Dynavax's SD-101 in Combination with KEYTRUDA® (pembrolizumab) Continues to Show a 70% Overall Response Rate in Advanced Melanoma Patients According to Data Presented Today at the ESMO 2018 Congress

October 20, 2018

- 70% overall response rate (33/47 patients) at 2 mg dose of SD-101 includes 17 additional patients -

-Progression free survival, response rate in patients with PDL-1 negative tumors and biomarker activity supports clinical impact of SD-101's activity-

- Conference call and webcast to review all Dynavax data presented at the ESMO 2018 Congress on Sunday, October 21st at 1:00 PM EDT-

BERKELEY, Calif., Oct. 20, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX) today presented interim data from its ongoing Phase 1b/2 SYNERGY-001 study investigating SD-101, Dynavax's intratumoral TLR9 agonist, in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy developed by Merck (known as MSD outside the United States and Canada) in patients with advanced melanoma naïve to anti-PD-1/L1 therapy. These data were presented in a late breaking poster and discussion session today at the ESMO 2018 Congress, in Munich, Germany.

The company reported results on a total of 87 patients (Intention to Treat population) comparing two different doses of SD-101. In the study, 47 patients received ≤2mg of SD-101 in 1-4 lesions and 40 patients received 8 mg in a single lesion. The primary endpoints of this dose-expansion/dose-finding study are safety and preliminary efficacy. The results showed a 70% overall response rate (ORR) in advanced melanoma patients naïve to anti-PD-1/L1 therapy who received the ≤ 2 mg dose of SD-101 and a 48% ORR in the group receiving the 8 mg dose of SD-101. The combination of SD-101 and KEYTRUDA remains well tolerated with adverse events related to SD-101 being transient, mild to moderate flu-like symptoms.

"These results are encouraging because the overall response rate in the 2 mg group has remained consistent with the data presented at the 2018 American Society for Clinical Oncology annual meeting, even though the number of patients increased by more than 50 percent. In addition, median progression-free survival has not yet been reached, but statistically is expected to be at least 15.2 months, providing further validation of the potential benefit of the combination therapy," said Rob Janssen, M.D., Chief Medical Officer. "These data underscore the value of stimulating the innate immune response through TLR9 and build on clinical evidence around the proposed mechanism of action for SD-101."

Highlights from the poster presentation (LBA45)

- ORR of 70% (33 of 47), for advanced melanoma patients who received the ≤ 2 mg dose of SD-101 per lesion
- Durable response in patients who received ≤ 2 mg dose of SD-101 with 85% 6-month progression-free survival (PFS) rate
- Median PFS not reached in patients who received ≤ 2 mg dose of SD-101 with a lower bound of the 95% confidence interval suggesting a minimum ongoing PFS of 15.2 months
- Observed responses in injected lesion(s) and non-injected distant lesions, including visceral metastases in the liver and lung
- Response rates appeared similar regardless of PD-L-1 status
- AEs related to SD-101 treatment were transient, mild to moderate flu-like symptoms at both the ≤ 2mg and the 8 mg dosing levels
- No increase in the frequency of immune-related adverse events over individual monotherapies reported in other studies[1,2] nor evidence of any new safety signals

Dynavax Conference Call and Webcast
Dynavax will host a conference call and webcast on Sunday at 1:00pm EDT (7:00 PM CEST). The live webcast can be accessed in the "Investors and Media" section of the company's website at www.dynavax.com. The conference call can be accessed by dialing (866) 420-4066 in the U.S. or (409) 217-8237 internationally, using the conference ID 2036717. A replay of the webcast will be available following the live event.

About SYNERGY-001 (KEYNOTE-184)
SYNERGY-001, previously referred to as MEL-01, is the dose-escalation and expansion study of SD-101 in combination with KEYTRUDA which includes patients with histologically or cytologically confirmed unresectable Stage IIIC/IV melanoma. The primary endpoints of the trial are safety and preliminary efficacy of intratumoral SD-101 in combination with KEYTRUDA.

About SD-101
SD-101, the Company's lead clinical candidate, is a proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. Dynavax is evaluating this intratumoral TLR9 agonist in several clinical studies to assess its safety and activity, including a Phase 2 study in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy, in patients with advanced melanoma and in patients with head and neck squamous cell cancer, in a clinical collaboration with Merck. 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's first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], was approved by the United States Food and Drug

Administration in November 2017 for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax's lead immunotherapy product, SD-101, is an investigational cancer immunotherapeutic currently being evaluated in Phase 1/2 studies and its second cancer immunotherapeutic, DV281, is in Phase 1 development. For more information, visit www.dynavax.com.

Forward Looking Statement
This press release contains "forward-looking" statements, including statements regarding the conduct of clinical trials of SD-101, including results from 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; issues arising in the regulatory process; the ability to successfully develop and commercialize SD-101; and 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, 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, 2017 and in Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, 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.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
1. Ribas A, et al. JAMA. 2016;315(15):1600-1609.
2. Specenier P. Expert Opin Biol Ther. 2017;17(6):765-780.

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