



February 28, 2017

## **Dynavax Announces FDA Acceptance for Review of Its Complete Response to November 2016 CRL and PDUFA Action Date for HEPLISAV-B(TM)**

BERKELEY, CA -- (Marketwired) -- 02/28/17 -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review Dynavax's responses to the Complete Response Letter (CRL) issued by the FDA in November 2016 for the Biologics License Application for HEPLISAV-B, the company's vaccine candidate for immunization against hepatitis B infection in adults 18 years of age and older. The FDA has established August 10, 2017 as the Prescription Drug User Fee Act (PDUFA) action date.

### ***About Hepatitis B***

Hepatitis B is a viral disease of the liver that can become chronic and can lead to cirrhosis of the liver, hepatocellular carcinoma and death. In the United States, the Centers for Disease Control and Prevention estimates that 19,000 hepatitis B infections continue to occur annually, with the vast majority occurring in adults. There is no cure for hepatitis B, and disease prevention through more effective vaccines is critical to reducing the spread of the disease.

### ***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 showed higher and earlier protection with fewer doses than a currently licensed hepatitis B vaccine. The most frequently reported local reaction was injection site pain. The most common systemic reactions were fatigue, headache and malaise, all of which were similar to an existing 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.<sup>1</sup> Those who do not complete the series may not be adequately protected against hepatitis B.

Dynavax has worldwide commercial rights to HEPLISAV-B.

### ***About Dynavax***

Dynavax is a clinical-stage immunology company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax is developing product candidates for use in multiple cancer indications, as a vaccine for the prevention of hepatitis B and as a disease modifying therapy for asthma. Dynavax's lead product candidates are SD-101, an investigational cancer immunotherapeutic currently in Phase 1/2 studies, and HEPLISAV-B, 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, 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 the FDA will find the response to the CRL to be satisfactory to support approval; whether the FDA will require additional information or studies; whether the FDA will identify additional issues following review of Dynavax's response to the CRL; whether the FDA will schedule a meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and if so whether it will impact the timing of FDA review, negatively impact the review or whether the VRBPAC will recommend approval; whether additional manufacturing process enhancements will be required or other issues will arise that will negatively impact the review and approval by the FDA; if approvable, whether the issues will negatively impact the potential scope of the label for HEPLISAV-B; 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.

<sup>1</sup> Nelson, J. et al. American Journal of Public Health, "Compliance with Multiple-Dose Vaccine Schedules Among Older Children, Adolescents and Adults: Results from a Vaccine Safety Datalink Study." 2009. Vol. 99 No. S2.

Contact:  
Ryan Spencer

VP, Corporate Strategy & Communications  
510.665.4618  
[rspencer@dynavax.com](mailto:rspencer@dynavax.com)

Source: Dynavax Technologies Corporation

News Provided by Acquire Media