

## **Dynavax Reports Positive Findings From Detailed Safety Analysis of HEPLISAV(TM)**

### **Comparable Safety Profile to Approved Commercial Vaccine; No Evidence for Increased Risk of Autoimmunity**

BERKELEY, CA, Mar 23, 2010 (MARKETWIRE via COMTEX News Network) -- Dynavax Technologies Corporation (NASDAQ: DVAX) will present for the first time a detailed analysis of safety data for HEPLISAV(TM), an investigational adult hepatitis B vaccine, including two major findings:

- The safety profile of HEPLISAV was comparable to that of Engerix-B(R), one of two currently licensed vaccines for the prevention of hepatitis B infection, and
- There is no difference in autoimmune adverse events or laboratory markers of autoimmunity between subjects vaccinated with HEPLISAV and Engerix-B.

The results of nine completed clinical studies comparing HEPLISAV to Engerix-B and an analysis of approximately 9,300 blood samples from subjects vaccinated with HEPLISAV or Engerix-B will be presented at the Drug Information Association's (DIA) Third Oligonucleotides-based Therapeutics Conference in Bethesda, MD on March 24, 2010. The safety data was originally prepared for submission to the FDA as part of extensive documentation that formed the basis upon which HEPLISAV's clinical development was allowed to resume in late 2009.

These data show that there was no difference between the HEPLISAV and Engerix-B groups in the occurrence of autoimmune adverse events (AEs), with 7 autoimmune AEs in 2,500 subjects immunized with HEPLISAV, a rate of 0.28%, versus 4 autoimmune AEs in 930 subjects immunized with Engerix-B, a rate of 0.43%. In addition, all other analyses presented, including AEs potentially associated with autoimmunity, anti-double stranded DNA antibodies, and ANCA antibodies, were indistinguishable between the two groups.

"Our retrospective analysis of clinical and laboratory safety from 2,500 HEPLISAV-vaccinated subjects in nine clinical trials provided no evidence of an increased risk of autoimmune disease. This thorough analysis has been discussed with the FDA and demonstrates that the safety profile of HEPLISAV is no different from that of Engerix-B, one of the safest vaccines on the market today," indicated Dr. Tyler Martin, Chief Medical Officer.

Engerix-B(R) is a trademark of GlaxoSmithKline.

#### **Review of Previously Reported Phase 3 HEPLISAV Data**

Dr. Martin also reviewed several earlier clinical studies that compared HEPLISAV to Engerix-B, and provided evidence of HEPLISAV's enhanced performance:

- The 2004 Phase 3 study of 412 subjects age 40-70 years old found:
  - 99% seroprotection for HEPLISAV vs. 25% for Engerix-B after the second dose;
  - Durable antibody levels that remained one year after the first dose; and
  - Greater protection in the oldest subjects studied, specifically between 56-70 years of age.
- The 2008 Phase 3 "PHAST" study of more than 2,400 subjects at 21 sites in Canada and Germany showed:
  - 98% of subjects who received two doses of HEPLISAV (n=1,819) developed protective antibodies to hepatitis B, vs. 81% of subjects who received three doses of Engerix-B (n=608);
  - The non-inferiority of HEPLISAV as compared to Engerix-B; and

- A significant difference in terms of efficacy (97% vs. 75% in less responsive populations, namely in the subject group age 40-55 years old).
  
- The 2007 Phase 1 study in 75 Chronic Kidney Disease patients showed:
  - Rapid, increased protection against hepatitis B viral infection with fewer doses (96% of patients receiving 3 doses of HEPLISAV achieved seroprotection at month 7, compared to 88% of patients receiving 8 doses of Engerix-B);
  - A rapid response of 83% vs. 44% seroprotection two months after the second dose;
  - High and durable antibody levels and seroprotection; and
  - Improved seroprotection in an immunocompromised population.

## About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine. The vaccine candidate is being evaluated in two Phase 3 studies that are directed toward fulfilling licensure requirements in the U.S., Canada and Europe. In a 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 Hepatitis B Vaccines

Currently available hepatitis B vaccines require three doses over six months to achieve full immunogenicity in healthy patient populations. Because compliance with this vaccine regimen is low, new vaccines are needed to provide increased protection in a shorter timeframe. Furthermore, currently available vaccines do not fully address the needs of several patient populations, including those with chronic kidney disease, HIV or chronic liver disease. In particular, patients with comprised immune systems require both rapid and enhanced protection, either because they are less responsive to conventional vaccine regimens or because they are at high risk of infection.

## About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases. The Company's lead product candidate is HEPLISAV, an investigational adult hepatitis B vaccine designed to enhance protection more rapidly and 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," 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 comparability data presented in the retrospective analyses will be replicated in other clinical studies, successful clinical and regulatory development and approval of HEPLISAV can occur in a timely manner or without significant additional studies or difficulties or delays in development or clinical trial enrollment, whether the 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; 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.

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