

# Dynavax's Chronic Kidney Disease Study Confirms HEPLISAV's Enhanced Seroprotection Against HBV Infection

## **Phase 2 Data Presented at National Kidney Foundation**

BERKELEY, CA, Apr 14, 2010 (MARKETWIRE via COMTEX News Network) -- Dynavax Technologies Corporation (NASDAQ: DVAX) today presented Phase 2 clinical data that demonstrate HEPLISAV(TM)'s immunogenicity and rapid protection in patients with chronic kidney disease. In a poster session at the National Kidney Foundation Spring Clinical Meeting in Orlando, FL, Dynavax results showed that two doses of HEPLISAV protected 100% of the dialysis and pre-dialysis patients measured at week 24 in the Phase 2 study.

"Chronic Kidney Disease patients undergoing hemodialysis are at high risk of HBV infection, are hyporesponsive to current HBV vaccines, and have a worse prognosis if infected with HBV," commented Tyler Martin, M.D., Dynavax's Chief Medical Officer. "These results demonstrate that HEPLISAV can effectively protect this susceptible patient population."

At its initiation, the Phase 2 single blind study in chronic kidney disease patients called for the comparison of two different HEPLISAV regimens, a single-dose vaccine and a double-dose vaccine, at 0, 1, and 6 months. A total of 41 subjects with progressive loss of renal function and between 40-70 years of age were enrolled. The vast majority of patients had received only the first two immunizations when the study was prematurely discontinued due to an FDA-imposed clinical hold on HEPLISAV. The clinical hold was subsequently removed. In the poster entitled, "Safety and Immunogenicity of a Novel hepatitis B Vaccine Adjuvanted with Immunostimulatory Sequence (ISS) in Renal Predialysis and Dialysis Patients," Dynavax presented safety and immunogenicity data for time points 4 weeks after the first immunization and 8 and 20 weeks after the second immunization.

HEPLISAV is currently being evaluated in a Phase 3 study in subjects with chronic kidney disease at multiple centers in the U.S., Canada and Germany. An additional Phase 3 study in subjects over the age of 40 is being conducted to demonstrate lot-to-lot consistency and complete the safety database for HEPLISAV. Dynavax anticipates submitting the initial BLA for HEPLISAV in 2011.

For a copy of the poster presentation, please visit <a href="http://investors.dynavax.com/newsevents.cfm">http://investors.dynavax.com/newsevents.cfm</a>.

#### 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 U.S., Canada and Europe. 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 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.

## Chronic Kidney Disease Market

The chronic kidney disease market is large and growing rapidly. In 2006, there were approximately 750,000 end-stage renal disease (ESRD) patients in the United States and the five major European markets; approximately 150,000 new patients are diagnosed each year. Vaccination against HBV is widely recommended for these patients. However, an estimated 35% of immunocompromised ESRD patients do not respond to vaccination, and 20% require boosters. Since patients are usually vaccinated at dialysis centers, this is a highly concentrated, renewable market that can be served by cost-effective, targeted sales and distribution networks.

### 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 provide more rapid and increased protection with fewer doses than current licensed vaccines. For more information visit <a href="https://www.dynavax.com">www.dynavax.com</a>.

## Forward-Looking Statements

This press release contains "forward-looking statements," that are subject to a number of risks and uncertainties, including the anticipated BLA submission date for HEPLISAV. 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 the reported results can be replicated in larger studies, 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 potential size and value of the chronic kidney disease market addressable with HEPLISAV, the commercial potential for HEPLISAV, and 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.

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