

# DYNAVAX TECHNOLOGIES CORP

## **FORM 8-K** (Current report filing)

Filed 06/05/17 for the Period Ending 06/02/17

Address	2929 SEVENTH STREET SUITE 100 BERKELEY, CA 94710
Telephone	5108485100
CIK	0001029142
Symbol	DVAX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

---

---

**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): **June 2, 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))

Indicate by check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

---

---

**Item 8.01. Other Events**

On June 2, 2017, Dynavax Technologies Corporation issued a press release titled “Dynavax Presents Updated Data for SD-101 in Combination with KEYTRUDA® (pembrolizumab) Highlighting an ORR in 7 out of 7 Patients Naïve to an Anti-PD-1 or Anti-PD-L1 Therapy.” 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 June 2, 2017, titled “Dynavax Presents Updated Data for SD-101 in Combination with KEYTRUDA® (pembrolizumab) Highlighting an ORR in 7 out of 7 Patients Naïve to an Anti-PD-1 or Anti-PD-L1 Therapy”

---

**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: June 5, 2017

By: /s/ STEVEN N. GERSTEN

Steven N. Gersten

Vice President

---

## EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
EX-99.1	Press Release, dated June 2, 2017, titled “Dynavax Presents Updated Data for SD-101 in Combination with KEYTRUDA® (pembrolizumab) Highlighting an ORR in 7 out of 7 Patients Naïve to an Anti-PD-1 or Anti-PD-L1 Therapy”



**Dynavax Presents Updated Data for SD-101 in Combination with KEYTRUDA<sup>®</sup> (pembrolizumab) Highlighting an ORR in 7 out of 7 Patients Naïve to an Anti-PD-1 or Anti-PD-L1 Therapy**

*– Data Presented at 2017 American Society of Clinical Oncology (ASCO) Annual Meeting –*

BERKELEY, CA – 6/2/17 – 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<sup>®</sup> (pembrolizumab), an anti-PD-1 therapy developed by Merck, known as MSD outside the United States and Canada. Results evaluating 19 patients for efficacy and 22 patients for safety were presented in a poster at the 2017 American Society of Clinical Oncology Annual Meeting in Chicago:

- In 7 anti-PD-1/L1-naïve patients, SD-101 used in combination with KEYTRUDA resulted in an overall response rate (ORR) of 100%, with a complete response (CR) rate of 29%. This is a meaningful increase over use of KEYTRUDA alone, which has already shown a 33% ORR, with a 6% CR.<sup>1</sup>
- In 12 patients with advanced (stage IIIc/IV) melanoma who had previously failed on anti-PD-1 treatment, introduction of SD-101 resulted in tumor shrinkage in 42% of patients, with 17% having a partial response (PR), indicating an anti-tumor immune response generated by SD-101.
- The combination of SD-101 and KEYTRUDA in this study, mobilized both innate and adaptive immune response in study participants.
- Tumor shrinkage was observed in non-injected visceral lesions.

“Having 7 out of 7 patients naïve to anti-PD-1/L1 treatment responding is very encouraging,” said Antoni Ribas, M.D., Ph.D., of the Jonsson Comprehensive Cancer Center at the University of California, Los Angeles, and lead investigator. “These results are supported by tumor shrinkage in patients who had previously progressed on anti-PD-1 treatment and by confirmatory laboratory biomarker assessments in tumor biopsies. If these clinical results are sustained in the ongoing trial, this combination, which mobilizes both innate and adaptive immune responses in patients, could represent an important advancement in immuno-oncology.”

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. The study also includes biomarker assessments, suggesting that treatment with SD-101 and KEYTRUDA resulted in increased tumor-infiltrating lymphocytes and decreased Th2 in tumor biopsies, consistent with induction of an antitumor immune response.

<sup>1</sup> [Keytruda.com https://www.keytruda.com/hcp/melanoma/efficacy-of-keytruda/](https://www.keytruda.com/hcp/melanoma/efficacy-of-keytruda/)

**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](http://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](http://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](http://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:**

Ryan Spencer  
VP, Corporate Strategy & Communications  
510.665.4618  
[rspencer@dynavax.com](mailto:rspencer@dynavax.com)