Dynavax Announces European Development Strategy for HEPLISAV Hepatitis B Vaccine

BERKELEY, Calif., Aug 12, 2009 (BUSINESS WIRE) -- Dynavax Technologies Corporation (Nasdaq:DVAX) today announced that it has met with the European Medicines Evaluation Agency (EMEA) to discuss its plans for continued clinical development of HEPLISAV™ Phase 3 investigational adult hepatitis B vaccine in Europe.

In a Scientific Advice letter, EMEA expressed a general agreement with Dynavax's proposed plan to develop HEPLISAV for adult populations that are less responsive to current licensed hepatitis B vaccines, including adults over 40 years of age, individuals with chronic kidney disease, and other groups. In addition, EMEA suggested that Dynavax consider the development of HEPLISAV for adults under 40 years of age who need rapid protection, a group that includes emergency personnel, healthcare workers and international travelers.

"As we advance our development plans for HEPLISAV, EMEA's scientific advice supports expansion of our targeted population in Europe to include subjects who need rapid protection against hepatitis B infection," commented Dino Dina, M.D., President and Chief Executive Officer of Dynavax. "A vaccine that demonstrates potential to provide faster and better protection than current vaccines could transform vaccination regimens and outcomes, particularly for individuals with increased risk of infection."

About HEPLISAV

HEPLISAV is a Phase 3 investigational adult hepatitis B vaccine designed to provide more rapid and increased protection with fewer doses than current licensed vaccines. Over 2,500 individuals have been vaccinated with HEPLISAV to date.

Dynavax has worldwide commercial rights to HEPLISAV, which combines hepatitis B surface antigen (HBsAg) with a proprietary Toll-like Receptor 9 agonist to enhance the immune response.

About Hepatitis B Vaccines

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 vaccination is critical to reducing the spread of the disease. The total worldwide market for adult hepatitis B vaccines is estimated at over $500 million annually.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious diseases. The Company's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide more rapid and increased protection with fewer doses than current licensed vaccines. 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 of communications with EMEA regarding HEPLISAV, submissions of documents, and potential clinical trials, and whether those submissions and trials may be acceptable to the EMEA. 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 and when the FDA will remove the clinical hold on 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 or difficulties or delays in development, the Company's ability to obtain additional financing to support its operations, possible claims against the Company based on the patent rights of others; 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.

SOURCE: Dynavax Technologies Corporation

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