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Dynavax Announces FDA Acceptance of HEPLISAV(TM) BLA

BERKELEY, CA -- (Marketwire) -- 06/26/12 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the Food and Drug Administration (FDA) has accepted for review the U.S. Biologics License Application (BLA) 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, "The FDA has established February 24, 2013, as the PDUFA action date. We look forward to working with the FDA in moving HEPLISAV through the regulatory review process over the next few months."

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

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 European Marketing Authorization Application (MAA) is expected to be submitted in the third quarter of 2012. 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 HEPLISAV MAA submission and supplemental BLA filing, 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 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 will be approved and the timely filing of the MAA; 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.

Source: Dynavax Technologies

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