Dynavax Provides Regulatory Update on sBLA for Four-Dose HEPLISAV-B® Regimen for Adults on Hemodialysis in the U.S.

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EMERYVILLE, Calif., May 14, 2024 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) today provided a regulatory update for the Company's supplemental Biologics License Application (sBLA) to include a four-dose HEPLISAV-B® vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted] regimen for adults on hemodialysis. The U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) in response to the sBLA, stating that the application did not provide sufficient data to support the full evaluation of effectiveness or safety of a four-dose regimen of HEPLISAV-B. The CRL has no impact on the approved indication for HEPLISAV-B in the U.S., the European Union, and Great Britain, which is for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older. The CRL also does not affect the approval decision received from the European Commission in October 2023 for the four-dose HEPLISAV-B regimen for the adult hemodialysis population.

The sBLA was comprised of clinical immunogenicity and safety data from the Phase 1 HBV-24 study of a four-dose regimen of HEPLISAV-B in 119 adults undergoing hemodialysis, as well as five supportive clinical trials of HEPLISAV-B in adults with chronic kidney disease or undergoing hemodialysis. The CRL stated that the data from HBV-24 were insufficient due to the destruction of data source documents by a third-party clinical trial site operator for approximately half of the subjects enrolled in the trial. In addition, the total number of subjects in the single-arm HBV-24 study was deemed to be insufficient to evaluate safety of the four-dose regimen.

"We remain confident in the data generated to support HEPLISAV-B vaccination for adult hemodialysis patients. All key data collected in HBV-24 were verified against original source documents during the conduct of the trial," said Rob Janssen, M.D., Chief Medical Officer of Dynavax. "We are reviewing the agency's feedback and intend to request a meeting with the FDA to evaluate options for providing additional data to support the four-dose regimen for this vulnerable patient population in the U.S."

Important U.S. Product Information

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

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

Important U.S. Safety Information (ISI)

Do not administer HEPLISAV-B to individuals with a history of a 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 innovative vaccines to help protect the world against infectious diseases. The Company has two commercial products, HEPLISAV-B® vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted], which is approved in the U.S., the European Union and Great Britain for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older, and CpG 1018® adjuvant, currently used in HEPLISAV-B and multiple adjuvanted COVID-19 vaccines. Dynavax is advancing CpG 1018 adjuvant as a premier vaccine adjuvant with adjuvanted vaccine clinical programs for shingles and Tdap, and through global collaborations, currently focused on adjuvanted vaccines for COVID-19, plague, seasonal influenza and universal influenza. For more information about our marketed products and development pipeline, visit www.dynavax.com.

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements. Forward-looking statements can generally be identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "intend," "will," "may," "plan," "project," "potential," "seek," "should," "think," "toward," "will," "would" and similar expressions, or the negatives thereof, or they may use future dates. Forward-looking statements made in this document include statements regarding requests for future meetings with the FDA and the potential timing or outcome of those meetings. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including, the availability, time and cost associated with any potential follow up studies or additional trials, availability and willingness of the FDA to meet, and the uncertainty of whether these efforts will achieve our desired results, as well as other risks detailed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the three months ended March 31, 2024 and periodic filings made thereafter, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. These forward-looking statements are made as of the date hereof, are

qualified in their entirety by this cautionary statement and 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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