Dynavax Presents Additional Phase 3 Data for HEPLISAVTM Hepatitis B Vaccine at DDW Medical Conference

HEPLISAV Demonstrates Rapid, Increased Protection for Adults

BERKELEY, Calif., Jun 03, 2009 (BUSINESS WIRE) -- Dynavax Technologies Corporation (Nasdaq:DVAX) today presented additional Phase 3 clinical data for HEPLISAV™ hepatitis B vaccine in a poster session at the Digestive Disease Week (DDW) medical conference in Chicago. In addition to meeting its primary endpoint in this Phase 3 trial as previously reported, HEPLISAV provided more rapid and increased seroprotection against hepatitis B viral infection and with fewer doses than the licensed vaccine. The data show the differences to be particularly significant in the subset of subjects over 40 years of age who are usually less likely to respond to immunization.

"Vaccination is critical for the prevention of hepatitis B viral infection and its spread, but the lengthy dosing regimen of current vaccines leaves many unprotected," commented Scott A. Halperin, M.D., Director Clinical Trials Research Center, Dalhousie University, IWK Heath Centre of Halifax, Nova Scotia and Lead Investigator in the Phase 3 trial. "The Phase 3 data demonstrate HEPLISAV's superior immunogenicity and similar safety profile versus the licensed vaccine, particularly for adults over 40 who are more difficult to protect against this preventable viral infection."

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.

In a subanalysis of subjects over 40 years of age, at each time point during the trial there was a statistically significant ($p < 0.0001$) difference in the seroprotection rate for subjects receiving HEPLISAV or Engerix-B.

Ages 40-55 Treatment Group	Dosing Regimen	Seroprotection Rate (1) at Month				
		1	2	3	6	7
HEPLISAV	2 doses (0, 1 month)	18%	84%	92%(2)	97%	97%
Engerix-B	3 doses (0, 1, 6 months)	3%	21%	17%	27%	75%(2)

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

(2) Primary endpoint

A copy of the poster is available at http://investors.dynavax.com/newsevents.cfm. Dynavax's abstract #587659 is titled "A Phase 3 Safety and Efficacy Study to Compare Immune Responses following Either Two Doses of Hepatitis B Surface Antigen Combined with Immunostimulatory Phosphorothioate Oligonucleotide (HBsAg-ISS) or Three Doses of Conventional Hepatitis B Vaccine."

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 (FDA). Dynavax is in active discussions with regulatory agencies to resolve the FDA's clinical hold on HEPLISAV and identify an appropriate path for its further development and approval in the United States, Europe, and the rest of the world.

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 a proprietary immunostimulatory sequence (ISS), which targets Toll-like Receptor 9, with hepatitis B surface antigen (HBsAg).

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.

About DDW

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 30 - June 4, 2009, at the McCormick Place, Chicago, IL. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit www.ddw.org.

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 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 FDA will remove the clinical hold for HEPLISAV, whether HEPLISAV can be further developed, financed or commercialized, 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, the Company's ability to obtain additional financing to support its operations; and other risks detailed in the "Risk Factors" section of our current periodic reports 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.

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

SOURCE: Dynavax Technologies Corporation

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