Dynavax Provides Business Update on COVID-19 Pandemic Impact

April 2, 2020

EMERYVILLE, Calif., April 02, 2020 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today provided a business update in relation to the impact of COVID-19 on the Company's operations.

"During the uncertainty caused by the COVID-19 pandemic, we have acted quickly to focus on four key areas," commented Ryan Spencer, Chief Executive Officer of Dynavax. "These include safeguarding the health and safety of our employees and customers; continuing effective operations to ensure patient access to HEPLISAV-B; maintaining our financial strength and stability; and supporting efforts to develop a COVID-19 vaccine. The Company's long-term value proposition remains unchanged, despite these short-term disruptions."

Mr. Spencer commented further: "This global health crisis reinforces the organization's commitment to our mission of developing vaccines to prevent infectious diseases. We are hopeful that societal learnings from this pandemic will increase support for adult immunization and highlight the importance of providing rapid protection to our healthcare workers and others who may be exposed to deadly viral diseases that are preventable. The potential for all stakeholders - governments, policy makers, healthcare systems, and consumers - to understand the benefits of vaccines and prevention will have a significant long-term positive impact on public health and the cost of healthcare for everyone."

Protecting Our Workforce and Minimizing the Spread of COVID-19

- The health and safety of Dynavax's employees and customers is of paramount importance.
- The Company has implemented remote working operations for employees at its corporate offices in Emeryville, California.
- The Company's manufacturing facility in Dusseldorf, Germany is employing special measures to continue operations safely.
- Dynavax has shifted from in-person interactions by its field sales force to virtual field calls in order to allow Dynavax to continue to serve the needs of physicians, patients, and customers during this critical time.

Ensuring Access to HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted]

- Dynavax has a secure supply chain that is able to meet U.S. market demand for HEPLISAV-B.
  - The Company continues to produce hepatitis B surface antigen at its facility in Dusseldorf, Germany.
  - The Contract Manufacturing Organization (CMO), located in the U.S., that produces the CpG 1018 adjuvant used in HEPLISAV-B remains capable of production.
- Dynavax estimates it currently has inventory of finished drug product sufficient to meet more than one year of projected demand and drug substance to fulfill approximately an additional year of estimated demand.

Continuing to Advance Clinical Trials of HEPLISAV-B

- HEPLISAV-B post marketing observational studies are fully enrolled and continuing uninterrupted. Due to the design and conduct of the studies, the Company does not anticipate an impact to the integrity of the studies as a result of the "shelter in place" mandates in California.
- HEPLISAV-B dialysis study continues to enroll patients. The study is focused on patients entering dialysis treatment, which is classified under the 'essential travel' exemptions and therefore will continue during this period of reduced medical services. The Company anticipates reporting data from the study's interim analysis later this month (April). This data was selected for presentation at the 2020 Annual Conference on Vaccinology Research (ACVR), which has been cancelled.

Delivering on the Promise of CpG 1018

- Dynavax has been actively pursuing opportunities to collaborate with other organizations on the development of additional vaccines, including a COVID-19 vaccine, by leveraging the Company's proprietary toll-like receptor 9 (TLR9) agonist adjuvant, CpG 1018, the adjuvant used in HEPLISAV-B, an adult hepatitis B vaccine approved by the U.S. Food and Drug Administration (FDA).
- Dynavax developed CpG 1018 to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 provides a well-developed technology with a significant safety database, potentially accelerating the development and large-scale manufacturing of vaccines for emerging pathogens, such as pandemic influenza and coronavirus.
- The Company has recently announced multiple collaborations focused on COVID-19, including with the Coalition for Epidemic Preparedness Innovations (CEPI), the University of Queensland, and Clover Biopharmaceuticals, and continues to work to identify other programs where CpG 1018 can be utilized to enhance the immune response to a coronavirus vaccine. The Company and its CMO are developing plans for scale-up activities to support pandemic level of production of CpG 1018 adjuvant, as necessary to support the Company's multiple collaborations to develop a coronavirus vaccine.

Updating Our Business Outlook

- Although to date Dynavax has seen limited financial impact from COVID-19 on HEPLISAV-B net product sales, the Company is seeing an impact on institutional access and vaccine utilization as many medical centers have closed clinics and are only providing care to the most severely affected patients.
- Due to uncertainties about the duration and effect of the COVID-19 pandemic and the potential impact on HEPLISAV-B product sales, the Company is withdrawing its full-year guidance for 2020 HEPLISAV-B® net product sales.
- Dynavax estimates it has already exceeded the HEPLISAV-B minimum product revenue covenant in its Term Loan Agreement of $30 million for the annual measurement period ending June 30, 2020.

About Dynavax

Dynavax is a commercial stage biopharmaceutical company developing and commercializing 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. Dynavax is also advancing CpG 1018 as a premier vaccine adjuvant through research collaborations and partnerships. For more information, visit www.dynavax.com and follow the company on LinkedIn.

Forward-Looking Statements

This press release contains "forward-looking" statements, including statements regarding financial estimates which are preliminary, based on unaudited financial results, subject to change upon completion of our audit, and may differ from what will be reflected in our consolidated financial statements for the quarter ended March 31, 2020, and regarding the Dynavax long-term value proposition. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of March 31, 2020. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in vaccine research and development, including the timing of completing development, the results of clinical trials, and whether and when a new vaccine will be approved for use, 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, 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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