UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

Current Report

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 18, 2011

Dynavax Technologies Corporation
(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

Delaware	**33-0728374**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**

2929 Seventh Street, Suite 100
Berkeley, CA 94710-2753
(Address of principal executive offices, including zip code)

(510) 848-5100
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On September 18, 2011, Dynavax Technologies Corporation (Dynavax) issued a press release titled “Dynavax Reports Complete Results from the HEPLISAV™ Phase 3 Trial in Healthy Adults Over Age 40” and presented complete results for the entire study population of its Phase 3 trial (HBV-16) at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Chicago, IL. A copy of the press release and the presentation are attached as Exhibit 99.1 and 99.2, respectively, to this current report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibit

Exhibit No.	Description
99.1	Press Release, dated September 18, 2011, titled “Dynavax Reports Complete Results from the HEPLISAV™ Phase 3 Trial in Healthy Adults Over Age 40”
99.2	Dynavax’s Oral Presentation at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DYNAVAX TECHNOLOGIES CORPORATION

Date: September 21, 2011

By: /s/ Michael S. Ostrach
Michael S. Ostrach
Vice President

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated September 18, 2011, titled “Dynavax Reports Complete Results from the HEPLISAV™ Phase 3 Trial in Healthy Adults Over Age 40”
99.2	Dynavax’s Oral Presentation at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)

Exhibit 99.1

2929 Seventh Street, Suite 100
Berkeley, CA 94710

Contact:
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Vice President and Chief Business Officer
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DYNAVAX REPORTS COMPLETE RESULTS FROM THE HEPLISAV™ PHASE 3 TRIAL IN HEALTHY ADULTS OVER AGE 40

Berkeley, CA – September 18, 2011 – Dynavax Technologies Corporation (NASDAQ: DVAX) today at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Chicago, IL presented complete results for the entire study population of its Phase 3 trial (HBV-16). The Phase 3 study, HBV-16, was a multi-center, observer-blinded study to determine if the immunogenicity of two doses of HEPLISAV was non-inferior/superior to three doses of Engerix-B® by comparing seroprotection rates (SPRs) at eight weeks post last dose.

The data reported at ICAAC demonstrate HEPLISAV's ability to generate a faster, higher, and longer-lasting response as compared to Engerix-B, as follows:

- HEPLISAV induced a superior immune response to Engerix-B throughout the study. The SPRs and Geometric Mean Concentrations (GMCs) in the HEPLISAV group were significantly higher than the SPRs and GMCs in the Engerix-B group at every visit from Week 4 through Week 52.
- HEPLISAV provided earlier seroprotection than Engerix-B. At the primary endpoint visit, Week 12 for HEPLISAV and Week 32 for Engerix-B, the SPR in the HEPLISAV group was 90% compared to 71% in the Engerix-B group. In fact, at Week 8, the SPR in the HEPLISAV group was higher (77%) than the peak SPR in the Engerix-B group. The GMC results also showed an earlier response from HEPLISAV; at Week 12, for HEPLISAV, GMCs were 93 mIU/mL compared to Engerix-B at Week 32 when GMCs were 61 mIU/mL.
- HEPLISAV provided higher rates of seroprotection than Engerix-B. The peak SPR for the HEPLISAV group was 95% at Week 24. The peak SPR for Engerix-B was 73% at Week 28. The peak GMC for HEPLISAV was 233 mIU/mL at Week 24, and was 89 mIU/mL for Engerix-B at Week 28.

– more –

- HEPLISAV provided longer-lasting antibody than Engerix-B. The immune response to HEPLISAV was longer-lasting than the immune response to Engerix-B. The SPR in the HEPLISAV group decreased from a peak of 95% at Week 24 to 92% at Week 52 while the SPR in the Engerix-B group decreased from a peak of 73% at Week 28 to 59% at Week 52. The GMC in the HEPLISAV group decreased from a peak of 233 mIU/mL at Week 24 to 151 mIU/mL at Week 52. In contrast, the GMC in the Engerix-B group decreased from a peak of 89 mIU/mL at Week 28 to 20 mIU/mL at Week 52.
- The safety of HEPLISAV was similar to Engerix-B. The rates of local and systemic post-immunization reactions, adverse events, serious adverse events, and autoimmune adverse events were similar in both groups.

According to Tyler Martin, M.D., President and Chief Medical Officer who made the oral presentation in a session entitled “New Trends in Vaccines” (#80), “The data clearly indicate that HEPLISAV induces an immune response that is faster, higher, and more durable than that produced by Engerix-B, with similar safety. These results, demonstrating the superiority of HEPLISAV to Engerix-B in a hyporesponsive population, will be the basis of our BLA filing that we intend to submit by the end of this year.”

Dynavax will present subgroup analyses of the study’s findings at upcoming annual medical meetings, including diabetics at the Infectious Diseases Society of America (IDSA), and other hyporesponsive groups at the American Association for the Study of Liver Diseases (AASLD) later this year.

About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine. In an earlier completed pivotal Phase 3 trial, HEPLISAV demonstrated increased, rapid protection with fewer doses than current licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV and is developing the vaccine for large, high-value populations that are less responsive to current licensed vaccines, including individuals with chronic kidney disease. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist known as ISS to enhance the immune response.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. The Company’s lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide rapid and superior protection with fewer doses than current licensed vaccines. For more information visit www.dynavax.com.

– more –

Forward-Looking Statements

This press release contains “forward-looking statements,” that are subject to a number of risks and uncertainties, including statements regarding the timing of the BLA submission. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including whether successful clinical and regulatory development and approval of HEPLISAV and our process for its manufacture can occur in a timely manner or without significant additional studies or difficulties or delays in development or clinical trial enrollment, whether our studies can support registration for commercialization of HEPLISAV; the results of clinical trials and the impact of those results on the initiation and completion of subsequent trials and issues arising in the regulatory process, including the outcome of pre-filing discussions with regulatory authorities; the Company’s ability to obtain additional financing to support the development and commercialization of HEPLISAV and its other operations, possible claims against the Company based on the patent rights of others; and other risks detailed in the “Risk Factors” section of our current periodic reports with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. Information on Dynavax’s website at www.dynavax.com is not incorporated by reference in the Company’s current periodic reports with the SEC.

# # #

Exhibit 99.2

An Observer-Blinded, Randomized, Parallel-Group, Multi-Center Study Comparing the Safety and Immunogenicity of HEPLISAV to Licensed Vaccine (Engerix-B®) among Healthy Subjects 40 to 70 Years of Age

Sunday, September 18, 2011

ICAAC

Chicago, IL

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Background: HBV in older adults

- HBV Vaccination for adults is recommended for persons at increased risk of infection
- Current HBV vaccines are less immunogenic in healthy adults age 40+ (Averhoff, AJPrevMed, 1998)
- There has been no decrease in the rate of HBV infection in adults age 40-59 in the US from 1988-2008 (McQuillan, NCHS Data Brief, 2010)
- >40% of reported acute HBV infections in the US occur in adults age 40+ (MMWR, 2009)
- >50% of reported acute HBV infections in Germany occur in adults age 40+ (RKI, 2011)

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Introduction: HBV Vaccine

Current licensed Hepatitis B virus (HBV) vaccine

- Contains 20 µg HBsAg adjuvanted with aluminum hydroxide
- Administered in 3 doses on a 0,1, 6 month schedule

HBsAg+ISS (HEPLISAV)

- Contains a new class of adjuvant (1018 ISS)
  - Toll-like Receptor 9 (TLR9) agonist
- 20 µg HBsAg mixed with 3000 µg 1018 ISS
- Administered in 2 doses on 0,1 month schedule

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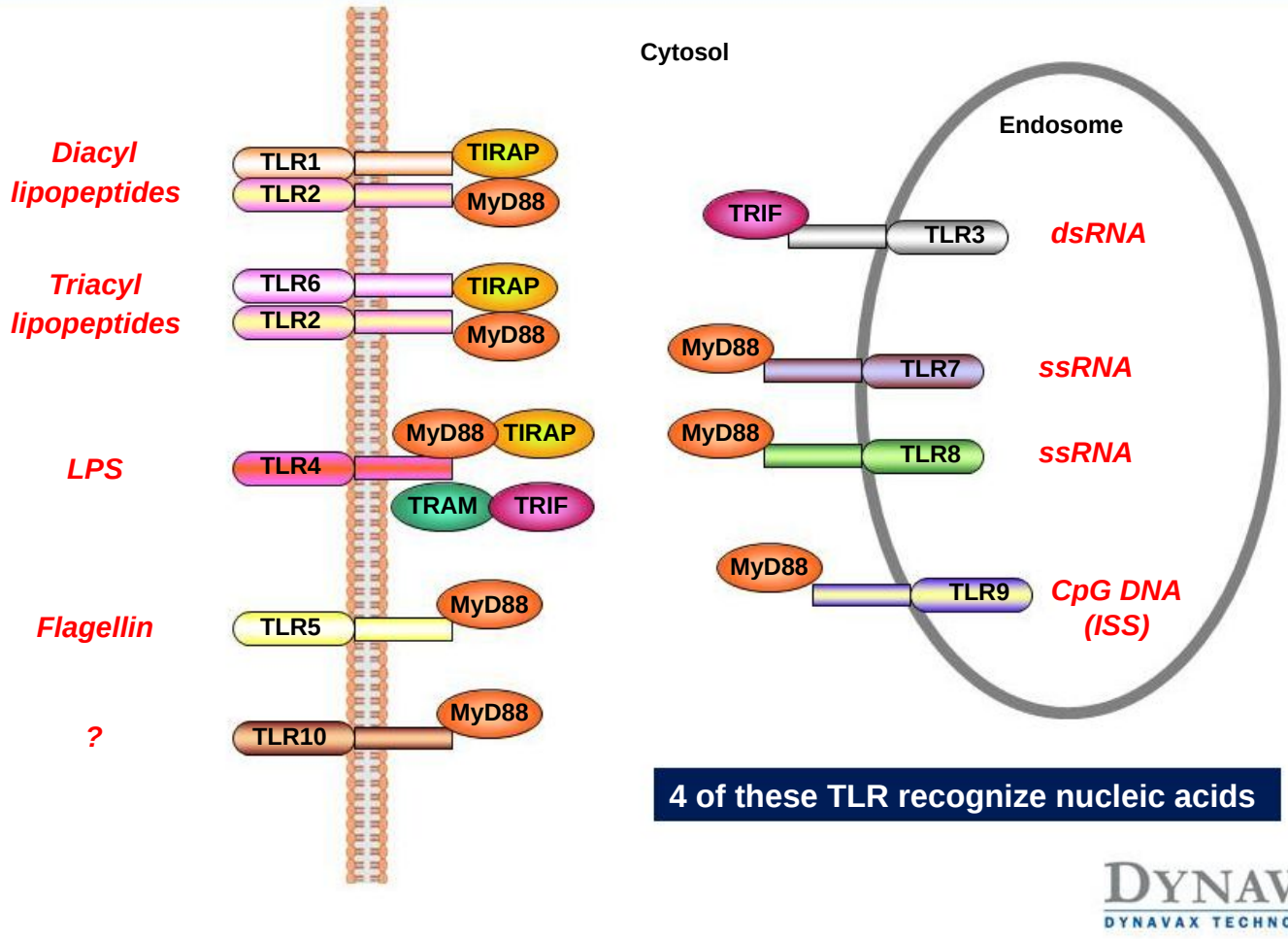
TLR Overview



4 of these TLR recognize nucleic acids

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HBV-16: Study Design

- Healthy adults, 40 to 70 years of age
- Two doses of HEPLISAV (0, 4 weeks) + 1 dose placebo (24 weeks) compared to 3 doses of Engerix-B (0, 4, 24 weeks)
- Immunogenicity assessed by Ortho Vitros ECi assay
- Seroprotection defined as anti-HBsAg $\geq$ 10 miU/ml
- Randomization – HEPLISAV to Engerix-B 4:1
- Randomization stratified by age, by site (ages 40 to 49 years, 50 to 59 years, 60 years and over)
- SEAC and DSMB oversight
- 3793 screened, 2452 randomized, 2449 treated, 2269 completed all visits

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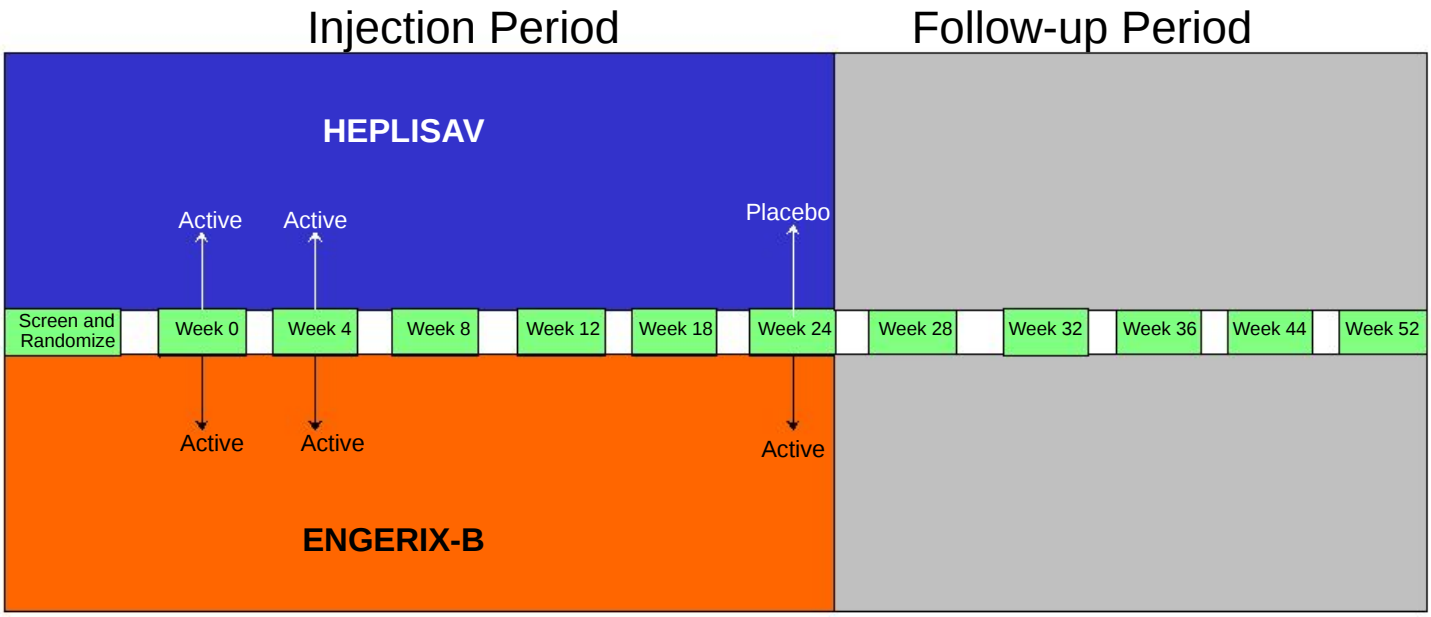
HBV-16: Visit Schedule



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HBV-16: Objectives - Immunogenicity

Primary
Demonstrate non-inferiority to Engerix-B at 8 weeks after the last injection
(week 12 for HEPLISAV *vs.* week 32 for Engerix-B)

Non-inferiority (week 12 HEPLISAV *vs.* week 32 Engerix-B)
HEPLISAV will be considered non-inferior to Engerix-B if the lower limit of the 95% confidence interval of the difference in seroprotection rates (SPR) (HEPLISAV SPR for the 3 new lots combined minus the Engerix-B SPR) is greater than -10%.

Superiority (week 12 HEPLISAV *vs.* week 32 Engerix-B)
If HEPLISAV is found to be non-inferior, then and only then will it be declared to be superior if the lower limit of this 95% confidence interval is greater than zero

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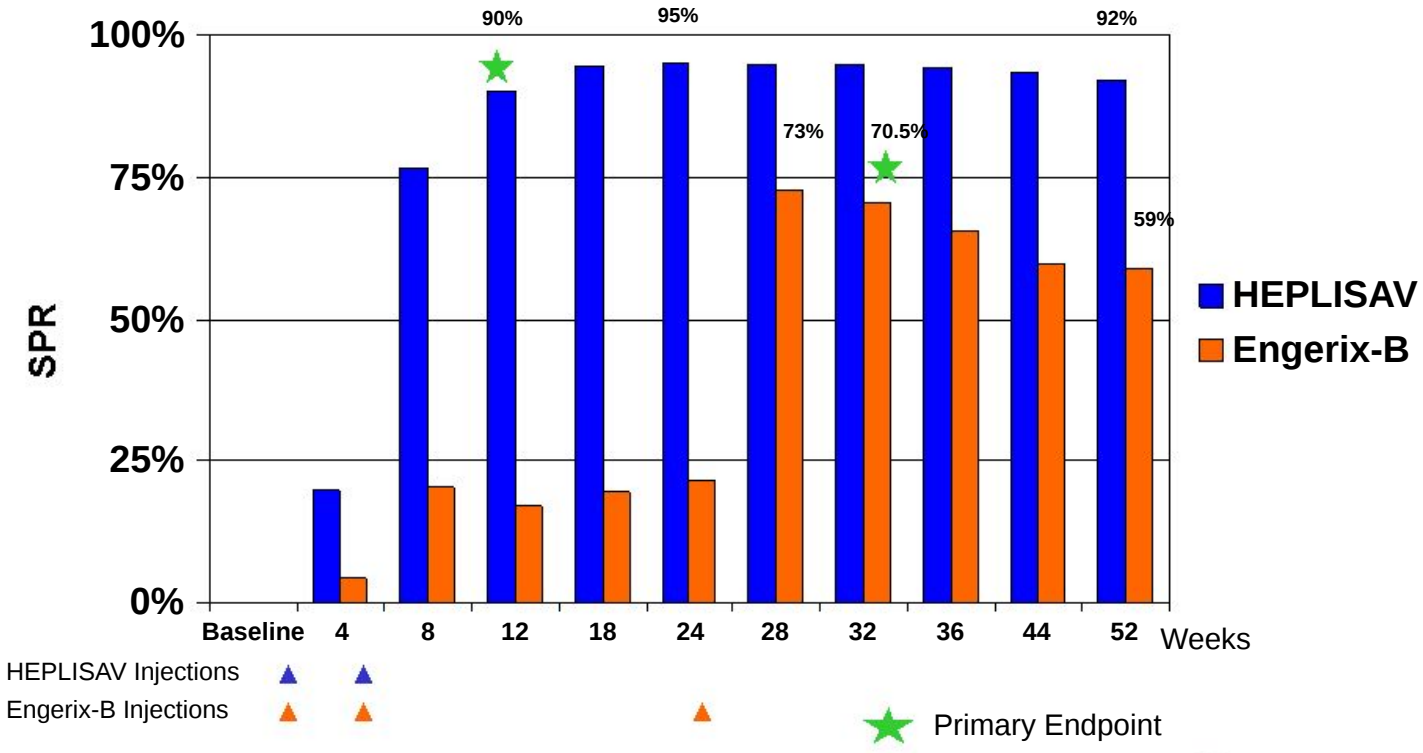
HBV-16: Seroprotection Rates (Primary Endpoint)

% Difference in SPR at 8 weeks after last active dose: 19.6% (95% CI 14.7%, 24.7%)
(N=1123 for HEPLISAV, 359 for Engerix-B)



Non-inferiority Per-Protocol Population

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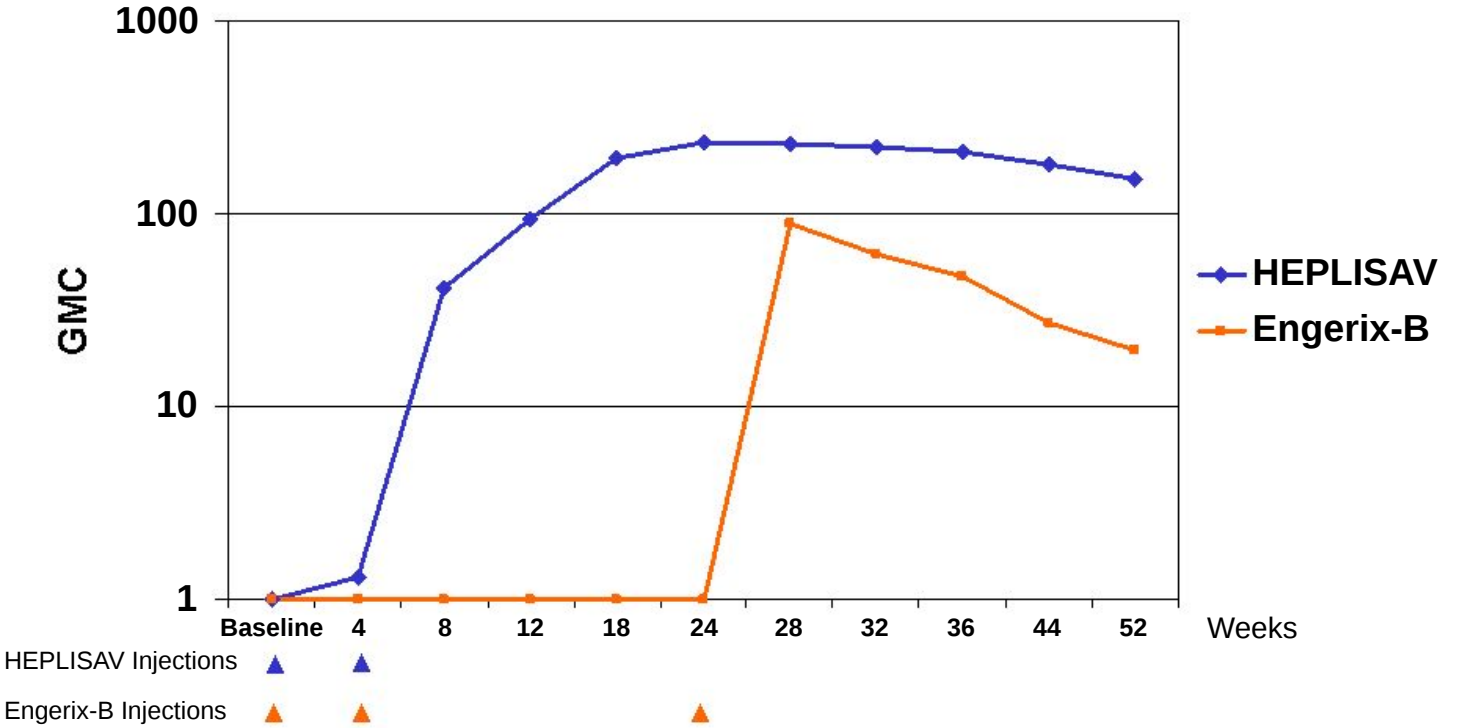
HBV-16: Anti-HBsAg Geometric Mean Concentration



Non-inferiority Per-Protocol Population

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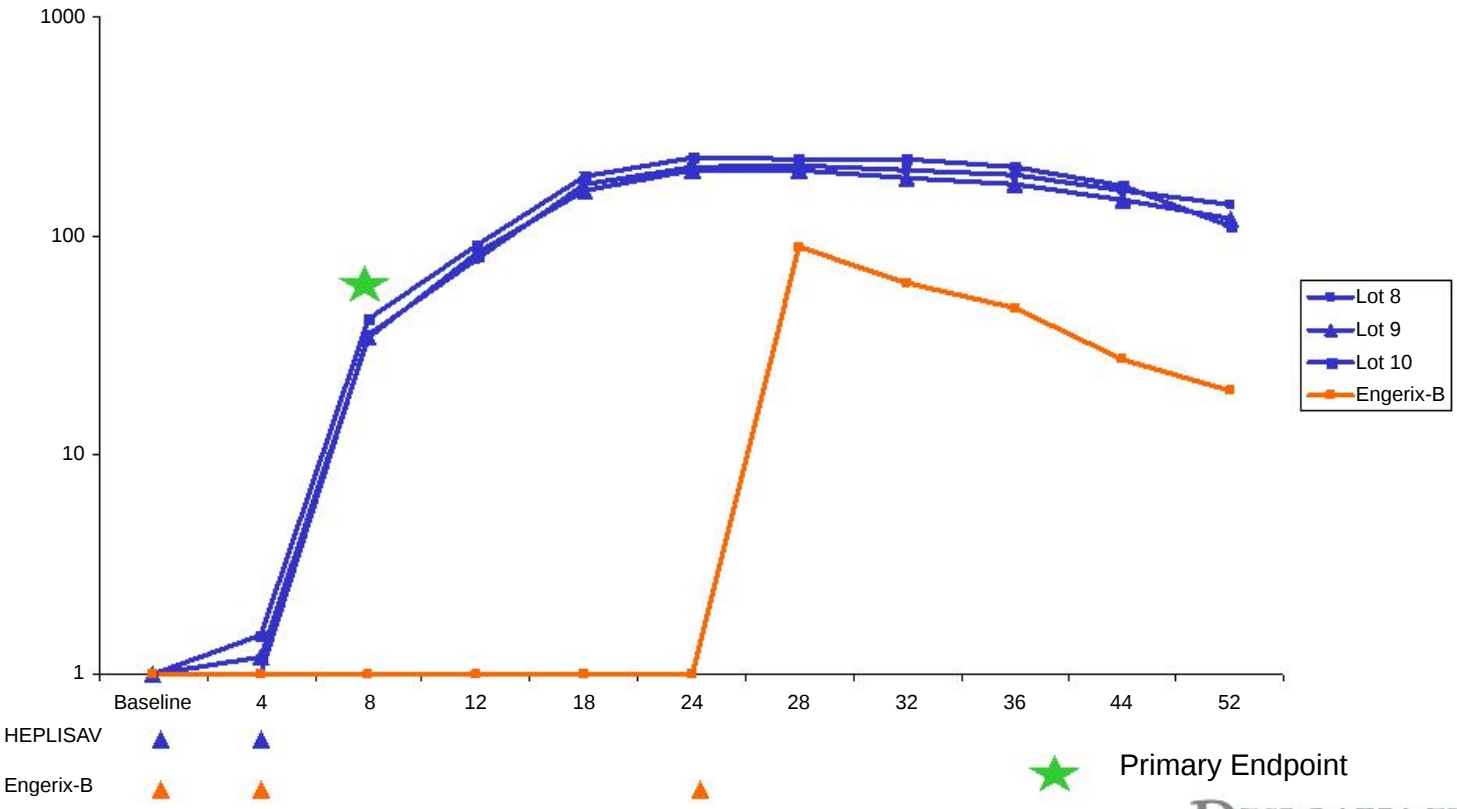
HBV-16 Anti-HBsAg Geometric Mean Concentration:
HEPLISAV Lot Consistency (Primary Endpoint)

(N= 428 for Lot 8; 438 for Lot 9; 424 for Lot 10)



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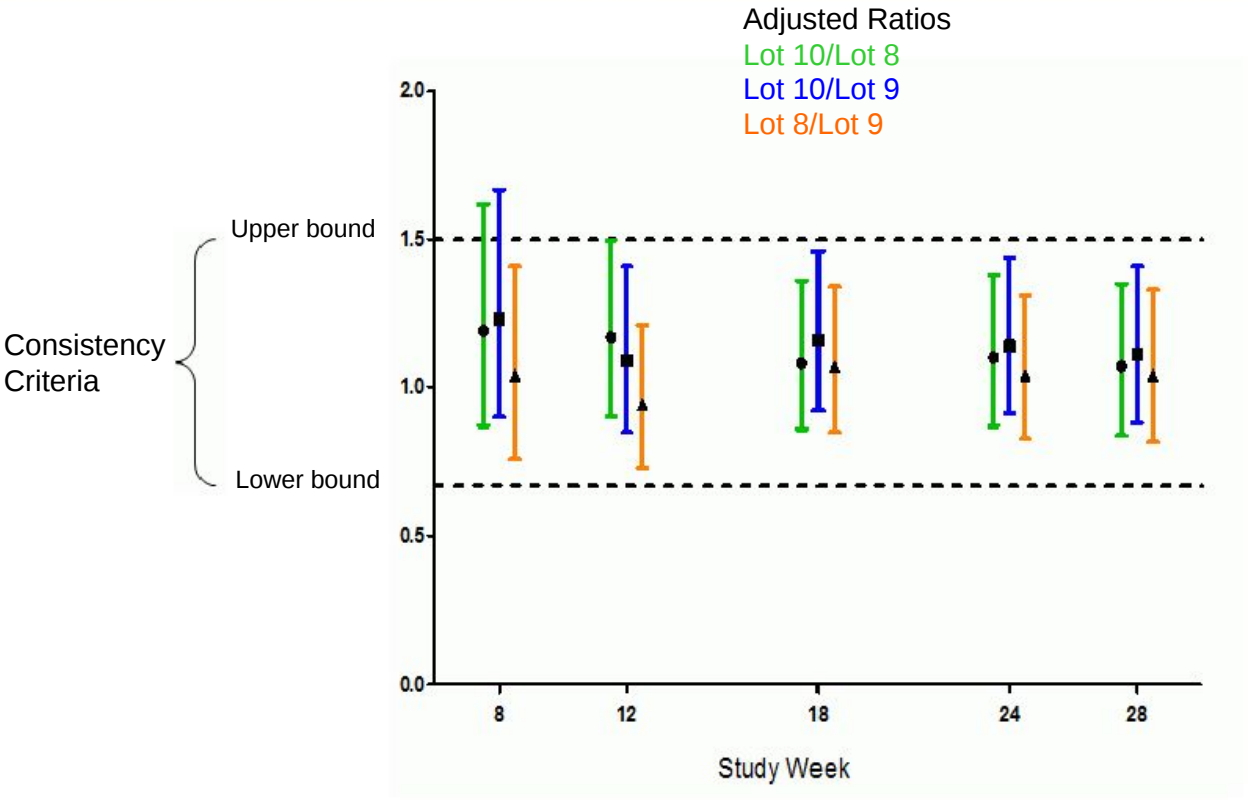
HBV-16: Ratio of GMCs for Lot Consistency



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HBV-16: Results - Safety

Post Injection Reactions

- Incidence similar in HEPLISAV (51.0%) *vs.* Engerix (49.4%)
- Severe reactions were uncommon and slightly lower in HEPLISAV (2.8% *vs.* 4.2%)
- Pain was more frequent in HEPLISAV (34.8% *vs.* 31.8%)
- Systemic post immunization reactions were less frequent in HEPLISAV (33.4% vs. 34.7%)
- Incidence decreased with subsequent injections

AEs

- Subjects experiencing at least 1 AE; HEPLISAV (50.5%) *vs.* Engerix-B (53.0%) - most common was nasopharyngitis (4.0% *vs.* 5.2%)
- Most AEs were mild to moderate in intensity – severe AEs (4.5% *vs.* 5.4%)
- AEs considered by PI to be treatment related (7.2% *vs.* 6.0%) – most common was injection site erythema (1.5% *vs.* 0.8%)

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HBV-16: Results - Safety

SAEs

- 123 SAEs reported in 99 subjects – 3.4% of subjects in HEPLISAV *vs.* 4.8% in Engerix-B
- Most common was in SOC of Musculoskeletal and Connective Tissue (1.1% HEPLISAV *vs.* 1.0% Engerix-B)
- 1 SAE was considered by PI to be treatment related – bronchial hyper-reactivity after 3rd injection (Engerix-B)
- 2 deaths – pulmonary embolism (HEPLISAV) and myocardial infarction (Engerix-B)

AIAEs

- 3 new onset autoimmune adverse events occurred during the trial
  - 2 cases of hypothyroidism and 1 case of vitiligo
  - all were in the HEPLISAV group (3/1968 vs 0/481, P=1.00)

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HBV-16: Conclusions

In healthy adults aged 40 to 70 years:

- HEPLISAV provided superior peak seroprotection with fewer doses than Engerix-B
- HEPLISAV provided earlier seroprotection compared to Engerix-B
- HEPLISAV provided superior duration of seroprotection with fewer doses than Engerix-B
- The clinical consistency of HEPLISAV was demonstrated
- The safety profile of HEPLISAV was similar to Engerix-B

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The HBV-16 Study Team

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