



Dynavax's Two Phase 3 HEPLISAV Trials Cleared by DSMB to Continue to Study Completion

Planned Safety Assessments Complete

BERKELEY, CA -- (MARKET WIRE) -- 02/23/11 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the Data Safety Monitoring Board (DSMB) established for Dynavax's two ongoing Phase 3 trials for HEPLISAV™ has completed its planned safety assessments. The DSMB determined that the studies may continue without protocol modification, and that no other formal meetings of the DSMB are required.

Tyler Martin, M.D., President and Chief Medical Officer, commented, "This DSMB review is an important milestone for our Phase 3 program. All subjects in our large safety and lot-to-lot consistency trial randomized to HEPLISAV are now eight months past their last dose. It would be unlikely to see a serious adverse event related to HEPLISAV at this time. Based on our progress, we look forward to completing the trials as planned and filing our BLA by the end of 2011."

The DSMB reviewed safety data from two ongoing multi-center Phase 3 trials evaluating HEPLISAV, the first a lot-to-lot consistency trial in adults 40 years and older, and the second a trial in chronic kidney disease patients. The DSMB is comprised of an independent group of medical experts who are responsible for reviewing and evaluating subject safety data at regular intervals during the ongoing trials.

About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine. The vaccine candidate is being evaluated in two Phase 3 studies that are directed toward fulfilling licensure requirements in the U.S., Canada and Europe. Enrollment has been completed for both studies. In a completed pivotal Phase 3 trial, 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 diseases. The Company's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to enhance protection more rapidly with fewer doses than current licensed vaccines. For more information visit www.dynavax.com.

Forward Looking Statements

This press release contains "forward-looking statements," that are subject to a number of risks and uncertainties, including statements regarding the timing of study completion and the BLA submission. 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 can occur in a timely manner or without significant additional studies or difficulties or delays in development or clinical trial enrollment, whether the 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; 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.

Contact:

Michael Ostrach

Vice President and Chief Business Officer

510-665-7257

Email Contact

Source: Dynavax Technologies

News Provided by Acquire Media