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Dynavax Marketing Authorization Application for HEPLISAV(TM) Accepted for Review by European Medicines Agency

BERKELEY, CA -- (Marketwire) -- 08/22/12 -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today that the European Medicines Agency (EMA) has accepted the filing of the Marketing Authorization Application (MAA) 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 and in patients with chronic kidney disease. Acceptance of the MAA confirms that the submission is sufficiently complete to permit a substantive review by the EMA.

"This milestone marks the initiation of the regulatory review for HEPLISAV in Europe," said Dynavax President and Chief Medical Officer, Tyler Martin, M.D. "We look forward to working through the review process with our designated rapporteur from Sweden and co-rapporteur from Belgium."

About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine for which a U.S. BLA has been accepted for review by the FDA and a MAA has been accepted for review by the EMA. 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 may contain "forward-looking statements". 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 review 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; 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 and MAA will be approved; our ability to obtain additional financing to support the development and commercialization of HEPLISAV and our other operations; our ability to successfully transition to a commercial operation and execute on our commercial strategy; possible claims against us, including enjoining sales of HEPLISAV, 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 our current periodic reports with the SEC.

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Source: Dynavax Technologies