

Dynavax Reports Final Phase 3 Data for HEPLISAV(TM) in CKD Patients and New Data From Booster Trial in Hemodialysis Patients

BERKELEY, CA -- (Marketwire) -- 03/27/12 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced final data from a pivotal Phase 3 trial in patients with chronic kidney disease (CKD) demonstrating early seroprotection and the durability of the immune response to HEPLISAV compared to Engerix-B®. In October 2011, Dynavax reported that the superiority endpoint had been met in this trial. The trial included 516 patients 18-75 years of age with CKD (stage 3b or higher) in the U.S., Canada and Germany who received 3 doses of HEPLISAV at 0, 1 and 6 months or 4 double doses of Engerix-B at 0, 1, 2 and 6 months (8 doses total).

Analysis of the final data demonstrated that:

- HEPLISAV provided seroprotection to 90% of patients compared to 82% for Engerix-B (P=0.01) at the primary endpoint (7 months), 1 month after the 3rd dose of HEPLISAV and the 8th dose of Engerix-B. This result demonstrated the previously reported superiority of HEPLISAV seroprotection over Engerix-B.
- HEPLISAV provided seroprotection to more than twice as many patients (HEPLISAV: 48%; Engerix-B: 20%) at 2 months, 1 month after the 2nd dose of HEPLISAV and the 4th dose of Engerix-B. This result confirmed the earlier seroprotection of HEPLISAV in this population.
- The geometric mean concentration (GMC) of antibody, which is commonly used to predict the duration of protection in patients with CKD, was approximately four-fold higher in the HEPLISAV group compared to the Engerix-B group. At Week 28, the GMC for HEPLISAV was 448 mIU/mL compared to the Engerix-B GMC of 109 mIU/mL. At one year, six months after completing the 3-dose regimen of HEPLISAV, the GMC was 121 mIU/mL compared to a GMC of 38 mIU/mL six months after completing the 8-dose regimen of Engerix-B.

In a separate trial, in CKD non-responder patients on hemodialysis who had failed to develop seroprotection after two or more previous vaccination series with the licensed vaccines, new data showed a higher seroprotection rate for HEPLISAV compared to each of Fendrix® and Engerix-B.

HEPLISAV is a trademark of Dynavax, and Fendrix® and Engerix-B® are registered trademarks of GlaxoSmithKline.

In this study of 119 patients in Germany, the immune responses were compared 4 weeks after a single booster dose of HEPLISAV or Fendrix or two booster doses of Engerix-B. Data from this booster study showed that HEPLISAV provided seroprotection to 44% of patients (17/39) compared to 31% (13/42) for Fendrix and 21% (8/38) for Engerix-B. Dynavax President and Chief Medical Officer, Tyler Martin, M.D., said, "These results add to the growing body of evidence of HEPLISAV's advantages. Patients with CKD are difficult to protect with current HBV vaccines, requiring 8 doses of Engerix rather than 3 doses for healthy adults. The pivotal CKD trial demonstrated the same profile as our healthy adult trials: earlier onset of seroprotection, higher peak seroprotection and improved duration. In addition, the results from the booster trial suggest HEPLISAV should be the preferred vaccine in this very difficult to protect population, which represents a substantial proportion of patients on hemodialysis."

Dynavax plans to submit a U.S. Biologics License Application (BLA) for HEPLISAV by the middle of May for an indication in healthy adults 18-70 years of age for a 2-dose vaccination regimen at 0 and 1 month. A supplemental BLA with an indication and 3-dose primary vaccination regimen for patients with CKD will be filed when the initial BLA is approved.

The Advisory Committee on Immunization Practices (ACIP) and other public health authorities recommend vaccination for all persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis and home dialysis patients. Specific regimens or formulations are recommended for both of the currently available hepatitis B vaccines due to the hypo-responsiveness of CKD patients. For immunocompromised persons, including dialysis patients, it is also recommended that additional vaccine be administered as needed to retain seroprotective levels of antibody against hepatitis B.

There are an estimated 750,000 persons with end-stage kidney disease in the United States and the five major European markets and an annual incidence of 150,000 new diagnoses and entry into dialysis. Dialysis patients typically receive dialysis treatments, vaccination and monitoring of antibody levels through a network of dialysis centers that include approximately 5,000 sites in the United States.

About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine. In Phase 3 trials, HEPLISAV demonstrated higher and earlier

protection with fewer doses than currently licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist 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 higher and earlier protection with fewer doses than currently licensed vaccines. For more information visit www.dynavax.com.

Forward-Looking Statements

This press release contains "forward-looking statements," including those relating to the potential benefits and use of HEPLISAV, planned indications and regimens, and timing of BLA submissions, 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 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 whether the BLA will be accepted for filing; 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.

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