Dynavax and Merck & Co., Inc. Announce Phase 3 Trial with Investigational Hepatitis B Vaccine (HEPLISAV(TM)) Met its Primary Endpoint

BERKELEY, Calif. & WHITEHOUSE STATION, N.J., Aug 05, 2008 (BUSINESS WIRE) -- Dynavax Technologies Corporation (Nasdaq:DVAX) and Merck & Co., Inc. announced today top-line immunogenicity results from a Phase 3 clinical trial comparing HEPLISAV(TM), an investigational hepatitis B virus (HBV) vaccine, to a currently marketed HBV vaccine, Engerix-B(R) (1). The study achieved its primary endpoint. HEPLISAV is being jointly developed by Dynavax and Merck for use in adults and in patients with end stage renal disease.

This study, called PHAST (Phase 3 HeplisAv Short-regimen Trial), evaluated a two-dose regimen of HEPLISAV administered at 0 and 1 month compared to a three-dose regimen of Engerix-B(R) administered at 0, 1 and 6 months. The primary endpoint was the proportion of subjects who developed protective antibodies to hepatitis B after administration. In PHAST, 95.1 percent of subjects who received two doses of HEPLISAV (n=1,819) developed protective antibodies to hepatitis B when measured at 12 weeks versus 81.1 percent of subjects who received three doses of Engerix-B(R) (n=608) when measured at 28 weeks. The multi-center study evaluated 2,427 subjects from 11 to 55 years of age in Canada and Germany. Results of additional analyses from this trial will be presented in the future.

As previously disclosed, the U.S. Food and Drug Administration (FDA) placed a clinical hold on the two Investigational New Drug (IND) Applications for HEPLISAV that is still in effect. In issuing the clinical hold, the FDA requested a review of clinical and preclinical safety data for HEPLISAV. Additionally, the FDA requested all available information about a single case of Wegener's granulomatosis reported in this Phase 3 trial.

HEPLISAV is based on Dynavax's proprietary immunostimulatory sequence (ISS) that specifically targets Toll-Like Receptor 9 (TLR9) to stimulate an innate immune response. HEPLISAV combines ISS with HBV surface antigen (HBsAg) and is designed to enhance the speed of protection.

Webcast Today

Dynavax will webcast a discussion of the HEPLISAV Phase 3 data along with the company's second quarter 2008 financial results on Tuesday, August 5, 2008 at 4:30 p.m. Eastern Daylight Time / 1:30 p.m. Pacific Daylight Time. The webcast can be accessed on Dynavax's website at http://investors.dynavax.com/events.cfm. A telephonic replay of the discussion will be available through August 19, 2008 by dialing 1-888-203-1112, access code: 4643391. International callers can dial 1-719-457-0820, access code: 4643391.

About Dynavax

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent infectious diseases, allergy, 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 clinical product candidates include: HEPLISAV, a hepatitis B vaccine partnered with Merck & Co., Inc.; a therapy for metastatic colorectal cancer; and therapies for hepatitis B and C. Our preclinical asthma and COPD program is partnered with AstraZeneca. The NIH partially funds our preclinical universal influenza vaccine program that is being coordinated with Novartis. Symphony Dynamo Inc. (SDI) funds our colorectal cancer and hepatitis C therapeutic programs. While the 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.

DYNAVAX Forward-Looking Statement

This press release contains "forward-looking statements." 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 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.

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.

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 upda te 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.

(1) Engerix-B(R) is a registered trademark of GlaxoSmith Kline

SOURCE: Dynavax Technologies Corporation

Dynavax
Shari Annes, 1-650-888-0902 or 1-510-665-7210
Investor Relations
Media
sannes@dynavax.com
or
Merck
Eva Boratto, 1-908-423-5185
Investor Relations
or
Global Communications
Tracy Ogden, 1-215-652-0344