Dynavax Announces HEPLISAV-B Post-Marketing Requirement Interim Report Completed

December 3, 2019

Similar rates of acute myocardial infarction between the two treatment arms at the interim analysis reinforces the view that HEPLISAV-B has the potential to be the leading hepatitis B vaccine for adults

EMERYVILLE, Calif. , Dec. 03, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced that it has filed a report on a cumulative analysis (comprising both required interim analyses) of its post-marketing study of HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted] for review by the U.S. Food and Drug Administration (FDA). The study is assessing the rates of occurrence of acute myocardial infarction (AMI) in persons receiving HEPLISAV-B compared with Engerix-B. The interim report assesses unadjudicated events of AMI. The event rates in this interim analysis were similar between the two treatment arms. The independent data monitoring committee (DMC) concurred this analysis showed no evidence of an increase in AMI events in the HEPLISAV-B arm. The study was initiated in August 2018 and will continue through November 2020. Final study results will be reported upon study completion.

"These results reinforce our previous clinical data regarding the safety of HEPLISAV-B and support our confidence that HEPLISAV-B can be the emerging standard of care for preventing hepatitis B infection in adults," commented Robert Janssen, MD, Chief Medical Officer. "We are pleased to collaborate with Kaiser Permanente Southern California for their rigorous conduct of this study, and look forward to a scientific presentation of the final data at an appropriate forum in the future."

The study, "Post-Marketing Observational Study to Evaluate the Occurrence of Acute Myocardial Infarction in Adults 18 Years of Age and Older Who Receive HEPLISAV-B Compared with Another Hepatitis B Vaccine," is a post-marketing requirement related to FDA approval of HEPLISAV-B on November 9, 2017. Dynavax previously announced the complete accrual of more than 30,000 patients who received HEPLISAV-B and more than 30,000 patients who received Engerix-B in the ongoing post-marketing study.

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 years with diabetes as soon as possible after their diagnosis, and for people age 60 years 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.[iv]

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/.

About Dynavax
Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. The Company launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. For more information, visit www.dynavax.com and follow the company on LinkedIn.

Forward-Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the ongoing observational comparative study, the expected completion of the study, and the potential for HEPLISAV-B to be the leading hepatitis B vaccine or become the emerging standard of care in preventing hepatitis B infection in adults. These forward-looking statements are based upon management's current expectations, are subject to known and unknown risks, and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events may differ materially from those anticipated in such forward-looking statements due to various risks and uncertainties inherent in our business, including, without limitation, the risk that the study may not be completed when expected, or at all; the risk that final study results may not be consistent with the interim analyses or may differ from them in a material way; the risk that prescribers and other key decision-makers at potential purchasing entities may not make the decision to switch to HEPLISAV-B; and the timing and quantity of actual purchases; risks related to market adoption and competing therapies; and risks related to whether payors will cover and provide timely and adequate reimbursement for HEPLISAV-B. These and other risks are described in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

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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.

Source: Dynavax Technologies Corporation