



Dynavax's HEPLISAV-B® ACIP Recommendations Published in the CDC's Morbidity and Mortality Weekly Report

April 23, 2018

HEPLISAV-B Now Meets a Critical Reimbursement Requirement for Many Insurance Plans

BERKELEY, Calif., April 23, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX) today announced that the Centers for Disease Control and Prevention (CDC) published the Advisory Committee of Immunization Practices' (ACIP) Recommendations for the use of HEPLISAV-B® [Hepatitis B Vaccine, Recombinant (Adjuvanted)] for adults in the US in the Morbidity and Mortality Weekly Report (MMWR) dated April 19. The publication can be found on the CDC's website [here](#).

"Publication in the MMWR represents the final endorsement that many policies require before they will provide reimbursement, so institutions are now able to purchase product knowing that they will be covered for their out of pocket expenses. The response to HEPLISAV-B we have seen in the market has exceeded our expectations, providing us with added confidence in our ability to reach profitability for this product by the end of 2019," said Eddie Gray, Chief Executive Officer.

Dynavax commercially launched HEPLISAV-B in the United States in January 2018 with a 60-person sales force. The vaccine can be ordered through a broad network of authorized distributors. The company is working with an extensive network of group purchasing organizations and government entities to help ensure adult patients have access to HEPLISAV-B. Dynavax is also working to support broad reimbursement of HEPLISAV-B by insurance plans. Proactive payer outreach is currently ongoing and will include the MMWR publication for HEPLISAV-B now that the ACIP recommendations have been approved by the CDC and U.S. Department of Health and Human Services (HHS). Information on authorized distributor and payer-specific coverage may be accessed by calling 1-84-HEPLISAV (1-844-375-4728), and speaking to a HEPLISAV-B Access Navigator. HEPLISAV-B Access Navigators are available Monday–Friday from 8:00am–8:00pm ET.

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. In 2015, new cases of acute hepatitis B increased by more than 20 percent nationally.ⁱⁱ 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.ⁱⁱⁱ 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.^{iv} Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.^v

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 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 fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers and develops novel vaccines and immuno-oncology therapeutics. The Company's first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the United States. Dynavax's lead immunotherapy product, SD-101, is an investigational cancer immunotherapeutic currently being evaluated in Phase 1/2 studies and its second cancer immunotherapeutic, DV281, is in Phase 1 development. For more information, visit www.dynavax.com.

Forward Looking Statement

This press release contains forward-looking statements, including statements regarding the commercialization of HEPLISAV-B. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether the company will be able to continue building the commercial infrastructure required to successfully launch HEPLISAV-B; whether payers will provide timely reimbursement for HEPLISAV-B; whether prescribers and other key decision-makers will switch to HEPLISAV-B; and whether potential claims against us, including those based on patent rights of others, will result in an injunction against sales or otherwise impact commercialization and sales. 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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US-18-01-00005

ⁱ CDC. <https://www.cdc.gov/hepatitis/hbv/bfaq.htm>.

ⁱⁱ CDC. <https://www.cdc.gov/hepatitis/statistics/2015surveillance/index.htm#tabs-5-8>. Fig 3.2

ⁱⁱⁱ CDC. <https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm>.

^{iv} CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.

^v CDC. <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

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Source: Dynavax Technologies Corporation