Dynavax Reports Interim Analysis of Ongoing Clinical Trial Evaluating HEPLISAV-B in Patients Undergoing Hemodialysis

April 28, 2020

- Demonstrated seroprotection rate of 86.4% at week 20 after 4 standard doses of HEPLISAV-B
- Safety data showed HEPLISAV-B was well tolerated
- Company to host webinar review of data Thursday, April 30, 2020 at 1:00 p.m. ET/10:00 a.m. PT

EMERYVILLE, Calif., April 28, 2020 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today reported immunogenicity and safety data from an interim analysis of the ongoing clinical trial evaluating HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted] in patients undergoing hemodialysis. This data was chosen for oral presentation at the National Foundation for Infectious Diseases (NFID) 2020 Annual Conference on Vaccinology Research (ACVR), a premier forum for the exchange of scientific and clinical knowledge in vaccinology, which was cancelled due to COVID-19.

Interim analysis of safety data in 70 patients in this clinical trial evaluating a 4-dose regimen of HEPLISAV-B in adults with end-stage renal disease (ESRD) who are initiating or undergoing hemodialysis, showed HEPLISAV-B was well tolerated with a seroprotection rate of 86.4% in 44 patients. Full study data are anticipated in the second half of 2020.

“We are pleased with these interim results from the hemodialysis trial which reinforce the existing clinical data set regarding the safety and rates of protection provided by HEPLISAV-B,” commented Robert Janssen, MD, Chief Medical Officer at Dynavax. “We are evaluating a 4-dose regimen of HEPLISAV-B in this study, which contrasts with the 8-dose regimen required by the legacy product and look forward to a scientific presentation of the final data at an appropriate forum in the future.”

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 end-stage renal disease (ESRD) who are undergoing hemodialysis and have not previously received a hepatitis B vaccine. The study is designed to evaluate HEPLISAV-B’s immunogenicity at study week 20 and safety over the 68-week study duration. Safety and effectiveness of a 4-dose regimen of HEPLISAV-B have not been established in adults on hemodialysis.

Webcast Information
As a result of the cancellation of the NFID ACVR, Randall N. Hyer, MD, PhD, MPH, Vice President, Clinical Development and Medical Affairs at Dynavax will host a webinar review of the interim analysis data this Thursday, April 30, 2020 at 1:00 p.m. ET/10:00 a.m. PT. The live audio webcast may be accessed through the “Events & Presentations” page on the “Investors” section of the Company’s website at www.dynavax.com.

To view this poster and the additional Dynavax submission that was also selected for presentation at ACVR titled “Consideration of Effective Seroprotection Rate and Cost Per Protected Patient as Estimates of Real-World Outcomes in Adult Hepatitis B Virus (HBV) Vaccination,” please visit the Publications & Presentations section of our website at https://www.dynavax.com/science/publications-presentations/.

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 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 launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval 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 an advanced vaccine adjuvant through research collaborations and partnerships. 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. 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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Source: Dynavax Technologies Corporation