Dynavax Confirms HEPLISAV(TM) Submission Strategies With U.S. FDA and EMA

BERKELEY, CA -- (MARKET WIRE) -- 10/27/11 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today said that the U.S. Food and Drug Administration (FDA) had concurred with the company's plan to submit a Biologics License Application (BLA) for HEPLISAV for persons over 40 years of age, followed by a supplemental BLA for licensure of a specific regimen for vaccinating chronic kidney disease (CKD) patients against hepatitis B infection at the time the initial application is approved. Dynavax also updated its timeline for the company's first BLA submission saying it expected to submit in the first quarter of 2012.

Dynavax also said that the European Medicines Agency (EMA) has advised the company it could submit the primary endpoint immunogenicity data and associated safety data for the over-40 population as well as the CKD indication as part of the initial Marketing Authorization Application (MAA) and that the outstanding CKD data can be submitted in the course of the application's review. Dynavax confirmed its plan to submit the MAA for European approval after the submission of its BLA in the U.S.

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.

Forward-Looking Statements

This press release contains "forward-looking statements," including those relating to our plans for the HEPLISAV BLA and MAA and the timing of the 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 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 is not incorporated by reference in the Company's current periodic reports with the SEC.

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