

October 16, 2013

Dynavax Reports on HEPLISAV(TM) Regulatory Path

Conference Call Tomorrow, October 17th at 8:30 a.m. ET

BERKELEY, CA -- (Marketwired) -- 10/16/13 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced the design of its next large-scale clinical study of HEPLISAV, its investigational adult hepatitis B vaccine, following discussions with the U.S. Food and Drug Administration (FDA or Agency). The planned study, HBV-23, is intended to provide a sufficiently-sized safety database for the Agency to complete its review of Dynavax's Biologics License Application (BLA). It will be an 8,000 subject, Phase 3, observer-blinded, randomized, active-controlled, multicenter trial of the safety and immunogenicity of HEPLISAV compared with Engerix-B[®] in adults 18 to 70 years of age.

The primary objectives of HBV-23 will be:

- To evaluate the overall safety of HEPLISAV with respect to clinically significant adverse events; and
- To demonstrate the noninferiority of the peak seroprotection rate (SPR) induced by HEPLISAV to Engerix-B in subjects with type 2 diabetes mellitus.

HBV-23 will include 5,500 HEPLISAV subjects and 2,500 Engerix-B subjects, randomized 2:1 and stratified by age and diabetes diagnosis. HEPLISAV subjects will receive two doses at 0 and 1 month, while Engerix-B subjects will receive three doses at 0, 1 and 6 months. All HEPLISAV subjects will be evaluated for safety for one year following the second dose and all potential autoimmune events will be adjudicated by a Safety Evaluation and Adjudication Committee. Immunogenicity assessments will be conducted in a subset of subjects, including those with type 2 diabetes.

"Following extensive discussion with FDA, we've finalized a study design that we believe will provide confidence to the Agency regarding HEPLISAV's safety profile, and importantly, will provide Dynavax with the opportunity to prospectively generate additional immunogenicity data in persons with diabetes, a population for whom there is a clear unmet medical need," commented Eddie Gray, Dynavax Chief Executive Officer.

Dynavax intends to initiate this study in the first quarter of 2014 and conclude subject visits by the end of 2015 and estimates the external costs of the study to be in the range of \$50-55 million.

Dynavax's Marketing Authorization Application for HEPLISAV remains on file in Europe. The Company is currently preparing its response to the European Medicines Agency's (EMA) 120-Day List of Questions to be submitted in the fourth quarter of 2013, following which the EMA will provide Dynavax its 180-Day List of Outstanding Issues expected in the first quarter 2014.

The 120-Day response will incorporate the target population for HEPLISAV and size of the safety database, and will address Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP)-related items, including questions arising from a recent EMA GCP inspection. Dynavax will continue to work through the European regulatory review process to determine the appropriate next steps, corrective actions, and possible post-approval commitments. The Company anticipates that some of these matters will need to be resolved following issuance of the 180-Day List of Outstanding Issues, which when received, will enable Dynavax to provide further clarification on HEPLISAV's potential path forward in Europe.

Engerix-B[®] is a registered trademark of GlaxoSmithKline.

Conference Call Tomorrow

Dynavax management will host a conference call tomorrow at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) and individuals may participate in the conference call by dialing (866) 428-9517 (domestic) or (224) 357-2389 (international).

To access a live audio webcast of the conference call, please visit the Company's website at <http://investors.dynavax.com/newsevents.cfm>

A replay of the webcast will be available on the Dynavax website approximately two hours after the conference call concludes through October 31, 2013.

About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine that combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV.

About Dynavax

Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious and inflammatory diseases and oncology. Dynavax's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine. For more information visit www.dynavax.com.

Forward-Looking Statements

This press release contains "forward-looking" statements, including expectations for HEPLISAV, our discussions with the FDA and the impact on our further plans to achieve approval, and the timing and nature of our responses to correspondence in the European regulatory review process, and whether our efforts may be sufficient to achieve approval in a timely manner or within the projected expense levels identified. 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 successful clinical and regulatory development and review and approval of HEPLISAV and our process for its manufacture can occur without significant delay or additional studies; whether our studies and manufacturing efforts are sufficient to support registration for commercialization of HEPLISAV in either or both of the US and Europe; the timing for and costs of achieving the size of the safety database that the FDA has provided guidance on; 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, including whether a BLA or European licensure application will be approved; our ability to obtain additional financing to support the development and commercialization of HEPLISAV and our other operations; possible claims against us, including enjoining sales of HEPLISAV, 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. Information on Dynavax's website at www.dynavax.com is not incorporated by reference in our current periodic reports with the SEC.

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Source: Dynavax Technologies

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