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Dynavax Announces Withdrawal of European Marketing Application for HEPLISAV(TM)

BERKELEY, CA -- (Marketwired) -- 02/18/14 -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced today that it has withdrawn the European Marketing Authorization Application (MAA) for HEPLISAV, its investigational hepatitis B vaccine. The Day 180 List of Outstanding Issues provided by the European Medicines Agency (EMA) indicated that the current HEPLISAV safety database is considered to be too small to rule out a risk of less common serious adverse events. Dynavax has chosen to withdraw the application because the required timeframe for response under the MAA procedure is not long enough to permit the collection of the necessary clinical data. Dynavax expects to begin shortly an additional HEPLISAV clinical trial, HBV-23, that is intended to provide a safety database sufficient to support licensure.

About HEPLISAV

HEPLISAV 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.

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, 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 timing and sufficiency of an additional clinical trial for HEPLISAV. 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 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 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 and our other operations; possible claims against us, including enjoining sales of HEPLISAV, 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.

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Source: Dynavax Technologies