Dynavax Initiates First Human Trial in Universal Flu Vaccine Program

BERKELEY, CA, Jul 07, 2010 (MARKETWIRE via COMTEX News Network) -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today the first human clinical trial in its Universal Flu vaccine program. The Phase 1 trial, which began vaccinating subjects in late June, will assess the safety and immunogenicity of N8295, the novel component of Dynavax's Universal Flu vaccine candidate. Approximately 40 subjects, divided into three dose groups, will receive two immunizations of N8295, one month apart. N8295 is a fusion protein comprised of NP and M2e, two highly conserved influenza antigens covalently linked to Dynavax's proprietary second-generation TLR9 agonist. Dynavax expects to report data by year-end 2010.

Novartis Vaccines and Diagnostics, Inc. is committed to supply influenza vaccine for Dynavax's clinical trials under a worldwide supply and option agreement signed in 2008. Novartis has an option to negotiate a joint development and commercialization agreement for Dynavax's Universal Flu vaccine and is obligated to provide commercial supplies of its vaccine once clinical proof-of-concept has been established. A clinical study to demonstrate proof-of-concept data is planned for 2011.

Dynavax's Universal Flu Vaccine is designed to offer protection against divergent influenza strains as well as to increase the efficacy of a standard trivalent inactivated influenza vaccine. Preclinical data have confirmed the expected immunogenicity and mechanistic effects of the vaccine candidate's novel components. The production of cytotoxic T-cells by NP and cytotoxic antibodies by M2e have been demonstrated in preclinical studies, as has an increase in neutralizing antibodies provided by a co-administered inactivated influenza vaccine. A GLP toxicity study demonstrated that this Universal Flu vaccine candidate is well-tolerated.

About Dynavax's Universal Flu Vaccine

Standard annual flu vaccines are designed to provide protection against the three strains of the influenza virus that are predicted to be most prevalent in an upcoming flu season. As such, these vaccines do not provide protection against divergent strains that emerge unexpectedly.

Dynavax's novel Universal Flu vaccine is designed to offer protection against divergent strains as well as increase the efficacy and potentially reduce the dose of standard flu vaccine. This unique approach is based on combining two highly conserved antigens and Dynavax's proprietary second-generation TLR9 agonist with standard flu vaccines:

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--  Two highly conserved antigens NP and M2e offer protection against
    divergent strains
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Dynavax's Universal Flu vaccine includes two conserved antigens, NP and M2e, which are present in all flu strains. NP, or nucleoprotein, is highly conserved across human and animal strains, while M2e, the extracellular domain of the matrix protein, is conserved but with some variations among species. NP provides cytotoxic T-cell protection and M2e offers protective antibodies for protection against divergent strains. Conventional flu vaccines do not induce a response to these antigens.

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--  Standard flu vaccine
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Dynavax's Universal Flu vaccine combines the conserved antigens NP and M2e linked to the Company's proprietary TLR9 agonist and the standard trivalent flu vaccine to produce neutralizing antibodies. The Company's proprietary component (N8295) could be combined with any standard flu vaccine, including standard trivalent influenza vaccine (TIV) and emerging strains such as H5N1 or H1N1.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases. The Company's lead product candidate is HEPLISAV(TM), an investigational adult hepatitis B vaccine designed to enhance protection more rapidly and with fewer doses than current licensed vaccines. For more information visit www.dynavax.com.

Forward-looking Statements

This press release contains "forward-looking statements," including statements related to the anticipated timing for the availability of data from the initial clinical trial in our universal flu vaccine program and for the proof-of-concept clinical study and the potential features of the vaccine. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including whether results of completed studies can be replicated in human studies, difficulties or delays in discovery or development, initiation and completion of preclinical or clinical studies, the results of those studies and the impact of those results on the initiation and completion of subsequent studies and issues arising in the regulatory process; achieving our Novartis agreement objectives; our ability to obtain additional financing to support our operations; and other risks detailed in the "Risk Factors" section of our current periodic reports filed with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

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