

## **Data From Two Phase 3 Studies Demonstrate HEPLISAV's Superiority in Immunizing Persons With Diabetes From Hepatitis B**

### **New National Recommendations Announced Today Urge Vaccinations for Unvaccinated Adults With Diabetes Under 60 Years of Age**

BERKELEY, CA -- (MARKET WIRE) -- 10/25/11 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today highlighted data from two phase 3 studies of its investigational vaccine HEPLISAV™, one of which was the first clinical trial to prospectively evaluate the effectiveness of vaccinations with recombinant hepatitis B vaccines in patients diagnosed with diabetes. The data for both studies demonstrated that HEPLISAV provides faster, more robust and convenient, and longer-lasting immunity in persons with diabetes than a currently available vaccine, Engerix-B®. An analysis of pooled data from these studies will be presented at Dynavax's analyst and investor day this Thursday, October 27, 2011 in New York City.

Also today, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend that hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are less than 60 years of age. This change significantly expands the number of persons for whom vaccination is recommended. Since 1991, infants in the U.S. have been recommended to be routinely vaccinated for hepatitis B.

At the annual meeting of the Infectious Disease Society of America (IDSA) in Boston last Friday, October 21, 2011, Dynavax reported the diabetic subset data from a modified intent to treat (MITT) analysis of the HEPLISAV Phase 3 trial in adults over age 40. These results represent an evaluation of the first prospectively defined diabetic population and demonstrate the superiority of HEPLISAV vs. Engerix-B.

Of the 218 subjects with diabetes in the MITT population (179 HEPLISAV; 39 Engerix-B), the seroprotection rates (SPRs) for HEPLISAV were superior to Engerix-B at Weeks 8 through 52.

- At the pre-specified primary comparison time points of Week 12 for HEPLISAV and Week 32 for Engerix-B, the SPR was 79% in the HEPLISAV group and 61% in the Engerix-B group.
- At Week 12, the SPR was 79% in the HEPLISAV group and 11% in the Engerix-B group.
- At Week 52, the SPR was 82% in the HEPLISAV group and 54% in the Engerix-B group.

Last year, in a late-breaker oral presentation on October 23, 2010 at the IDSA annual meeting in Vancouver, British Columbia, Dynavax also reported data showing superior seroprotection of HEPLISAV in persons with diabetes compared to Engerix-B. These data reflected a post hoc subset analysis of 62 adults with diabetes in Dynavax's previously reported Phase 3 multicenter PHAST study, as follows:

- At 12 weeks, 84 percent of adult with diabetes who received HEPLISAV achieved seroprotection as compared to 0 percent of adult diabetics who received Engerix-B.
- At Week 28, 93% of subjects in the HEPLISAV group versus 35% in the Engerix-B group achieved seroprotection.

Dynavax President and Chief Medical Officer, Tyler Martin, M.D., said, "There is a significant unmet medical need in hepatitis B vaccination. Given today's ACIP recommendation, we believe HEPLISAV will, if approved, play an important role in meeting the needs of these patients. In addition, Dynavax has demonstrated similar advantages in other hard-to-immunize populations, including males, smokers and obese subjects."

Today's vote to recommend hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are less than 60 years of age reflects the ACIP conclusion after a multi-year analysis on the need for preventing hepatitis B infection in diabetics. According to the CDC, there are at least 18 million people diagnosed with diabetes in the United States with an incidence of 2 million new diagnoses annually. New diagnosis of diabetes in adults is made at a mean age of 53 years with two-thirds of new diagnoses being in persons 40-64 years of age.

The ACIP is an advisory body to the CDC that provides advice and guidance regarding control of vaccine-preventable diseases in the United States civilian population. This recommendation to vaccinate adults with diabetes against hepatitis B infection amends the previous categories of adults recommended to receive hepatitis B vaccination published in December

2006 (MMWR, Vol. 55, RR-16).

#### *About HEPLISAV*

HEPLISAV is an investigational adult hepatitis B vaccine. In earlier Phase 3 trials, 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](http://www.dynavax.com).

#### *Forward-Looking Statements*

This press release contains "forward-looking statements," including the potential role of HEPLISAV, diabetes diagnoses forecasts and our plans to present at an Analyst and Investor Day, that are subject to a number of risks and uncertainties. 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 the recommendations will be approved by the Director of CDC and the Department of Health and Human Services, 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](http://www.dynavax.com) is not incorporated by reference in the Company's current periodic reports with the SEC.

Enerix-B® is a registered trademark of GlaxoSmithKline

Contact :

Michael Ostrach

Vice President and Chief Business Officer

510-665-7257

Email Contact

Source: Dynavax Technologies

News Provided by Acquire Media