HEPLISAV-B Post-Marketing Observational Study Results Presented at 2021 Annual Conference on Vaccinology Research (ACVR)

April 27, 2021

- Data provide reassurance about the real-world safety of HEPLISAV-B in adults

EMERYVILLE, Calif., April 27, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (NASDAQ: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced the results of the post-marketing study assessing the rates of occurrence of acute myocardial infarction (AMI) in persons receiving HEPLISAV-B compared with Engerix-B. The results were selected for an oral presentation at the National Foundation for Infectious Diseases (NFID) 2021 Annual Conference on Vaccinology Research (ACVR), a premier forum for the exchange of scientific and clinical knowledge in vaccinology, being held virtually April 26-27, 2021.

The post-marketing observational, non-inferiority surveillance study (HBV-25) evaluated the occurrence of AMI in approximately 31,000 patients who received HEPLISAV-B® and approximately 38,000 patients who received Engerix-B. The AMI rate per 1000 person years was 1.67 for HEPLISAV-B and 1.86 for Engerix-B. The hazard ratio comparing the rate of AMI in the HEPLISAV-B group with the Engerix-B group was 0.92 with a 95% confidence interval of 0.63 to 1.32. The upper bound of the 95% confidence interval of the hazard ratio comparing the rate of AMI in the HEPLISAV-B group to the Engerix-B group was less than 2.0, meeting the primary endpoint. Thus, these results provide evidence there is no increased risk of AMI associated with vaccination with HEPLISAV-B compared to Engerix-B. The study was conducted by Kaiser Permanente Southern California's Center for Vaccine Safety and Effectiveness.

"These results reinforce our previous clinical data regarding the safety of HEPLISAV-B and support our confidence in its ability to prevent hepatitis B infection in adults," commented Robert Janssen, MD, Chief Medical Officer. "We are pleased to collaborate with Kaiser Permanente Southern California's Center for Vaccine Safety and Effectiveness and appreciate their rigorous conduct of this study."

Abstract presentations are available for on-demand viewing for registered attendees April 26, 2021, through June 30, 2021. A conference virtual Oral Abstract Q&A Session is scheduled for Tuesday, April 27, 2021, from 3:00 – 4:00pm ET.

About the Annual Conference on Vaccinology Research (ACVR)
Sponsored by the National Foundation for Infectious Diseases (NFID) for more than 20 years, the Annual Conference for Vaccinology Research (ACVR) is a well-established forum for the exchange of the latest scientific and clinical research in vaccinology between healthcare professionals, trainees and young investigators, government officials, and representatives from industry and academia. The 2021 ACVR sponsored by NFID will be held virtually on April 26-27, 2021. Visit www.nfid.org/acvr for more information.

Please see Important Safety Information below.

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

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] Because people with diabetes are particularly vulnerable to infection, the CDC recommends vaccination for adults age 19 to 59 years with diabetes as soon as possible after their diagnosis, and for people age 60 years and older with diabetes at their physician's discretion.[iii] Approximately 20 million U.S. adults have diabetes and 1.5 million new cases of diabetes are diagnosed each year.[iv]

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 CpG 1018 to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

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

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%).

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

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. and European Union for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also advancing its CpG 1018 adjuvant 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
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the observational comparative study. These forward-looking statements are based upon management's current expectations, are subject to known and unknown risks, and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events may differ materially from those anticipated in such forward-looking statements due to various risks and uncertainties inherent in our business, including, without limitation; the risk that prescribers and other key decision-makers at potential purchasing entities may not make the decision to switch to or continue prescribing HEPLISAV-B; risks related to market adoption and competing therapies; and risks related to whether payors will cover and provide timely and adequate reimbursement for HEPLISAV-B. These and other risks are described in the "Risk Factors" section of our most recent periodic report, 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.

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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.
[ii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.
[iii] CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.
[iv] CDC. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.