



## **Dynavax Reports Complete Results From the HEPLISAV(TM) Phase 3 Trial in Healthy Adults Over Age 40**

BERKELEY, CA -- (MARKET WIRE) -- 09/18/11 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Chicago, IL presented complete results for the entire study population of its Phase 3 trial (HBV-16). The Phase 3 study, HBV-16, was a multi-center, observer-blinded study to determine if the immunogenicity of two doses of HEPLISAV was non-inferior/superior to three doses of Engerix-B® by comparing seroprotection rates (SPRs) at eight weeks post last dose.

The data reported at ICAAC demonstrate HEPLISAV's ability to generate a faster, higher, and longer-lasting response as compared to Engerix-B, as follows:

- HEPLISAV induced a superior immune response to Engerix-B throughout the study. The SPRs and Geometric Mean Concentrations (GMCs) in the HEPLISAV group were significantly higher than the SPRs and GMCs in the Engerix-B group at every visit from Week 4 through Week 52.
- HEPLISAV provided earlier seroprotection than Engerix-B. At the primary endpoint visit, Week 12 for HEPLISAV and Week 32 for Engerix-B, the SPR in the HEPLISAV group was 90% compared to 71% in the Engerix-B group. In fact, at Week 8, the SPR in the HEPLISAV group was higher (77%) than the peak SPR in the Engerix-B group. The GMC results also showed an earlier response from HEPLISAV; at Week 12, for HEPLISAV, GMCs were 93 mIU/mL compared to Engerix-B at Week 32 when GMCs were 61 mIU/mL.
- HEPLISAV provided higher rates of seroprotection than Engerix-B. The peak SPR for the HEPLISAV group was 95% at Week 24. The peak SPR for Engerix-B was 73% at Week 28. The peak GMC for HEPLISAV was 233 mIU/mL at Week 24, and was 89 mIU/mL for Engerix-B at Week 28.
- HEPLISAV provided longer-lasting antibody than Engerix-B. The immune response to HEPLISAV was longer-lasting than the immune response to Engerix-B. The SPR in the HEPLISAV group decreased from a peak of 95% at Week 24 to 92% at Week 52 while the SPR in the Engerix-B group decreased from a peak of 73% at Week 28 to 59% at Week 52. The GMC in the HEPLISAV group decreased from a peak of 233 mIU/mL at Week 24 to 151 mIU/mL at Week 52. In contrast, the GMC in the Engerix-B group decreased from a peak of 89 mIU/mL at Week 28 to 20 mIU/mL at Week 52.
- The safety of HEPLISAV was similar to Engerix-B. The rates of local and systemic post-immunization reactions, adverse events, serious adverse events, and autoimmune adverse events were similar in both groups.

According to Tyler Martin, M.D., President and Chief Medical Officer who made the oral presentation in a session entitled "New Trends in Vaccines" (#80), "The data clearly indicate that HEPLISAV induces an immune response that is faster, higher, and more durable than that produced by Engerix-B, with similar safety. These results, demonstrating the superiority of HEPLISAV to Engerix-B in a hyporesponsive population, will be the basis of our BLA filing that we intend to submit by the end of this year."

Dynavax will present subgroup analyses of the study's findings at upcoming annual medical meetings, including diabetics at the Infectious Diseases Society of America (IDSA), and other hyporesponsive groups at the American Association for the Study of Liver Diseases (AASLD) later this year.

Engerix-B® is a registered trademark of GlaxoSmithKline

### *About HEPLISAV*

HEPLISAV is an investigational adult hepatitis B vaccine. In an earlier completed pivotal Phase 3 trial, HEPLISAV demonstrated increased, rapid protection with fewer doses than current licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV and is developing the vaccine for large, high-value populations that are less responsive to current licensed vaccines, including individuals with chronic kidney disease. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist known as ISS to enhance the immune response.

### *About Dynavax*

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to

prevent and treat infectious and inflammatory diseases. The Company's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide rapid and superior protection with fewer doses than current licensed vaccines. For more information visit [www.dynavax.com](http://www.dynavax.com).

#### *Forward-Looking Statements*

This press release contains "forward-looking statements," that are subject to a number of risks and uncertainties, including statements regarding the timing of the BLA submission. 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 approval of HEPLISAV and our process for its manufacture can occur in a timely manner or without significant additional studies or difficulties or delays in development or clinical trial enrollment, whether our studies can support registration for commercialization of HEPLISAV; 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 the outcome of pre-filing discussions with regulatory authorities; the Company's ability to obtain additional financing to support the development and commercialization of HEPLISAV and its other operations, possible claims against the Company 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](http://www.dynavax.com) is not incorporated by reference in the Company's current periodic reports with the SEC.

Contact:

Michael Ostrach

Vice President and Chief Business Officer

510-665-7257

Email Contact

Source: Dynavax Technologies

News Provided by Acquire Media