Dynavax Announces Final Immunogenicity and Interim Safety Results from Clinical Trial Evaluating HEPLISAV-B in Patients Undergoing Hemodialysis

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- Demonstrated seroprotection rate of 89.3% at week 20 after 4 standard doses of HEPLISAV-B

- HEPLISAV-B is well tolerated; no safety concerns were observed

EMERYVILLE, Calif., Jan. 7, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing vaccines, today announced final immunogenicity and interim safety results of the ongoing clinical trial evaluating HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted] in patients undergoing hemodialysis.

Final immunogenicity data in 119 patients in this clinical trial evaluating a 4-dose regimen of HEPLISAV-B in adults with end-stage renal disease (ESRD) undergoing hemodialysis, demonstrated a seroprotection rate of 89.3% with high levels of anti-HBs antibodies, which are critical to maintain protection in patients undergoing hemodialysis. Interim safety data showed HEPLISAV-B is well tolerated and no safety concerns were observed. Full safety data are expected by the end of 2021.

"We are pleased with these positive results from the ongoing hemodialysis trial which reinforce the existing clinical data regarding the safety and ability of HEPLISAV-B to provide high rates of protection," commented Robert Janssen, MD, Chief Medical Officer at Dynavax. "We believe the 4-dose regimen of HEPLISAV-B, we are evaluating in this study, can provide an important hepatitis B vaccination alternative for patients undergoing hemodialysis by delivering high levels of protection with fewer doses compared to the current standard of care which requires up to 8 injections to complete the regimen."

The study, HBV-24, is an ongoing, open-label, single-arm trial being conducted in the United States to evaluate a new 4-dose regimen of HEPLISAV-B in adults with ESRD who are undergoing hemodialysis and have not previously received a hepatitis B vaccine. The study is designed to evaluate the immunogenicity of HEPLISAV-B at study week 20 and safety over the 68-week study duration. Safety and effectiveness of HEPLISAV-B have not been established in adults on hemodialysis.

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 U.S. Centers for Disease Control (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 with diabetes as soon as possible after their diagnosis, and for people age 60 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 adjuvant 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. 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 use of HEPLISAV-B in adults undergoing hemodialysis. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether and when the clinical study will be completed and what the final results will reflect, and whether additional studies will be required to demonstrate safety and effectiveness of HEPLISAV-B in person's undergoing hemodialysis, and if further studies are required, when they would be completed and what the results will reflect. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Dynavax in general, see 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 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.

[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.

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