European CHMP Adopts Positive Opinion for HEPLISAV-B®, Dynavax's Two Dose Adult Hepatitis B Adjuvanted Vaccine

December 10, 2020

- Positive CHMP recommendation based on safety and immunogenicity results from three Phase 3 clinical trials and post-marketing safety results

- Statistically significantly higher and faster rates of protection, with similar safety compared to Engerix-B in all three trials

- If approved, HEPLISAV-B will be the only two dose adult hepatitis B vaccine offering protection in just one month

EMERYVILLE, Calif., Dec. 10, 2020 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced that the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion on the company's Marketing Authorization Application, recommending the granting of marketing authorization for HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted] for the active immunization against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older. The CHMP recommendation was based on the assessment of HEPLISAV-B demonstrated by the safety and immunogenicity results from three Phase 3 clinical trials and post-marketing safety results.

"Hepatitis B is a highly infectious and potentially deadly virus with increasing infection rates, and over 250 million people infected worldwide. Thankfully, it can be prevented with effective vaccination," commented Ryan Spencer, Chief Executive Officer of Dynavax. "With a regimen of only two doses in just one-month, HEPLISAV-B provides a unique opportunity to address known challenges with patient compliance, while delivering faster and higher rates of seroprotection compared to the three dose regimen over 6 months for the comparator vaccine. The positive CHMP opinion is an important step to extending the benefits of HEPLISAV-B beyond the United States, where it was approved in 2017."

In the European Union (EU), HEPLISAV-B is not yet approved. Under the EU regulatory process, the European Commission will now review the CHMP recommendation and the final decision on Marketing Authorization is expected in the first quarter of 2021. If approved by the European Commission, Dynavax would receive marketing authorization for HEPLISAV-B in all EU Member States.

Please see Important Safety Information below.

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, 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.

About HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted]
HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist CpG 1018 to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

Indication and Use in Approved U.S. Label
HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

For full U.S. Prescribing Information for HEPLISAV-B, click here.

Important Safety Information (ISI)
Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B. Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B. Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration. The most common patient reported adverse reactions reported within 7 days of vaccination were injection site pain (23% to 39%), fatigue (11% to 17%) and headache (8% to 17%).

About Dynavax
Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. 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 is also advancing CpG 1018 as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. For more information, visit www.dynavax.com and follow the company on LinkedIn.

Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding the potential for HEPLISAV-B to be approved for marketing in the EU in the first quarter of 2021. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including, whether and when HEPLISAV-B will be approved for marketing in the EU, and if approved, whether we will

successfully commercialize it in the EU, 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, 2019, 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.

In the EU, HEPLISAV-B is investigational and not approved. Its efficacy and safety have not been established. More information about clinical trials with HEPLISAV-B is available at www.clinicaltrials.gov.

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