Dynavax Announces Positive Interim Results From Phase 2/3 Hepatitis B Vaccine Trial

Highly Statistically Significant Protective Response (p=0.0001) Achieved in Difficult to Immunize Population After Two Doses

BERKELEY, Calif., Dec 9, 2004 /PRNewswire-FirstCall via COMTEX/ -- Dynavax Technologies (Nasdaq: DVAX) announced that data from an interim analysis of the company's hepatitis B virus (HBV) vaccine Phase 2/3 clinical trial showed statistically significant superiority in protective antibody response and robustness of protective effect after two vaccinations when compared to GlaxoSmithKline's Engerix-B™ vaccine in an older adult population that is traditionally more difficult to immunize with conventional vaccine. The primary endpoint of the ongoing Phase 2/3 trial is seroprotection four weeks after administration of the third dose. Based on these positive interim results, as well as previously reported data showing that Dynavax's HBV vaccine induced more rapid immunogenicity and more durable protective response compared to Engerix-B in healthy young adults, Dynavax intends to pursue a broad Phase 3 clinical program in multiple age groups, anticipated to begin in mid-2005. Dynavax's HBV vaccine combines its proprietary immunostimulatory sequence (ISS) co-administered with HBV surface antigen (HBsAg), designed to significantly enhance the level, speed and longevity of protection. The study is being conducted by Dr. Lim Seng Gee at the National University Hospital, and Dr. Chow Wan Cheng, at the Singapore General Hospital. The Phase 2/3 trial should be completed in mid-2005.

"These positive interim Phase 2/3 results strengthen our confidence that our HBV vaccine can provide important advantages in terms of rapidity and level of seroprotection in an adult population known to be difficult to immunize, and increase our belief that our vaccine represents a significant commercial opportunity for our company," said Dino Dina, M.D., president and chief executive officer. "Despite the prevalence of HBV vaccination in major markets worldwide, there are serious limitations to the effectiveness of conventional vaccines due to the widespread challenge of patient compliance with the required three dose regimen. We intend to implement a broad, confirmatory Phase 3 program in mid 2005 in multiple populations, as we believe that Dynavax's HBV vaccine has the potential to change vaccination practices, establish new industry standards of effectiveness, and provide significant public health and pharmacoeconomic benefits."

Phase 2/3 Trial Design and Results

The ongoing Phase 2/3 clinical trial is 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 interim analysis was based on results four weeks after administration of the second dose. Dynavax plans to follow up with subjects for an additional five months and anticipates completing the study in mid 2005.

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

- Four weeks following the second dose, 91.3% of the Dynavax HBV vaccine group had a protective antibody response compared to 50% of the Engerix-B treated group (p=0.0001).
- The Dynavax HBV vaccine treated group had GMT of 539 mIU/ml compared to 9.9 mIU/ml in the Engerix-B treated group.
- There were no serious adverse events and no severe adverse events in either group four weeks after the second dose. There was no difference in either local or systemic reactions between the two treated groups.

In November 2004, Dynavax presented data from a randomized, double-blind Phase 2 clinical trial of the company's prophylactic Hepatitis B virus (HBV) vaccine conducted in young adults (18-28 years) that showed superior results compared to GlaxoSmithKline's Engerix-B® vaccine. Protective antibody responses were achieved faster and were maintained longer with Dynavax's HBV vaccine than with Engerix-B.

Planned Phase 3 Clinical Trial Design

Dynavax intends to initiate Phase 3 clinical trials of its HBV vaccine targeting adolescent, young adult and older adult populations. The first of these trials involving older adults in Asia is anticipated to begin in mid-2005. Phase 3 studies in young adults are anticipated to begin later in 2005 in Canada and Europe. These trials will be designed as confirmatory and could be completed in 2006. The trials will be designed to compare Dynavax's HBV vaccine with Engerix-B and could include different

dosing regimens for different populations. One potential target population is kidney dialysis patients, all of whom must be vaccinated against HBV, and for whom a shorter and more effective immunization regimen could have significant therapeutic benefit.

Dynavax is currently evaluating commercialization and distribution strategies for its HBV vaccine in countries outside of the United States. In 2003, Dynavax and Berna Biotech (Bern, Switzerland) entered into a clinical and commercial supply agreement for HBV surface antigen. Dynavax estimates the HBV vaccine market outside of the US to be approximately $500 million.

About ISS

ISS are short synthetic DNA molecules that stimulate a Th1 immune response while suppressing Th2 immune responses. ISS contain specialized sequences that activate the innate immune system. ISS are recognized by a specialized subset of dendritic cells containing a unique receptor called Toll-Like Receptor 9, or TLR-9. The interaction of TLR-9 with ISS triggers the biological events that lead to the suppression of the Th2 immune response and the enhancement of the Th1 immune response. ISS influence helper T cell responses in a targeted and highly specific way by redirecting the response of only those T cells involved in a given disease. ISS, in conjunction with an allergen or antigen, establish populations of memory Th1 cells, allowing the immune system to respond appropriately to each future encounter with a specific pathogen or allergen, leading to long-lasting therapeutic effects.

The Public Health Challenge of Hepatitis B

Hepatitis B is a common chronic infectious disease with an estimated 350 million chronic carriers worldwide. HBV is a major cause of acute and chronic viral hepatitis, with effects ranging from asymptomatic infection to liver failures, cancer and death. Vaccination is central to managing the spread of the disease, particularly in regions of the world with large numbers of chronically infected individuals. While many countries have instituted infant vaccination programs, compliance is not optimal. Moreover, there are large numbers of individuals born prior to the implementation of these programs who are unvaccinated and are at risk for the disease. In addition, not all individuals respond to currently approved vaccines. Annual sales of hepatitis B vaccines in 2003 exceeded $1.0 billion globally.

Compliance with the immunization regimen of currently approved HBV vaccines is a significant issue, as many patients fail to receive all three doses. According to a survey of U.S. adolescents and adults published by the Centers for Disease Control, only 53% of those who received the first dose of vaccine received the second dose of vaccine and only 30% received the third. Dynavax believes that compliance rates in other countries are similar, if not lower. Consequently, an unacceptably large number of individuals who start the immunization series remain susceptible to infection. Poor field efficacy is of particular concern in regions with high hepatitis B prevalence and constitutes a major public health issue.

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. ISS are being developed in three initial indications: ragweed allergy immunotherapeutic, currently in a Phase 2/3 clinical trial; a Hepatitis B vaccine, currently in a Phase 2/3 clinical trial; and an asthma immunotherapeutic that has completed a Phase 2 exploratory 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 plans to advance its hepatitis B vaccine into confirmatory Phase 3 clinical trials, the therapeutic and commercial potential of its HBV vaccine, 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" section of Dynavax's Annual Report on Form 10-K filed on March 30, 2004, and in the section titled "Additional Factors That May Affect Future Results" within Dynavax's quarterly report on Form 10-Q filed on November 8, 2004. 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.

SOURCE Dynavax Technologies Corporation

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