



## **Dynavax Announces Termination of Partnership With Merck for HEPLISAV(TM) Hepatitis B Vaccine**

### **All Rights Revert to Dynavax**

BERKELEY, Calif., Dec 19, 2008 (BUSINESS WIRE) --

Dynavax Technologies Corporation (Nasdaq:DVAX) today announced the termination of a global license and development collaboration agreement with Merck & Co., Inc. for HEPLISAV<sup>TM</sup>, a Phase 3 hepatitis B virus (HBV) vaccine. All rights to develop and commercialize HEPLISAV revert to Dynavax.

Dynavax will continue to evaluate regulatory options for the development of HEPLISAV indicated for adults outside of the United States and for the global end-stage renal disease markets, which the Company estimates represent approximately 70% of the total market opportunity for this vaccine. If the regulatory feedback is favorable, Dynavax plans to pursue a new partner or financing arrangement to support the completion of HEPLISAV's development for these markets.

"We believe the economics for HEPLISAV, which has been shown to be clinically superior in our trials, favor identifying an appropriate regulatory path in the U.S. and Europe," commented Dino Dina, M.D., President and Chief Executive Officer of Dynavax. "In the first quarter of 2009, we expect to gain additional insight into the regulatory path for HEPLISAV that will enable us to evaluate further development and pursue partnering agreements with potential collaborators or investors. Independently of HEPLISAV, with our current cash position and strong pharmaceutical partnerships, we have the ability to continue to advance our diversified, well-funded pipeline of products to position Dynavax for future success."

### **Update to 2008 Cash Outlook**

Dynavax's consolidated cash, cash equivalents, marketable securities and investments held by Symphony Dynamo, Inc., or total cash, is projected to be over \$65 million at December 31, 2008, an increase from the previous guidance of over \$50 million. This increase is due to the \$10 million initial payment under Dynavax's worldwide strategic alliance with GlaxoSmithKline as well as the Company's conservatively managed cash burn rate. Due to the termination of the Merck partnership, Dynavax anticipates that it will accelerate the recognition of approximately \$31 million of non-cash revenue previously reported as deferred revenue.

### **About HEPLISAV**

HEPLISAV is a Phase 3 hepatitis B vaccine that combines HBV surface antigen (HBsAg) with Dynavax's proprietary immunostimulatory sequences (ISS), which specifically target Toll-Like Receptor 9 (TLR9) to stimulate an innate immune response. Clinical data demonstrate HEPLISAV's highly effective protection against HBV with a more rapid onset of protection, superior 2-dose regimen, and longer lasting seroprotection compared to current vaccines. In a recent Phase 3 trial, 95% of subjects receiving 2 doses of HEPLISAV were seroprotected compared to 81% of subjects receiving 3 doses of Engerix-B. In 9 clinical trials conducted over a period of nearly 10 years, a total of approximately 2,500 individuals have been vaccinated with more than 5,000 doses of HEPLISAV.

In October 2008, the U.S. Food and Drug Administration (FDA) requested additional information prior to considering further development of HEPLISAV in end-stage renal disease patients but advised that the balance of risk versus potential benefit no longer favors continued clinical evaluation of HEPLISAV in healthy adults and children. The clinical hold on the two U.S. IND Applications for HEPLISAV has been in effect since March 2008 following the FDA's request for a complete review of safety data, including all available information about a single case of Wegener's granulomatosis reported in a Phase 3 clinical trial.

HEPLISAV is not on clinical hold in any market outside of the U.S.

### **About Dynavax**

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops a diversified, well-funded pipeline of novel Toll-like Receptor (TLR) product candidates. Based on Dynavax's proprietary technology platform, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. Dynavax's product programs are supported by global partnerships with leading pharmaceutical companies such as

GlaxoSmithKline, AstraZeneca AB, and Novartis as well as funding from Symphony Dynamo, Inc. and the National Institutes of Health. For more information visit [www.dynavax.com](http://www.dynavax.com).

### **Dynavax Forward-Looking Statement**

This press release contains "forward-looking statements," including statements related to our plans to evaluate regulatory options for HEPLISAV and the timing of that evaluation, the prospects for HEPLISAV and the determination of whether further clinical development of HEPLISAV will be undertaken, and if undertaken, whether further development can be partnered or financed; and our projected year end cash position. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including difficulties or delays in development, initiation and completion of clinical trials, 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 scope and validity of patent protection and the possibility of claims against us based on the patent rights of others; our ability to obtain additional financing to support our operations; and other risks detailed in the "Risk Factors" section of our Quarterly Report on Form 10-Q. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

SOURCE: Dynavax Technologies Corporation

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