Dynavax Announces Receipt of Communication from the U.S. FDA on HEPLISAVTM Hepatitis B Vaccine

BERKELEY, Calif., Feb 09, 2009 (BUSINESS WIRE) -- Dynavax Technologies Corporation (Nasdaq: DVAX) today announced receipt of communication from the U.S. Food and Drug Administration (FDA) regarding the clinical hold on the two HEPLISAV™ Investigational New Drug (IND) Applications, for healthy adults and patients with end-stage renal disease (ESRD). In this communication, the FDA has requested additional clinical and safety information which the agency indicated may be helpful in its risk assessment of the two INDs and may assist in finding a development path forward for HEPLISAV hepatitis B vaccine, not only in ESRD patients but also in healthy adults.

This communication followed a Clinical Hold Oversight Meeting held at the FDA on January 8, 2009. Dynavax believes the information requested by the FDA is available and intends to provide this to the agency in the near future.

Since March 2008, the two INDs for HEPLISAV have been and remain on clinical hold by the FDA in the United States.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops a diversified, well-funded pipeline of novel Toll-like Receptor (TLR) product candidates. Based on Dynavax's proprietary technology platforms, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. Dynavax's product programs are supported by global partnerships with leading pharmaceutical companies such as GlaxoSmithKline, AstraZeneca AB, 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," including statements related to the nature and timing of communications with the FDA regarding the current HEPLISAV clinical hold and whether or not further clinical development will be permitted. 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; whether HEPLISAV can be further developed, or even if further development is permitted, that successful clinical development can occur in a timely manner or without significant additional studies; 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; obtaining regulatory approval for HEPLISAV; 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.

SOURCE: Dynavax Technologies Corporation

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