Dynavax Begins Phase 1b Study for Universal Flu Vaccine

Phase 1a Study of Novel Flu Component Completed

BERKELEY, CA, Sep 23, 2010 (MARKETWIRE via COMTEX News Network) -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that it has begun to immunize subjects in a Phase 1b clinical trial of its Universal Flu Vaccine candidate. The study will evaluate the safety of the combination of N8295, the novel component of Dynavax's Universal Flu vaccine candidate, and Novartis' investigational H5N1 avian influenza vaccine. 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.

The Phase 1b study is being initiated six months ahead of schedule based on preliminary Phase 1a safety data on N8295 alone. In an ongoing Phase 1a trial initiated during the second quarter of 2010, no dose limiting toxicities were identified. The trial is assessing three dose levels of N8295, and all immunizations have been completed. Follow-up data will be available by year-end 2010.

Establishing the safety -- first, of the novel component, N8295, and now, of the combination -- is key to the continued development of Dynavax's Universal Flu Vaccine. By assessing N8295 in combination with H5N1 vaccine, Dynavax expects to improve its understanding of the immunologic properties of the company's universal flu vaccine candidate in the absence of pre-existing immunity to the H5N1 flu strain in human subjects. With additional positive data from both the Phase 1a and 1b studies, Dynavax plans to design a proof-of-concept study to generate data that could trigger Novartis' option on joint development and commercialization of the product.

"Our success in moving forward to a Phase 1b study ahead of plan was a result of the positive preliminary data produced in the first safety study. Equally important, however, was close coordination of Novartis with our team and its commitment to supply H5N1 vaccine to meet the accelerated schedule," said Tyler Martin, Dynavax President and Chief Medical Officer.

Principal Investigator, Dr. John E. Ervin, will conduct the study at The Center for Pharmaceutical Research in Kansas City, MO. A total of 15 subjects will be divided into three different dose groups of N8295, each dose of which will be combined with the same amount of H5N1 vaccine. All subjects will receive two immunizations, separated by one month. Preliminary data is expected to be available early in 2011. Subjects will continue to be monitored for approximately one year.

Dynavax's Universal Flu Vaccine is designed to offer protection against divergent influenza strains as well as to increase the efficacy of an 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.

Under a 2008 agreement Novartis Vaccines and Diagnostics is providing Dynavax with influenza vaccine for both clinical trial use and potential vaccine sales. Novartis has an exclusive option to negotiate a Joint Development and Commercialization agreement with Dynavax pending proof-of-concept data.

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" that are subject to a number of risks and uncertainties, including statements related to the anticipated timing and design of clinical trials of our universal flu vaccine candidate, the nature and availability of data from the clinical trials and the 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 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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