Dynavax Starts HEPLISAV(TM) Phase 3 in Europe; U.S. Study; and Phase 2 in ESRD in Canada

Licensure-directed clinical trials in place for planned 2008 BLA

BERKELEY, Calif., June 26, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) announced today the initiation of three clinical trials to support licensure of HEPLISAV(TM), its novel hepatitis B virus (HBV) vaccine:

-- The ongoing multi-center pivotal Phase 3 trial in Canada has been expanded to include seven sites in Germany as planned;

-- A U.S. study is enrolling subjects 11 through 55 years of age. The data from the U.S. study, plus the Phase 3 trials in Canada and Europe, and subsequent lot-to-lot consistency trials will contribute to a safety database of approximately 4,000 subjects for a planned BLA submission in 2008. The lot-to-lot consistency studies will compare three consecutive lots of HEPLISAV manufactured at Dynavax Europe and are planned to begin in the second half of the year in the U.S., Canada, and Germany.

-- A Phase 2 trial in patients with end-stage renal disease (ESRD) has been approved by Health Canada and is expected to begin enrolling subjects shortly.

According to President and Chief Executive Officer Dino Dina, M.D., "These three trials are critical milestones on the regulatory path for the licensure of HEPLISAV and for commercialization of this novel vaccine. With the trials in place, we can efficiently build upon the already strong safety and immunogenicity database for HEPLISAV and begin preparing for our BLA submission planned for the second half of 2008."

Enrollment in the multi-center Phase 3 pivotal trial, known as PHAST (Phase 3 HeplisAv Short-regimen Trial) began in Germany on June 14. This comparative immunogenicity trial, initiated in late 2006 in Canada, is enrolling subjects 11 through 55 year of age. The trial compares a two-dose regimen of HEPLISAV administered at 0 and 1 month to the conventional three- dose regimen of Engerix-B marketed by GlaxoSmithKline. The total enrollment target for the Phase 3 pivotal study in Canada and in Germany is approximately 2,000 subjects.

An immunogenicity and safety study in the United States began enrolling subjects in early June. Consistent with the PHAST trial, subjects 11 through 55 years of age are receiving a two-dose regimen of HEPLISAV, at 0 and 1 month. The primary endpoint of this trial will be measured four weeks after the second dose.

A Phase 2 trial evaluating the safety and immunogenicity of two different doses of HEPLISAV was approved by Health Canada to begin enrolling ESRD patients in Canada. The trial will enroll adults 40 through 70 years of age who have progressive loss of renal function (GFR less than or equal to 45 mL/min) and are either pre-dialysis or hemodialysis patients. This is a difficult-to-immunize patient population for whom conventional hepatitis B vaccines have shown limited efficacy.

About HEPLISAV

Dynavax's HBV vaccine, HEPLISAV, is based on its proprietary immunostimulatory sequence (ISS) that specifically targets Toll-Like Receptor 9 (TLR9) 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. Previously reported clinical trials results have shown 100% seroprotection after two doses in subjects 18 to 39 years of age and after three doses in difficult-to-immunize subjects 40 to 70 years of age.

About Dynavax

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent infectious diseases, allergies, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists 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. Our product candidates include: HEPLISAV, a hepatitis B vaccine in Phase 3; TOLAMBA(TM), a ragweed allergy immunotherapy; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B also in Phase 1. Our preclinical asthma and COPD program is partnered with AstraZeneca. The National Institutes of Health (NIH) partially funds our preclinical work on a vaccine for influenza. Symphony Dynamo, Inc. (SDI) funds our colorectal cancer trials and our preclinical hepatitis C therapeutic program. While the NIH and SDI provide program support, Dynavax has retained rights to seek strategic partners for future development and commercialization. For more information, please visit http://www.dynavax.com.

This press release contains forward-looking statements that are subject to a number of risks and uncertainties, including statements about the initiation of clinical trials for HEPLISAV, the potential safety and efficacy of HEPLISAV and the potential for HEPLISAV to meet regulatory requirements and achieve clinical and commercial success. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including difficulties or delays in development, initiation and completion of clinical trials, 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; achieving our collaborative and licensing agreement objectives and obtaining regulatory approval; the scope and validity of patent protection and the possibility of claims against us based on the patent rights of others; our ability to obtain additional financing to support our operations; and other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K and Quarterly Report on Form 10-Q. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

SOURCE Dynavax Technologies Corporation

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