



April 4, 2016

## **Dynavax to Present Data From Pivotal Phase 3 HEPLISAV-B(TM) Trial**

### **Data to Be Presented at NFID's Annual Conference on Vaccine Research, Monday April 18th in Baltimore**

BERKELEY, CA -- (Marketwired) -- 04/04/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that it will present HEPLISAV-B pivotal Phase 3 data at the National Foundation for Infectious Diseases' 19th Annual Conference on Vaccine Research (ACVR). The Conference will take place in Baltimore, Maryland from April 18<sup>th</sup> through April 20<sup>th</sup>. The Dynavax presentation is scheduled for Monday, April 18<sup>th</sup> at 3:45 p.m. EDT.

In late 2015, Dynavax completed its Phase 3 study of HEPLISAV-B (HBV-23) compared with Engerix-B® in adults 18-70 years of age. This study provided head-to-head safety and immunogenicity data compared with the current market leader in adult hepatitis B vaccines.

In January 2016, [Dynavax reported top-line results](#) demonstrating that both co-primary endpoints were met in this study. The rates of clinically significant adverse events were consistent with randomization and HEPLISAV-B provided a statistically significant higher rate of seroprotection than Engerix-B in diabetic participants and in all participants. The FDA has established September 15, 2016 as the Prescription Drug User Fee Act (PDUFA) action date for the HEPLISAV-B Biologics License Application.

#### **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, offering rapid protection. 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, 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 data or interpretation; whether the final study results 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.

<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.

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