine versus Engerix-B Vaccine in Healthy Adults Aged 40-70 Years HBV-16 Trial: Adverse Reactions

Adverse Event, no. (%)	Heplisav-B (n = 1,968)	Engerix-B (n = 481)
Local reaction (among n=1953)		
Total	666 (34)	154 (32)
Severe	11 (0.6)	3 (0.6)
Systemic reaction (among n=1953)		
Total	586 (30)	166 (35)
Severe	42 (2)	19 (4)
Any related adverse event (AE)	142 (7)	29 (6)
Any related severe AE (grade 3 or above)	0	1 (0.2)
Any AE leading to study discontinuation	17 (0.9)	2 (0.4)
Death	1 (0.05)	1 (0.2)

Source: Heyward WL, et al. Vaccine. 2013;31:5300-5.

Heplisav-B Vaccine versus Engerix-B Vaccine in Healthy Adults Aged 40-70 Years HBV-16 Trial: Conclusions

Conclusions: “When compared to the HBsAg-Eng three-dose regimen given at 0, 1, and 6 months, HBsAg-1018 demonstrated superior seroprotection with only two doses at 0 and 1month. The safety profile of HBsAg-1018 was comparable to that of the licensed vaccine, HBsAg-Eng. HBsAg-1018 would provide a significant public health contribution toward the prevention of hepatitis B infection.”

Source: Heyward WL, et al. Vaccine. 2013;31:5300-5.

This slide deck is from the University of Washington's *Hepatitis B Online* and *Hepatitis C Online* projects.

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www.hepatitisB.uw.edu

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