Dynavax and Merck & Co., Inc. Report Clinical Hold of Investigational Vaccine HEPLISAV

Dynavax to Hold Conference Call Today, Monday, March 17, at 4:30 p.m. EDT

BERKELEY, Calif. & WHITEHOUSE STATION, N.J., Mar 17, 2008 (BUSINESS WIRE) -- Dynavax Technologies Corporation (Nasdaq:DVAX) and Merck & Co., Inc. announced today that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on the two Investigational New Drug (IND) applications for HEPLISAV(TM), an investigational hepatitis B vaccine being jointly developed for use in adults by Dynavax and Merck. A clinical hold is an order issued by FDA to the sponsor to delay a proposed clinical trial or suspend an ongoing clinical trial.

The FDA has placed the clinical hold on the investigational vaccine because of a serious adverse event (SAE) that occurred in one subject who received HEPLISAV in a Phase 3 study being conducted outside the United States. The subject was preliminarily diagnosed as having Wegener's granulomatosis, an uncommon disease in which the blood vessels are inflamed. All subjects in this Phase 3 study have received all doses per the study protocol and all will continue to be monitored. Administration of vaccine has been suspended in the only study of HEPLISAV in which injections were being administered actively, a fully enrolled Phase 2 study in End Stage Renal Disease subjects being conducted in Canada. A total of approximately 2,500 individuals have been vaccinated with more than 5,000 doses of HEPLISAV in 10 clinical trials spanning approximately seven years. There were no prior reports of Wegener's granulomatosis in these trials.

No additional clinical trials with HEPLISAV will be initiated until the clinical hold has been resolved. Dynavax and Merck, along with additional collaborators, including clinical investigators and leading experts, are evaluating the medical history of the individual who experienced the SAE to understand better the timing and onset of the disease symptoms, including whether it was a pre-existing condition or was related to vaccine administration.

Dynavax Conference Call

Dynavax will hold a conference call today at 4:30 p.m. EDT (1:30 p.m. PDT) to discuss the current status of its HEPLISAV program. The live webcast can be accessed by visiting the investor relations section of the Company's website at http://investors.dynavax.com/events.cfm. A replay of the webcast will be available on the Dynavax website approximately two hours after completion of the call and will be archived for two weeks on the Investor page of the Dynavax website.

About Dynavax

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent infectious diseases, allergies, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists 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. Our product candidates include: HEPLISAV, a hepatitis B vaccine in Phase 3 partnered with Merck & Co. Inc.; TOLAMBA(TM), a ragweed allergy immunotherapy in Phase 2; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B also in Phase 1. Our preclinical asthma and COPD program is partnered with AstraZeneca. The National Institutes of Health (NIH) partially funds our preclinical work on a vaccine for influenza. Symphony Dynamo, Inc. (SDI) funds our colorectal cancer trials and our preclinical hepatitis C therapeutic program, and Deerfield Management has committed funding for our allergy programs. While Deerfield, NIH and SDI provide program support, Dynavax has retained rights to seek strategic partners for future development and commercialization. For more information, please visit http://www.dynavax.com.

About Merck

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit www.merck.com.

Dynavax Forward-looking Statement

This press release contains "forward-looking statements," including statements related to the clinical status of HEPLISAV, the

timing of discussions with the FDA regarding the current clinical hold and whether or not and under what additional requirements, if any, further clinical development will be permitted. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including difficulties or delays in development, initiation and completion of clinical trials, the results of clinical trials and the impact of those results on the initiation and completion of subsequent trials and issues arising in the regulatory process; achieving our Merck collaborative agreement objectives and obtaining regulatory approval for HEPLISAV; the scope and validity of patent protection and the possibility of claims against us based on the patent rights of others; our ability to obtain additional financing to support our operations; and other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

Merck Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2007, and in its periodic reports on Form 10-Q and current reports on Form 8-K, if any, which the Company incorporates by reference.

SOURCE: Dynavax Technologies Corporation

Dynavax
Shari Annes, 1-650-888-0902
1-510-665-7210
(Investor Relations & Media)
sannes@dynavax.com
or
Merck
Graeme Bell, 1-908-423-5185 (Investor Relations)
Kelley P. Dougherty, 1-215-652-0059 (Communications)