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Dynavax Initiates Phase 3 Study of HEPLISAV-B(TM)

BERKELEY, CA -- (Marketwired) -- 04/15/14 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced initiation of a new phase 3 clinical trial of HEPLISAV-B, its investigational adult hepatitis B vaccine. This large safety and immunogenicity study (known as HBV-23) was designed to address the Complete Response Letter regarding the HEPLISAV-B Biologics License Application that was issued to Dynavax by the U.S. Food and Drug Administration in February, 2013.

HBV-23 will provide greater clarity regarding the safety profile of HEPLISAV-B by significantly expanding the overall database of vaccinated subjects. The study will also assess the immunogenicity of HEPLISAV-B in subjects for whom approved hepatitis B vaccines are less effective. Dynavax expects that all study subjects will be enrolled by the end of 2014 and all follow-up will be completed by the fourth quarter of 2015.

HBV-23 Study Design

HBV-23 is an observer-blinded, randomized, active-controlled, trial being conducted at approximately 40 sites in the U.S. Approximately 8,250 adult subjects between the ages of 18 and 70 will be randomized in a 2:1 ratio to receive a 2-dose series of HEPLISAV-B or a 3-dose series of a control vaccine, Engerix-B®. Enrollment will be stratified by site, age group and type 2 diabetes mellitus status. Safety follow-up will continue for all subjects through study week 56.

The co-primary objectives of HBV-23 are to:

- Evaluate the overall safety of HEPLISAV-B with respect to clinically significant adverse events (AEs), and
- Demonstrate the noninferiority of the seroprotection rate induced by HEPLISAV-B compared with Engerix-B at Week 28 in subjects with type 2 diabetes mellitus.

The study also includes multiple secondary objectives intended to further elucidate the safety profile of HEPLISAV-B with respect to specific outcomes and to assess its immunogenicity in subpopulations including smokers, men, individuals with higher body mass, and those aged 40 years and older.

All AEs from HBV-23 that are considered to represent potential autoimmune disorders will be reviewed by an independent Safety Evaluation and Adjudication Committee (SEAC). The SEAC will provide an opinion whether each event is autoimmune in origin, pre-existing or new-onset, and related or not related to study treatment. The full safety dataset will be reviewed periodically by an independent Data and Safety Monitoring Board (DSMB) to ensure the safety of subjects and scientific integrity of the study. The DSMB will perform at least three prespecified reviews.

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 an additional clinical trial for HEPLISAV-B. 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; whether our studies and manufacturing efforts are sufficient to support registration for commercialization of HEPLISAV-B in

either or both of the US and Europe; the timing for and costs of achieving the size of the safety database; the results of clinical trials and the impact of those results on the initiation and completion of subsequent trials and issues arising in the regulatory process, including whether a US or European licensure application will be approved; 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.

Source: Dynavax Technologies