# Dynavax Announces European Medicines Agency Accepts Marketing Authorization Application for HEPLISAV-B® for Prevention of Hepatitis B in Adults

March 28, 2019

BERKELEY, Calif., March 28, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX), a fully-integrated biopharmaceutical company focused on discovering and developing novel vaccines and immuno-oncology therapeutics, today announced that the European Medicines Agency (EMA) has accepted the Company's Marketing Authorization Application (MAA) for review of HEPLISAV-B [Hepatitis B Vaccine, Recombinant (Adjuvanted)] for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

This acceptance follows Dynavax's submission of the MAA on March 11 and marks the beginning of the regulatory review process for HEPLISAV-B in the European Union (EU). The outcome of the MAA review by the EMA is expected next year.

"The acceptance of the HEPLISAV-B application for review by the EMA signifies an important milestone in our journey to help prevent hepatitis B in adults through vaccination," said Robert Janssen, M.D., chief medical officer of Dynavax. "Many at-risk adults remain unprotected against this highly infectious virus. HEPLISAV-B has been shown to provide higher rates of protection with fewer doses than currently available vaccines. We hope to make HEPLISAV-B available beyond the U.S. to help address the global hepatitis B public health problem."

In 2017, the U.S. Food and Drug Administration (FDA) approved HEPLISAV-B for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. HEPLISAV-B was the first new hepatitis B vaccine in the U.S. in more than 25 years and the only two-dose hepatitis B vaccine for adults.

The MAA for HEPLISAV-B is based upon the successful outcomes from three Phase 3 non-inferiority trials of nearly 10,000 adult participants who received HEPLISAV-B. The pivotal studies compared HEPLISAV-B administered in two doses over one month to Engerix-B administered in three doses over a six-month schedule. Results from the largest Phase 3 trial, which included 6,665 participants, showed that HEPLISAV-B demonstrated a statistically significantly higher rate of protection of 95% compared with 81% for Engerix-B. Across the three clinical trials, the most common local reaction was injection site pain (23% to 39%). The most common systemic reactions were fatigue (11% to 17%) and headache (8% to 17%).

**About Hepatitis B**

Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer and death. The hepatitis B virus is 50 to 100 times more infectious than HIV,[i] and transmission is on the rise. There is no cure for hepatitis B, but effective vaccination can prevent the disease.

In adults, hepatitis B is spread through contact with infected blood and through unprotected sex with an infected person. The CDC recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas.[ii]

**About HEPLISAV-B**
HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax’s proprietary Toll-like Receptor (TLR) 9 agonist to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

For more information about HEPLISAV-B, visit http://heplisavb.com/.

**About Dynavax**
Dynavax is a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers and develops novel vaccines and immuno-oncology therapeutics. The Company’s first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax's lead immunotherapy product, SD-101, is an investigational cancer immunotherapeutic currently being evaluated in Phase 1/2 studies and its second cancer immunotherapeutic, DV281, is in Phase 1 development. For more information, visit www.dynavax.com.

**Forward-Looking Statements**
This press release contains "forward-looking" statements, including statements regarding HEPLISAV-B and the potential timing of an EMA review decision. These statements are subject to a number of risks, including whether the EMA will find the submission to be complete or whether it will seek further information, including the conduct of additional clinical trials; whether it will complete its review of the MAA within the anticipated timeframe; and whether the outcome of its review will be an approval, as well as other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. 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 is not incorporated by reference in our current periodic reports with the SEC.

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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.
[ii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.

Source: Dynavax Technologies Corporation