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Dynavax Announces Independent DSMB Recommendation to Continue Phase 3 Study of HEPLISAV-B(TM)

BERKELEY, CA -- (Marketwired) -- 11/10/14 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that the independent Data and Safety Monitoring Board (DSMB) charged with periodically reviewing safety data from the ongoing phase 3 clinical trial of HEPLISAV-B, its investigational adult hepatitis B vaccine, has completed its first prespecified review and has recommended that the study continue unchanged.

This large safety and immunogenicity study (known as HBV-23) is observer-blinded, randomized, and active-controlled. Adult subjects were randomized in a 2:1 ratio to receive a 2-dose series of HEPLISAV-B or a 3-dose series of the control vaccine, Engerix-B®. The DSMB for HBV-23 is an independent panel of physicians otherwise unaffiliated with the study that is charged with performing at least three comprehensive reviews of interim safety data at predetermined time points.

The first DSMB review included safety data for all enrolled subjects collected through the data cut-off in October. As of the cut-off, over 50% of subjects had reached 12 weeks follow-up after the first immunization. The DSMB reviewed unblinded tables and listings presenting safety data for HEPLISAV-B and Engerix-B immunized subjects. Based on this review, the panel recommended continuing HBV-23 with no change to the study protocol, patient consent or other study materials.

Two additional prespecified DSMB reviews will occur during the conduct of HBV-23. Safety observation is scheduled to continue for 12 months following each subject's second immunization and all study visits are expected to be completed by October, 2015.

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. Dynavax has worldwide commercial rights to HEPLISAV-B.

About Dynavax

Dynavax, a clinical-stage biopharmaceutical company, uses TLR biology to discover and develop novel vaccines and therapeutics in the areas of infectious and inflammatory diseases and oncology. Dynavax's lead product candidate is HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine. For more information visit www.dynavax.com.

Forward-Looking Statements

This press release contains "forward-looking" statements, including expectations for the conduct, timing and sufficiency of any additional clinical trials for HEPLISAV-B and whether the DSMB will identify safety issues or concerns that could result in changes to or stoppage of the ongoing phase 3 clinical study. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including whether successful clinical and regulatory development and review and approval of HEPLISAV-B and our process for its manufacture can occur without significant delay or additional studies and other risks detailed in the "Risk Factors" section of our current periodic reports with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, 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.

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