July 28, 2017

Dynavax Announces FDA Advisory Committee Vote in Favor of HEPLISAV-B(TM)

BERKELEY, CA -- (Marketwired) -- 07/28/17 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 12 to 1 that the safety data for HEPLISAV-B [Hepatitis B Vaccine, Recombinant (Adjuvanted)] support licensure for immunization against hepatitis B infection in adults 18 years of age and older. Three members of the panel abstained. Additionally, the Committee provided commentary on the design of Dynavax's proposed post-marketing pharmacovigilance plan for HEPLISAV-B. The FDA did not ask this VRBPAC panel to vote on the immunogenicity of HEPLISAV-B. A prior VRBPAC panel voted 13 to 1 that the data from Phase 3 clinical trials supports the immunogenicity of HEPLISAV-B.

"We are encouraged by the committee's positive vote in favor of HEPLISAV-B, which we believe will become an important new tool in the fight against hepatitis B infection if approved by the FDA," said Eddie Gray, chief executive officer of Dynavax. "Clinical studies of HEPLISAV-B have shown that the vaccine provides increased rates of seroprotection. In addition, the two-dose regimen offers the potential to increase patient compliance, which physicians and advocates agree is essential to preventing more cases of hepatitis B and achieving the public health goal of eradication. We look forward to completing our ongoing discussions with the FDA regarding an appropriate post-marketing commitment as it finalizes its review."

The incidence of hepatitis B in the U.S. is increasing[i] and there is no cure for the disease. Therefore, disease prevention through effective vaccination is critical to reducing its spread. Currently marketed hepatitis B vaccines are administered in three doses over a six-month schedule. The HEPLISAV-B regimen is two doses over one month. Results of a published Vaccine Safety Datalink study showed that only 54 percent of adults completed the currently available three-dose hepatitis B vaccine series in one year.[ii] Those who do not complete the series may not be adequately protected against hepatitis B.

The FDA is not bound by the committee's recommendation but takes its advice into consideration when reviewing marketing applications. HEPLISAV-B has a Prescription Drug User Fee Act (PDUFA) date of August 10, 2017. If the FDA approves HEPLISAV-B, Dynavax will seek a recommendation from the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) during its October 2017 meeting. Dynavax plans to launch the vaccine commercially in the U.S. in early 2018 on its own or through a commercial partner.

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 U.S., the number of reported cases of acute hepatitis B increased more than 20 percent in 2015.[iii] After adjusting for under-reporting, the CDC estimated that 21,900 new hepatitis B virus infections occurred in 2015. In addition to new cases of hepatitis B, chronic HBV infection remains a major public health challenge. The CDC estimates that approximately 850,000 persons are living with hepatitis B virus in the U.S.

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. 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.

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 Complete Response Letter (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 decide not to approve HEPLISAV-B despite a

positive recommendation of the Vaccines and Related Biological Products Advisory Committee; whether the FDA will delay approval of HEPLISAV-B; whether additional manufacturing process enhancements will be required or other issues will arise that will negatively impact the review and approval by the FDA; whether the issues will negatively impact the potential scope of the label for HEPLISAV-B; the nature and scope of any post-marketing study that the FDA will require; whether the Centers for Disease Control and Prevention's Advisory Committee on Immunization will provide a recommendation for HEPLISAV-B if approved by the FDA; and other risks detailed in the "Risk Factors" section of our most recent current periodic report filed with the SEC. 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 is not incorporated by reference in our current periodic reports with the SEC.

[i] https://www.cdc.gov/hepatitis/statistics/2015surveillance/commentary.htm#Ref10. Accessed July 5, 2017.

[ii] Nelson JC, et al. Compliance with multiple-dose vaccine schedules among older children, adolescents and adults: Results from a Vaccine Safety Datalink study. Am J Public Health. 2009;99(S2); S389-S397.

[iii] https://www.cdc.gov/hepatitis/statistics/2015surveillance/commentary.htm#Ref10. Accessed July 5, 2017.

Contact:
Ryan Spencer
VP, Corporate Strategy & Communications
510.665.4618
rspencer@dynavax.com

Media Contact:
Leslie Bryant
WCG
562.505.9290
lbryant@w2ogroup.com

Source: Dynavax Technologies