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Dynavax Initiates US-Based Phase 1 Clinical Trial of HEPLISAV(TM) Hepatitis B Vaccine in Dialysis Population

BERKELEY, Calif., Nov. 1 /PRNewswire-FirstCall/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) announced the initiation of a Phase 1 clinical trial of HEPLISAV, its ISS-based hepatitis B (HBV) vaccine in patients with end-stage renal failure (pre-dialysis). The trial will be conducted at multiple centers in the United States and will compare HEPLISAV to GlaxoSmithKline's Engerix-B® vaccine. The trial is designed to yield safety, tolerability, pharmacokinetic and efficacy data and is anticipated to be completed within 12-18 months.

"We believe that the dialysis population is largely underserved by current hepatitis B vaccines and that Dynavax's HEPLISAV could offer meaningful medical benefits to these patients who are at high risk of infection," said Dan Levitt, MD, chief medical officer. "In previous clinical studies, we have demonstrated HEPLISAV's superior ability to confer rapid and durable seroprotection and its magnitude of immune response in an older adult population that is difficult to immunize with conventional vaccine. Conventional dosing of HBV vaccines only confer approximately 50% seroprotection in dialysis patients. The goal of our clinical and regulatory strategy in pre-dialysis patients is to determine an appropriate dosing regimen that could demonstrate the ability to provide superior protection for this vulnerable population."

"The cornerstone of Dynavax's commercial strategy for HEPLISAV is targeting high-risk populations with an urgent need for protection against HBV," said Dino Dina, MD, president and chief executive officer. "Simultaneous with pursuing a global regulatory strategy that is designed to obtain broad registration of our HBV vaccine, we are expanding our clinical program with targeted studies in people with compromised immune systems who are at risk for HBV infection and for whom we believe HEPLISAV may offer therapeutic benefit, such as pre-dialysis patients. These populations could also include people infected with HIV or hepatitis C."

HEPLISAV has demonstrated statistically significant superior seroprotection in clinical trials to date when compared to the industry standard HBV vaccine, Engerix-B. In June 2005, Dynavax initiated the first of two pivotal Phase 3 trials for HEPLISAV and anticipates initiating a second pivotal Phase 3 trial in the first half of 2006.

HEPLISAV Phase 1 Trial Design

HEPLISAV is based on Dynavax's proprietary immunostimulatory sequence (ISS) that specifically targets Toll-Like Receptor 9 (TLR-9) to stimulate an innate immune response. HEPLISAV combines ISS with HBV surface antigen (HBsAg) and is designed to significantly enhance the level, speed and longevity of protection.

The Phase 1 trial will enroll 96 patients with diagnosed chronic renal failure, aged 40 or older, who are seronegative for HBV and who have not been previously vaccinated against HBV. Patients will be randomized in a three-to-one ratio, HEPLISAV to Engerix-B, and dosed in three sequential, dose-escalating cohorts of 32 patients. The trial will compare three immunizations with HEPLISAV with four immunizations with Engerix-B. HEPLISAV-treated patients will receive immunizations at weeks zero, four and 24, and a placebo injection at week eight. Engerix-B-treated patients will receive immunizations with the vaccine on the same zero, four, eight and 24-week schedule.

The primary endpoint of the trial is safety and tolerability through week 28. The secondary endpoints are seroprotection (HBsAg antibody titers greater or equal to 10 mIU/mL, four weeks after each immunization) and Geometric Mean Concentrations (GMCs) four weeks after each immunization. A pharmacokinetic analysis will be performed on a subset of trial participants. All trial participants will be followed for 50 weeks.

About Dynavax

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative products to treat and prevent allergies, infectious diseases, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our clinical development programs are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation. Dynavax's pipeline includes: a ragweed allergy immunotherapeutic, currently in a large-scale Phase 2/3 clinical trial, and in a supportive clinical trial in ragweed allergic children; a hepatitis B vaccine that is currently in a pivotal Phase 3 clinical trial; a cancer therapy currently in a Phase 2 clinical trial; and an asthma immunotherapeutic that has shown preliminary safety and pharmacology in a Phase 2a clinical trial.

Dynavax cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements, including without limitation all statements related to the ability to provide seroprotection for pre-hemodialysis patients and other populations with compromised immune systems, to demonstrate the superiority of HEPLSAV compared to conventional vaccines, and to execute on its regulatory strategy for HEPLISAV; statements concerning the company's other clinical programs and its ability to demonstrate the potential of its ISS technology. Words such as "believes," "anticipates," "plans," "expects," "intend," "will," "slated," "goal" and similar expressions are intended to identify forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Dynavax that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Dynavax's business including, without limitation, risks relating to: the clinical outcome of the trial in pre-dialysis patients; the ability to demonstrate safety, efficacy and superiority in a clinical trial of HEPLISAV compared to Engerix-B in pre-dialysis patients; the timelines for completing the clinical trial of HEPLISAV in pre-dialysis patients; plans to initiate a second pivotal Phase 3 clinical trial for HEPLISAV; the progress and timing of clinical trials for the company's other products in development; difficulties or delays in developing, testing, obtaining regulatory approval of, producing and marketing its HBV and other products; the scope and validity of patent protection for its products; competition from other pharmaceutical or biotechnology companies; its ability to obtain additional financing to support its operations; its ability to maintain effective financial planning and internal controls; and other risks detailed in the "Risk Factors" sections of Dynavax's Annual Report on Form 10-K filed on March 18, 2005, Dynavax's quarterly report on Form 10-Q filed on August 9, 2005, and Dynavax's Prospectus Supplement filed on October 11, 2005. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Dynavax undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

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