# 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): November 9, 2016

# **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))

#### Item 8.01. Other Events

On November 9, 2016, Dynavax Technologies Corporation ("Dynavax" or the "Company") issued a press release titled "Dynavax Presents Early Clinical Data from Lead Cancer Immunotherapy Candidate, SD-101, at Society for Melanoma Research." A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Also on November 9, 2016, Dynavax's collaborator AstraZeneca, informed the Company that it had initiated dosing in a Phase 2a safety and efficacy trial of AZD1419 in asthma patients. The \$7.2 million milestone due to Dynavax under the collaboration and license agreement between the two companies will be applied against the approximately \$7.4 million remaining from advance payments previously received by the Company for its collaboration research and development expenses under the agreement.

#### Item 9.01. Financial Statements and Exhibits

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

99.1 Press Release, dated November 9, 2016, titled "Dynavax Presents Early Clinical Data from Lead Cancer Immunotherapy Candidate, SD-101, at Society for Melanoma Research"

# 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

By: /s/ STEVEN N. GERSTEN

By: <u>/s/ STEVEN N. GE</u> Steven N. Gersten Vice President

Date: November 9, 2016

Exhibit No.	Description
EX-99.1	Press Release, dated November 9, 2016, titled "Dynavax Presents Early Clinical Data from Lead Cancer Immunotherapy Candidate, SD-101, at Society for Melanoma Research"



# Dynavax Presents Early Clinical Data from Lead Cancer Immunotherapy Candidate, SD-101, at Society for Melanoma Research

SD-101 in Combination with Merck's Anti-PD-1 Therapy, KEYTRUDA® (pembrolizumab) Shows Encouraging Preliminary Clinical Activity in Advanced Melanoma

BERKELEY, CA. — November 9, 2016-- Dynavax Technologies Corporation (Nasdaq: DVAX) announced the presentation of findings from an ongoing Phase 1b/2 study investigating SD-101, Dynavax's intratumoral TLR9 agonist, in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy. Early results investigating 13 patients with metastatic melanoma for efficacy and 19 patients for safety were reported. In patients naïve to anti-PD-1 treatment, objective responses were observed in four out of five (80%) patients, including one complete response (CR) and three partial responses (PR's). Four patients with progressive disease, while receiving anti-PD-1 monotherapy prior to enrollment, were observed to have stable disease (SD) while receiving KEYTRUDA and SD-101. These data were presented by Dr. Antoni Ribas in the late-breaking clinical update session on Wednesday, November 9, at the Society for Melanoma Research (SMR) 13<sup>th</sup> International Congress in Boston, MA, USA.

SD-101 in combination with KEYTRUDA 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. No immune-related adverse events were reported, and the most common treatment-emergent adverse events were grade 1 to 2 flu-like symptoms, including fever, chills and myalgia consistent with the engagement of TLR9 and production of interferon alpha. The study also included 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.

"We are encouraged with the early stage data we are observing from our immuno-oncology program and will continue to advance SD-101 in melanoma and other indications," stated Eddie Gray, chief executive officer of Dynavax.

# About MEL-01 (KEYNOTE-184)

The ongoing 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, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious and inflammatory diseases and oncology. Dynavax's lead product candidates are HEPLISAV-B<sup>™</sup>, a Phase 3 investigational adult hepatitis B vaccine and SD-101, an investigational cancer immunotherapeutic currently in several Phase 1/2 studies. For more information, visit <u>www.dynavax.com</u>.

# **Dynavax 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, initiate one or more studies, enroll a sufficient number of subjects and ultimately complete any study, 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 <u>www.dynavax.com</u> is not incorporated by reference in our current periodic reports with the SEC. Contact: Michael Ostrach Chief Financial Officer 510-665-7257 mostrach@dynavax.com

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