Dynavax Announces Initiation of Phase II/III Hepatitis B Trial

BERKELEY, Calif., June 22 /PRNewswire-FirstCall/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on the discovery, development, and commercialization of innovative products to treat and prevent allergies, infectious diseases and chronic inflammatory diseases, today announced that a Phase II/III clinical trial of its hepatitis B (HBV) prophylactic vaccine candidate has been initiated in Singapore.

The double-blind study will compare Dynavax's HBV vaccine candidate with GlaxoSmithKline's marketed HBV vaccine, Engerix B®, the best selling hepatitis B vaccine. The trial involves 80 subjects at two study centers in Singapore and will be completed in early 2005. The subjects will all be between 40 and 70 years of age and not yet immunized against HBV. The immunization schedule consists of three injections over six months, with antibody titer levels measured four weeks after each injection. The primary endpoint of the Phase II/III HBV prophylactic vaccine study will be comparative protective antibody titer levels measured after the third injection. The study will be conducted by Dr. Lim Seng Gee at the National University Hospital, and Dr. Chow Wan Cheng, at the Singapore General Hospital.

"The initiation of this Phase II/III trial represents the first in a series of trials in Asia for our HBV prophylactic vaccine," said Dr. Dino Dina, president and CEO of Dynavax. "This trial is designed to show if Dynavax's vaccine can serve an unmet medical need by providing superior protection against HBV infection for a large segment of the population that responds poorly to currently marketed vaccines. The Phase III trials planned for 2005 in multiple countries will expand the immunization to additional age groups, including healthy young adults and adolescents."

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 separate indications: a ragweed allergy program, a Hepatitis B vaccine program in late stage clinical development, and an asthma program completing a Phase II exploratory trial.

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; 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 May 12, 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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    /CONTACT:  Dino Dina, M.D., President and Chief Executive Officer of
Dynavax Technologies Corporation, +1-510-848-5100/
    /Web site:  http://www.dynavax.com /
    (DVAX)
CO:  Dynavax Technologies Corporation
ST:  California
IN:  HEA MTC BIO
SU:
JO
-- SFTU088 --
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