

## **Dynavax Presents New Efficacy Data on Hepatitis B Vaccine, HEPLISAV-B(TM), in Adults With Type 2 Diabetes at ADA Scientific Sessions**

### **Pivotal Phase 3 Data Show Investigational Two-Dose Hepatitis B Vaccine Provides a Significantly Higher Rate of Seroprotection Than an Approved Vaccine in Patients With Type 2 Diabetes**

BERKELEY, CA -- (Marketwired) -- 06/11/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced preliminary results from a pivotal Phase 3 trial demonstrating that HEPLISAV-B [Hepatitis B Vaccine, Recombinant (Adjuvanted)] provided a significantly higher rate of seroprotection than Engerix-B®, an approved hepatitis B vaccine, in adults with type 2 diabetes mellitus. The data are being presented at the 76th Annual Scientific Sessions of the American Diabetes Association (ADA) in New Orleans.

Adults with diabetes are particularly vulnerable to infection with hepatitis B. According to the Centers for Disease Control and Prevention (CDC), people ages 23 to 59 with diabetes are about twice as likely to develop acute hepatitis B as individuals without diabetes. The CDC recommends that all adults age 19 to 59 should be vaccinated against hepatitis B as soon as possible after their diagnosis of diabetes, and those who are age 60 and older may be vaccinated at their physician's discretion after assessing their risk and the likelihood of an adequate immune response. Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.

The Phase 3 trial, HBV-23, was a randomized, observer-blinded, active-controlled, multi-center study that compared two doses of HEPLISAV-B with three doses of Engerix-B in adults age 18 to 70. Among the over 8,000 randomized participants, there were 1,144 adults with type 2 diabetes of whom two-thirds had diabetes for five years or more. Demographics consisting of age, sex and race were generally similar between the two treatment arms.

Results showed that HEPLISAV-B provided seroprotection in 90.0 percent of participants with diabetes compared with 65.1 percent for Engerix-B - a statistically significant difference of 24.9 percent. Larger differences were observed in participants age 60 to 70, with HEPLISAV-B demonstrating an 85.8 percent rate of seroprotection compared with 58.5 percent for Engerix-B. For participants with a body mass index greater than or equal to 30, HEPLISAV-B demonstrated an 89.5 percent rate of seroprotection compared to 61.4 percent for Engerix-B.

In the total trial population, the rates of adverse events, serious adverse events and deaths were similar between the HEPLISAV-B and Engerix-B groups. All adverse events considered to represent potential immune-mediated disorders were reviewed by an independent, blinded Safety Evaluation and Adjudication Committee, which classified these events as not related to vaccination.

"The hepatitis B virus can spread easily through contact with contaminated medical equipment, such as blood glucose monitors, posing a serious health risk to people living with diabetes," said Rob Janssen, M.D., chief medical officer for Dynavax. "Results of this study show that, with two doses over one month, HEPLISAV-B provided a significantly higher rate of seroprotection in participants with type 2 diabetes than an existing hepatitis B vaccine."

The U.S. Food and Drug Administration has established December 15, 2016, as the Prescription Drug User Fee Act (PDUFA) action date for the HEPLISAV-B Biologics License Application.

#### **About Hepatitis B**

Hepatitis B is a viral disease of the liver that can become chronic and can lead to cirrhosis of the liver, hepatocellular carcinoma and death. In the U.S., the CDC estimates that approximately 20,000 hepatitis B infections continue to occur annually, with the vast majority occurring in adults. There is no cure for hepatitis B, and disease prevention through effective vaccination is critical to reducing the spread of the disease. Currently marketed hepatitis B vaccines are administered in three doses over a six-month schedule. Results of a published Vaccine Safety Datalink study showed that only 54 percent of adults completed the three-dose hepatitis B vaccine series in one year. Those who do not complete the series may not be adequately protected against hepatitis B.

#### **About HEPLISAV-B**

HEPLISAV-B is an investigational adult hepatitis B vaccine that combines hepatitis B surface antigen with a proprietary Toll-

like Receptor 9 agonist to enhance the immune response. In Phase 3 trials, HEPLISAV-B demonstrated higher and earlier protection with fewer doses than Engerix-B, a currently licensed hepatitis B vaccine. HEPLISAV-B was administered in two doses over one month.

The investigational vaccine's safety profile is based on clinical trials that generated safety data from more than 14,000 participants. The most frequently reported local reaction was injection site pain. The most common systemic reactions were fatigue, headache and malaise, all of which were similar to Engerix-B.

Dynavax has worldwide commercial rights to HEPLISAV-B.

### ***About Dynavax***

Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious diseases and oncology. Dynavax's lead product candidates are HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine, and SD-101, an investigational cancer immunotherapeutic currently in several Phase 1/2 studies. For more information, visit [www.dynavax.com](http://www.dynavax.com).

### ***Forward-Looking Statements***

This press release contains forward-looking statements, including statements regarding HEPLISAV-B and FDA review. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether there will be changes in the data or interpretation; whether the final study results will be deemed satisfactory by the FDA; whether additional studies or manufacturing process enhancements will be required or other issues will arise that will delay the BLA review or negatively impact the review and approval by the FDA; initiation, enrollment and completion of pre-clinical studies and clinical trials of our other product candidates, including SD-101; the results of clinical trials and the impact of those results on the initiation or continuation of subsequent trials and issues arising in the regulatory process; and other risks detailed in the "Risk Factors" section of our most recent current periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this press release. We do not undertake any obligation to update publicly any such forward-looking statements, even if new information becomes available. Information on Dynavax's website at [www.dynavax.com](http://www.dynavax.com) is not incorporated by reference in our current periodic reports with the SEC.

#### Media Contact:

Katie Hogan  
WCG  
415.658.9745  
[Email contact](#)

#### Investor Contact:

Michael Ostrach  
Chief Financial Officer  
Dynavax  
510.665.7257  
[Email contact](#)

Source: Dynavax Technologies

News Provided by Acquire Media