Dynavax Completes Enrollment for Phase 3 Study of HEPLISAV(TM) in Subjects With Chronic Kidney Disease

BERKELEY, CA -- (MARKET WIRE) -- 01/10/11 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced completing the enrollment of its Phase 3 study of HEPLISAV™, Dynavax's novel vaccine for the prevention of hepatitis B infection, in subjects with chronic kidney disease. The multi-center study, conducted in the U.S., Germany and in Canada, included 69 sites. To date over 500 first immunizations have been administered. According to the protocol, all patients will receive immunizations over a period of six months, with the primary endpoint evaluated at month 7. The primary endpoint of the study is non-inferiority of three injections of HEPLISAV at times 0, 1 and 6 months versus eight injections of Engerix-B® consisting of double doses at times 0, 1, 2 and 6 months.

Tyler Martin, M.D., President and Chief Medical Officer of Dynavax, noted, "Completion of enrollment in this trial is another important milestone in the development of HEPLISAV and keeps us on track for BLA submission in Q4 2011. We expect the last immunizations to be administered in June 2011."

In September, 2010, Dynavax reported that the first subjects enrolled in the Phase 3 chronic kidney disease study were 12 months past their first dose, and that no safety issues had been identified by the DSMB monitoring safety of the trial. 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.

In a poster session on Saturday, October 31, 2009 at the 47th Annual Meeting of the Infectious Disease Society of America (IDSA), Dynavax reported data from two Phase 2 studies in subjects with chronic kidney disease. Vaccinated with HEPLISAV, chronic kidney disease patients demonstrated rapid, increased protection against hepatitis B viral infection in fewer doses than patients receiving licensed vaccine. 96% of patients (n = 36) receiving 3 doses of HEPLISAV achieved seroprotection at month 7, compared to 88% of patients (n = 10) receiving 8 doses of Engerix-B.

Engerix-B® is a registered trademark of GlaxoSmithKline

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 Hepatitis B Vaccines

Currently available hepatitis B vaccines require three doses over six months to achieve full immunogenicity in healthy patient populations. Because compliance with this vaccine regimen is low, new vaccines are needed to provide increased protection with fewer doses in a shorter timeframe. Furthermore, currently available vaccines do not fully address the needs of several patient populations, including those with chronic kidney disease, HIV or chronic liver disease. In particular, patients with compromised immune systems require both rapid and enhanced protection, either because they are less responsive to conventional vaccine regimens or because they are at high risk of infection.

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 and 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 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.

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Source: Dynavax Technologies