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# Dynavax's Flu Vaccine Shows Immunity to Divergent and Potentially Pandemic Flu Strains in Preclinical Tests

Conjugation of TLR9 Agonists to Conserved Viral Proteins Shows Protection Against 'Antigenic Shift,' the Precursor of a Flu Pandemic

BERKELEY, Calif., Aug. 21 /PRNewswire-FirstCall/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) today presented new preclinical data showing that its influenza (flu) vaccine confers immunity to widely divergent viral strains and has potential as a universal flu vaccine. Dynavax's flu vaccine is based on the company's proprietary TLR-9 agonist-based immunostimulatory sequence (ISS) technology and is specifically designed to overcome the limitations of both development-stage pandemic vaccines and standard seasonal flu vaccines.

In preclinical tests in mice, Dynavax's ISS-based flu vaccine has demonstrated the potential to confer cross-protective cellular and antibody- induced immunity against widely divergent flu strains. Results in mice and primates show that co-administration of Dynavax's flu vaccine with standard vaccine enhances the immune response to the standard vaccine, and may allow reduction of dosage while inducing comparable protective immunity. In addition, the enhanced immunogenicity and cross-protection of the Dynavax vaccine may provide immunity that can last for more than one year, potentially enabling the elimination of annual vaccination and stockpiling of vaccine for pandemic use.

"The unique advantage of Dynavax's flu vaccine is our proprietary conjugation technology that chemically links the ISS molecule with highly conserved viral antigens to confer a potent immunogenic and cross-protective effect regardless of the viral strain," said Gary Van Nest, PhD., vice president, preclinical research at Dynavax. "We believe that our flu vaccine represents a potential breakthrough in the prevention of disease caused by serious, widespread viral outbreaks and may be a first line of defense against the event of a flu pandemic. Importantly, the Dynavax approach may offer protection against any potentially pandemic strain, in contrast to other vaccine development efforts that specifically target an individual H5 or other strain. Our goal is to accelerate the completion of preclinical studies and initiate clinical trials of our flu vaccine as expeditiously as possible." Dynavax's data were presented at the Conference on Novel Vaccines: Bridging Research, Development and Production, sponsored by the Cambridge Healthtech Institute, Cambridge, MA.

Dynavax's Flu Vaccine Targets Highly Conserved Viral Antigens

Standard flu vaccines are designed to generate neutralizing antibodies against viral surface proteins (hemagglutinin, or HA and neuraminidase, or NA). These proteins mutate rapidly and a match between vaccine and current circulating virus is required to generate immunity.

In contrast, Dynavax's flu vaccine is produced by conjugating ISS with two highly conserved viral proteins, nucleoprotein (NP) and the extracellular domain of matrix protein 2 (M2e). The conjugates can be combined with the standard flu vaccine to confer cross-protective effect and to generate antigens capable of inducing potent immune responses.

* The NP-ISS conjugate induces strong type-1 helper T cell responses (Th1) and cytotoxic T cell responses (CTL) that can effectively kill virus- infected cells;

* The M2e-ISS conjugate induces strong cytotoxic antibody responses that can kill virus-infected cells.

* The ISS component of both conjugates enhances the response to standard flu vaccine.

Protection Against Antigenic Drift and Antigenic Shift

In these models, Dynavax's flu vaccine protects against both "antigenic drift" and "antigenic shift." Antigenic drift occurs when there are mutations in HA and NA viral surface proteins, leading to reduced efficacy of vaccines not precisely matched to these mutations. Antigenic shift occurs when there is exchange of genetic material between flu virus subtypes, creating an entirely new and potentially pandemic viral strain.

Dynavax has previously presented data showing that immunization with NP- ISS induces potent NP-specific Th1 and cytotoxic T lymphocyte responses as well as enhanced responses to HA when co-delivered with conventional or split vaccine.

New data were presented today by Dynavax on its NP-ISS and, for the first time, on its M2e conjugate.

Key new data presented today are as follows.

* Mice immunized with the NP-ISS conjugate and then challenged with drift and shift virus strains demonstrated statistically significant lower viral titers and higher survival rates compared to mice immunized with NP alone or a PBS placebo.

* Mice immunized with an M2e-ISS conjugate generated an M2e-specific antibody response that was enhanced with NP formulations.

* Both NP-ISS and M2e-ISS have been shown to enhance responses to co- administered standard vaccine in mice.

* Primates (baboons) immunized with NP-ISS co-administered with standard vaccine (Fluzone®, sanofi-aventis) demonstrated enhanced NP and Fluzone-specific antibody responses.

The presentation was entitled, "Use of Conserved Influenza Antigens Linked to Immunostimulatory DNA (ISS) to Generate Broad Immunity to Divergent and Potentially Pandemic Virus Strains," and were presented by Debbie Higgins, Senior Manager, Preclinical Programs, Dynavax Technologies. Preclinical data were generated by Dynavax and collaborators at The Influenza Research Center, Baylor College of Medicine.

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 cooperative research program administered by the National Institute of Allergy and Infectious Disease (NIAID), a division of the National Institutes of Health.

About Dynavax

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR-9 agonist-based products to treat and prevent allergies, infectious diseases, cancer, 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: TOLAMBA™, a ragweed allergy immunotherapeutic, for which a major safety and efficacy trial is currently underway, and that is in a supportive clinical trial in ragweed allergic children; HEPLISAV™, a hepatitis B vaccine that is currently in a Phase 3 clinical trial; SUPERVAX, a hepatitis B vaccine; a cancer therapy currently in a Phase 2 clinical trial and anticipated to enter clinical trials in solid tumors; an asthma immunotherapeutic that has shown preliminary safety and pharmacology in a Phase 2a clinical trial; and preclinical programs in hepatitis B therapy and hepatitis C therapy.

Dynavax cautions you that this press release contains forward-looking statements, including without limitation the potential of Dynavax's flu vaccine to confer broad immunity to divergent and potentially pandemic flu strains, plans to initiate clinical trials of Dynavax's flu vaccine, and the potential for continued development of existing clinical programs. 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 and timing of its current and anticipated clinical trials and other risks detailed in the "Risk Factors" section of Dynavax's Annual Report on Form 10-K and Quarterly Report on Form 10-Q. All forward-looking statements are made as of the date hereof and Dynavax undertakes no obligation to revise or update information provided in this press release.

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