November 14, 2016

Dynavax Receives Complete Response Letter from U.S. Food and Drug Administration for Biologics License Application for HEPLISAV-B

Company to Host Conference Call Today at 8:30 a.m. Eastern Time

BERKELEY, CA -- (Marketwired) -- 11/14/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)] for immunization of adults 18 years and older against hepatitis B infection. The FDA issues CRLs to communicate that the Agency has completed a review cycle of an application and to request additional information for review and approval. Dynavax expects a Class 2 designation for a resubmission of the BLA, which would result in a target review period of six months.

The CRL seeks information regarding several topics, including clarification regarding specific adverse events of special interest (AESIs), a numerical imbalance in a small number of cardiac events in a single study (HBV-23), new analyses of the integrated safety data base across different time periods, and post-marketing commitments. In the CRL, the FDA acknowledged that it has not yet completed its review of responses received from Dynavax in early October, including those pertaining to AESIs and the numerical imbalance in cardiac events. The responses included an extensive analysis that included independent expert consultation supporting our view that the imbalance was driven by an unexpectedly low number of events in the comparator arm. It would appear the Agency could not fully assess the responses in the current review period. In the CRL, there is no request for additional clinical trials and there are no apparent concerns with rare serious autoimmune events.

"The CRL is consistent with our opinion that HEPLISAV-B is approvable and we are seeking to meet with the FDA as soon as possible," said Eddie Gray, chief executive officer of Dynavax. "However, the time and resources that will be required to gain approval leads us to consider that we may not be able to advance this program on our own and we are moving swiftly to identify a potential pharmaceutical or financial partner. We will maintain our efforts on the oncology programs, including our lead cancer immunotherapy candidate, SD-101, for which we recently announced encouraging early clinical data in metastatic melanoma."

Conference Call Details
The Dynavax management team will host a conference call and webcast today, Monday, November 14, 2016, at 8:30 a.m. Eastern, to provide more information about the CRL. The live call can be accessed by phone by dialing (877) 479-1857 (domestic) or +1 (503) 343-6309 (international) and specifying conference call code 19882810. A link to the live webcast may be accessed by visiting the "Investors" section of the Dynavax website or directly at (www.dynavax.com). A replay of the conference call may be accessed for one week following the call by dialing (855) 859-2056 (domestic) or +1 (404) 537-3406, and the passcode is 19882810.

About Hepatitis B
Hepatitis B is a viral disease of the liver that can become chronic and can lead to cirrhosis of the liver, hepatocellular carcinoma and death. In the United States, the CDC estimates that approximately 20,000 hepatitis B infections continue to occur annually,(i) with the vast majority occurring in adults. There is no cure for hepatitis B, and disease prevention through effective vaccination is critical to reducing the spread of the disease. Currently marketed hepatitis B vaccines are administered in three doses over a six-month schedule. Results of a published Vaccine Safety Datalink study showed that 54 percent of adults completed the currently available three-dose hepatitis B vaccine series in one year. Those who do not complete the series may not be adequately protected against hepatitis B.

About HEPLISAV-B
HEPLISAV-B is an investigational adult hepatitis B vaccine that combines hepatitis B surface antigen with a proprietary Toll-like receptor 9 agonist to enhance the immune response. HEPLISAV-B is administered in two doses over one month.

In Phase 3 trials, HEPLISAV-B demonstrated higher and earlier protection with fewer doses than a currently licensed hepatitis B vaccine. The investigational vaccine's safety profile is based on clinical trials that generated safety data from more than 14,000 participants. The most frequently reported local reaction was injection site pain. The most common systemic reactions were fatigue, headache and malaise, all of which were similar to an existing vaccine.

Dynavax has worldwide commercial rights to HEPLISAV-B.

About Dynavax
Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious diseases and oncology. Dynavax's lead product candidates are HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine, and SD-101, an investigational cancer immunotherapeutic currently in several Phase 1/2 studies. For more information, visit www.dynavax.com.

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding the FDA's Complete Response Letter ("CRL") to the BLA for HEPLISAV-B, the Company's plans to respond to the CRL, plans and the ability to identify pharmaceutical or financial partners for the future development of HEPLISAV-B, plans to reduce spending on HEPLISAV-B, and the Company's focus on its oncology program, including SD-101. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether HEPLISAV-B may be approved by the FDA, the timing and ability for Dynavax to respond to the CRL, whether Dynavax will be able to find a pharmaceutical or financial partner for HEPLISAV-B, the timing of the FDA's review if Dynavax is able to respond to the CRL, and whether the issues identified in the CRL are resolvable with respect to questions involving the data or interpretation of the data submitted in support of the BLA; whether or not the FDA will require additional clinical trials, whether or not the FDA will identify additional issues after Dynavax responds to the CRL; whether there will be a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting and if so, whether it will impact the timing of FDA review or negatively impact the review and approval of the BLA; whether additional studies or manufacturing process enhancements will be required, or other issues will arise that will delay the BLA review or negatively impact the review and approval by the FDA; if approvable, whether the issues will negatively impact the potential scope of the label claims for HEPLISAV-B; initiation, enrollment and completion of pre-clinical studies and clinical trials of our other product candidates, including SD-101; the ability to successfully develop and commercialize SD-101; the results of clinical trials and the impact of those results on the initiation or continuation of subsequent trials and issues arising in the regulatory process; and other 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.

(i) Schillie S, Murphy TV, Sawyer M, Ly K, Hughes E, et al. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. MMWR. Recommendations and reports. Centers for Disease Control. 2013;62(RR-10):1-19.

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