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# Dynavax's Hepatitis B Vaccine Shows More Rapid Immunogenicity, More Durable Protective Response Than Engerix-B in Phase 2 Clinical Trial

### 100% Protective Response Sustained More Than One Year Later After Two-Dose Regimen of Dynavax's ISS-based Vaccine

BERKELEY, Calif., Nov 1, 2004 /PRNewswire-FirstCall via COMTEX/ -- Dynavax Technologies (Nasdaq: DVAX) announced that data from a randomized, double-blind Phase 2 clinical trial of the company's prophylactic hepatitis B virus (HBV) vaccine 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. 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.

Results from the completed Phase 2 clinical trial demonstrated that recipients of Dynavax's HBV-ISS vaccine more rapidly achieved seroprotection after each dose when compared to Engerix-B (79% and 100% seroprotection one month after one and two doses administered over two months, respectively, compared to 12% and 64% for the Engerix-B-treated group). The seroprotection achieved by the HBV-ISS treated group after only two doses was sustained more than one year later. The Engerix-B treated group required three doses to achieve 98% seroprotection that fell to 90% six months later. The company believes that results from this Phase 2 clinical trial conducted in healthy young adults, combined with anticipated interim results from its Phase 2/3 clinical trial currently underway in Singapore in an older, more difficult-to-treat adult population, should provide a strong rationale for initiating a confirmatory Phase 3 program in mid-2005.

"From a clinical as well as a public health perspective, the benefit of achieving and maintaining a 100% protective antibody response after only two doses in two months of Dynavax's ISS-based HBV vaccine is medically meaningful, as many individuals do not comply with a two or three-dose immunization regimen that must be carried out over six months," said Scott A. Halperin, M.D., of Dalhousie University, Halifax, Nova Scotia, Canada, the principal investigator in the Phase 2 clinical trial. "Hepatitis B infection represents a serious and growing societal challenge especially in countries outside of North America and Western Europe where the incidence of the disease is increasing, and the need for more effective preventive intervention is acute."

"We believe that Dynavax's ISS-based HBV vaccine has demonstrated significant advantages over the Engerix-B vaccine, and that our approach represents an important potential alternative to currently marketed vaccines that require multiple doses and demand a high level of patient compliance while producing a suboptimal level of seroprotection," said Dino Dina, M.D., president and chief executive officer, Dynavax. "Our strategy is to aggressively pursue completion of our Phase 3 hepatitis B prophylaxis program and, assuming a positive outcome, cultivate entry points into markets outside the US that have very large at-risk populations that are currently underserved by available vaccines."

The Phase 2 data were presented in a late-breaker poster session at the 44th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). The data were presented by Dr. Halperin and by Daniel Levitt, M.D., Ph.D., vice president and chief medical officer of Dynavax, in a poster entitled, "Hepatitis B Virus Surface Antigen (HBV) Co-administered with an Immunostimulatory Phosphorothioate Oligonucleotide (HBV-ISS) Achieves Protective Antibody Levels More Quickly and with Fewer Doses than a Licensed Hepatitis B Vaccine." The poster can be viewed online at www.icaac.org.

Study Design

The Phase 2 clinical trial enrolled 99 healthy, seronegative 18-28 year-old adults (65% female; mean age 22.6 years). Participants were randomized to two treatment groups. One group received two doses of HBV-ISS, administered at a dose of 20 micrograms HBsAg plus 3 milligrams of ISS, by intramuscular injection at zero (0) and at eight (8) weeks, and received a placebo at 24 weeks. The other group received three doses of Engerix-B administered at a dose of 20 micrograms HBsAg by intramuscular injection, on the same zero/eight/24-week schedule. Adverse events were collected one and four weeks after each dose. Antibody levels were measured four weeks after the first dose; before and at one and four weeks after the second dose; before and at one and four weeks after the third dose; and at one year.

Study Results

A protective antibody response is defined in titers as greater than or equal to 10 mIU/mL (milli-international units per milliliter). The results of the Phase 2 trial, all expressed in geometric mean titers, showed that:

- Four weeks following the first dose, 79% of the HBV-ISS treated group had a protective antibody response (23.0 mIU/mL) compared to 12% (1.87 mIU/ML) of the Engerix-B recipient group.
- At one week following the second dose, 100% of the HBV-ISS treated group had protective levels compared to 18% of the Engerix-B treated group (1603 versus 2.40 mIU/mL, respectively).
- By four weeks following the second dose, the HBV-ISS group still had protective levels of 100% compared to 64% for the Engerix-B treated group (2074 versus 32.3 mIU/mL, respectively).
- At four weeks following administration of the third dose to the Engerix-B treated group, 98% had protective levels (5239 mIU/mL) that fell to 89% six months later (617 mIU/mL).
- Despite receiving a placebo at the third dosing schedule, the HBV-ISS treated group's protective levels remained at 100% four weeks later and more than one year later (1408 and 851 mIU/mL, respectively).

Rates of fever, muscle aches, nausea, vomiting diarrhea, headache, fatigue, chills and joint pain were low and similar in both treated groups. Headache and fatigue were the most common systemic adverse events in up to one third of both groups. Mild injection site reactions were more common after administration of HBV-ISS. Tenderness was reported by 74-83% of the HBV-ISS treated group versus 34-58% of the Engerix-B treated group (p equal to or less than 0.029).

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 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. Factoring together published clinical efficacy with compliance data, Dynavax estimates "field efficacy" of current vaccines to be approximately 50%.

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 that has completed a Phase 2 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 HBV clinical programs and 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 progress, timing and potential outcome of its Phase 3 HBV clinical trials; difficulties or delays in developing, testing, obtaining regulatory approval of, producing and marketing its HBV vaccine and other potential 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 August 9, 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.

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