

# Dynavax Reports Feedback From FDA Meeting Regarding HEPLISAV(TM) Biologic License Application

# Conference Call Scheduled for 9:00 a.m. ET Today

BERKELEY, CA -- (Marketwired) -- 06/10/13 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today reported that it recently concluded a meeting with the U.S. Food and Drug Administration (FDA or Agency) regarding its Biologic License Application (BLA) for HEPLISAV, an investigational adult hepatitis B vaccine. The meeting followed recommendations expressed in November 2012 by the Vaccines and Related Biological Products Advisory Committee (VRBPAC) regarding the size of Dynavax's safety database. The meeting with FDA resulted in the following messages:

- The safety database does indeed need additional subjects;
- VRBPAC's strong endorsement of HEPLISAV's demonstrated immunogenicity was acknowledged;
- Analyzing the benefit/risk of HEPLISAV's use in discrete patient populations did not fundamentally address the shortfall in the safety database. It was concluded that to do so would unnecessarily restrict the patient population that could benefit from HEPLISAV's approval;
- The additional safety data collected would facilitate review for an indication in adults 18-70 years of age.

"We are encouraged by the supportive feedback received from the FDA and appreciate the informative interactions and clarity provided regarding HEPLISAV's path toward approval in the broader indication," commented Eddie Gray, Dynavax's Chief Executive Officer. "We understand the rationale for the Agency's recommendations and will give full consideration to their feasibility and timing as we advance HEPLISAV's development."

Dynavax will meet with the FDA shortly to discuss the protocol for collecting the additional safety data, which is expected to be incorporated into the existing BLA. The Company also continues to work on the questions raised by the FDA in the Complete Response Letter (CRL) regarding the manufacturing and testing of HEPLISAV. Dynavax will provide updates as appropriate.

#### Conference Call Today

Dynavax management will host a conference call today at 9:00 a.m. Eastern Time (6:00 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 <a href="http://investors.dynavax.com/newsevents.cfm">http://investors.dynavax.com/newsevents.cfm</a>

A replay of the webcast will be available on the Dynavax website approximately two hours after the conference call concludes through June 21, 2013.

## About HEPLISAV

HEPLISAV is an investigational adult hepatitis B vaccine for which US and European licensure applications have been accepted for review by the FDA and the EMA. Dynavax has worldwide commercial rights to HEPLISAV. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist to enhance the immune response.

## About Dynavax

Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. Dynavax's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine. For more information visit <a href="https://www.dynavax.com">www.dynavax.com</a>.

#### 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 expected timing of our responses with respect to the feedback from the regulatory agencies. 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 can support registration for commercialization of HEPLISAV; the timing for 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 <a href="https://www.dynavax.com">www.dynavax.com</a> is not incorporated by reference in our current periodic reports with the SEC.

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