



April 27, 2016

## **Dynavax Receives Notification of PDUFA Extension for HEPLISAV-B to December 15, 2016**

BERKELEY, CA -- (Marketwired) -- 04/27/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the U.S. Food and Drug Administration (FDA) will require additional time to complete its review of the Biologics License Application (BLA) for HEPLISAV-B™, Dynavax's investigational vaccine for immunization of adults against hepatitis B infection. In a notice received from the FDA, the Prescription Drug User Fee Act (PDUFA) action date for HEPLISAV-B has been extended by three months to December 15, 2016.

On April 8, in response to an FDA request, Dynavax submitted individual trial data sets that had been provided as integrated data in the March 2016 BLA resubmission. FDA then determined that the addition of these large data sets represented a major amendment to the BLA and thus extended the PDUFA action date to allow for a full review.

The HEPLISAV-B BLA is based on results from clinical trials that have generated data in more than 14,000 total participants.

"We appreciate the commitment of the FDA staff to conduct a complete review of all of the data supporting our BLA and we remain committed to working closely with them over the coming months in order to achieve HEPLISAV-B approval in 2016," said Eddie Gray, chief executive officer of Dynavax.

### **About HEPLISAV-B**

HEPLISAV-B 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. In Phase 3 trials, HEPLISAV-B demonstrated higher and earlier protection with fewer doses than a currently licensed hepatitis B vaccine.

HEPLISAV-B is administered in two doses over one-month. Currently marketed hepatitis B vaccines are administered in three doses over a six-month schedule. Results of a published Vaccine Safety Datalink study showed that only 54 percent of adults completed the three-dose hepatitis B vaccine series in one year. Those who do not complete the series may not be adequately protected against hepatitis B.

HEPLISAV-B has a safety profile similar to that of existing vaccines. The investigational vaccine's safety profile is based on clinical trials that generated safety data from more than 10,000 HEPLISAV-B compared with more than 4000 ENGERIX-B participants. The most frequently reported local reaction was injection site pain. The most common systemic reactions were fatigue, headache and malaise.

Dynavax has worldwide commercial rights to HEPLISAV-B.

### **About Dynavax**

Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious diseases and oncology. Dynavax's lead product candidates are HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine, and SD-101, an investigational cancer immunotherapeutic currently in several Phase 1/2 studies. For more information, visit [www.dynavax.com](http://www.dynavax.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding HEPLISAV-B and FDA review. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether there will be changes in the PDUFA target date, the data supporting the BLA or their interpretation; whether the BLA will be deemed satisfactory by the FDA; whether additional studies or manufacturing process enhancements will be required or other issues will arise that will negatively impact the review and approval by the FDA; initiation, enrollment and completion of pre-clinical studies and clinical trials of our other product candidates, including SD-101; the results of clinical trials and the impact of those results on the initiation or continuation of subsequent trials and issues arising in the regulatory process; and other risks detailed in the "Risk Factors" section of our most recent current periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this

press release. We do not undertake any obligation to update publicly any such forward-looking statements, 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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