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Dynavax Announces Completion of Enrollment of Phase II/III Hepatitis B Prophylactic Vaccine Trial

BERKELEY, Calif., Sept. 2 /PRNewswire-FirstCall/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), today announced that it has completed enrollment and administered the first round of immunizations in a Phase II/III clinical trial of its hepatitis B (HBV) prophylactic vaccine candidate containing Dynavax's Immunostimulatory Sequence (ISS). The study conducted at two study centers in Singapore began enrollment in June.

The double-blind study compared Dynavax's HBV vaccine candidate with GlaxoSmithKline's marketed HBV vaccine, Engerix-B® in 94 subjects. The subjects ranging between 40 and 70 years of age had not previously been immunized against HBV. The full immunization schedule will consist of three injections over six months, with antibody levels measured one month after each injection. The third injection is scheduled to be administered in early 2005.

The primary endpoint of the study will be comparative protective antibody levels measured after the third injection. Comparative protective antibody levels measured after the first injection are a secondary endpoint. 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.

"We are pleased with the rapid enrollment of this study and are on track to receive interim results from this trial early next year," said Dr. Dino Dina, President and CEO of Dynavax. "If these data show that our HBV vaccine can provide superior protection against HBV infection for this sizeable segment of the population that historically respond poorly to currently marketed vaccines, we will initiate in the first half of 2005 phase III studies that would confirm this efficacy on a larger scale. In parallel, we will test this vaccine more broadly in young adults and adolescents."

Hepatitis B is a common infectious disease with an estimated 350 million chronic carriers worldwide. Prevention of hepatitis caused by the hepatitis B virus is central to managing the spread of the disease, particularly in regions of the world with large numbers of chronically infected individuals. Annual sales of hepatitis B vaccines in 2001 exceeded $1.0 billion globally. Currently approved hepatitis B vaccines confer protective hepatitis B antibody responses to approximately 95% of healthy young adults, if the full dosing regimen is completed. According to the Centers for Disease Control, only 53% of all those who received the first dose of vaccine typically receive the second dose of vaccine, and only 30% receive the third, resulting in greatly impaired protection levels. Furthermore, the protective hepatitis B antibody responses achieved by conventional vaccines is lower in older adults, and for persons who are overweight or who smoke.

Data previously reported from Dynavax's phase II hepatitis B prophylactic vaccine trial in young adults showed superior efficacy after both one and two immunizations as compared to Engerix-B®. These results demonstrated that protective hepatitis B antibody responses were produced more quickly and with fewer injections with Dynavax's HBV vaccine.

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. In addition to the hepatitis B vaccine, ISS are being developed in other indications that include: a ragweed allergy program in phase II/III, and an asthma program in phase II testing.

Dynavax cautions you that statements included in this press release that are not a description of historical facts are 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, statements about: the progress and timing of its clinical trials; difficulties or delays in development, testing, obtaining regulatory approval, producing and marketing its 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.

SOURCE Dynavax Technologies Corporation
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