Dynavax Presents Additional Phase 3 Data for HEPLISAV(TM)Hepatitis B Vaccine at EASL Medical Conference

BERKELEY, Calif., Apr 27, 2009 (BUSINESS WIRE) -- Dynavax Technologies Corporation (Nasdaq:DVAX) today announced the oral presentation of additional Phase 3 clinical data for HEPLISAV**(TM)** hepatitis B vaccine in a session for late-breaking abstracts at the 44th Annual Meeting of the European Association for the Study of Liver Disease (EASL) in Copenhagen, Denmark. As previously reported, HEPLISAV met its primary endpoint in this Phase 3 trial and demonstrated the vaccine's potential to provide more rapid and increased protection against hepatitis B viral infection and with fewer doses than the licensed vaccine.

This Phase 3 trial referred to as PHAST (Phase 3 HeplisAv Short-regimen Trial) evaluated more than 2,400 adults. The seroprotection rate at the primary endpoint was 95% in subjects receiving 2 doses of HEPLISAV at 0 and 1 month, compared to 81% in subjects receiving 3 doses of licensed vaccine Engerix-B(R) at 0, 1, and 6 months. At each time point, there was a statistically significant ($p < 0.0001$) difference in the seroprotection rate for subjects receiving HEPLISAV or Engerix-B.

Treatment Group	Dosing Regimen	Seroprotection Rate [1] at Month 1	2	3	6	7
HEPLISAV	2 doses (0, 1 month)	24%	89%	95%[2]	98%	98%
Engerix-B	3 doses (0, 1, 6 months)	4%	26%	23%	32%	81%[2]

[1] Seroprotection rate - percentage of subjects with anti-HBsAg antibodies â%¥ 10 mIU/mL

[2] Primary endpoint

As previously reported, safety results from this trial demonstrated the safety profile of HEPLISAV and Engerix-B appeared similar. Subjects were randomized 3 to 1 to receive HEPLISAV or Engerix-B and one case of vasculitis was reported in each of the treatment groups. Following the report of the severe adverse event of Wegener's granulomatosis, an uncommon form of vasculitis, HEPLISAV was placed and remains on clinical hold by the U.S. Food and Drug Administration. Dynavax is clarifying the remaining regulatory requirements for the potential development and licensure of HEPLISAV in the United States and Europe.

A copy of the presentation is available at http://investors.dynavax.com/events.cfm. Dynavax's abstract #587659 was titled "A Phase 3 Safety and Efficacy Study Comparing Immunogenicity of Two Doses of Hepatitis B Surface Antigen Combined with Immunostimulatory Sequence with Three Doses of Licensed Hepatitis Vaccine."

About HEPLISAV

HEPLISAV is a Phase 3 hepatitis B vaccine aimed at unmet medical needs in the vaccination of adults and end-stage renal disease patients by providing rapid and increased protection with fewer doses. HEPLISAV combines Dynavax's proprietary immunostimulatory sequences (ISS), which target Toll-like Receptor 9, with hepatitis B surface antigen (HBsAg). HEPLISAV targets an estimated $500 million global market opportunity for adult hepatitis B vaccines.

About Hepatitis B

Hepatitis B is a chronic disease which can lead to cirrhosis of the liver and hepatocellular carcinoma. There is no cure for hepatitis B and disease prevention through effective vaccines is critical to reducing the spread of the disease. Current hepatitis B vaccines for adults usually require 3 doses given over 6 months to provide seroprotection of approximately 30%, 75%, and 90% after the first, second, and third doses respectively. The effectiveness of current vaccines is further compromised because only 30% of people receive all 3 doses.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops a diversified pipeline of novel Toll-like Receptor (TLR) based product candidates. Based on Dynavax's proprietary technologies, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. Dynavax has partnerships with leading pharmaceutical companies such as GlaxoSmithKline, AstraZeneca, and Novartis as well as funding from Symphony Dynamo, Inc. and the National Institutes of Health. 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 nature and timing of communications with regulatory agencies regarding HEPLISAV. 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 the provision of additional information requested by the FDA is found to be satisfactory to remove the clinical hold for HEPLISAV, whether HEPLISAV can be further developed, or even if further development is permitted, that successful clinical development and regulatory approval can occur in a timely manner or without significant additional studies and difficulties or delays in development; 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.

Engerix-B(R) is a registered trademark of GlaxoSmithKline

SOURCE: Dynavax Technologies Corporation

Dynavax Technologies Corporation
Amy Figueroa, 510-665-7211
Investor Relations and Corporate Communications
afigueroa@dynavax.com