

February 25, 2013

## **Dynavax Receives FDA Complete Response Letter on HEPLISAV(TM) Biologic License Application**

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

BERKELEY, CA -- (Marketwire) -- 02/25/13 -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA or Agency) regarding its Biologic License Application (BLA) for HEPLISAV, an investigational adult hepatitis B vaccine.

In the CRL, the FDA specified that the indication in adults 18-70 years of age cannot be approved without further evaluation of safety in this broad age group. The FDA also continues to express concern that novel adjuvants may cause rare autoimmune events. However, the Agency indicated its willingness to continue discussions regarding a more restricted use of HEPLISAV. Dynavax plans to discuss the CRL with the FDA to identify the most expeditious path to approval for HEPLISAV, particularly in adults who may receive the greatest benefit from HEPLISAV.

Furthermore, the FDA requested additional data from Dynavax's process validation program and clarifying information on the manufacturing controls and facilities related to the assurance of the quality of the commercial product. Dynavax believes it can provide the information but the exact timeframe for its response cannot be determined until it has met with the Agency.

Dynavax plans to meet with the FDA to discuss the steps necessary for potential approval of HEPLISAV and currently believes the meeting can take place within 6 weeks. Following its meeting with the FDA, Dynavax will provide updates as appropriate.

Dynavax's BLA was accepted for review by the FDA in June 2012. On November 15, 2012, the FDA's Vaccines and Related Biological Products Advisory Committee (Committee) voted 8 to 5 with 1 abstention that there was insufficient data to adequately support the safety of HEPLISAV, although the Committee voted 13 to 1 that HEPLISAV data adequately demonstrated immunogenicity.

Dynavax's Marketing Authorization Application continues to be under review in Europe.

### *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 <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 March 8, 2013.

### *About HEPLISAV*

HEPLISAV is an investigational adult hepatitis B vaccine. 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 [www.dynavax.com](http://www.dynavax.com).

### *Forward-Looking Statements*

This press release contains "forward-looking" statements. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including our ability to meet with the FDA within six weeks;

the identification of an adult patient population that would support studies for potential approval; FDA's willingness to favorably consider a more restricted use of HEPLISAV; our ability to provide additional data requested by FDA from our process validation and manufacturing controls and facilities; 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 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 the BLA and the 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](http://www.dynavax.com) is not incorporated by reference in our current periodic reports with the SEC.

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