

# Oral Abstract Presentations: Session 3B

## HBV-24: Immunogenicity and Safety of HEPLISAV-B® in Hemodialysis Patients

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**ACVR 2020**

# Disclosures

Randall N. Hyer – employee, Dynavax.

Phase 1 Single-Arm, Multi-Center Study of Four Single Doses of HEPLISAV-B® in  
Adults on Hemodialysis:

Interim Analysis

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**19<sup>th</sup> Annual Conference on Vaccine Research**

**March 24, 2020**

**Washington, DC**

## Financial Disclosure

- All authors are current Dynavax employees or consultants

## Background

- Patients on hemodialysis (HD) are at risk of hepatitis B infection
  - HBV infections continue in HD population
    - Nosocomial (CDC 2001)
- Patients on dialysis are difficult to immunize
  - Engerix-B (20mcg), 4 double doses, 0,1,2,6 month regimen
    - SPR = 74% (Ye 2017)
  - Recombivax HB (40mcg), 3 doses, 0,1,6 month regimen
    - SPR = 64% (Ye 2017)

## HEPLISAV-B

- Contains 20 mcg rHBsAg
- Contains 3000 mcg 1018
  - Adjuvant (CpG oligonucleotide)
  - Short, single-stranded oligonucleotide with unmethylated CpG motifs
  - Toll-like receptor 9 (TLR9) agonist
  - Mimics natural response to infection
- FDA approved as a 2-dose regimen in healthy adults in a 0,1 month schedule
  - Safety and effectiveness of HEPLISAV-B have not been established in adults on hemodialysis.
- HBV-24: Investigational 4-dose regimen in patients on hemodialysis in a 0,1,2,4 month schedule

## Selected Study Objectives

### Primary

- To evaluate safety of HEPLISAV-B
- To evaluate percentage of subjects with anti-HBs concentration  $\geq 10$  mIU/mL (seroprotection rate or SPR) at Week 20

### Secondary

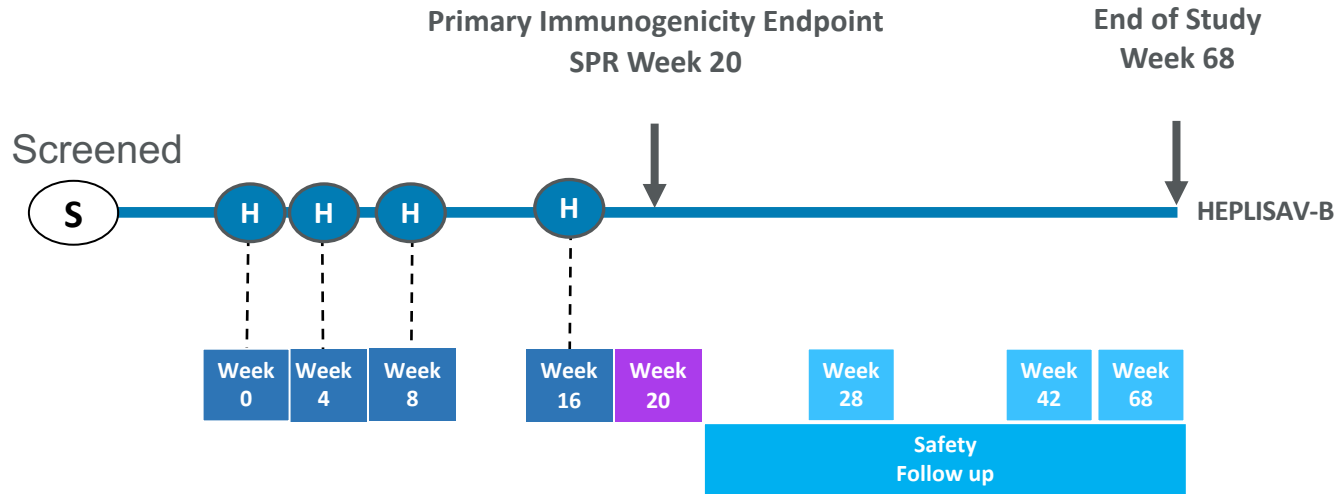
- To evaluate SPR, percentage of subjects with anti-HBs concentration  $\geq 100$  mIU/mL, and GMC at each study visit through Week 20

## Study Design

- Single arm, multi-center study to evaluate HEPLISAV-B in adults with end-stage renal disease who are initiating or undergoing hemodialysis
  - Sample size ~115
- Safety
  - Medically-attended adverse events (MAEs)
  - Serious adverse events (SAEs)
  - Acute myocardial infarctions (AMIs)
  - Immune-mediated adverse events of special interest (AESI)
  - AMIs and AESIs will be reviewed periodically by a Safety Monitoring Committee (SMC)
- Immunogenicity
  - Seroprotection defined as anti-HBs  $\geq 10$  mIU/mL



# Study Design



*44 patients with Week 20 data*

## Demographic and Baseline Characteristics Enrolled Population

Characteristics	HEPLISAV-B (N =88) n (%)
Mean Age (SD), years	60.1 (12.49)
Sex	
Men	47 (53.4)
Race	
Black	46 (52.3)
White	38 (43.2)
Asian	1 (1.1)
Other / Multiple	3 (3.4)
BMI $\geq$ 30 kg/m <sup>2</sup>	45 (51.1)
Smoker	18 (20.5)
Type 2 diabetes mellitus on medication	46 (52.3)

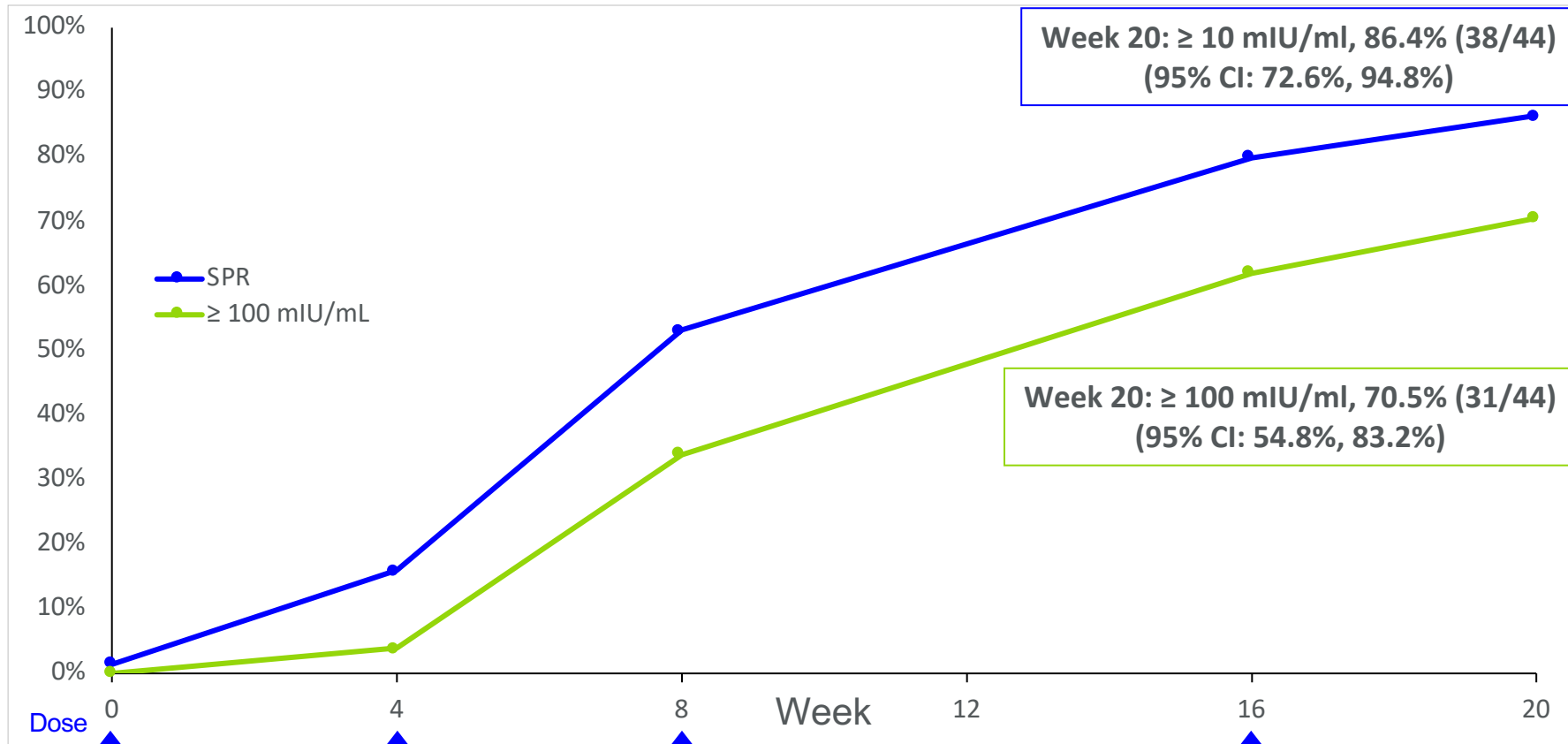
## Post Injection Reactions (PIRs)

	HEPLISAV-B N = 85 n (%)
Any solicited PIR	32 (37.6)
Local PIR	26 (30.6)
Pain	15 (17.6)
Redness	19 (22.4)
Swelling	15 (17.6)
Systemic PIR	20 (23.5)
Fatigue	16 (18.8)
Headache	10 (11.8)
Myalgia	11 (12.9)
Malaise	9 (10.6)

# Overview of Adverse Events

Adverse Event	HEPLISAV-B N = 70 n (%)
Any Medically Attended Adverse Event (MAE)	37 (52.9)
Related	1 (1.4)
Severe (Grade 3 or 4)	16 (22.9)
Any Serious Adverse Event (SAE)	26 (37.1)
Related SAE	0
Acute Myocardial Infarction (AMI)	1 (1.4)
Immune-mediated Adverse Event of Special Interest (AESI) [potential]	1 (1.4)
Death	5 (7.1)
Related	0

# Immunogenicity by Visit mITT Population



## Conclusions

- HEPLISAV-B regimen of 4 single doses (20mcg HBsAg) over 4 months in hemodialysis patients
  - Well tolerated
  - Induced seroprotection in a high proportion of patients
- This interim analysis of the 4 single-dose regimen of HEPLISAV-B provides important preliminary data to assess whether this regimen could be a potential option for protection against HBV in hemodialysis patients.

## Acknowledgements

### HBV-24 Investigators

Awad	Lynn
Buridi	Ntoso
Calhoun	Raissi
Connaire	Rajan
Dhillon	Reddivari
Durham	Reich
Henderson	Rich
Hernandez	Shah
Kusnir	Tolins
Lakshminarayanan	Vishnepolsky

### Dynavax internal team

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