DYNAVAX TECHNOLOGIES

September 22, 2014

Dynavax Completes Enrollment of Phase 3 Study of HEPLISAV-B(TM)

BERKELEY, CA -- (Marketwired) -- 09/22/14 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced completion of planned enrollment in the ongoing phase 3 clinical trial of HEPLISAV-B, its investigational adult hepatitis B vaccine. More than 8,250 adults, including over 1,100 diabetic subjects, have been enrolled at 40 sites in the U.S.

This large safety and immunogenicity study (known as HBV-23) is intended to provide an adequately-sized database of vaccinated subjects to enable the U.S. Food and Drug Administration to complete its review of the pending HEPLISAV-B Biologics License Application. The study is also designed to assess the immunogenicity of HEPLISAV-B in adults for whom approved hepatitis B vaccines are less effective, including those with type-2 diabetes mellitus.

"Concluding enrollment of HBV-23 is a major milestone in the path to potential approval of HEPLISAV-B. I am pleased with the team's efforts to complete this key phase of the trial three months ahead of schedule" said Eddie Gray, Chief Executive Officer of Dynavax. "HEPLISAV-B is the most advanced demonstration of our leadership in TLR biology and validates our targeted approach to modulating the immune system to prevent and treat disease."

HBV-23 is an observer-blinded, randomized, active-controlled trial. Adult subjects between the ages of 18 and 70 have been 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®. Safety follow up will continue for 12 months following each subject's second vaccination. All study visits will be completed by October, 2015.

Additional details regarding HBV-23 are available at www.clinicaltrials.gov.

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, discovers and develops 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 HBV-23. 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 a sufficient number of subjects enrolled in HBV-23 complete the study; 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; whether our studies and manufacturing efforts are sufficient to support registration for commercialization of HEPLISAV-B; our ability to obtain additional financing to support the development and commercialization of HEPLISAV-B and our other operations; possible claims against us, including enjoining sales of HEPLISAV-B, based on the patent rights of others; 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.

Contact:
Michael S. Ostrach
Vice President, Chief Business and Principal Financial Officer
510-665-7257
Email Contact

Source: Dynavax Technologies