Dynavax Announces Strategic Restructuring to Focus on its Vaccine Business

May 23, 2019

- *Company will explore strategic alternatives for its immuno-oncology programs*
- *Company will align its resources to focus on HEPLISAV-B commercialization*
- *Eddie Gray, CEO, to retire*

BERKELEY, Calif., May 23, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX), today announced a strategic restructuring to prioritize its vaccine business by focusing on the company's first commercial product HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted]. As part of the restructuring, the company will explore strategic alternatives for its immuno-oncology portfolio and will reduce the company's workforce and operations to focus resources on HEPLISAV-B commercialization. While the company's near-term focus will be on HEPLISAV-B sales execution, the company is assessing additional opportunities to leverage its 1018 adjuvant, as well as evaluating other opportunities for growth.

"Following a comprehensive analysis of our assets, strengths and opportunities, we have determined we should focus our resources on our approved vaccine, HEPLISAV-B, which, as the only two-dose hepatitis B vaccine, is gaining market share and is well positioned to become the new standard of care in the U.S," said Eddie Gray, chief executive officer of Dynavax. "We plan to curtail further investment in our immuno-oncology portfolio and will seek strategic alternatives for these programs. As a result, the board and management have made the difficult decision to reduce our workforce. We want to express our deepest appreciation to our employees for their invaluable contributions."

Mr. Gray continued. "I am proud of the role our employees and collaborators have played to advance Dynavax's immuno-oncology portfolio of innate immune TLR9, 7/8 agonists and antigen-enhanced immunotherapy. Encouraging clinical data to date highlight the importance of recruiting both innate and adaptive immune effectors to elicit an integrated anti-tumor response and to eradicate established tumors. Local induction of innate immunity holds tremendous promise and will likely be instrumental in advancing the treatment of cancer. The decision to seek strategic alternatives expands the pool of potential investment options to further development of these important assets. Dynavax will work with investigators to wind down the immuno-oncology trials with an emphasis on patient care."

"In addition, given this strategic decision to separate our two businesses, I've determined it's the optimal time for me to transition from the company and so I will retire as CEO and as a Director of Dynavax, as of August 1, 2019. It has been my pleasure to lead Dynavax through pivotal milestones, including FDA approval of HEPLISAV-B, and I look forward to watching its future success," Mr. Gray added.

The company's board of directors has created an interim Office of the President and has appointed David Novack, currently Senior Vice President, Operations, and Ryan Spencer, currently Senior Vice President, Commercial, as Co-Presidents, effective immediately.

"On behalf of the Board, I would like to thank Eddie for his dedication and many contributions to Dynavax. We will miss his leadership and professionalism," said Arnold L. Oronsky, Ph.D., Chairman of the Board of Directors of Dynavax. "The board is very pleased to have such experienced executives to step in to lead the new vaccine-focused company. David and Ryan have been critical contributors to the launch of HEPLISAV-B. David, who leads operations and manufacturing, has more than 20 years of direct vaccine industry experience. Ryan, who has extensive finance experience, has skillfully built and led our commercial organization. Their collective expertise will be instrumental to the future success of the company."

Mr. Novack has been at Dynavax since 2013, and has led the company's technical operations, supply chain, and quality teams through FDA approval, launch and commercialization of HEPLISAV-B. Mr. Novack has more than 30 years of relevant industry experience, with more than 20 years of direct vaccine industry experience. Prior to Dynavax, Mr. Novack was at Novartis where he served in various roles, including Global Head of Technical Operations and Supply Chain for Diagnostics, and Global Head of Manufacturing Strategy for Vaccines.

Mr. Spencer, who joined Dynavax in 2006, has spearheaded the commercialization of HEPLISAV-B, including creating and managing HEPLISAV-B commercial operations. Throughout his time at Dynavax, Mr. Spencer has held a variety of positions with increasing responsibility, building from a foundation in corporate finance to business strategy and investor relations and culminating in his current role as Senior Vice President, Commercial, responsible for leading the launch and commercialization of HEPLISAV-B.

The board will conduct a search for the company's next CEO and will consider both internal and external candidates.

In connection with the decision to focus on the vaccine business the company is eliminating approximately 82 current positions, representing approximately 37% of its current U.S. workforce. The company is providing severance, continuation of employee benefits and outplacement assistance to the employees affected by the restructuring. The positions eliminated are primarily related to research and clinical development for the immuno-oncology programs and general and administrative functions. Restructuring costs and retirement costs related to compensation and benefit expenses as well as severance costs, are expected to be approximately $5.5 million, exclusive of stock compensation. The company may incur additional restructuring expenses including retirement of fixed assets and facility-related costs.

The workforce reduction is expected to reduce compensation and benefits cost by approximately $16 million dollars annually. After all existing oncology trials and commitments are complete, the Company estimates its operating expenditures related to external oncology costs will be reduced by approximately $8 million per quarter as compared to the first quarter ended March 31, 2019. The company will be responsible for certain wind-down costs and committed contractual costs for the immuno-oncology programs, including the I-SPY trial that will run through the second quarter of next year.

As of March 31, 2019, the company reported cash, cash equivalents and marketable securities totaling $183.2 million.

About Hepatitis B
Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer and death. The hepatitis B virus is 50 to 100 times more infectious than HIV,[i] and transmission is on the rise. There is no cure for hepatitis B, but effective vaccination can prevent the disease.

In adults, hepatitis B is spread through contact with infected blood and through unprotected sex with an infected person. The CDC recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas.[ii] Because people with diabetes are particularly vulnerable to infection, the CDC recommends vaccination for adults age 19 to 59 with diabetes as soon as possible after their diagnosis, and for people age 60 and older with diabetes at their physician's discretion.[iii] Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.[iv]

About HEPLISAV-B
HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

For more information about HEPLISAV-B, visit http://heplisavb.com/.

About Dynavax
Dynavax is a biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers, develops and commercializes novel vaccines. The Company launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. For more information, visit www.dynavax.com .

Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding the commercialization of HEPLISAV-B and exploring strategic alternatives for our immuno-oncology programs and anticipated costs and cost savings. 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 and when prescribers and other key decision-makers at potential purchasing entities will make the decision to switch to HEPLISAV-B, and the timing and quantity of actual purchases; our ability to successfully explore strategic alternatives for our immuno-oncology programs; and the actual amount of costs and cost savings resulting from the restructuring , as well as other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. 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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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm.
[ii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.
[iii] CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf.
[iv] CDC. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

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