

Dynavax Initiates Large-Scale Phase 3 Trial of HEPLISAV(TM)

BERKELEY, CA, Feb 08, 2010 (MARKETWIRE via COMTEX News Network) -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today initiation of a large-scale Phase 3 trial designed to demonstrate the lot-to-lot consistency of commercial vaccine and to complete the safety database for HEPLISAV(TM), the Company's investigational adult hepatitis B vaccine. This study and the ongoing Phase 3 trial in chronic kidney disease patients are directed toward fulfilling licensure requirements in the U.S., Canada and Europe. HEPLISAV has been shown in two pivotal Phase 3 trials to enhance protection more rapidly and with fewer doses than a currently licensed vaccine.

The lot-to-lot consistency trial will enroll 2,000 patients in Canada and in the U.S., 1600 of whom will receive HEPLISAV. Patients randomized to the comparator arm will receive Engerix-B(R), a currently licensed hepatitis B vaccine. The primary objectives are:

- Non-inferiority of the immune response to HEPLISAV vaccination as measured by the seroprotection rate at 8 weeks after the last active dose, compared to Engerix-B vaccination at 8 weeks after the last active dose; and
- Lot-to-lot consistency for immune response as measured by geometric mean concentration at 4 weeks after the last active dose among 3 consecutively manufactured lots of HEPLISAV.

The secondary objectives include the safety of HEPLISAV as compared to Engerix-B.

Data from this trial is expected in the first half of 2011. The hepatitis B surface antigen in the HEPLISAV lots being evaluated was produced in Dynavax's manufacturing facility in Duesseldorf, Germany. This facility was recently upgraded and licensed in the European Union for commercial production of hepatitis B surface antigen.

About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine. 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.

Engerix-B(R) is a trademark of GlaxoSmithKline.

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 comprised 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, an 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 expectations of clinical trial regulatory requirements 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 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 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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