Dynavax Announces Great Britain Marketing Authorization for HEPLISAV B®, a Two-Dose Adult Hepatitis B Adjuvanted Vaccine

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- HEPLISAV B is the only two-dose adult hepatitis B vaccine offering protection in just one month

EMERYVILLE, Calif., Feb. 28, 2023 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing innovative vaccines, today announced that the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) has granted Marketing Authorization in Great Britain 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 approval was based on the positive benefit-risk for HEPLISAV B as demonstrated by the safety and immunogenicity results of three Phase 3 clinical trials. The approval was issued to Dynavax's affiliate Dynavax GmbH via the European Commission Decision Reliance Procedure (ECDRP).

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"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. "We are very pleased that HEPLISAV B has received this latest approval and look forward to continuing on-going discussions with potential commercial partners for Great Britain. This approval highlights the capabilities and continued successful execution of the organization."

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. WHO estimates that 296 million people were living with chronic hepatitis B infection in 2019, with 1.5 million new infections each year.

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

Important Great Britain/MHRA Product Information

HEPLISAV B is indicated for active immunisation against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older. The use of HEPLISAV B should be in accordance with official recommendations.

It can be expected that hepatitis D will also be prevented by immunisation with HEPLISAV B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

Do not receive HEPLISAV B if you have had a sudden life-threatening, allergic reaction after receiving HEPLISAV B in the past, or if you are allergic to any of components of this vaccine, including yeast. Signs of an allergic reaction may include itchy skin, rash, shortness of breath and swelling of the face or tongue.

Appropriate medical treatment and supervision should be readily available in case of rare anaphylactic reactions following the administration of the vaccine.

The administration of HEPLISAV B should be postponed in subjects suffering from acute severe febrile illness.

Immunocompromised persons may have a diminished immune response to HEPLISAV B.

Because of the long incubation period of hepatitis B, it is possible for unrecognised HBV infection to be present at the time of immunisation. HEPLISAV B may not prevent HBV infection in such cases.

There are very limited data on the immune response to HEPLISAV B in individuals who did not mount a protective immune response to another hepatitis B vaccine.

As a precautionary measure, it is preferable to avoid the use of HEPLISAV B during pregnancy. Vaccination during pregnancy should only be performed if the risk-benefit ratio at the individual level outweighs possible risks for the fetus.

The most common patient-reported side effects reported within 7 days of vaccination were pain, swelling or redness at the injection site, feeling tired, headache, muscle aches, feeling unwell and fever.

Important U.S. Product Information

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 U.S. 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 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 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 and follow Dynavax on LinkedIn.

Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding the potential United Kingdom launch of HEPLISAV B. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including, our ability to identify and engage a commercialization partner and the timing of the potential launch of HEPLISAV B in Great Britain, whether commercialization of HEPLISAV B in Great Britain will be successful, 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, 2022, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). 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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