



Dynavax and Merck & Co., Inc. Provide Update on U.S. FDA Clinical Hold on Investigational Vaccine HEPLISAV(TM)

BERKELEY, Calif. & WHITEHOUSE STATION, N.J., Oct 21, 2008 (BUSINESS WIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX) and Merck & Co., Inc. have received communication from the U.S. Food and Drug Administration (FDA) regarding the two companies' response to the agency's request for safety information relating to the clinical hold on the two Investigational New Drug (IND) Applications for HEPLISAV(TM), an investigational hepatitis B virus (HBV) vaccine.

The FDA has advised the companies that the balance of risk versus potential benefit no longer favors continued clinical evaluation of HEPLISAV in healthy adults and children. The FDA has also advised the companies that there may be potential for an acceptable risk versus benefit profile for HEPLISAV in patients with renal failure, and requested additional information from the companies before considering further pursuit of clinical studies in those patients. Dynavax and Merck are evaluating the FDA's response in considering next steps. In the meantime, the clinical hold on the two U.S. IND Applications for HEPLISAV remains in effect.

In March 2008, the FDA placed a clinical hold on the two IND Applications for HEPLISAV and requested for review the clinical and preclinical safety data including all available information about a single case of Wegener's granulomatosis reported in a Phase 3 clinical trial in adults. HEPLISAV is being jointly developed by Dynavax and Merck under a global collaboration agreement.

About Dynavax

Dynavax Technologies Corporation is a clinical-stage biopharmaceutical company that develops innovative products for the treatment of infectious diseases, respiratory diseases, and cancer. Our novel Toll-like Receptor 9 (TLR9) agonist products are based on our proprietary immunostimulatory sequences (ISS), which are short DNA sequences that stimulate an innate immune response. Our clinical product candidates include: HEPLISAV, a hepatitis B vaccine partnered with Merck & Co., Inc.; a therapy for hepatitis B; and therapies for cancer and hepatitis C funded by Symphony Dynamo, Inc. Our preclinical pipeline includes an asthma and COPD drug candidate partnered with AstraZeneca and a Universal Flu vaccine. For more information, visit 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 assessment of and next steps with respect to the FDA response to the clinical hold on HEPLISAV, whether Merck will continue our collaboration agreement and the determination of whether further clinical development of HEPLISAV will be undertaken. 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; 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 Quarterly Report on Form 10-Q. 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 any risk factors or cautionary statements contained in the Company's periodic reports on Form 10-Q or current reports on Form 8-K, which the Company incorporates by reference.

SOURCE: Dynavax Technologies Corporation and Merck & Co., Inc.

For Dynavax:

Amy Figueroa, 1-510-665-7211

(Investor Relations and Corporate Communications)

afigueroa@dynavax.com

or

For Merck:

Eva Boratto, 1-908-423-5185

(Investor Relations)

Ian McConnell, 1-908-423-3046

(Corporate Media Relations)

Copyright Business Wire 2008

News Provided by COMTEX