

Hepelisav-B versus Engerix-B in Adults with Chronic Kidney Disease (CKD) HBV-17: Diabetes Mellitus Subgroup Analysis

Heplisav-B versus Engerix-B in Adults with CKD HBV-17 DM Subgroup Analysis: Design

- **Background**

- Phase 3 randomized, observer-blinded, active controlled, conducted in multiple centers in United States and Canada trial to compare the safety and efficacy of 3 doses of Heplisav-B versus 4 double-doses of Engerix B in adults with chronic kidney disease (CKD)

- **Participants**

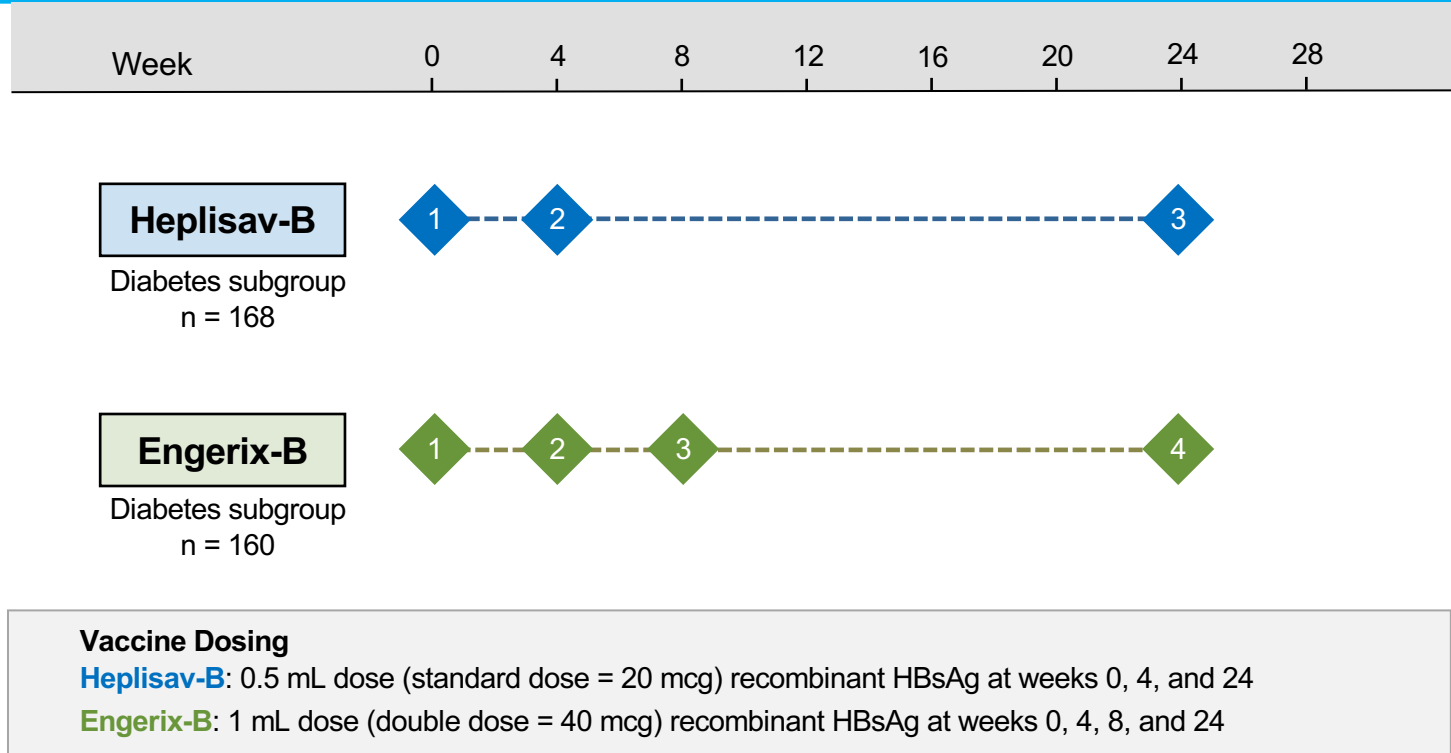
- n = 328 randomized (n = 326 analyzed in modified intent-to-treat (mITT))
- Ages: 18-75 years
- Chronic kidney disease: GFR ≤ 45 mL/min/1.73 m² +/- hemodialysis
- Type 2 diabetes mellitus
- HBV vaccine naïve
- Exclusions: HBV*, HIV, HCV, pregnancy or lactation, autoimmune or other clinically significant illness, immunosuppressed

- **Study End Point**

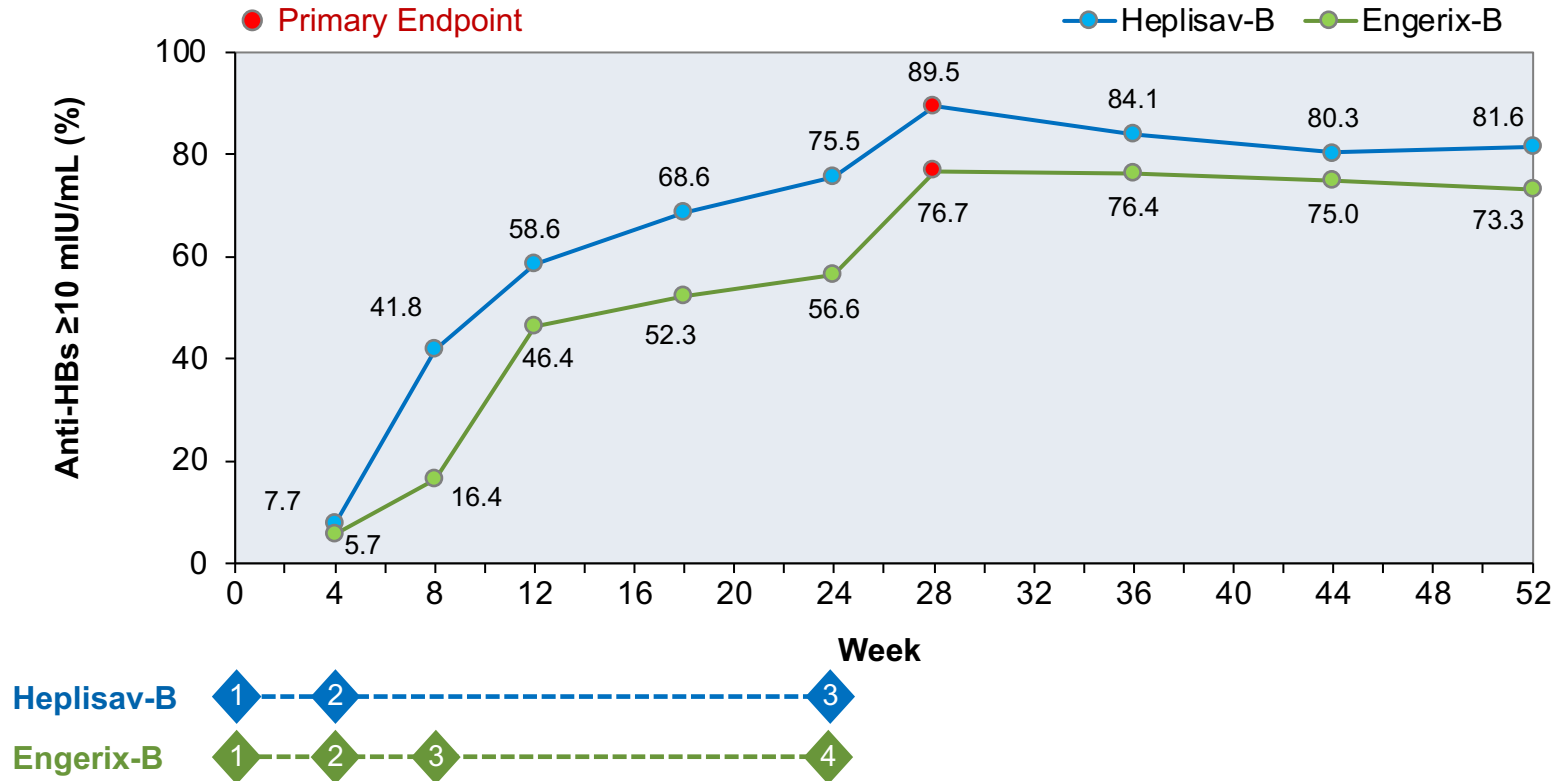
- Seroprotection = anti-HBs antibody level ≥ 10 mIU/mL

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

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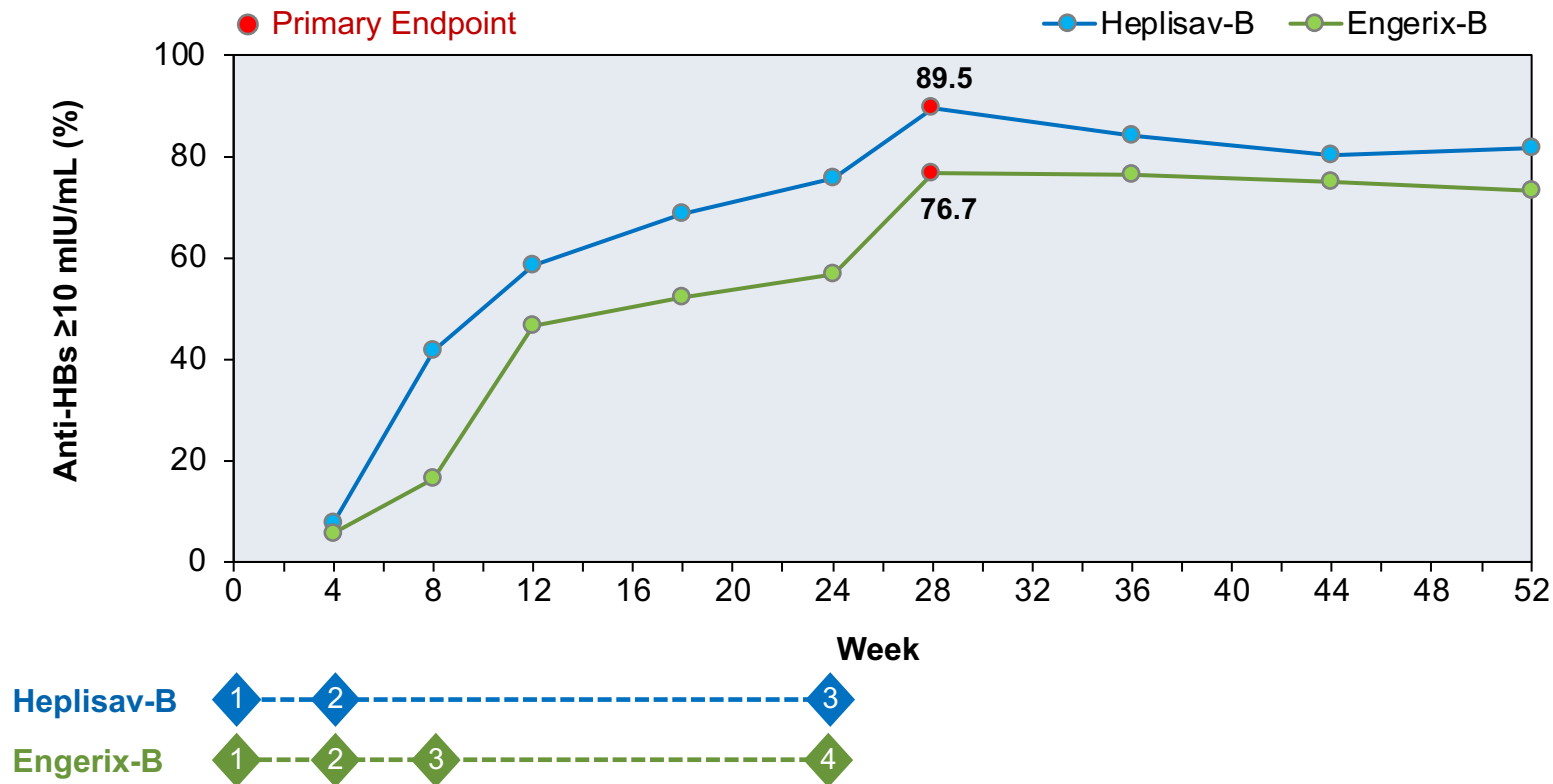


Hepelisav-B versus Engerix-B in Adults with CKD HBV-17 DM Subgroup Analysis: Results



Source: Janssen JM, et al. Vaccine. 2015;3:833-7.

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Hepelisav-B versus Engerix-B in Adults with CKD HBV-17 DM Subgroup Analysis: Conclusions

Conclusions: “HBsAg-1018 induced significantly higher seroprotection than HBsAg-Eng in CKD patients with diabetes.”

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

Hepatitis B Online

www.hepatitisB.uw.edu

Hepatitis C Online

www.hepatitisC.uw.edu

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