Dynavax's HEPLISAV(TM) Hepatitis B Vaccine Shows Statistically Significant Results in Phase 3 Trial

In Difficult-to-Immunize Population, Shows Clear Superiority to Conventional Vaccine

BERKELEY, Calif., Nov. 28 /PRNewswire-FirstCall/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) announced today statistically significant results from the primary endpoint analysis of a Phase 3 trial comparing HEPLISAV, its hepatitis B virus (HBV) vaccine, to GlaxoSmithKline's Engerix-B® vaccine in a difficult-to-immunize population of older adults. The primary endpoint is seroprotection four weeks after the third immunization.

The data show that after three doses, HEPLISAV provided seroprotection to 100% of subjects versus 73.1% for Engerix-B ($p < 0.0001$). The greatest difference in seroprotection after three doses was seen in subjects 56 to 70 years of age where HEPLISAV provided 100% seroprotection and Engerix-B provided 56.1%. Data for the entire study population show that after two doses, HEPLISAV provided 98.5% seroprotection versus Engerix-B's 25%. Furthermore, HEPLISAV provided a level of immunity as measured by geometric mean concentrations of anti-HBsAg antibodies 18.5 times higher than Engerix-B four weeks after the third dose.

According to Dino Dina, M.D., president and chief executive officer, "These results once again demonstrate HEPLISAV's superior effectiveness over conventional hepatitis B vaccine. The most striking outcome from the trial is the vaccine's ability to generate 98.5% protection after two doses in older difficult-to-immunize adults. This has the potential to drive an important change in the way people are immunized against hepatitis B."

The Phase 3 trial enrolled more than 400 seronegative subjects, 40 to 70 years of age, at study sites in Singapore, Korea and the Philippines. One group of subjects received three doses of Dynavax's HBV vaccine; the other group received three doses of Engerix-B.

In December 2005, Dynavax reported the results of a smaller Phase 2/3 trial in older adults as part of a poster at the 45th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), specifically the superiority of HEPLISAV compared to Engerix-B relative to the primary efficacy endpoint of seroprotection (100% in the HEPLISAV-treated group compared to 90.5% in the Engerix-B treated group; $p = 0.033$) and relative to geometric mean concentration or GMC (1698 compared to 569 mIU/mL; $p = 0.023$). Dr. Lim Seng Gee, study investigator, 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 trial was conducted in 89 older adults, 40 to 70 years of age. HEPLISAV was well tolerated and did not induce serious adverse effects.

Dynavax plans to pursue approval of a two-dose regimen administered at zero and one month, and expects to initiate multi-center, international Phase 3 trials in Europe, Canada and the United States before the year-end, comparing the two-dose regimen against Engerix-B in patients from 11 to 55 years of age. The first dosing is expected in Canada, followed in early 2007 by dosing in the U.S. and in Europe. These trials are expected to be completed in 2008.

Dynavax's HBV vaccine is based on its proprietary immunostimulatory sequence (ISS) that specifically targets Toll-Like Receptor 9 (TLR9) 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. Dynavax indicates that as a result of its acquisition of Rhein Biotech in April 2006, the company has secured manufacturing capabilities in Dusseldorf, Germany for producing both clinical and commercial quantities of the vaccine.

Conference Call and Webcast Tomorrow

Dynavax will hold a conference call/webcast to discuss the Hepatitis B vaccine data tomorrow, Wednesday, November 29, 2006 at 9:00 a.m. Eastern Time / 6:00 a.m. Pacific Time. The webcast can be accessed on Dynavax Technologies' website at http://www.dynavax.com under the Investors tab or via Thomson StreetEvents (www.streetevents.com), a password-protected site. A telephonic replay of the call will be available through December 6, 2006 by dialing 888-286-8010, access code: 94926525. International callers can dial 617-801-6888.

About Dynavax

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent allergies, infectious diseases, 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 pipeline includes: TOLAMBA™, a ragweed allergy immunotherapeutic, for which a major safety and efficacy trial (DARTT) is currently underway, and that is in a supportive clinical trial in ragweed allergic children; HEPLISAV™, a hepatitis B vaccine in Phase 3; and a therapy for non-Hodgkin's lymphoma in Phase 2. Our pre-clinical asthma and COPD programs are partnered with AstraZeneca. Funding for our other preclinical programs in cancer, hepatitis B and hepatitis C therapies, and for an influenza vaccine has been provided by Symphony Dynamo, Inc. and the NIH, and these programs represent future partnering opportunities. For more information, please visit www.dynavax.com.

This press release contains forward-looking statements that are subject to a number of risks and uncertainties, including statements about the potential safety and efficacy of HEPLISAV, whether successful results may be shown in additional clinical studies, whether HEPLISAV may show similar or supportive results in the upcoming Phase 3 clinical studies and the potential for HEPLISAV to 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, achieving the objectives of our collaborative and licensing agreements and obtaining regulatory approval for our products; the scope and validity of patent protection for our products; possible claims against us on the patent rights of others; competition from other companies; 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
11/28/2006
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