Dynavax Reports on Heplisav(TM) Pre-BLA Meeting With FDA

BERKELEY, CA -- (MARKET WIRE) -- 02/02/12 -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today that it met with the Food and Drug Administration (FDA) in a Pre-Biologics License Application (pre-BLA) meeting, and Dynavax and the FDA have agreed that the initial HEPLISAV BLA submission will be for an indication in healthy adults 18-70 years of age. This agreement represents a significant expansion of the previously anticipated population of healthy adults age 40 and over. In addition, it was confirmed that a supplemental BLA with an indication for patients with chronic kidney disease will be filed when the initial BLA is approved.

According to Dr. Tyler Martin, President and Chief Medical Officer of Dynavax, "This meeting with the FDA marks an important milestone for Dynavax. We have clarified the indication, scope and structure of the BLA submission. Following the submission, the BLA will undergo review and the HEPLISAV manufacturing facilities must be inspected prior to regulatory approval."

Dynavax said it is now making the required modifications to the BLA to support the expanded indication and plans to submit the BLA by the middle of May.

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. 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 the HEPLISAV BLA, planned indications, timing of the submissions and the FDA regulatory process, 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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Source: Dynavax Technologies