January 8, 2018

Dynavax Announces HEPLISAV-B™ is Now Available in the United States for the Prevention of Hepatitis B in Adults

HEPLISAV-B is the First and Only Two-Dose Vaccine in U.S. for Hepatitis B Prevention in Adults

BERKELEY, Calif., Jan. 08, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX) today announced that HEPLISAV-B™ [Hepatitis B Vaccine (Recombinant), Adjuvanted] is now available in the United States for the prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. HEPLISAV-B was approved by the U.S. Food and Drug Administration (FDA) on November 9, 2017. It is the first new hepatitis B vaccine in the United States in more than 25 years and the only two-dose hepatitis B vaccine for adults.

"Dynavax is prepared and proud to launch our first product, HEPLISAV-B, in the United States," said Eddie Gray, chief executive officer of Dynavax. "We believe the increase in the rate of infections and poor compliance with current three-shot regimens has the medical community eager for access to HEPLISAV-B for adults. Given its two-dose schedule and delivery of high rates of protection, HEPLISAV-B is an important tool for preventing hepatitis B in the United States."

HEPLISAV-B can now be ordered through a network of distributors, which will broaden over the next few weeks. The Wholesale Acquisition Cost (WAC) for HEPLISAV-B of $115 per dose, or $230 per regimen, reflects the value HEPLISAV-B brings to the healthcare system. Dynavax is currently working with an extensive network of group purchasing organizations and government entities to ensure all patients have access to HEPLISAV-B. A list of the current distributors in the Dynavax network can be accessed by calling 1-84-HEPLISAV (1-844-375-4728).

Dynavax has begun activities to support broad reimbursement of HEPLISAV-B by insurance plans. Importantly, the American Medical Association has published a new and active Current Procedural Terminology (CPT) code for a two-dose adult hepatitis B vaccine, which was created to accommodate HEPLISAV-B's two-dose, one-month schedule. A majority of plans currently have this unique code loaded into their claims processing systems. Some plans will require recommendation from the CDC's Advisory Committee on Immunization Practices (ACIP) prior to covering HEPLISAV-B. The next ACIP meeting is scheduled for February 21-22, 2018. Proactive payer outreach is currently ongoing, and will include updated ACIP information specific to HEPLISAV-B as it becomes available. Dynavax has staged the deployment of its field sales team to coincide with the upcoming ACIP meeting.

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 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 commercial launch 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 launch HEPLISAV-B; whether payers will provide timely reimbursement for HEPLISAV-B; whether the CDC's Advisory Committee on Immunization Practices (ACIP) will add HEPLISAV-B to its adult vaccination schedule during its February 2018 meeting, or at all; 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.

Contact:
Ryan Spencer
VP, Corporate Strategy & Communications
510.665.4618
rspencer@dynavax.com

Media Contact:
Rachel St. Martin
W2O wcg
646.894.5757
rstmartin@w2ogroup.com

[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.

Source: Dynavax Technologies Corporation