



Dynavax Reports Data for Phase 1b/2 Trial of SD-101 in Combination with KEYTRUDA® (pembrolizumab) in Advanced Melanoma at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

June 4, 2018

Overall Response Rate (ORR) of 70% and 6-month Progression Free Survival (PFS) rate of 76% in Patients Naïve to Anti-PD-1 Treatment who Received the ≤ 2mg Dose of SD-101

Combination showed Similar Rates of Immune-related Adverse Events as Seen with KEYTRUDA Monotherapy

2mg SD-101 Dose Selected for Phase 3

BERKELEY, Calif., June 04, 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® (pembrolizumab), an anti-PD-1 therapy developed by Merck (known as MSD outside the United States and Canada) in patients with advanced melanoma.

The company reported results on a total of 69 patients comparing two doses of SD-101, ≤ 2mg (n=30) versus 8mg (n=39) administered by intratumoral injection. These data are being presented in poster and discussion session today at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting, in Chicago, IL. The primary endpoints of this dose-expansion/dose-finding study are safety and preliminary efficacy. The results of this study showed a 70% overall response rate (ORR) in advanced melanoma patients who received the ≤ 2 mg dose of SD-101 in up to four lesions versus a 38% ORR in the group receiving the 8 mg dose of SD-101 in one lesion. The combination of SD-101 and KEYTRUDA was well tolerated with adverse events related to SD-101 being transient, mild to moderate flu-like symptoms.

"These data provide further evidence of the potential for SD-101 to improve responses in first-line advanced melanoma patients in combination with an anti-PD-1 therapy," commented Eddie Gray, Chief Executive Officer. "Our studies continue to demonstrate the potential value of SD-101 across multiple tumor types. We plan to build upon this momentum and update our progress with additional data planned for a medical conference later in the year."

Highlights from Poster Presentation (Abstract #9513)

- Overall response rate (ORR) of 70% (21 of 30), with a complete response (CR) rate of 17%, for advanced melanoma patients who received the ≤ 2 mg dose of SD-101 in up to four lesions
- ORR of 38% (15 of 39) in patients who received the 8 mg dose of SD-101 in one lesion
- Durable response in patients who received ≤ 2 mg dose of SD-101 with 74% 6-month progression free survival (PFS) rate
- Observed responses in injected lesion(s) and distant lesions, including visceral metastases in the liver
- Responders included 8 of 10 PD-L1 negative patients in the ≤ 2 mg dose cohort
- 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

Additional details on response rates based on patient characteristics including stage of disease, ECOG score, and PD-L1 status are also included in the poster presentation which can be accessed [here](#).

"We are moving forward with the 2mg dose of SD-101 for our Phase 3 trial which we believe is the optimal dose based on these efficacy, safety and biomarker data showing increased immune activation consistent with the biology of TLR9 activation. We continue to collect and analyze data from this trial to finalize details of the Phase 3 study design," stated Rob Janssen, Chief Medical Officer.

The details of the poster presentation and discussion session are as follows:

Phase 1b/2, open label, multicenter, study of the combination of SD-101 and pembrolizumab in patients with advanced melanoma who are naïve to anti-PD-1 therapy

Session Title: Melanoma/Skin Cancers

Abstract: 9513

Poster Board: 340

Poster Session Date/Time: Monday, June 4, 2018, 1:15 PM - 4:45 PM CDT

Poster Session Location: McCormick Place South, Hall A, Advanced Disease Poster Section

Discussion Session Date/Time: Monday, June 4, 2018, 4:45 PM - 6:00 PM CDT

Discussion Session Location: McCormick Place Lakeside Center, Level 4 - E451

Analyst/Investor Presentation

Today at 6:30pm CDT, Dynavax will host a presentation for analysts and investors. The presentation will be available via live webcast only and can be

accessed in the "Investors and Media" section of the company's website at www.dynavax.com.

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, planned optimal dosage for the Phase 3 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; 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 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 March 31, 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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