Dynavax Presents Analysis of Data for Participants Aged 60 to 70 with Diabetes from its Phase 3 Trial of HEPLISAV-B®

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In a Post-Hoc Analysis of Elderly Diabetic Patients, HEPLISAV-B was Well-Tolerated and Induced Higher Rates of Seroprotection than Engerix-B

Data Presented at 2018 American Diabetes Association Annual Meeting

BERKELEY, Calif., June 25, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX) today announced results of a post hoc analysis of data from HBV 23, the pivotal Phase 3 trial of its hepatitis B vaccine HEPLISAV-B® [Hepatitis B Vaccine, Recombinant (Adjuvanted)]. HBV 23 was a randomized, observer-blinded, active-controlled, multi-center study that compared two doses of HEPLISAV-B over four weeks with three doses of Engerix-B® [Hepatitis B Vaccine (Recombinant)] over 24 weeks in 8,374 adults age 18 to 70. This post hoc analysis evaluated data from the trial for participants with type 2 diabetes aged 60 to 70. These data were presented at the 2018 American Diabetes Association (ADA) Annual Meeting in Orlando, FL on Monday, June 25 at 12:00pm ET.

Highlights from Poster Presentation

- In the per protocol (PP) analysis, the seroprotection rate at week 28 for HEPLISAV-B (n=274) was 85.8% compared to 58.5% for Engerix-B (n=130), a treatment difference of 27.3% (95% CI: 18.0% – 36.8%)
- HEPLISAV-B induced higher geometric mean concentration (GMCs) (137.3 mIU/mL) in the per-protocol analysis at week 24 than Engerix-B at week 28, with a GMC ratio of 2.7 (95%, [CI: 1.6 – 4.4])
- HEPLISAV-B had a similar safety profile compared to Engerix-B, regardless of study subgroup, which included smoking status, body mass index and sex
    - In the HEPLISAV-B group, 64.2% of the participants reported a medically attended adverse event (MAE), of those 23.5% experienced a grade 3 or 4 MAE; in the Engerix-B group 55.6% of participants experienced MAEs, of those 22.2% reported a grade 3 or 4 MAE

“These data in elderly diabetic patients show the benefit of HEPLISAV-B in a population that is more difficult to protect and, when infected, typically demonstrates a more severe hepatitis B disease,” said Dr. Rob Janssen, chief medical officer of Dynavax. “We believe there is a great opportunity for Dynavax to contribute to the overall health of the adult population with diabetes.”

The post hoc analysis consisted of participants from the randomized study that received either two doses of HEPLISAV-B (n=327) or three doses of Engerix-B (n=153). HEPLISAV-B was administered at 0 and 4 weeks, followed by placebo at 24 weeks to maintain blinding. Engerix-B was injected at 0, 4, and 24 weeks. Both vaccines were administered intramuscularly into the deltoid muscle.

The phase 3 trial included a total of 961 participants with type 2 diabetes aged 18 to 70. The primary endpoint for this subgroup compared the seroprotection rate at Week 28 for HEPLISAV-B (n= 640) with that at Week 28 for Engerix-B (n= 321). This analysis showed that HEPLISAV-B resulted in a 90.0% seroprotection rate compared to a 65.1% seroprotection rate from Engerix-B.

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 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 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 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.

Engerix-B is a registered trademark of the GSK group of companies.

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