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Dynavax Presents Data Showing That HEPLISAV-B Provides Significantly Higher Seroprotection Rates Against Hepatitis B Infection in Populations Known to Have a Reduced Immune Response to Currently Licensed Vaccines

Analysis of Sub-Group Data from Pivotal Phase 3 Study Presented at IDWeek 2016

BERKELEY, CA -- (Marketwired) -- 10/26/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced sub-group results from HBV-23, the pivotal Phase 3 trial of its investigational hepatitis B vaccine HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)]. The new subgroup analysis demonstrated that HEPLISAV-B, when administered as two doses over one month, induced significantly higher seroprotection rates than the approved hepatitis B vaccine Engerix-B®, when administered as three doses over six months. This result was observed in all prespecified groups of study participants, including those with characteristics that are known to have a reduced immune response to currently licensed hepatitis B vaccines. These characteristics include older age, high body mass index (BMI), diabetes mellitus, male gender and persons who smoke. The data were presented today in the "Vaccines: New and Novel" Poster Abstract Session at the Infectious Diseases Society of America's (IDSA) annual IDWeek 2016 meeting in New Orleans.

"Hepatitis B remains an important health problem in the United States with approximately 20,000 new infections in adults every year. Although hepatitis B vaccines have been available for 25 years and served an important role in preventing the disease, approved hepatitis B vaccines have several limitations, including lower protection rates in some populations," said Rob Janssen, M.D., chief medical officer for Dynavax. "We were encouraged to see that HEPLISAV-B administered as two doses over one month provided a significantly higher rate of seroprotection in these individuals than the existing hepatitis B vaccine. The lower immunogenicity observed in sub-groups in the Engerix-B arm of this Phase 3 study demonstrates the critical need for a hepatitis B vaccine that can provide higher rates of seroprotection with fewer doses to adequately protect adults against the consequences of this chronic viral infection."

Results of New Analysis of Phase 3 Study (Poster #754)
The pivotal Phase 3 trial, HBV-23, was a randomized, observer-blinded, active-controlled, multi-center study that compared two doses of HEPLISAV-B over four weeks with three doses of Engerix-B over 24 weeks in 8,374 adults age 18 to 70. Demographics consisting of age, sex and race were generally similar between the two treatment arms. Overall study results showing a significantly higher seroprotection rate with HEPLISAV-B versus Engerix-B (95.4 percent at week 24 vs. 81.3 percent at week 28, respectively) and comparable safety were previously reported.

The new analysis presented at IDWeek 2016 compared seroprotection rates for HEPLISAV-B with Engerix-B in subgroups of study participants by age, sex, BMI, diabetes mellitus status and smoking status. Results showed that HEPLISAV-B provided significantly higher seroprotection than Engerix-B for these subgroups of participants at increased risk of inadequate seroprotection. The largest differences were observed in study participants who were older, had diabetes, high BMI, or who smoked:

- ***Diabetes*** -- HEPLISAV-B provided seroprotection in 90.0 percent of participants compared with 65.1 percent for Engerix-B -- a statistically significant difference of 24.9 percent.
- ***Body mass index greater than or equal to 30*** -- The seroprotection rate with HEPLISAV-B was 94.7 percent compared with 75.4 percent for Engerix-B -- a statistically significant difference of 19.4 percent.
- ***Age 60 to 70*** -- HEPLISAV-B provided a 91.6 percent rate of seroprotection compared with 72.6 percent for Engerix-B -- a statistically significant difference of 19.0 percent.
- ***Smokers*** -- The seroprotection rate with HEPLISAV-B was 95.9 percent compared with 78.6 percent for Engerix-B -- a statistically significant difference of 17.3 percent.

In the total Phase 3 trial population, the rates of adverse events, serious adverse events and deaths were similar between the HEPLISAV-B and Engerix-B groups. The most common local adverse event was injection site pain and the most common systemic adverse events were fatigue, headache and malaise. All adverse events considered to represent potential immune-mediated disorders were reviewed by an independent, blinded Safety Evaluation and Adjudication Committee (SEAC). The SEAC classified all potential immune-mediated disorders as unrelated to vaccination.

The Biologics License Application for HEPLISAV-B is currently being reviewed by the U.S. Food and Drug Administration, which has established a Prescription Drug User Fee Act (PDUFA) action date of December 15, 2016.

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 United States, the CDC estimates that approximately 20,000 hepatitis B infections continue to occur annually,(i) 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 54 percent of adults completed the currently available 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. HEPLISAV-B is administered in two doses over one month.

In Phase 3 trials, HEPLISAV-B demonstrated higher and earlier protection with fewer doses than a currently licensed hepatitis B vaccine. 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 an existing vaccine.

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.

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding the status of the HEPLISAV-B BLA currently under 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 that impact the timing of and potential for approval of HEPLISAV-B and whether a determination by the FDA will occur by the scheduled PDUFA date; resolvable issues with respect to questions involving the data or interpretation of the data submitted in support of the BLA; whether the final study results will be deemed satisfactory by the FDA; whether there will be an Advisory Committee meeting and if so whether it will impact the timing of FDA review or negatively impact the review and approval of the BLA; 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; if approvable, whether the issues will negatively impact the potential scope of the label for HEPLISAV-B; 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 is not incorporated by reference in our current periodic reports with the SEC.

(i) Schillie S, Murphy TV, Sawyer M, Ly K, Hughes E, et al. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. MMWR. Recommendations and reports. Centers for Disease Control. 2013;62(RR-10):1-19.

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