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Dynavax Flu Vaccine Shows Potential Against Pandemic Flu in Preclinical Model

Data Generated Under NIAID Grant to Develop Pandemic Flu Vaccine

BERKELEY, Calif., May 9, 2005 /PRNewswire-FirstCall via COMTEX/ -- Dynavax Technologies (Nasdaq: DVAX) presented data today from preclinical studies showing that the company's immunostimulatory sequence (ISS) based influenza (flu) vaccine induces an immune response potentially capable of eradicating cells infected by highly divergent influenza viruses. It also has the potential to augment the protective antibody response generated by standard flu vaccine. These combined responses may provide effective immunity against multiple strains of the flu virus and may represent a potent new vaccine approach against divergent or pandemic strains of the flu virus.

The data were presented today at the Eighth Annual Conference on Vaccine Research in Baltimore, Maryland, in a poster entitled, "Influenza Nucleoprotein Conjugated to Immunostimulatory DNA as a Potential Vaccine Against Pandemic Influenza."

"Dynavax's flu vaccine represents an innovative approach for protection against the increasing pandemic influenza threat," said Dino Dina, MD, president and chief executive officer. "Our approach addresses a key challenge in vaccine development today, namely, the difficulty in matching vaccine viral strains with the highly variable viral strains that emerge with each new flu season. By linking ISS to a key, highly-conserved flu antigen, we believe our vaccine can enhance protection against influenza even if the vaccine strains are not well matched and may provide a first-line vaccine defense against divergent or pandemic flu strains. This novel approach has the potential to provide reduced morbidity and mortality for millions of people worldwide."

Continued Dr. Dina: "We anticipate continuing preclinical development of our flu vaccine through IND-enabling studies, with the goal of seeking corporate partner support to facilitate initiation of a broad clinical program."

Human viral influenza is an acute respiratory disease of global dimension with high morbidity and mortality in annual epidemics. In the U.S. there are an estimated 35,000 viral influenza-associated deaths per year. Pandemics occur infrequently, on average every 33 years, with high rates of infection resulting in increased mortality. The last pandemic occurred 37 years ago, and health officials are closely monitoring the continuing spread of 'bird flu' (H5N1) in Asia, which has pandemic potential.

In 2003, Dynavax was awarded a $3.0 million grant over three and a half years to fund research and development of a pandemic influenza vaccine under a program for biodefense administered by the National Institute of Allergy and Infectious Disease (NIAID), a division of the National Institutes of Health. This funding should enable Dynavax to complete preclinical feasibility experiments and manufacturing of sufficient GMP-grade materials for IND- enabling toxicology studies.

Study Design and Results

Dynavax's flu vaccine links ISS to nucleoprotein (NP), a key, highly- conserved flu antigen that varies little between viral strains or from year to year, and then adds the NP-ISS to conventional vaccine to augment its activity. Immunity to nucleoprotein alone may not prevent viral infection, but serves to ameliorate the severity of the disease by eliminating virus infected cells. Due to the conserved nature of the NP antigen, the induced response would not be strain specific, and could be expected to provide immunity against most viral strains without the need for yearly modification. The addition of linked ISS-nucleoprotein to conventional vaccine also has the potential to increase antibody responses capable of blocking viral infections as well as conferring protective immunity against divergent influenza strains. These combined immune responses may provide protection from divergent and potentially pandemic viral strains.

In the experiments described in today's presentation, mice were immunized twice with NP-ISS with or without a split monovalent flu vaccine (containing viral components from only one strain of virus). Sera were analyzed two weeks after the second immunization for antibody responses against NP and hemagglutinin (HA), a viral surface antigen involved in viral infection. Tests were also performed to evaluate NP-specific and HA-specific cell-mediated immune responses. Results showed that NP-ISS was immunogenic, and induced high antigen-specific immune globulin G2a (IgG2a) ($p<0.001$) and interferon (IFN) gamma responses ($p<0.001$), indicative of a protective Th1 response, while immunization with NP alone induced predominantly IgG1 and interleukin-5 (IL- 5), indicative of an inflammatory Th2 response. Data also indicated induction significant NP-specific class I-restricted IFN gamma production ($p<0.01$) as well as the induction of significant CD8+ cytotoxic activity in mice immunized with NP-ISS ($p<0.001$). Co-delivery of NP-ISS with split vaccine significantly enhanced overall HA antibody titers ($p<0.01$) as well as inducing a significant HA-specific IFN gamma response ($p<0.01$).

In conclusion, data indicated that immunization with NP-ISS induces potent NP-specific Th1 and cytotoxic T lymphocyte (CTL) responses, as well as enhanced responses to HA when co-delivered with split vaccine. Induction of both NP-specific CTL and

HA-specific antibody responses are key features of Dynavax's novel vaccine approach, designed to enhance protection from viral infection and limit the severity of disease. Dynavax believes that these data suggest that its ISS-based flu vaccine shows potential to induce protective immunity against divergent and potentially pandemic influenza strains.

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. Dynavax's pipeline includes: a ragweed allergy immunotherapeutic, currently in a large-scale Phase 2/3 clinical trial, and in a Phase 3 clinical trial in ragweed allergic children; a hepatitis B vaccine that is currently in a Phase 2/3 clinical trial; and an asthma immunotherapeutic that has shown preliminary safety and pharmacology in a Phase 2a clinical 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 preclinical program in developing a vaccine against the human influenza virus 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 of its preclinical program in developing a flu vaccine; the progress and timing of its anticipated Phase 3 clinical trials in ragweed allergy and hepatitis B; difficulties or delays in developing, testing, obtaining regulatory approval of, 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 18, 2005. 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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