

DYNAVAX TECHNOLOGIES CORP

FORM 8-K (Current report filing)

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 6, 2017**

Dynavax Technologies Corporation

(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

Delaware
(State or other jurisdiction
of incorporation)

33-0728374
(IRS Employer
Identification No.)

2929 Seventh Street, Suite 100
Berkeley, CA 94710-2753
(Address of principal executive offices, including zip code)

(510) 848-5100
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events

On March 6, 2017, Dynavax Technologies Corporation issued a press release titled “Dynavax Presents Promising Clinical Data from Lead Immuno-Oncology Candidate, SD-101, at the International Congress on Targeted Anticancer Therapies.” A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits. The following exhibit is filed herewith:

99.1 Press Release, dated March 6, 2017, titled “Dynavax Presents Promising Clinical Data from Lead Immuno-Oncology Candidate, SD-101, at the International Congress on Targeted Anticancer Therapies”

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dynavax Technologies Corporation

Date: March 6, 2017

By: /s/ MICHAEL OSTRACH

Michael Ostrach

Senior Vice President

EXHIBIT INDEX

Exhibit No.	Description
EX-99.1	Press Release, dated March 6, 2017, titled “Dynavax Presents Promising Clinical Data from Lead Immuno-Oncology Candidate, SD-101, at the International Congress on Targeted Anticancer Therapies”



Dynavax Presents Promising Clinical Data from Lead Immuno-Oncology Candidate, SD-101, at the International Congress on Targeted Anticancer Therapies

BERKELEY, CA – 3/6/17 -- Dynavax Technologies Corporation (NASDAQ: DVAX) announced the presentation of findings in patients with metastatic melanoma in the dose escalation phase of an 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. Results evaluating 17 patients for efficacy and 22 patients for safety were reported. In patients naïve to anti-PD-1 treatment, responses were observed in six out of seven patients, for an Overall Response Rate (ORR) of 86%. This includes two (29%) complete responses (CR) and four (57%) partial responses (PR). Target tumor shrinkage was observed in all 7 evaluable patients. In 10 patients with progressive disease who initiated KEYTRUDA anti-PD-1 monotherapy prior to enrollment, one PR was observed and five patients had stable disease (SD) while receiving KEYTRUDA and SD-101, with four of the 10 patients experiencing target tumor shrinkage. These data are being presented by Robert Janssen, M.D., chief medical officer for Dynavax, in an oral presentation at the International Congress on Targeted Anticancer Therapies which begins today in Paris, France.

“We are pleased with the response in the anti-PD-1 naïve group with 2 complete responses and tumor shrinkage in all 7 evaluable patients,” said Dr. Janssen. “In addition, we are encouraged to have seen a partial response at the highest dose in the anti-PD-1 refractory group with little toxicity. This allows us to explore higher doses of SD-101 in anti-PD-1 refractory patients in the expansion phase to further develop the best path forward for this hard to treat population.”

SD-101 in combination with KEYTRUDA generally was well-tolerated. No dose-limiting toxicities of the combination were observed in any dose cohort, and a maximum tolerated dose (MTD) was not identified. 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 that respond to over the counter medications such as acetaminophen. The study also includes biomarker assessments, suggesting that treatment with SD-101 and KEYTRUDA resulted in elevation of gene signatures consistent with an increase in Th1 immune cell types as well as an increase in immune cell infiltrates such as CD8+ T-cells in the tumor microenvironment.

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 is Dynavax's proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. SD-101 is being studied for its multiple anti-tumor activities in innate immune cells and activation of plasmacytoid dendritic cells to stimulate T cells specific for antigens released from dying tumor cells. TLR9 agonists such as SD-101 enhance T and B cell responses and provide potent Type 1 interferon induction and maturation of plasmacytoid dendritic cells to antigen-presenting cells. SD-101 is being evaluated in several Phase 1/2 oncology studies to assess its safety and activity.

For information about SD-101 trials that are currently recruiting patients, please visit www.clinicaltrials.gov.

About Dynavax

Dynavax is a clinical-stage immunology company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax is developing product candidates for use in multiple cancer indications, as a vaccine for the prevention of hepatitis B and as a disease modifying therapy for asthma. Dynavax's lead product candidates are SD-101, an investigational cancer immunotherapeutic currently in Phase 1/2 studies, and HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine. For more information, visit www.dynavax.com.

Forward-Looking Statements

This press release contains "forward-looking" statements, including expectations for the conduct and timing 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.

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