Dynavax's HEPLISAV(TM) Hepatitis B Vaccine Shows Statistically Significant Efficacy In Phase 2/3 Clinical Trial

Primary Endpoint Results Showing Superior Seroprotection, Robustness and Durability of Protective Effect Over GSK's Engerix-B® in Older Adult Population Presented at ICAAC

BERKELEY, Calif., Dec 19, 2005 /PRNewswire-FirstCall via COMTEX News Network/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) announced positive results from the primary endpoint analysis of the company's Phase 2/3 clinical trial comparing HEPLISAV, its hepatitis B virus (HBV) vaccine, with GlaxoSmithKline's Engerix-B vaccine. Results showed superiority of HEPLISAV compared to Engerix-B relative to the primary efficacy endpoint of seroprotection (100% seroprotection in the HEPLISAV-treated group compared to 90.5% in the Engerix-B treated group; p=0.034) and relative to geometric mean concentration or GMC (1698 compared to 569 mIU/mL; p=0.023). Results also showed that subjects treated with HEPLISAV experienced more durable seroprotection. At week 50, the HEPLISAV-treated group measured 100% seroprotection and GMC of 499 mIU/mL compared to 86% and 153 mIU/mL for the Engerix-B treated group (p=0.009 and p=0.005, respectively). The Phase 2/3 trial was conducted in an older adult population, aged 40-70 years, in whom achieving seroprotection with conventional vaccine is more difficult than in younger adults. The primary endpoint of the trial was seroprotection following three doses, and a key secondary endpoint was GMC, a measure of the robustness of antibody response. The safety profile of the vaccine was highly favorable.

"The clear demonstration of superior efficacy of HEPLISAV in a patient population that is more difficult to immunize with conventional vaccine than younger individuals is a major achievement for Dynavax, and affirms our belief that HEPLISAV has the potential to provide meaningful clinical benefit to people in need of protection against exposure to hepatitis B," said Dr. Seng Gee Lim, National University Hospital, Singapore, and principal investigator for the clinical trial.

"We believe that HEPLISAV has the potential to become the first toll-like receptor 9 agonist-based product to seek regulatory approval," said Dino Dina, MD, president and chief executive officer. "The pivotal Phase 3 clinical program is well underway. Our commercial strategy is designed to target high-value, high-risk patient populations whose need for rapid and effective protection against HBV is urgent and who are underserved by conventional vaccines. We are initially focusing on patients with chronic renal failure who are either about to undergo hemodialysis or already on hemodialysis, and who are at substantial risk for HBV infection. We also intend to focus on people with HIV and hepatitis C infections for whom co-infection with HBV is a serious concern. We believe that healthcare workers and emergency personnel, who face significant occupational risks of infection, as well as discretionary travelers, also represent important potential markets for HEPLISAV."

The data from the Phase 2/3 trial were presented in a poster entitled, "Recombinant Hepatitis B Surface Antigen (rHBsAg) Co-adminstered with an Immunostimulatory Phosphorothioate Oligonucleotide (1018 ISS) Provides Superior Protection in Older Subjects" at the 45th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), held in Washington, DC. The Phase 2/3 trial was conducted by Dr. Lim Seng Gee at the National University Hospital, and Dr. Chow Wan Cheng, at the Singapore General Hospital. Dr. Lim presented the poster at ICAAC.

Phase 2/3 Clinical Trial Design and Results

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

The Phase 2/3 clinical trial was a double-blind, controlled study. On an intent-to-treat basis, the study involved 88 healthy, seronegative subjects (with no detectable HBV antibodies) aged 40-70, four of whom had a history of smoking and 26 of whom were overweight (body mass index greater than 27 kilograms per meter-squared). The subjects were randomized into two treatment groups. One group received three doses of Dynavax's HBV vaccine, administered at a dose of 20 micrograms HBsAg plus 3 milligrams of ISS, by intramuscular injection at zero, two months and six months. The other group received three doses of Engerix-B administered at a dose of 20 micrograms HBsAg by intramuscular injection at zero, one and six months. The primary endpoint analysis was based on results four weeks after administration of the third dose (week 28). Subjects were followed for an additional five months to assess duration of protective response.

A protective antibody response is defined in concentrations greater than or equal to 10 mIU/mL (milli-international units per milliliter). The results of the Phase 2/3 trial are expressed in geometric mean concentration (GMC).

-- Four weeks following the third dose (week 28), 100% of the HEPLISAV-treated group had a protective antibody response compared to 90.5% of the Engerix-B treated group (p=0.034).

-- Four weeks following the third dose (week 28), the HEPLISAV-treated group had GMC of 1698 mIU/ml compared to 569 mIU/ml in the Engerix-B treated group (p=0.023).

-- There were no serious adverse events and no severe adverse events in either group four weeks after the third dose. There was no difference in either local or systemic reactions between the two treated groups.

-- At week 50, the HEPLISAV-treated group maintained 100% seroprotection while the Engerix-B-treated group declined to 86% (p=0.009).

-- At week 50, the HEPLISAV-treated group had GMC of 499 mIU/mL compared to 153 mIU/mL (p=0.005).

Measurements of seroprotection levels and GMC were also taken at weeks 12 and 24. At week 12, the HEPLISAV-treated group had a seroprotection level of 91.3% compared to 50.0% in the Engerix-B treated group (p less than 0.0001), and GMC of 256 compared to 5.7 mIU/mL (p less than 0.001). At week 24, the HEPLISAV treated group had a seroprotection level of 95.6% compared to 57.1% in the Engerix-B treated group, and GMC of 238 compared to 10.0 mIU/mL (p less than 0.001). These data indicate that two doses of HEPLISAV provided superior protection to three doses of Engerix-B.

"What is particularly compelling about the superiority of Dynavax's HBV vaccine after just two doses is the high level of protection afforded to subjects who may not complete the full vaccination regimen," said Dr. Dina. "The Centers for Disease Control and Prevention has reported that only about 30% of people fully comply with the recommended three-dose, six-month vaccination regimen, resulting in large populations who remain unprotected and at risk of infection. With our vaccine, even those people who fail to comply fully achieve a very high protective response after only two months. We believe this represents an important public health benefit."

Pivotal Phase 3 Trial and Pre-Dialysis Trial Underway

Dynavax initiated the first of two pivotal Phase 3 clinical trials of HEPLISAV in June 2005. This trial involves 400 subjects, aged 40-70, and is being conducted in Singapore, Korea, the Philippines and Taiwan. A second Phase 3 trial is anticipated to begin in the first half of 2006. Dynavax initiated a Phase 1 trial in pre-dialysis patients in the US in October 2005. The company also plans to conduct additional trials in selected high-risk populations.

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 therapeutic and commercial potential of HEPLISAV, its HBV vaccine, the potential for regulatory approval for HEPLISAV, its plans to initiate and timing of a second pivotal Phase 3 trial for HELPISAV, and its commercial strategies; 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 ability of the company to demonstrate safety and effectiveness of its HBV vaccine in Phase 3 clinical trials; the progress and timing of initiating its Phase 3 clinical program in HBV; the ability of the company to develop and implement effective commercial strategies for its HBV vaccine; 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 November 14, 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

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