Dynavax Presents Phase 2 Data on SD-101 in Combination with KEYTRUDA® (pembrolizumab) for Patients with Head and Neck Squamous Cell Carcinoma at the 2019 ASCO Annual Meeting

June 1, 2019

- *24% overall response rate in ITT population*
- *Responses were observed in SD-101 injected and non-injected lesions*
- *The combination of SD-101 and pembrolizumab was well-tolerated*

BERKELEY, Calif., June 01, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX), today announced favorable results from the Phase 2 cohort expansion of the Phase 1b/2, open-label, multicenter study of intratumoral SD-101 in combination with KEYTRUDA® (pembrolizumab) in anti-PD-1 treatment-naïve patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC). The results were presented today in a poster session at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.

“We are pleased with the results, particularly when we see a 24% response rate in second-line head and neck squamous cell carcinoma, a tumor that has historically low rates of response to anti-PD-1 treatments,” said Robert Janssen, M.D., chief medical officer of Dynavax. “When we look at patients with a combined positive PD-L1 score of less than 20%, their rate of response at 29% was similar to the 25% rate of response for those patients with higher PD-L1 positive scores. Additionally, more than a third of patients with HPV-positive tumors responded. Further, our biomarker data support these clinical outcomes and demonstrate that immunologically cold tumors reach similarly high levels of immune cell infiltration as immunologically hot tumors.”

In the Phase 1b/2 clinical study (NCT02521870) in patients with recurrent or metastatic HNSCC, SD-101 is administered intratumorally with 8 mg in 1 lesion or 2 mg in 1–4 lesions combined with intravenous administration of 200 mg of pembrolizumab.

Key highlights from the clinical data presentation include:

- An overall response rate (ORR) of 24% (ITT) n = 50 was observed.
    - An ORR of 22.2% in the 2 mg cohort and an ORR of 26.1% in the 8 mg cohort were observed.
    - An ORR of 33.3% and a disease control rate (DCR) of 41.6% were observed in patients with low PD-L1 status at baseline.
    - An ORR of 36% was observed in patients with HPV-positive tumors.
- Biomarker data are consistent with the mechanism of action of SD-101 and demonstrate strong immunomodulation of the tumor microenvironment including infiltration of activated T cells and upregulation of Type I and Type II Interferon (IFN).
- Importantly, similar to what was reported for melanoma patients who had not received anti-PD-1 therapy (ASCO 2019 Abstract 9534), patients whose tumors exhibited an immunologically cold tumor microenvironment at baseline (low IFNγ and T cell signatures) showed clinical response during SD-101 plus pembrolizumab treatment.
- The combination of SD-101 and pembrolizumab was well-tolerated, consistent with previous reports.
    - No evidence of an increased incidence or severity of adverse events (AEs) over pembrolizumab monotherapy.
    - No increase in immune-related AEs over pembrolizumab monotherapy.
    - AEs associated with SD-101 were mainly mild to moderate injection-site reactions and flu-like symptoms that were manageable with over-the-counter medication.

About SD-101
SD-101 is a proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. Dynavax is evaluating SD-101 in several clinical studies to assess its safety and activity, including a Phase 2 study in combination with KEYTRUDA® (pembrolizumab) in advanced melanoma and metastatic or recurrent head and neck squamous cell cancer in collaboration with Merck, and in high risk breast cancer in collaboration with I-SPY 2. Dynavax maintains all commercial rights to SD-101.

About Dynavax
Dynavax is a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers and develops novel vaccines and immuno-oncology therapeutics. The Company is currently exploring strategic alternatives for its immuno-oncology portfolio. 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 conduct of clinical trials of SD-101, including results from the Phase 2 cohort expansion of the Phase 1b/2 trial, and potential value of SD-101 across multiple tumor types. 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 we can timely provide adequate clinical supplies; initiation, enrollment and completion of clinical trials of SD-101; whether interim and final results of current and future clinical trials will support the initiation or continuation of subsequent trials by us or another party; issues arising in the regulatory process; the ability to successfully develop or pursue strategic alternatives for SD-101, including the funding of future studies, 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 (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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