



## **Dynavax Reports Modified Intent to Treat Analysis From the HEPLISAV(TM) Phase 3 Trial in Healthy Adults Over Age 40**

BERKELEY, CA -- (MARKET WIRE) -- 10/03/11 -- Dynavax Technologies Corporation (NASDAQ: DVAX) presented yesterday at the 5th Global Vaccine Congress in Seattle, WA an analysis of the modified intent to treat population from its Phase 3 trial (HBV-16), showing the superiority of HEPLISAV vs. Engerix-B®. The previously reported per protocol analysis compared the three consistency lots of HEPLISAV to Engerix-B and included 1123 HEPLISAV and 359 Engerix-B subjects who completed the vaccination regimens according to the protocol. The modified intent to treat (MITT) populations of 1947 HEPLISAV subjects and 476 Engerix-B subjects included all subjects that had received at least one dose of any of the four HEPLISAV lots or Engerix-B and had at least one post vaccination immunogenicity result. 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 demonstrate HEPLISAV's ability to generate a faster, higher, and longer-lasting response as compared to Engerix-B in both the per protocol and the modified intent to treat populations, as follows:

- For the MITT population, 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 89% compared to 69 % in the Engerix-B group.
  - In the previously reported per protocol analysis, 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.
- For the MITT population, HEPLISAV also provided higher rates of seroprotection than Engerix-B. The peak SPR for the HEPLISAV group was 95% at Week 24. The peak SPR for the Engerix-B group was 71% at Week 28.
  - As previously reported for the per protocol analysis, the peak SPR for the HEPLISAV group was 95% at Week 24. The peak SPR for the Engerix-B group was 73% at Week 28.
- For the MITT population, HEPLISAV provided longer-lasting antibody than Engerix-B, and the immune response to HEPLISAV was longer-lasting than the immune response to Engerix-B. The SPR in the HEPLISAV group was 92% at Week 52 while the SPR in the Engerix-B group was 59% at Week 52.
  - As previously reported for the per protocol analysis, the SPR in the HEPLISAV group was 92% at Week 52 while the SPR in the Engerix-B group was 59% 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, "The results of the modified intent to treat analysis corroborate the previously reported per protocol analysis and support the robustness of our conclusion that HEPLISAV is superior to Engerix-B in this hyporesponsive population."

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. 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.

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