

## **Dynavax Reports HEPLISAV(TM) BLA Submission**

BERKELEY, CA -- (Marketwire) -- 04/26/12 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that it has submitted a U.S. Biologics License Application (BLA) to the Food and Drug Administration (FDA) for HEPLISAV, pursuing an indication for immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 through 70 years of age.

Dynavax President and Chief Medical Officer, Tyler Martin, M.D., said:

This submission is a very important milestone for Dynavax. The final document consists of 305 volumes, and the expansion of the indicated age group following the pre-BLA meeting required complete rewrites of the clinical summaries. The entire HEPLISAV team did outstanding work to complete the revisions and submit the BLA ahead of schedule.

We have requested priority review for HEPLISAV, as we believe it is a significant improvement compared to marketed products. We look forward to working with the FDA on the BLA and to ultimately bringing the benefits of HEPLISAV to the public.

The Company anticipates submitting a European Marketing Authorization Application (MAA) for HEPLISAV in the third quarter of 2012. Upon approval of the initial HEPLISAV BLA, Dynavax plans to submit a supplemental BLA with an indication and 3-dose primary vaccination regimen for patients with chronic kidney disease.

## 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 <u>www.dynavax.com</u>.

## Forward-Looking Statements

This press release contains "forward-looking statements," including those relating to the HEPLISAV planned indications and regimens and timing of BLA and MAA 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 <u>www.dynavax.com</u> is not incorporated by reference in the Company's current periodic reports with the SEC.

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Source: Dynavax Technologies

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