Dynavax Announces First Patient Enrolled in Study of HEPLISAV-B® [Hepatitis B Vaccine, Recombinant (Adjuvanted)] in Adults With End-Stage Renal Disease

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Trial to evaluate immunogenicity and safety of Hepatitis B vaccine, HEPLISAV-B, in patients with end-stage renal disease who are initiating or undergoing dialysis

BERKELEY, Calif., May 02, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX), a fully-integrated biopharmaceutical company focused on discovering, developing and commercializing novel vaccines and immuno-oncology therapeutics, today announced the enrollment of the first patient in the company's open-label, single-arm study of HEPLISAV-B in adults with end-stage renal disease who are initiating or undergoing hemodialysis.

"Although vaccination to prevent hepatitis B infection has been standard practice for decades for dialysis patients and healthcare workers, there remains a need to provide improved overall protection safely through a greater and more durable antibody response," said Robert Janssen, M.D., chief medical officer of Dynavax. "HEPLISAV-B consistently demonstrated higher seroprotection rates than a comparator in head-to-head clinical trials and we're hopeful that this patient population may benefit from this new and shortened dosing schedule as compared to currently approved treatments. The initiation of this open-label study evaluating the immunogenicity and safety of HEPLISAV-B for patients with kidney failure is an important step in understanding how this treatment may help this vulnerable patient population."

This open-label, single arm study will evaluate HEPLISAV-B in adults with end-stage renal disease who are initiating or undergoing hemodialysis. The primary endpoints are to evaluate the immunogenicity induced by HEPLISAV-B at week 20 as measured by seroprotection rate and to evaluate the safety of HEPLISAV-B with respect to clinically significant adverse events.

The trial will enroll approximately 100 end-stage renal disease patients who are initiating or undergoing hemodialysis at dialysis centers in the United States. More information about the trial is available at www.clinicaltrials.gov, identifier NCT03934736.

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. 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.[ii] 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.[iii] Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.i[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.

For more information about HEPLISAV-B, visit: http://heplisavb.com/

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, develops and commercializes novel vaccines and immuno-oncology therapeutics. The Company's first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. 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.

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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.

[ii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.

[iii] CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.

[iv] CDC. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

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