January 7, 2016

Dynavax Reports Top Line Results of Phase 3 HEPLISAV-B(TM) Study

BLA Resubmission Targeted for End of Q1 2016; Webcast Conference Call to Review Clinical Data Scheduled for Today at 8:30 am ET

BERKELEY, CA -- (Marketwired) -- 01/07/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today reported preliminary top-line results from HBV-23, a Phase 3 trial of the safety and immunogenicity of its investigational hepatitis B vaccine, HEPLISAV-B, compared with a currently marketed vaccine, Engerix-B®Â , in adults 18 to 70 years of age. HEPLISAV-B participants received two doses, at zero and one month, and Engerix-B participants received three doses, at zero, one and six months. Both co-primary endpoints were met. The rates of clinically significant adverse events were consistent with randomization and similar to rates in prior trials and HEPLISAV-B provided a statistically significant higher rate of seroprotection than Engerix-B in diabetic participants and in all participants as a group.

Safety results from HBV-23

The co-primary endpoint of HBV-23 was to evaluate the overall safety of HEPLISAV-B with respect to clinically significant adverse events. Participants were randomized to HEPLISAV-B or Engerix-B in a two to one ratio. HEPLISAV-B participants were followed for 52 weeks after the last dose and Engerix-B participants were followed for 28 weeks after last dose. All adverse events considered to represent potential autoimmune disorders (Adverse Events of Special Interest, or AESIs) were reviewed by an independentÂ panel of experts from the Mayo Clinic.

Preliminary safety evaluation results include:

- 22 HEPLISAV-B participants experienced an AESI and 11 Engerix-B participants experienced an AESI. All were classified as not related to vaccination.
- Of the 33 AESIs in the study, 21 were adjudicated to be autoimmune events by the independent panel, with 11 reported in participants who received HEPLISAV-B and 10 in participants who received Engerix-B.Â
- In a secondary safety endpoint, there were no cases of Wegener's Granulomatosis (granulomatosis with polyangiitis) or Tolosa Hunt syndrome.Â
- One event in the HEPLISAV-B arm of the study was coded by a site investigator based solely on a radiological diagnosis as a rare autoimmune disease, Takayasu's arteritis.Â The independent panel of experts concluded the diagnostic criteria for the initial radiological diagnosis were not met and adjudicated the event as not related to vaccination.

The total safety database for HEPLISAV-B now comprises 10,038 participants.

Seroprotection results from HBV-23

The co-primary endpoint of noninferiority of seroprotection in participants with diabetes mellitus was met and the greater percentage of seroprotection provided by HEPLISAV-B compared to Engerix-B was statistically significant.Â

Immunogenicity data from the trial demonstrated:

- The peak seroprotection rate (SPR) in participants with type 2 diabetes mellitus who received HEPLISAV-B was 90.0% compared to 65.1% for Engerix-B, demonstrating non-inferiority and a statistically significant higher percentage of seroprotection provided by HEPLISAV-B compared to Engerix-B
- In additional secondary endpoints:
  - The peak SPR in the entire HBV-23 HEPLISAV-B group (95.4%) was statistically significantly higher than the peak SPR in the Engerix-B group (81.3%)
  - The peak SPR in the HEPLISAV-B group was statistically significantly higher than the peak SPR in the Engerix-B group in each age decile
  - The peak SPR in the HEPLISAV-B group was statistically significantly higher than the peak SPR in the Engerix-B group in each prespecified subpopulation analyzed, including by sex, body mass index, and smoking status

"We are delighted to report these topline results from HBV-23 and confirm our intention to resubmit the HEPLISAV-B BLA by the end of March. These results support our belief that HEPLISAV-B, if approved, could offer benefits to adults at risk for

hepatitis B, particularly given that these significant differences in seroprotection were demonstrated in a controlled setting, where compliance is optimized," said Eddie Gray, Chief Executive Officer.

"These topline results are consistent with our expectations. With regard to the principal safety focus, Adverse Events of Special Interest, the results reflect a distribution consistent with randomization. To see such statistically significant differences in immunogenicity so consistently and across all groups and patient subsets, confirms the potential of HEPLISAV-B for people in need of protection," said Robert Janssen, Chief Medical Officer.

Dynavax plans to resubmit the HEPLISAV-B Biologics License Application (BLA) at the end of the first quarter of 2016 and anticipates a six-month review by the FDA. In the revised BLA, Dynavax plans to address all issues raised by the FDA in a February 2013 Complete Response Letter by submitting the results of HBV-23, integrated with previous clinical data, and responses to CMC issues in the Complete Response Letter.

Conference Call Today

DynavaxÂ management will host a conference call today, January 7, 2016 atÂ 8:30 a.m.Â Eastern TimeÂ and individuals may participate in the conference call by dialing (877) 479-1857 (domestic) or (503) 343-6309 (international). The passcode is 16055092.

To access a live audio webcast of the conference call, please visit the Company's website atÂ http://investors.dynavax.com/events.cfm

A replay of the webcast will be available on theÂ DynavaxÂ website approximately two hours after the conference call concludes and can be accessed for one week. The replay numbers are (855) 859-2056 (domestic) or (800) 585-8367 (international). The passcode is 16055092.

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.Â

About*Â *Dynavax

Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious and inflammatory 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, visitÂ www.dynavax.com.

Â ***Forward-Looking Statements***

This press release contains forward-looking statements, including statements regarding preliminary results from HBV-23 and whether those results will be confirmed in final analysis, the timing of Dynavax's BLA submission to the FDA, the duration of FDA review of the BLA and whether the FDA will find the resubmission sufficient for regulatory approval. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether there will be changes in the data or interpretation, whether the final study results will be deemed satisfactory by the FDA; whether additional studies or manufacturing process enhancements will be required or other issues will arise that will delay the BLA resubmission or review or negatively impact the acceptance, review and approval by the FDA; initiation, enrollment and completion of pre-clinical studies and clinical trials of our other product candidates, including 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.comÂ is not incorporated by reference in our current periodic reports with the SEC.

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