

Dynavax Phase 3 Demonstrates Superiority and Safety of HEPLISAV™ vs. Engerix-B®

BERKELEY, CA -- (MARKET WIRE) -- 07/20/11 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today said that top-line data from its Phase 3 trial comparing HEPLISAV, an investigational hepatitis B virus (HBV) vaccine, to a currently marketed HBV vaccine, Engerix-B, demonstrated non-inferiority, superiority and the safety of HEPLISAV. The study evaluated a two-dose regimen of HEPLISAV administered at 0 and 1 month compared to a three-dose regimen of Engerix-B administered at 0, 1 and 6 months. The trial studied 2,449 healthy adults 40 to 70 years of age, randomized to HEPLISAV or Engerix-B in a 4:1 ratio. Data supporting the consistency of three consecutively manufactured lots of HEPLISAV have been submitted to the Food and Drug Administration (FDA), and Dynavax expects confirmation of its analysis shortly.

Immunogenicity data demonstrated:

- At the primary endpoint, 8 weeks post the last dose of vaccine, 12 weeks for HEPLISAV and 32 weeks for Engerix-B, the seroprotection rate (SPR) was 90% for HEPLISAV and 70% for Engerix-B, demonstrating the non-inferiority and superiority of HEPLISAV to Engerix-B.
- The peak SPR for HEPLISAV occurred at 24 weeks and was 95%. The peak SPR for Engerix-B occurred at 28 weeks and was 73%.
- At the final visit, week 52, 48 weeks after the last dose of HEPLISAV and 28 weeks after the last dose of Engerix-B, the SPRs were 92% for HEPLISAV and 59% for Engerix-B.

Dynavax also reported that the trial's safety data showed HEPLISAV to be safe and well tolerated, and similar to Engerix-B. Careful safety evaluation over the 12 month duration of trial demonstrated:

- 50% of HEPLISAV subjects and 53% of Engerix-B subjects experienced an adverse event.
- 7% of HEPLISAV subjects and 6% of Engerix-B subjects experienced possibly related adverse events.
- 4% of HEPLISAV subjects and 5% of Engerix-B subjects experienced a serious adverse event.
- 3 new onset autoimmune adverse events were confirmed by the Safety Evaluation and Adjudication Committee (SEAC), none of which were serious adverse events. All three occurred in the HEPLISAV group, consistent with the 4:1 randomization.
- There were no cases of ANCA-associated vasculitis or Wegener's Granulomatosis.

With respect to the consistency analysis of three consecutively manufactured lots of HEPLISAV, Dynavax concluded that the study had demonstrated consistency based on the complete immunogenicity data demonstrated by the three vaccine lots over the six months following second immunization.

- By Geometric Mean Antibody Concentration (GMC), the results met the pre-specified consistency criteria at 12, 18, 24 and 28 weeks, but not at 8 weeks, the pre-specified primary endpoint. The GMC of one HEPLISAV lot was slightly higher than the other two lots, which resulted in not meeting the consistency criteria at week 8.
- By SPR, the results met the pre-specified consistency criteria at 12, 18, 24 and 28 weeks, but not at 8 weeks.
- At all of these timepoints, each lot of HEPLISAV was superior to Engerix-B.

Dynavax said it had submitted these data and its analysis supporting lot-to-lot consistency to the FDA and expects confirmation from the agency in the near future.

"These results confirm and expand the superiority of HEPLISAV vs. Engerix-B in this hyporesponsive population of persons age 40 and above. HEPLISAV again demonstrated the rapid onset of seroprotection and superior peak protection compared to Engerix-B. A new finding in this trial is the superior duration of HEPLISAV to Engerix-B. Based on the results of intensive safety monitoring over 12 months, we have again demonstrated that HEPLISAV has a similar safety profile to Engerix-B, generally considered to be a very safe vaccine. Finally, we believe the consistency of the peak immune response of three lots of HEPLISAV was clearly demonstrated in this trial," commented Tyler Martin, M.D., President and Chief Medical Officer.

Dynavax said it will present complete results from the Phase 3 trial in an oral presentation at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) on Sunday, September 18, 2011 in Chicago, IL.

Webcast and Conference Call Today

Dynavax will host a conference call and webcast a discussion of the HEPLISAV Phase 3 top-line data along with the company's second quarter 2011 financial results on Wednesday, July 20, 2011 at 9:00 a.m. Eastern Daylight Time / 6:00 a.m. Pacific Daylight Time. To join the Conference Call, please dial 1-877-280-7280. International callers can dial 1-707-287-9365. A telephonic replay of the discussion will be available 90 minutes after its conclusion and through August 3, 2011 by dialing 1-855-859-2056, access code: 85190076. International callers can dial 1-404-537-3406, access code: 85190076. The webcast can be accessed on Dynavax's website at <http://investors.dynavax.com/events.cfm>. A webcast replay of the discussion will be available on Dynavax's website, 90 minutes after its conclusion and through August 3, 2011.

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

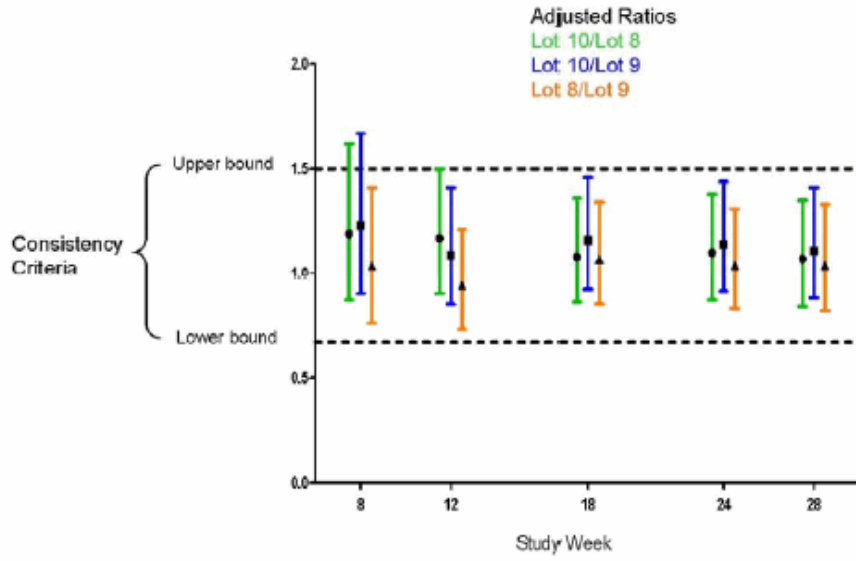
Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops novel products to prevent and treat infectious and inflammatory diseases. The Company's lead product candidate is HEPLISAV, a Phase 3 investigational adult hepatitis B vaccine designed to provide rapid and superior protection with fewer doses than current licensed vaccines. For more information visit www.dynavax.com.

Forward Looking Statements

This press release contains "forward-looking statements," that are subject to a number of risks and uncertainties, including statements regarding our expectation of confirmation in the near future by the FDA of our assessment of lot-to-lot consistency. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including the FDA's assessment of the data from this study and any requests it may make to conduct additional studies, 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; 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 is not incorporated by reference in the Company's current periodic reports with the SEC.

Engerix-B® is a registered trademark of GlaxoSmithKline

Ratio of GMCs for Lot Consistency by Timepoint



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