

Sam's Club and Dynavax Technologies Corporation Announce Collaboration to Make HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted] Available to Sam's Club Patients

January 8, 2019

BERKELEY, Calif., Jan. 08, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX), a leader in developing immunotherapies based on toll-like receptor (TLR) biology, and Sam's Club, a leading membership warehouse club offering superior products, savings and services to millions of members in nearly 600 clubs, have teamed up to introduce HEPLISAV-B into Sam's Club retail pharmacies nation-wide where pharmacists can immunize patients. HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. This is the first new hepatitis B vaccine in the United States in more than 25 years, and the only two-dose, one-month hepatitis B vaccine for adults.

"Giving our patients access to superior care and value is our priority," said David Badeen, Vice President of Healthcare for Sam's Club. "Having HEPLISAV-B available at Sam's Club pharmacies gives our patients access to an option for vaccination against hepatitis B that is convenient with just two doses in one month, while also providing a high level of protection."

"We recognize community pharmacists, and the retail pharmacy setting of care, as instrumental to our goal of making HEPLISAV-B available to adult patients seeking vaccination against hepatitis B," said Ryan Spencer, Vice President of Commercial Operations for Dynavax. "We are excited that Sam's Club recognizes the benefits of HEPLISAV-B and that HEPLISAV-B will be available at all Sam's Club pharmacy locations. In addition, we are hoping to collaborate with Sam's Club to address the important unmet need for higher levels of protection against hepatitis B in diabetic patients."

Please see Important Safety Information below. For more information about HEPLISAV-B, visit http://heplisavb.com/.

About Sam's Club

Sam's Club®, a division of Walmart, Inc. (NYSE: WMT), is a leading membership warehouse club offering superior products, savings and services to millions of members in nearly 600 clubs in the U.S. and Puerto Rico. Now in its 35th year, Sam's Club continues to redefine warehouse shopping with its highly curated assortment of high quality fresh food and Member's Mark items, in addition to market leading technologies and services like Scan & Go, Club Pickup and home delivery service in select markets. To learn more about Sam's Club, visit the Sam's Club Newsroom, shop at Sam's Club Newsroom, and interact with Sam's Club on Twitter, Instagram and Facebook.

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. Hepatitis B is a major public health issue in the United States, where an estimated 20,000 new infections occur each year, and approximately 850,000 people are currently living with this chronic disease. In 2015, new cases of acute hepatitis B increased by more than 20 percent nationally. 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 that individuals at high risk for hepatitis B infection due to their jobs, lifestyle, living situations and travel to certain areas be immunized.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 commercial-stage 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, a hepatitis B vaccine for adults, 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 Statements

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; and whether payers will provide timely reimbursement for HEPLISAV-B. 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.

ⁱCDC. https://www.cdc.gov/hepatitis/hbv/bfag.htm.

iiCDC. https://www.cdc.gov/hepatitis/statistics/2015surveillance/index.htm#tabs-5-8_Fig 3.2

iiiCDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.

ivCDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.

VCDC, https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

Contact

Heather Rowe Vice President, Investor Relations & Corporate Communications 510-665-7269



Source: Dynavax Technologies Corporation