

## **Dynavax Restructures and Emphasizes Immuno-Oncology Program**

### **Cost Reductions Support Continued Advancement of Cancer Therapeutics; Maintains Scalable Infrastructure to Progress HEPLISAV-B through FDA Review Process; Company to Host Conference Call Today at 4:30 p.m. Eastern Time**

BERKELEY, CA -- (Marketwired) -- 01/05/17 -- Dynavax Technologies Corporation (NASDAQ: DVAX), a clinical-stage biopharmaceutical company, today announced that it is reshaping its strategy and operations to prioritize its emerging clinical and preclinical immuno-oncology portfolio. The company has implemented significant organizational restructuring and cost reductions to align around its immuno-oncology business, while allowing it to advance HEPLISAV-B™ [Hepatitis B Vaccine, Recombinant (Adjuvanted)], its investigational hepatitis B vaccine candidate, through the U.S. Food and Drug Administration (FDA) review process and an approval decision. Dynavax continues to believe that HEPLISAV-B is an approvable product and plans to submit its response to the FDA's outstanding questions shortly.

To achieve these savings, Dynavax has suspended manufacturing for HEPLISAV-B and reduced its global workforce by 38 percent. The company will incur restructuring costs, currently estimated to be \$3.0 million, primarily in the first quarter of 2017. The company estimates that its cash, cash equivalents and marketable securities were approximately \$81.4 million as of December 31, 2016. Going forward, it expects HEPLISAV-B costs prior to any FDA decision to be less than \$1 million per month, and all other operating costs to be less than \$60 million per year to support continued development of its oncology program. This restructuring is currently estimated to result in approximately a 40 percent reduction in cash burn. The company will continue to evaluate the possibility of a partnership to support HEPLISAV-B as it increasingly concentrates its own strategic focus on oncology.

"We value all of our colleagues, so reducing our workforce is a sad and difficult decision. But it is one we believe is necessary to align our organization to reflect that of a clinical R&D-stage company with a promising immuno-oncology pipeline, which has become a strategically important area of our business and one we believe can potentially benefit thousands of people with cancer," said Eddie Gray, chief executive officer of Dynavax. "These measures will increase our financial strength and position us well to create significant long-term clinical and financial value. They also will allow us to advance HEPLISAV-B toward approval while we continue to evaluate the possibility of a partnership to support its approval and launch. We are grateful to all affected employees for their dedication to bringing us this far."

#### ***Prioritizing Diversified Immuno-Oncology Pipeline***

Dynavax has made notable progress in the rapidly advancing area of immuno-oncology, and is focusing on two promising compounds that have shown potential to enhance the immune response against cancer.

The company's lead clinical candidate, SD-101, an investigational cancer immunotherapeutic, is currently being studied in several Phase 1/2 studies evaluating its potential to be broadly effective against multiple solid tumors and hematologic malignancies. SD-101, an intratumoral TLR9 agonist, has shown encouraging early clinical data in metastatic melanoma.

At the Society for Melanoma Research conference in November 2016, Dynavax announced the first findings from an ongoing Phase 1/2 study of SD-101 in combination with Keytruda® (pembrolizumab), Merck's anti-PD-1 treatment. Early results evaluating 13 patients with metastatic melanoma for efficacy and 19 patients for safety were reported. In patients naïve to anti-PD-1 treatment, objective responses were observed in four of five patients (80 percent), including one complete response and three partial responses. In a small number of patients with progressive disease stable disease was observed while receiving Keytruda and SD-101 in combination. The combination of the two drugs was well-tolerated with no dose-limiting toxicities. These encouraging clinical data will be enhanced by a dose-expansion phase to further explore the efficacy of this combination.

Dynavax is also developing a second TLR9 agonist, DV281, which has completed preclinical testing in models for lung cancer. Lung cancer remains an area of high unmet need, with fewer than 20 percent of patients responding to the most recently-approved immunotherapies. DV281 will be administered as an inhaled therapeutic. Dynavax intends to begin Phase 1 studies of DV281 in the second quarter of 2017.

The company expects to present additional data from its immuno-oncology portfolio at medical conferences throughout 2017, including at the American Association for Cancer Research (AACR), the American Society of Clinical Oncology (ASCO) and the European Society for Medical Oncology (ESMO).

### ***Continuing to Advance HEPLISAV-B while Maintaining Manufacturing Capacity at Reduced Cost***

Dynavax plans to respond this month to the November 2016 Complete Response Letter (CRL) from the FDA regarding its Biologics License Application (BLA) for HEPLISAV-B, and will advance the vaccine through an expected six-month FDA review period. The company remains confident that the existing clinical data package meets the requirements for approval. During the regulatory review period, Dynavax will retain, but furlough, the majority of the workforce supporting its manufacturing facility in Germany. This approach will enable the company to leverage the existing stockpiled inventory of HEPLISAV-B, while providing it with the ability to re-activate and scale for commercial launch activities.

### ***Conference Call Details***

The Dynavax management team will host a conference call and webcast today, Thursday, January 5, 2017, at 4:30 p.m. Eastern Time, to provide more information about the restructuring. The live call can be accessed by phone by dialing (877) 479-1857 (domestic) or +1 (503) 343-6309 (international) and specifying conference call code 47911578. A link to the live webcast may be accessed by visiting the "Investors" section of the Dynavax website or directly at [www.dynavax.com](http://www.dynavax.com). A replay of the conference call may be accessed for one week following the call by dialing (855) 859-2056 (domestic) or +1 (404) 537-3406, and using the passcode 47911578.

### ***About SD-101***

SD-101 is Dynavax's proprietary CpG-C class oligodeoxynucleotide. SD-101 is a potent activator of dendritic cells, activating them to mature and produce Type 1 interferons through specific binding to TLR9, a key recognition receptor in the innate immune system. SD-101 is delivered directly to the tumor, where it can stimulate highly effective immune responses to tumor antigens. SD-101 is being evaluated in several Phase 1/2 oncology studies to assess its safety and activity.

### ***About DV281***

DV281, a newly developed TLR9 agonist, is a CpG-C class oligodeoxynucleotide developed specifically for inhaled delivery to lung tumors that are not easily accessible for intratumoral injection. Inhaled DV281 induces dendritic cell activation and tumor microenvironment changes comparable to intratumoral injection of SD-101. Studies in animal models of lung tumors show that DV281 dramatically reduces lung tumor burden and leads to immune-mediated control of tumor metastases outside the lung. Dynavax intends to initiate a Phase 1 study in the second quarter of 2017.

### ***About HEPLISAV-B***

HEPLISAV-B is an investigational adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary TLR 9 agonist to enhance the immune response. HEPLISAV-B is administered in two doses over one month. In Phase 3 trials, HEPLISAV-B demonstrated higher and earlier protection with fewer doses than a currently licensed hepatitis B vaccine. The investigational vaccine's safety profile is based on clinical trials that generated safety data from more than 14,000 participants. The most frequently reported local reaction was injection site pain. The most common systemic reactions were fatigue, headache and malaise, all of which were similar to an existing vaccine.

Dynavax has worldwide commercial rights to HEPLISAV-B.

### ***About Dynavax***

Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious diseases and oncology. Dynavax's lead product candidates are SD-101, an investigational cancer immunotherapeutic currently in several Phase 1/2 studies, HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine, and DV-281, an investigational immunotherapy for lung cancer, for which Phase 1 studies will be initiated in 2017. For more information, visit [www.dynavax.com](http://www.dynavax.com).

### ***Forward-Looking Statements***

This press release contains "forward-looking" statements and estimates, including estimated December 31, 2016 cash balance, anticipated cost reductions, estimated restructuring costs, expectations for the conduct and timing of clinical trials for SD-101 and DV281, the company's plans to respond to the FDA's CRL for HEPLISAV-B, and plans and the ability to identify a partner for the advancement of HEPLISAV-B through FDA review and commercial launch. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether the preliminary, unaudited December 31, 2016 cash balance will differ from the amount reflected in our audited financial statements; anticipated cost reductions will be achieved; whether we can timely provide adequate clinical supplies; initiation, enrollment and completion of clinical trials of SD-101 and DV281; the results of clinical trials and the impact of those results on the initiation or continuation of subsequent trials and issues arising in the regulatory process; the ability to successfully develop and commercialize SD-101 and DV281; whether or not Dynavax and parties with whom we are collaborating may reach any future agreement on further studies or a more extensive collaboration beyond the clinical trials contemplated under the existing agreements; whether HEPLISAV-B may be approved by the FDA; the timing and ability for Dynavax to respond to the CRL; whether Dynavax will be able to find a partner for HEPLISAV-B; the timing of the FDA's review if Dynavax is able to respond to the CRL; and whether the issues identified in the CRL are resolvable with respect to

questions involving the data or interpretation of the data submitted in support of the BLA; whether or not FDA will require additional clinical trials; whether FDA will identify additional issues after Dynavax responds to the CRL; whether there will be a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting and if so, whether it will impact the timing of FDA review or negatively impact the review and approval of the BLA; whether additional studies or manufacturing process enhancements will be required, or other issues will arise that will delay the BLA review or negatively impact the review and approval by the FDA; if approvable, whether the issues will negatively impact the potential scope of the label claims and nature of the label content for HEPLISAV-B; and other risks detailed in the "Risk Factors" section of our most recent periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this press release. We do not undertake any obligation to update publicly any such forward-looking statements, 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 our current periodic reports with the SEC.

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