



Dynavax Reports Interim Data for SD-101 in Combination with KEYTRUDA® (pembrolizumab) in Patients with Advanced Squamous Cell Carcinoma of the Head and Neck

April 16, 2018

BERKELEY, Calif., April 16, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX) today announced data from its ongoing Phase 1b/2 study investigating SD-101, Dynavax's intratumoral TLR9 agonist, in combination with KEYTRUDA®, an anti-PD-1 therapy developed by Merck (known as MSD outside the United States and Canada). These data were presented in a poster session at the 2018 American Association for Cancer Research (AACR) Annual Meeting. The results from this dose escalation study showed encouraging response rates in patients with advanced head and neck squamous cell carcinoma. In addition, the combination was well tolerated. The full poster presentation can be accessed at <http://investors.dynavax.com/events-presentations>.

"Results from our Phase 1b/2 trial of SD-101 in combination with KEYTRUDA are promising in head and neck cancer, a condition for which patients typically have a poor prognosis," said Eddie Gray, Chief Executive Officer of Dynavax. "This is another tumor type in which SD-101, based on early data, has demonstrated encouraging activity while being well tolerated. As understanding of combination therapy matures we believe an effective immune stimulating agonist with an attractive tolerability profile will play a significant role in a wide range of tumors."

"On Tuesday, April 17, 2018 we are also presenting updated data from our Phase1b/2 study at AACR from a cohort of melanoma patients, where a durable response was observed in patients naïve to anti-PD-1/L1 therapy as well as patients with prior treatment. We are excited about the overall results to date and believe this underscores the potential breadth of our immuno-oncology platform," Mr. Gray added.

Highlights from Poster Presentation of HNSCC Data

- Interim data from evaluable patients showed an ORR of 33% (6 out of 18) (38% among patients who received at least one scan on study)
- Well tolerated with no dose limiting toxicities
- No increase in frequency or severity of the treatment-related adverse events that have been reported in clinical studies of KEYTRUDA® as a monotherapy, nor evidence of a unique safety signal for the combination.
- Biomarker analyses showed induced broad immune activity, including increase in CD8 T cells, and Th1 response in the tumor microenvironment, consistent with findings reported in advanced melanoma

Highlights from Abstract of Advanced Melanoma Durability Data

- 86% of initial responses were ongoing after a median of 18 months of follow up in patients that were naïve to anti-PD-1/L1 monotherapy (n=7)
- 2 of 12 evaluable patients with progressive disease on prior anti-PD-1/L1 monotherapy achieved a partial or stable disease response for at least 10.5 months
- Median progression-free survival (PFS), duration of response, and median overall survival have not been reached
- Treatment was well tolerated with no Grade 3 or higher treatment-related AEs in longer term follow up

Details for the poster presentation are as follows:

Durability of responses to the combination of SD-101 and pembrolizumab in advanced metastatic melanoma: Results of a phase Ib, multicenter study

Session Title: Phase I Trials in Progress

Abstract: CT139

Poster Board Number: 22

Date/Time: Tuesday Apr 17, 2018:00 AM - 12:00 PM CDT

Location: McCormick Place South, Hall A, Poster Section 42

SD-101 in combination with KEYTRUDA generally was well tolerated. The most common treatment-emergent adverse events were injection site reactions and transient grade 1 to 2 flu-like symptoms, including fever, chills and myalgia.

About MEL-01 (KEYNOTE-184)

The dose-escalation and expansion study of SD-101 in combination with KEYTRUDA includes patients with histologically or cytologically confirmed unresectable Stage IIIc/IV melanoma. The primary endpoints of the trial are MTD and evaluation of the safety of intratumoral SD-101 in combination with KEYTRUDA. In addition, the trial is investigating response as assessed by the investigator according to RECIST v1.1, biomarker assessments and duration of response. Patients previously treated with anti-PD-1 and other immunotherapies are included.

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 metastatic 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], is approved in the United States. 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. 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; 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 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 current periodic reports with the 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.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

Contact:

David Burke
Director, Investor Relations & Corporate Communications
510.665.7269
dburke@dynavax.com

[Primary Logo](#)

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