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): October 20, 2018

Dynavax Technologies Corporation
(Exact name of registrant as specified in its charter)

Commission File Number: 001-34207

Delaware	**33-0728374**
(State or other jurisdiction of incorporation)	**(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 October 20, 2018, Dynavax Technologies Corporation ("Dynavax"), issued a press release and presented a corresponding poster announcing data from its ongoing Phase 1b/2 SYNERGY-001 study investigating SD-101, Dynavax's intratumoral TLR9 agonist, in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy developed by Merck & Co., Inc. (known as MSD outside the United States and Canada) in patients with advanced melanoma naïve to anti-PD-1/L1 therapy, at the 2018 European Society for Medical Oncology Congress, in Munich, Germany ("ESMO"). Dynavax presented two additional posters at ESMO, one was presented October 20, 2018, and the other October 21, 2018. On October 21, 2018, Dynavax held a conference call and webcast to review all data the company presented at ESMO. A copy of the press release, posters and the conference call presentation are filed as Exhibits 99.1, 99.2 and 99.3 to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press release, dated October 20, 2018
99.2	Posters presented at the 2018 European Society for Medical Oncology Congress on October 20-21, 2018
99.3	Conference Call and Webcast Presentation of October 21, 2018

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: October 22, 2018

By: /s/ DAVID JOHNSON
David Johnson
Vice President

Dynavax's SD-101 in Combination with KEYTRUDA® (pembrolizumab) Continues to Show a 70% Overall Response Rate in Advanced Melanoma Patients According to Data Presented Today at the ESMO 2018 Congress

- 70% overall response rate (33/47 patients) at 2 mg dose of SD-101 includes 17 additional patients -

-Progression free survival, response rate in patients with PDL-1 negative tumors and biomarker activity supports clinical impact of SD-101's activity-

- Conference call and webcast to review all Dynavax data presented at the ESMO 2018 Congress on Sunday October 21st at 1:00 PM EDT

BERKELEY, Calif., October 20, 2018 (GLOBE NEWSWIRE) — Dynavax Technologies Corporation (NASDAQ:DVAX) today presented interim data from its ongoing Phase 1b/2 SYNERGY-001 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 naïve to anti-PD-1/L1 therapy. These data were presented in a late breaking poster and discussion session today at the ESMO 2018 Congress, in Munich Germany.

The company reported results on a total of 87 patients (Intention to Treat population) comparing two different doses of SD-101. In the study, 47 patients received £2mg of SD-101 in 1-4 lesions and 40 patients received 8 mg in a single lesion. The primary endpoints of this dose-expansion/dose-finding study are safety and preliminary efficacy. The results showed a 70% overall response rate (ORR) in advanced melanoma patients naïve to anti-PD-1/L1 therapy who received the £ 2 mg dose of SD-101 and a 48% ORR in the group receiving the 8 mg dose of SD-101. The combination of SD-101 and KEYTRUDA remains well tolerated with adverse events related to SD-101 being transient, mild to moderate flu-like symptoms.

"These results are encouraging because the overall response rate in the 2 mg group has remained consistent with the data presented at the 2018 American Society for Clinical Oncology annual meeting, even though the number of patients increased by more than 50 percent. In addition, median progression-free survival has not yet been reached, but statistically is expected to be at least 15.2 months, providing further validation of the potential benefit of the combination therapy," said Rob Janssen, M.D., Chief Medical Officer. "These data underscore the value of stimulating the innate immune response through TLR9 and build on clinical evidence around the proposed mechanism of action for SD-101."

Highlights from the poster presentation (LBA45)

- ORR of 70% (33 of 47), for advanced melanoma patients who received the £ 2 mg dose of SD-101 per lesion
- Durable response in patients who received £ 2 mg dose of SD-101 with 85% 6-month progression-free survival (PFS) rate
- Median PFS not reached in patients who received £ 2 mg dose of SD-101 with a lower bound of the 95% confidence interval suggesting a minimum ongoing PFS of 15.2 months

- Observed responses in injected lesion(s) and non-injected distant lesions, including visceral metastases in the liver and lung
- Response rates appeared similar regardless of PD-L-1 status
- 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

Dynavax Conference Call and Webcast

Dynavax will host a conference call and webcast on Sunday at 1:00pm EDT (7:00 PM CEST). The live webcast can be accessed in the "Investors and Media" section of the company's website at www.dynavax.com. The conference call can be accessed by dialing (866) 420-4066 in the U.S. or (409) 217-8237 internationally, using the conference ID 2036717. A replay of the webcast will be available following the live event.

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, 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; whether interim and final results of current and future clinical trials will support the initiation or continuation of subsequent trials; 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 June 30, 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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LBA45: Phase 1b/2, Open Label, Multicenter, Study of t
Advanced Melanoma Who Are Naïve to Anti-PD-1/L1 Th

G. Long[1], M. Milhem[2], A. Amin[3], C. J. Hoimes[4], T. Medina[5], R. Conry[6], C. Lao[7], G. Daniel
A. Candia[16], E. Gamelin[16], R. Janssen[16], A. Ribas[17]

[1]Melanoma Institute Australia, The University of Sydney and Royal North Shore and Mater Hospitals, Sydney, Australia; [2]University of Iowa, Iowa City, U
Birmingham, USA; [7]University of Michigan Health System, Ann Arbor, USA; [8]University of California, San Diego, USA; [9]Stanford University, Stanford, U
Cancer Center North, Tucson, USA; [14]University Hospital Magdeburg, Magdeburg, Germany; [15]Merck & Co., Inc., Kenilworth, NJ, USA; [16]Dynavax Tech

BACKGROUND

- PD-1 blockade has significantly improved outcomes in advanced melanoma, yet durable responses are elicited in less than half of the patients, therefore this remains an area of unmet need.[1]
- KEYTRUDA® (pembrolizumab) is an anti-PD-1 monoclonal antibody (mAb) that is approved by the FDA to treat patients with unresectable or metastatic melanoma.[1]
- SD-101 is a synthetic class-C CpG-oligodeoxynucleotide, agonist of toll-like receptor 9 (TLR9). SD-101 stimulates human plasmacytoid dendritic cells to release interferon-alpha and mature into efficient antigen-presenting cells, enhancing both innate and adaptive immune responses.[2]
- Preclinical studies in multiple mouse tumor models demonstrated that intratumoral injection of SD-101, in combination with PD-1 blockade, suppressed the growth of tumors not only at the injected site, but also at distant non-injected sites.[3]
- In a previous phase 1b/2 study of patients with indolent non-Hodgkin's lymphoma, treatment of a single lesion with low dose radiation and intratumoral SD-101 induced abscopal tumor shrinkage in 83% of patients.[4]
- Here, we report the latest results from the phase 1b dose escalation and phase 2 expansion cohort of patients with advanced melanoma naïve to anti-PD-1/L1 therapy who were treated with the combination of SD-101 and pembrolizumab. (Updates data presented at ASCO 2018 (Abstract 9513)[5]. Results of the phase 1b portion of this study were published in Ribas, A., et al., Cancer Discovery (2018).[6]

METHODS

Phase 1b/2 Trial (SYNERGY-001/KEYNOTE-184)

Phase 1b
Dose Escalation*

- SD-101 **2 mg** i.t. + Pembrolizumab 200 mg i.v.
- SD-101 **4 mg** i.t. + Pembrolizumab 200 mg i.v.
- SD-101 **8 mg** i.t. + Pembrolizumab 200 mg i.v.
- SD-101 **1 mg** i.t.† + Pembrolizumab 200 mg i.v.

Phase 2
Dose Expansion

SD-101 **2 mg i.t. in up to 4 lesions**
+
Pembrolizumab **200 mg** i.v.

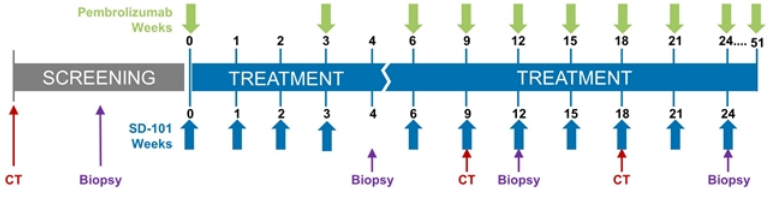
OR

SD-101 **8 mg i.t. in one lesion**
+
Pembrolizumab **200 mg** i.v.

*DLT period 29 days; †3 patients received 1 mg/lesion; i.t.= intratumoral; i.v. = intravenous. Data Cutoff: September 21, 2018

- **Patients:**
  - Unresectable Stage IIIC, Stage IV Metastatic Melanoma
  - ECOG performance status of 0 or 1
  - No prior anti-PD-1/L1 therapy
  - At least one injectable lesion

Figure 1. Study Design



CT, computed tomography scan

- **Primary Endpoint:** Objective response rate assessed by RECIST v1.1
- **Secondary Endpoints:** Safety and tolerability, progression-free survival, duration of response, and immunophenotype of the tumor environment

RESULTS

Table 1. Demographics and Baseline Characteristics (Phas

Characteristics	2 mg/lesion n = 47
Median age, years (Min, Max)	66 (36, 85)
> 65 years, n (%)	30 (64)
Male, n (%)	33 (70)
ECOG PS 0, n (%)	30 (64)
Baseline LDH, median (Q1, Q3)	193 (162, 234)
> ULN, n (%)	8 (17)
Stage at Screening, n (%)	
IIIC	10 (21)
IV	37 (79)
M1a	16 (34)
M1b	9 (19)
M1c	12 (26)
PD-L1 Expression, n (%)*	
Positive (≥1%)	19 (40)
Negative (<1%)	15 (32)
Pending	13 (28)
Prior lines of therapy, 0 / 1 / 2 / ≥3. n (%)	34 / 11 / 2 / 0 (72 / 23 / 4 / 0)

ECOG PS = Eastern Cooperative Oncology Group performance status; LDH = lactate dehydrogenase; Q1 = quartile; ULN = upper limit of normal; * Expression determined by tumor proportion score using Dako 22C3 a

Safety

Table 2. Safety Summary

Event, N (%)	2 mg/lesion n = 47	8 mg/lesion n = 40
Any Treatment-related AE	43 (91)	37 (93)
Grade 3-4	12 (26)	16 (40)
Chills	4 (9)	1 (3)
Myalgia	5 (11)	0
Fatigue	2 (4)	3 (8)
Headache	4 (9)	2 (5)
Malaise	3 (6)	2 (5)
Any irAEs	10 (21)	6 (15)
Grade 3-4	3 (6)	1 (3)
AEs leading to d/c of either or both drug	7 (15)	13 (33)
SAEs	14 (30)	15 (38)
Death	0	1 (3)

irAE = immune-related adverse event; d/c = discontinuation; SAE = serious adverse event.
Note: death was considered not related to drug

Table 3. Immune-Related Adverse Events

Event	2 mg/lesion n = 47	8 mg/lesion n = 40
irAEs all grades, n (%)		
Hypothyroidism	7 (15)	3 (8)
Pneumonitis	2 (4)	1 (3)
Myositis	1 (2)	1 (3)
Autoimmune retinopathy	0	1 (3)
Autoimmune hepatitis	0	1 (3)
Myasthenia gravis	0	1 (3)
Colitis	1 (2)	0
Autoimmune colitis	1 (2)	0
Hypophysitis	2 (4)	0
Hyperthyroidism	1 (2)	0
Autoimmune myocarditis	0	1 (3)
Optic neuritis	0	1 (3)

Abstract 3781: Phase 1b/2, Open-Label, Multicenter Stud
With Advanced Melanoma Resistant/Refractory to Anti-P

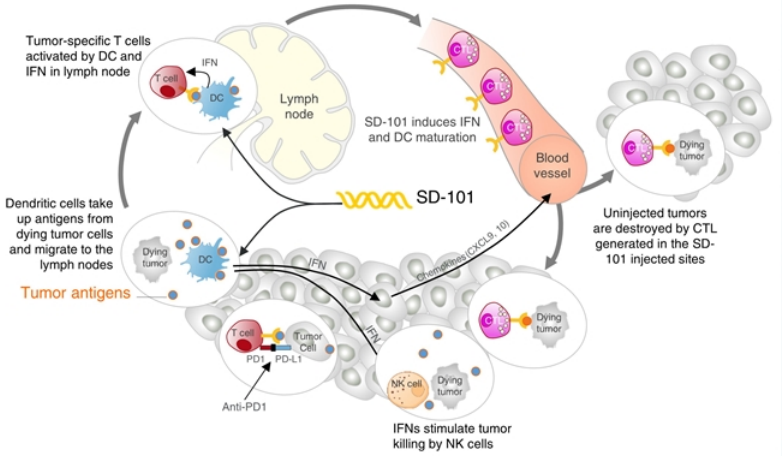
A. Ribas[1], I. Mehmi[2], T. Medina[3], C. Lao[4], S. Kummar[5], A. Amin[6], S. Deva[7], A. K. Salama[8]
S. Chandra[17], E. V. Schmidt[18], R. Janssen[19], G. V. Long[20]

[1]Jonsson Comprehensive Cancer Center, UCLA, Los Angeles, USA; [2]Mary Babb Randolph Cancer Center, West Virginia University, Morgantown, USA
USA; [7]Auckland City Hospital, Auckland, NZ; [8]Duke University, Durham, USA; [9]University Hospital Madgeburg, Madgeburg, DE; [10]University of Iowa, Io
Center, Inova Char Cancer Institute, Fairfax, USA; [15]Mary Crowley Cancer Research, Dallas, USA; [16]Affinity Research, Nedlands, AU; [17]Northwestern U

BACKGROUND

- PD-1 blockade has significantly improved outcomes in advanced melanoma, yet durable responses are elicited in less than half of the patients, therefore this remains an area of unmet need.[1]
- KEYTRUDA® (pembrolizumab) is an anti-PD-1 monoclonal antibody (mAb) that is approved by the FDA to treat patients with unresectable or metastatic melanoma.[1]
- SD-101 is a synthetic class-C, CpG-oligodeoxynucleotide, toll-like receptor nine (TLR9) agonist, which stimulates human plasmacytoid dendritic cells (PDCs) to release interferon-alpha and mature into efficient antigen-presenting cells, enhancing both innate and adaptive immune responses (Figure 1).[2]
- Preclinical studies of anti-PD-1 non-responder mouse tumor models demonstrated that intratumoral injection of SD-101, in combination with PD-1 blockade, suppressed the growth of tumors not only at the injected site, but also at distant un-injected sites.[3]
- In the phase 1b portion of this study, intratumoral injections of SD-101 in combination with pembrolizumab demonstrated clinical responses in both injected and distant lesions of patients with metastatic melanoma.[4]
- Here, we report the results from a phase 2 expansion cohort of patients with advanced melanoma resistant/refractory (R/R) to anti-PD-1/PD-L1 therapy who were treated with the combination of SD-101 and pembrolizumab. Preliminary results from the phase 1b portion of this study were presented at AACR 2018 (Abstract: CT139) and published in Cancer Discovery (2018): Ribas, A., et al.[5,6]

Figure 1. Both Innate and Adaptive Immune Responses Are Increased by Intratumoral Injection of SD-101



CTL = cytotoxic (CD8+) T cell; DC = dendritic cells; IFN = interferon; NK = natural killer

- SD-101 induces PDCs to secrete high levels of interferon-alpha, a potent immunomodulatory cytokine that is able to boost NK cell cytotoxic activity and induce recruitment of T cells. In addition, SD-101 induces DC maturation cross-presentation of tumor associated antigens, inducing CD8+ T cell responses.

STUDY OBJECTIVE

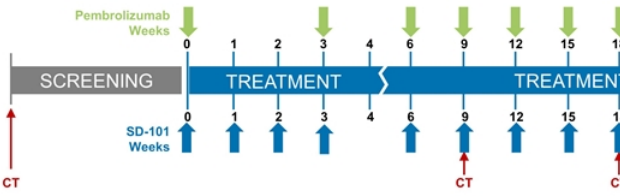
- To confirm the safety profile and assess the efficacy of SD-101 and pembrolizumab combination therapy in patients with advanced melanoma who were R/R to anti-PD-1 therapy.

METHODS

**Ongoing Phase 1b/2, Open-label, Multicenter, Expansion Study of Intr
in Combination With Pembrolizumab (SYNERGY-001, MEL-01, NCT02**

- **Patients:**
  - Stage IIIC, Stage IV Metastatic Melanoma
  - Resistant or refractory to prior anti-PD-1/PD-L1 therapy
  - ECOG performance status of 0 or 1
  - At least 2 lesions that qualify as a target lesion per RECIST v1. qualifying lesions must be easily accessible and amenable to m intratumoral injections. The target lesion should be of sufficient required tumor biopsies do not significantly affect tumor assess v1.1.
- **Study Treatment:**
  - SD-101 was administered intratumorally in one target lesion, 8 doses then Q3W x 7 doses*
  - Pembrolizumab was administered IV (200 mg Q3W)

Figure 2. Study Design



CT, computed tomography scan

- Primary Endpoint: Overall response rate assessed by RECIST v1.1
- Secondary Endpoints: Safety and tolerability, duration of response, an immunophenotype of the tumor environment

*Out of 38 patients, 4 patients treated with 4 mg per injection and 4 patients treated with up to 2 mg per injectio excluded; 30 patients have been treated with 8 mg per injection.

RESULTS

Table 1. Demographics and Baseline Characteristic

Characteristics	
Median age, years (Min, Max)	6
Male, n (%)	
ECOG PS 0/1, n (%)	
Baseline LDH, mean (SD)	223
≤ULN, n (%)	
>1 to ≤2 ULN, n (%)	
>2 ULN, n (%)	
Stage at Screening, n (%)	
IIIC	
IV	
Missing	
Metastases involving:	
Skin/Subcutaneous tissue	
Lymph Nodes	
Liver	
Lung	
Bones	
Other	
PD-L1 expression, n (%)*	
Positive (≥1%)	
Negative (<1%)	
Pending	

ECOG PS = Eastern Cooperative Oncology Group performance status; LDH = lactate dehydrogenase; SD

ULN = upper limit of normal; * Expression determined using Dako 22C3 antibody

Abstract 3560: Phase 1b/2, Open-Label, Multicenter Study of I Naïve Patients With Recurrent or Metastatic Head and Neck S

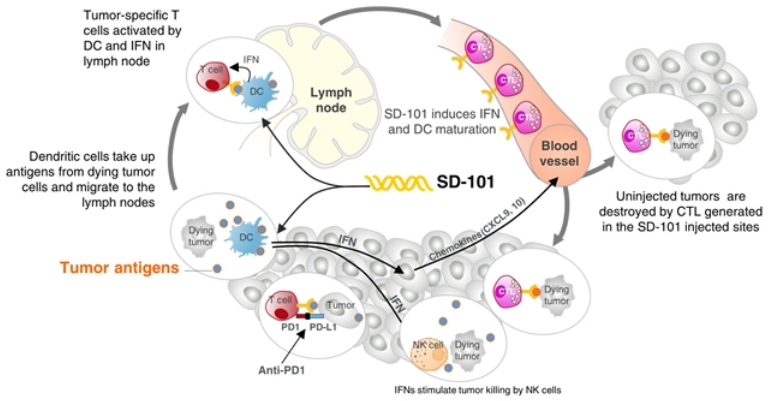
Ezra Cohen,[1] Alain Algazi,[2] Douglas Laux,[3] Deborah Wong,[4] Asim Amin,[5] L

[1]Moores Cancer Center, University of California San Diego, La Jolla, CA USA; [2]University of California Sa
[5]Levine Cancer Institute, Charlotte, NC USA; [6]University of Alabama at Birmingham, Birmingham, AL USA

BACKGROUND

- Historically, patients with recurrent unresectable or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) have had a poor prognosis, with limited second-line treatment options (including methotrexate, cetuximab, and paclitaxel) providing an estimated overall response rate (ORR) of 4-14%, a median duration of response (DOR) of 4-7 months, an estimated median progression-free survival (mPFS) of 1.7-3.5 months, and an estimated median overall survival (OS) of less than 7 months.[1]
- KEYTRUDA® (pembrolizumab) is a anti-PD-1 monoclonal antibody (mAb) that received accelerated approval by the FDA to treat patients with R/M HNSCC with disease progression on or after platinum-containing chemotherapy based on results of the KEYNOTE-012 study showing that pembrolizumab monotherapy provided an ORR of 18% with 85% of those responses lasting ≥6 months.[2,3]
- SD-101 is a synthetic Class-C CpG-oligodeoxynucleotide toll-like receptor nine (TLR9) agonist, which stimulates human plasmacytoid dendritic cells (PDCs) to release interferon-alpha and mature into efficient antigen-presenting cells, enhancing both innate and adaptive immune responses (Figure 1).[4]
- Preclinical mouse models of head and neck tumors demonstrated that intratumoral injection of SD-101, in combination with PD-1 blockade, suppressed the growth of tumors not only at the injected site, but also at distant un-injected sites.[5]
- In a phase 1b/2 study of patients with metastatic melanoma, intratumoral injections of SD-101 in combination with pembrolizumab demonstrated clinical responses in both injected and distant lesions.[6]
- Here, we report the results from a phase 2 cohort expansion of patients with R/M HNSCC who were treated with the combination of SD-101 and pembrolizumab.

Figure 1. Both Innate and Adaptive Immune Responses Are Increased by Intratumoral Injection of SD-101



CTL = cytotoxic (CD8+) T cell; DC = dendritic cells; IFN = interferon; NK = natural killer

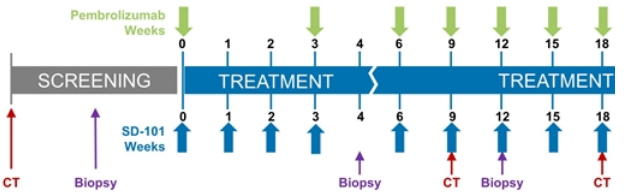
- SD-101 induces PDCs to secrete high levels of interferon-alpha, a potent immunomodulatory cytokine that is able to boost NK cell cytotoxic activity and induce recruitment of T cells. In addition, SD-101 induces DC maturation cross-presentation of tumor associated antigens, inducing CD8+ T cell responses.

METHODS

Ongoing Phase 1b/2, Open-label, Multicenter, Expansion Study of Intratumo Combination With Pembrolizumab (NCT02521870, SYNERGY-001 DV3-MEL-

- **Patients:**
  - Advanced/metastatic head and neck squamous cell carcinoma
  - Prior anti-PD-1/PD-L1 naïve
  - ECOG performance status of 0 or 1
  - At least one injectable lesion
- **Study Treatment:**
  - Two dose levels were assessed: **8 mg one lesion** and **2 mg per lesion up t**
  - Pembrolizumab was administered IV (200 mg Q3W)

Figure 2. Study Design



CT, computed tomography scan.

- **Primary Endpoint:** Overall response rate assessed by RECIST v1.1 and reported fo to-treat (mITT) population that excludes patients on study who have not yet reached
- **Secondary Endpoints:** Safety and tolerability, DOR, time to relapse, pharmacodyna immunophenotype of the tumor environment
- **Data cutoff date**: August 16, 2018

RESULTS

Table 1. Demographics and Baseline Characteristics

Characteristics	8 mg (n=23)
Median age, years (Min, Max)	65 (43, 91)
Male/female sex, %	91/9
ECOG PS 0 or 1, %	100
Primary tumor location, n (%)	
Hypopharyngeal	1 (4.3)
Nasopharyngeal	1 (4.3)
Oral	10 (43.4)
Oropharyngeal	5 (21.7)
Laryngeal	3 (13.0)
Unknown	3 (13.0)
HPV status, n (%)	
Negative	6 (26.0)
Positive	3 (13.0)
Unknown	14 (60.8)

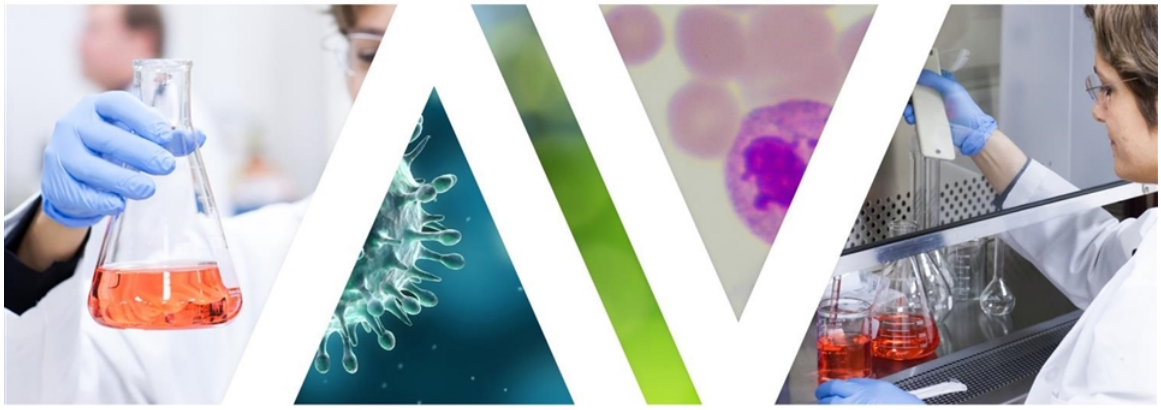
ECOG PS = Eastern Cooperative Oncology Group performance status; HPV = human papi

Table 2. Baseline Disease Characteristics: SD-101 8 mg or 2 m

Characteristics	8 mg (n=23)
Prior radiotherapy, n (%)	18 (78.3)
Prior surgery, n (%)	21 (91.3)
0/1/2/≥3 prior lines of therapy, n	4/11/5/3
Prior systemic therapy*	19 (82.6)
Organ involvement, n (%)	
Liver	1 (4.3)
Lung	6 (26.1)
Bone	2 (8.7)
Skin/subcutaneous tissue	7 (30.4)
Lymph nodes	11 (47.8)
Other organs	15 (65.2)
Number of Target Lesions:	
1	6 (26.1)
2	5 (21.7)
3	8 (34.8)
4	1 (4.3)
5	2 (8.7)

* No patients received prior PD-1/PD-L1/CTLA-4 therapy

DYNAVAX
INNOVATING IMMUNOLOGY



Intro Slide

BACKGROUND

- PD-1 blockade has significantly improved outcomes in advanced melanoma, yet durable responses are elicited in less than half of the patients. There remains an area of unmet need in patients who are anti-PD-1 naïve or experienced.
- KEYTRUDA® (pembrolizumab) is an anti-PD-1 monoclonal antibody (mAb) that is approved by the FDA to treat patients with unresectable or metastatic melanoma and recurrent or metastatic HNSCC.
- SD-101 is a synthetic class-C, CpG-oligodeoxynucleotide, toll-like receptor nine (TLR9) agonist

BACKGROUND CONT.

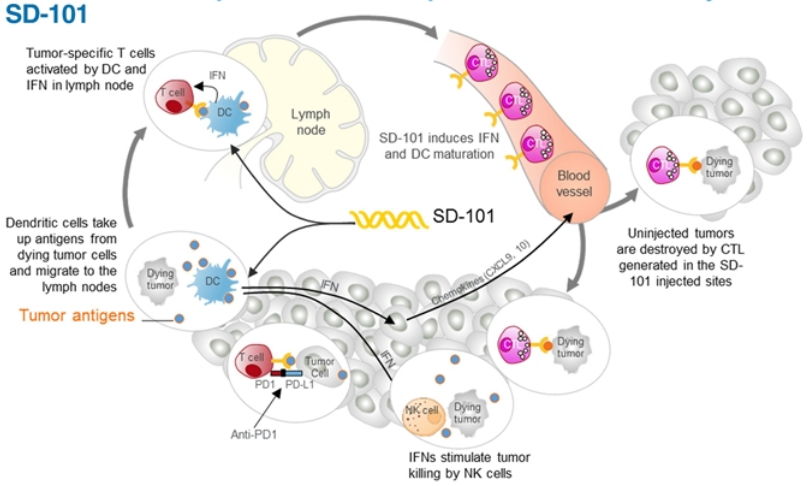
- In preclinical studies of anti-PD-1 non-responder mouse tumor models, intratumoral injection of SD-101, in combination with PD-1 blockade, suppressed the growth of tumors at the injected and distant non-injected sites. Wang S, et al., PNAS, 2016. 113(46): p. E7240-e7249
- In a previous phase 1b/2 study of patients with indolent non-Hodgkin's lymphoma, treatment of a single lesion with low dose radiation and intratumoral SD-101 induced abscopal tumor shrinkage in 83% of patients. Frank, M.J., et al. Cancer Discovery 2018. DOI: 10.1158/2159-8290
- In the phase 1b portion of SYNERGY-001/MEL-01, intratumoral injections of SD-101 in combination with pembrolizumab demonstrated clinical responses in both injected and distant lesions of patients with metastatic melanoma, both those who were naïve to anti-PD-1/L1 therapy or experienced. Ribas A, et al. Cancer Discovery 2018; DOI: 10.1158/2159-8290.CD-18-0280

BACKGROUND CONT.

- Here, we report the results presented at ESMO from the ongoing phase 2 expansion of SYNERGY-001 in patients with:
  - advanced melanoma resistant/refractory (R/R) to anti-PD-1/L1 therapy;
  - advanced melanoma naïve to anti-PD-1/L1 therapy; and
  - advanced head and neck squamous cell carcinoma naïve to anti-PD-1/L1 therapy.

BACKGROUND CONT.

Figure 1. Both Innate and Adaptive Immune Responses Are Increased by Intratumoral Injection of SD-101

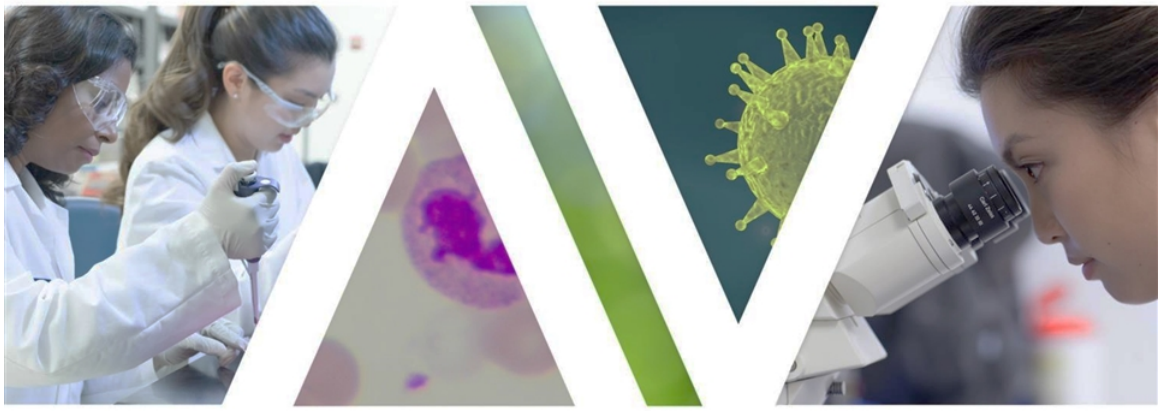


CTL = cytotoxic (CD8+) T cell; DC = dendritic cells; IFN = interferon; NK = natural killer

- SD-101 induces PDCs to secrete high levels of interferon-alpha, a potent immunomodulatory cytokine that is able to boost NK cell cytotoxic activity and induce recruitment of T cells. In addition, SD-101 induces DC maturation cross-presentation of tumor associated antigens, inducing CD8+ T cell responses.

DYNAVAX

INNOVATING IMMUNOLOGY



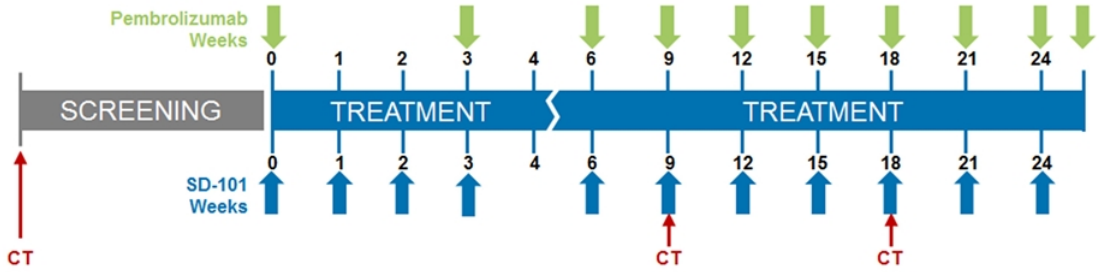
Abstract 3781: Phase 1b/2, Open-Label, Multicenter Study of Intratumoral SD-101 in Combination With Pembrolizumab in Patients With Advanced Melanoma Resistant/Refractory to Anti-PD-1/PD-L1 Therapy (SYNERGY-001/KEYNOTE-184, NCT02521870)

A. Ribas[1], I. Mehmi[2], T. Medina[3], C. Lao[4], S. Kummar[5], A. Amin[6], S. Deva[7], A. K. Salama[8], T. Tueting[9], M. Milhem[10], C. J. Hoimes[11], G. Daniels[12], M. Shaheen[13], S. Jang[14], M. Barve[15], A. Powell[16], S. Chandra[17], E. V. Schmidt[18], R. Janssen[19], G. V. Long[20]

[1]Jonsson Comprehensive Cancer Center, UCLA, Los Angeles, USA; [2]Mary Babb Randolph Cancer Center, West Virginia University, Morgantown, USA; [3]University of Colorado Cancer Center, Aurora, USA; [4]University of Michigan Health System, Ann Arbor, USA; [5]Stanford University School of Medicine, Stanford, USA; [6]Levine Cancer Institute, Charlotte, USA; [7]Auckland City Hospital, Auckland, NZ; [8]Duke University, Durham, USA; [9]University Hospital Madgeburg, Madgeburg, DE; [10]University of Iowa, Iowa City, USA; [11]Case Western Reserve University, Cleveland, USA; [12]University of California, San Diego, USA; [13]University of Arizona Cancer Center North, Tucson, USA; [14]Melanoma and Skin Cancer Center, Inova Char Cancer Institute, Fairfax, USA; [15]Mary Crowley Cancer Research, Dallas, USA; [16]Affinity Research, Nedlands, AU; [17]Northwestern University, Chicago, USA; [18]Merck & Co., Inc., Kenilworth, NJ, USA; [19]Dynavax Technologies Corporation, Berkeley, USA; [20]Melanoma Institute Australia, University of Sydney, AU

METHODS CONT.

Figure 2. Study Design



CT, computed tomography scan

- Primary Endpoint: Overall response rate assessed by RECIST v1.1
- Secondary Endpoints: Safety and tolerability, duration of response, and immunophenotype of the tumor environment

*Out of 38 patients, 4 patients treated with 4 mg per injection and 4 patients treated with up to 2 mg per injection in other cohorts were excluded; 30 patients have been treated with 8 mg per injection.

RESULTS

Table 1. Demographics and Baseline Characteristics

Characteristics	N = 30
Median age, years (Min, Max)	64 (53, 76)
Male, n (%)	23 (76.7)
ECOG PS 0, n (%)	16 (53.3)
Baseline LDH, mean (SD) ≤ULN, n (%) >1 to ≤2 ULN, n (%) >2 ULN, n (%)	223 (3.0, 1886.0) 17 (55%) 9 (29%) 4 (13%)
Stage at Screening, n (%)	
IIIC	10 (33.3)
IV	19 (63.3)
Missing	1 (3.3)
Metastases involving:	
Skin/Subcutaneous tissue	20 (66.7)
Lymph Nodes	15 (50)
Liver	9 (30)
Lung	6 (20)
Bones	3 (10)
Other	13 (43.3)

ECOG PS = Eastern Cooperative Oncology Group performance status; LDH = lactate dehydrogenase; SD = standard deviation; ULN = upper limit of normal; * Expression determined using Dako 22C3 antibody

RESULTS CONT.

Table 2. Baseline Disease Characteristics

Characteristics, n (%)	N = 30
Prior radiotherapy	6 (20)
Prior surgery	28 (93.3)
Prior lines of therapy, 1/2/≥3	11/8/11
PD1/PD-L1 therapy	
Resistant*	18 (60)
Refractory**	12 (40)
Prior CTLA-4 therapy	12 (40)

* Resistant: progressive disease after at least 3 months on treatment and initial objective response or stable disease. A disease with a relapse while on adjuvant treatment or within 6 months after the end of an adjuvant treatment is also considered resistant.
**Refractory: tumor initially resistant, best confirmed response is progressive disease while on treatment.

RESULTS CONT.

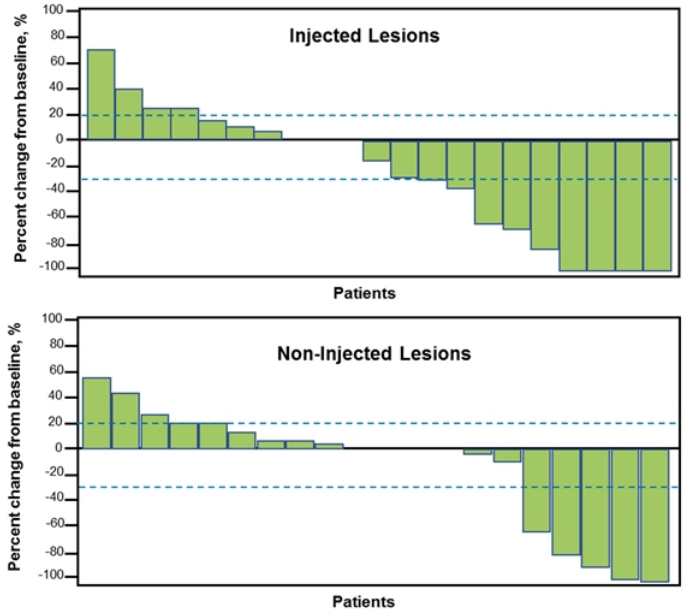
Efficacy

Table 3. Best Overall Response in mITT by RECIST

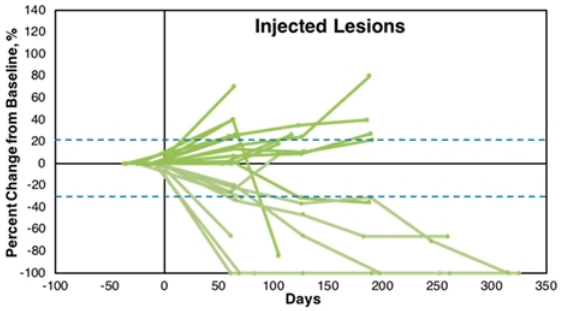
Best ORR, n (%)	N = 29 (mITT*)
Objective response rate	6 (20.7)
Complete response	1 (3.4)
Partial response	5 (17.2)
Duration of response (months), median (min, max)	2.1 (1.0, 6.1)
Stable disease	5 (17.2)
Disease Control Rate	11 (37.9)
Progressive disease	11 (37.9)

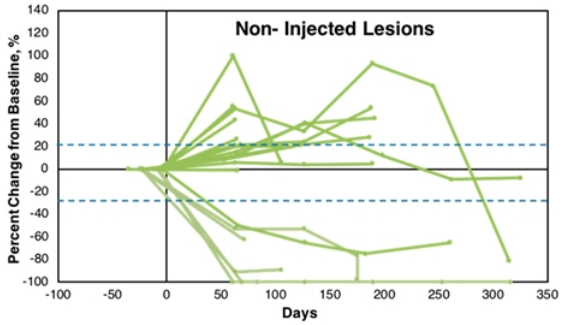
Note: Patients receiving 1 and 2 mg dosing were excluded (1 of 4 patients who received 1 or 2 mg dosing experienced a partial response)
*mITT: excluding patients on treatment but did not yet have their first CT scan and tumor assessment

RESULTS CONT.



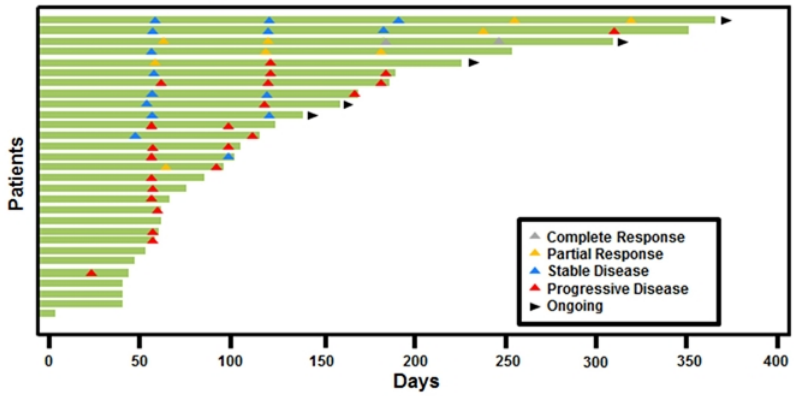
RESULTS CONT.





RESULTS CONT.

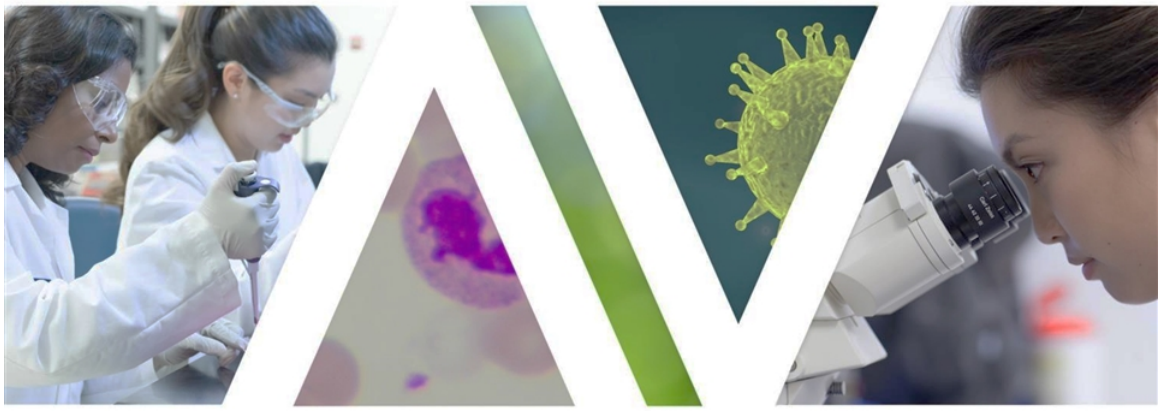
Figure 5. Patient Response History and Current Status



CONCLUSIONS

- Preliminary data show encouraging efficacy, with an ORR of 21%
  - Responses were observed in both SD-101 injected and non-injected lesions; however, it is too early to determine the durability of responses
  - The addition of SD-101 to pembrolizumab appears to restore tumor sensitivity to PD-1 inhibitors in patients who are R/R to such therapy
- Based on data from the anti-PD-1/L1 naïve melanoma population, 25 patients with R/R disease are being enrolled to receive 2 mg per injection

DYNAVAX
INNOVATING IMMUNOLOGY



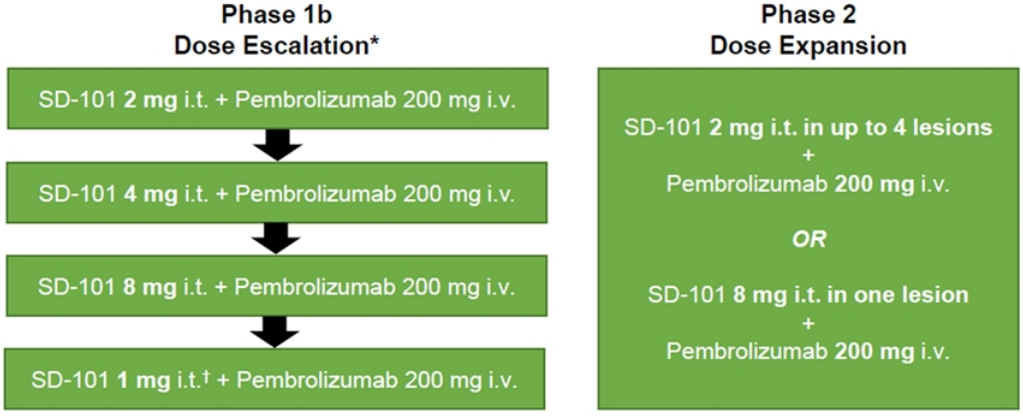
LBA45: Phase 1b/2, Open Label, Multicenter, Study of the Combination of SD-101 and Pembrolizumab in Patients with Advanced Melanoma Who Are Naïve to Anti-PD-1/L1 Therapy (SYNERGY-001/KEYNOTE-184, NCT02521870)

G. Long[1], M. Milhem[2], A. Amin[3], C. J. Hoimes[4], T. Medina[5], R. Conry[6], C. Lao[7], G. Daniels[8], S. Reddy[9], I. Mehmi[10], R. Andtbacka[11], M. Barve[12], M. Shaheen[13], T. Tueting[14], M. Chisamore[15], B. Xing[16], A. Candia[16], E. Gamelin[16], R. Janssen[16], A. Ribas[17]

[1]Melanoma Institute Australia, The University of Sydney and Royal North Shore and Mater Hospitals, Sydney, Australia; [2]University of Iowa, Iowa City, USA; [3]Levine Cancer Institute, Charlotte, USA; [4]Case Western Reserve University, Cleveland, USA; [5]University of Colorado Cancer Center, Aurora, USA; [6]University of Alabama School of Medicine, Birmingham, USA; [7]University of Michigan Health System, Ann Arbor, USA; [8]University of California, San Diego, USA; [9]Stanford University, Stanford, USA; [10]Mary Babb Randolph Cancer Center, West Virginia University, Morgantown, USA; [11]University of Utah, Salt Lake City, USA; [12]Mary Crowley Cancer Research, Dallas, USA; [13]University of Arizona Cancer Center North, Tucson, USA; [14]University Hospital Magdeburg, Magdeburg, Germany; [15]Merck & Co., Inc., Kenilworth, NJ, USA; [16]Dynavax Technologies Corporation, Berkeley, USA; [17]Jonsson Comprehensive Cancer Center, UCLA, Los Angeles, USA

METHODS

Phase 1b/2 Trial (SYNERGY-001/KEYNOTE-184)



*DLT period 29 days; †3 patients received 1 mg/lesion; i.t.= intratumoral; i.v. = intravenous. Data Cutoff: September 21, 2018

- **Patients:**
  - Unresectable Stage IIIC, Stage IV Metastatic Melanoma
  - ECOG performance status of 0 or 1
  - No prior anti-PD-1/L1 therapy
  - At least one injectable lesion

RESULTS

Table 1. Demographics and Baseline Characteristics (Phase 1b/2)

Characteristics	2 mg/lesion n = 47	8 mg/lesion n = 40
Median age, years (Min, Max)	66 (36, 85)	66 (33, 89)
> 65 years, n (%)	30 (64)	23 (58)
Male, n (%)	33 (70)	26 (65)
ECOG PS 0, n (%)	30 (64)	30 (75)
Baseline LDH, median (Q1, Q3) > ULN, n (%)	193 (162, 234) 8 (17)	195 (177, 238) 10 (25)
Stage at Screening, n (%)		
IIIC	10 (21)	8 (20)
IV	37 (79)	32 (80)
M1a	16 (34)	11 (28)
M1b	9 (19)	9 (23)
M1c	12 (26)	12 (30)
PD-L1 Expression, n (%)*		
Positive (≥1%)	19 (40)	13 (33)
Negative (<1%)	15 (32)	15 (38)
Pending	13 (28)	12 (30)
Prior lines of therapy, 0 / 1 / 2 / ≥3. n (%)	34 / 11 / 2 / 0 (72 / 23 / 4 / 0)	28 / 11 / 0 / 1 (70 / 28 / 0 / 3)

ECOG PS = Eastern Cooperative Oncology Group performance status; LDH = lactate dehydrogenase; Q1 = first quartile; Q3 = third quartile; ULN = upper limit of normal; * Expression determined by tumor proportion score using Dako 22C3 antibody

RESULTS CONT.

Safety

Table 2. Safety Summary

Event, N (%)	2 mg/lesion n = 47	8 mg/lesion n = 40	Total N = 87
Any Treatment-related AE	43 (91)	37 (93)	80 (92)
Grade 3-4	12 (26)	16 (40)	28 (32)
Chills	4 (9)	1 (3)	5 (6)
Myalgia	5 (11)	0	5 (6)
Fatigue	2 (4)	3 (8)	5 (6)
Headache	4 (9)	2 (5)	6 (7)
Malaise	3 (6)	2 (5)	5 (6)
Any irAEs	10 (21)	6 (15)	16 (18)
Grade 3-4	3 (6)	1 (3)	4 (5)
AEs leading to d/c of either or both drug	7 (15)	13 (33)	20 (23)
SAEs	14 (30)	15 (38)	29 (33)
Death	0	1 (3)	1 (1)

irAE = immune-related adverse event; d/c = discontinuation; SAE = serious adverse event.
Note: death was considered not related to drug

RESULTS CONT.

Efficacy

Table 4. Best Overall Response by RECIST v1.1 (ITT Population)

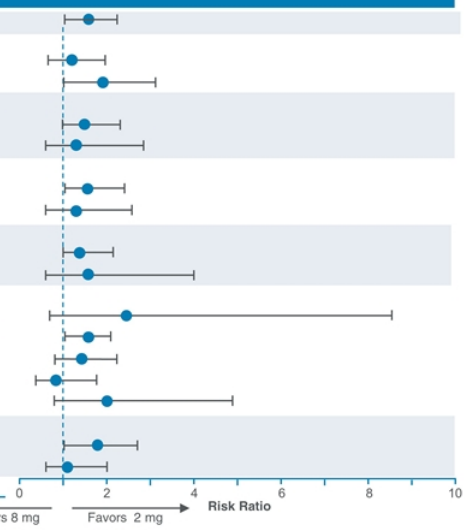
	2 mg/lesion n = 47	8 mg/lesion n = 40
Objective response rate, n (%) [95% CI]	**33 (70) [56, 81]**	**19 (48) [33, 63]**
Complete response	5 (11)	2 (5)
Partial response	28 (60)	17 (43)
Time to response, median (months)	2.1	2.3
Duration of response, median (months) (95% CI)	**Not reached (9.0, NE)**	**Not reached (8.2, NE)**
Stable disease, n (%)	4 (9)	8 (20)
Disease Control Rate, n (%)	37 (79)	27 (68)
Progressive disease, n (%)	6 (13)	9 (23)
Non-evaluable*, n (%)	4 (9)	4 (10)

*Patients discontinued prior to first scan: 2 mg—clinical progression (n=2), irAE (n=1), withdrew consent (n=1); 8 mg—clinical progression (n=1), unrelated AE/death (n=1); irAE (n=1), withdrew consent (n=1). CI = confidence interval; ITT= Intention to treat; NE=not estimable

NOTE: Two patients in the 2 mg group with recently reported PRs are not reflected in the figures

Subgroup Analyses Favor 2 mg Dose

	2 mg		8 mg		
	N	ORR	N	ORR	RR (95% CI)
Overall	47	70%	40	48%	1.5 (1.0. 2.2)
Age, year					
< 65	17	71%	17	59%	1.2 (0.7, 2.0)
≥ 65	30	70%	23	39%	1.8 (1.0, 3.1)
Sex					
Male	33	76%	26	50%	1.5 (1.0, 2.3)
Female	14	57%	14	43%	1.3 (0.6, 2.8)
ECOG PS					
0	30	73%	30	47%	1.6 (1.0, 2.4)
1	17	65%	10	50%	1.3 (0.6, 2.6)
LDH					
≤ ULN	39	72%	30	50%	1.4 (1.0, 2.2)
> ULN	8	63%	10	40%	1.6 (0.6, 4.0)
Stage at screening					
IIIC	10	60%	8	25%	2.4 (0.7, 8.8)
M1a-c	37	73%	32	53%	1.5 (1.0, 2.1)
M1a	16	88%	11	64%	1.4 (0.8, 2.2)
M1b	9	56%	9	67%	0.8 (0.4, 1.8)
M1c	12	67%	12	33%	2.0 (0.8, 4.9)
Number of prior lines of therapy					
0	34	74%	28	43%	1.7 (1.0, 2.8)
1+	13	62%	12	58%	1.1 (0.6, 2.0)



CI = confidence interval; ECOG = Eastern Cooperative Oncology Group performance status; LDH = lactate dehydrogenase; ORR = objective response rate; RR = risk ratio; ULN = upper limit of normal

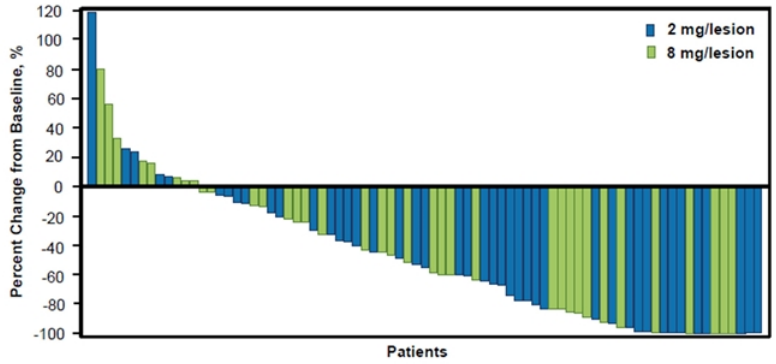
RESULTS CONT.

Table 5. Responses in Both PD-L1 Negative and Positive Tumors

PD-L1 Expression	2 mg/lesion		8 mg/lesion	
	N	ORR (%)	N	ORR (%)
≥1%	19	79	13	62
<1 %	15	80	15	33
Pending/missing	13	46	12	50

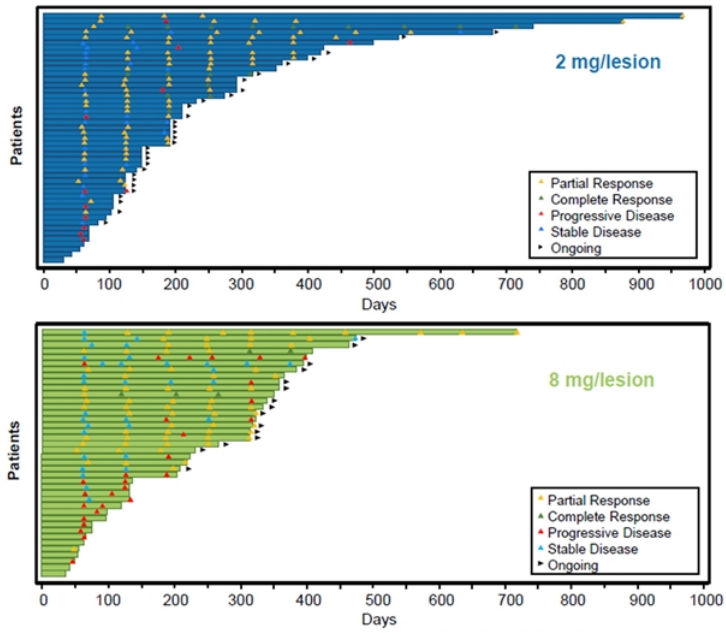
ORR= objective response rate; PD-L1 expression based on tumor proportion score (Dako 22C3 antibody)

Figure 2. Best Percent Change From Baseline in All Target Lesions



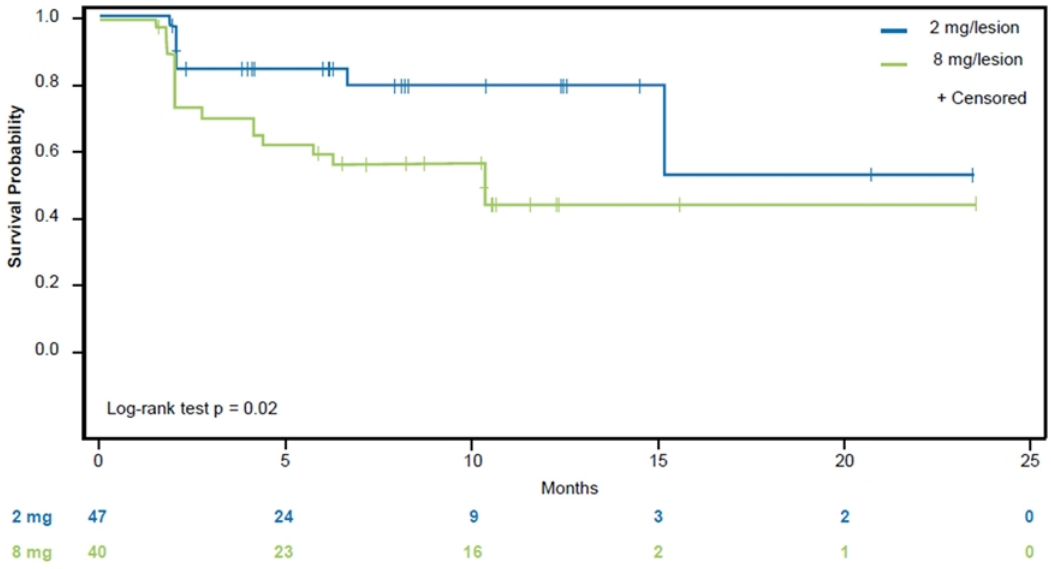
RESULTS CONT.

Figure 3. Duration of Follow Up and Patient Status



RESULTS CONT.

Figure 5. Progression-free Survival (ITT Population)



2 mg	47	24	9	3	2	0
8 mg	40	23	16	2	1	0

RESULTS CONT.

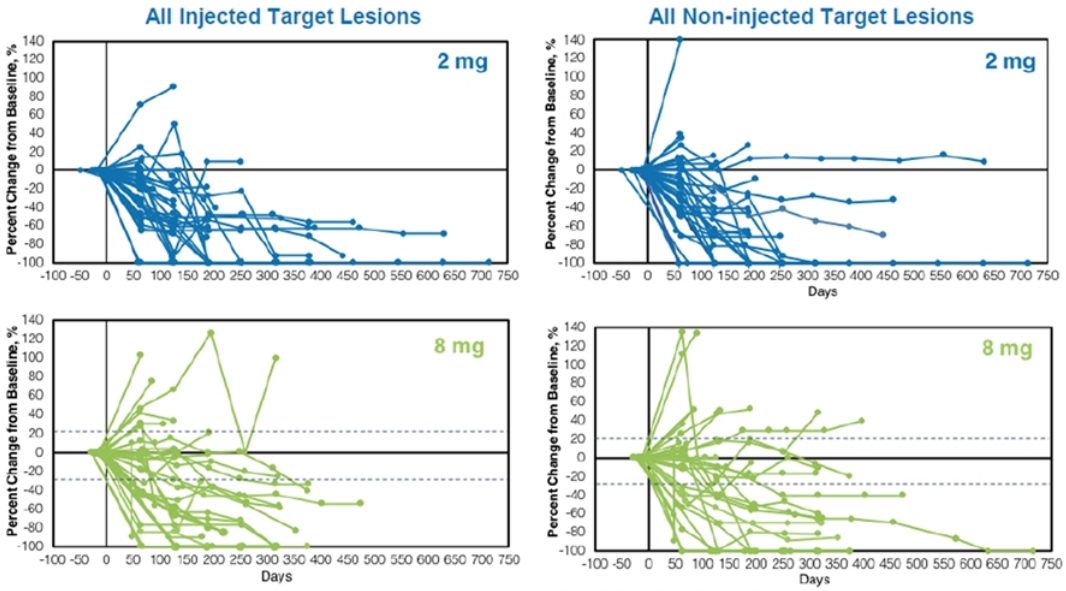
Table 6. Progression-free Survival (ITT Population)

	2 mg/lesion	8 mg/lesion
PFS (Kaplan-Meier method)		
6-month rate (95% CI)	85% (70, 93)	60% (42, 73)
Median (months) (95% CI)	not reached (15.2, NE)	10.4 (4.2, NE)
Follow-up, median (months)	5.9	6.9

. CI = confidence interval; ITT = intention to treat; NE=not estimable; PFS = progression-free survival

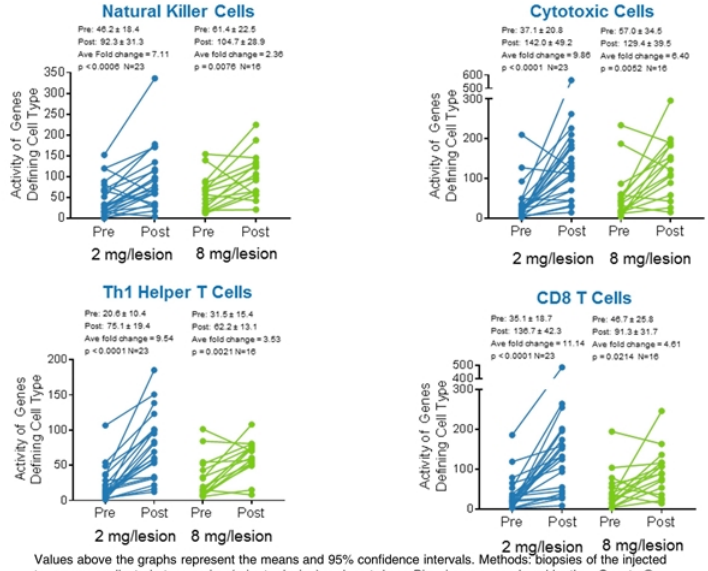
RESULTS CONT.

Figure 6. Percent Change From Baseline Over Time for Target Lesions in Patients Who Received 2 mg or 8 mg SD-101 Per Lesion



IMMUNE-RELATED BIOMARKERS

Figure 8. Changes in Immune Activity in the Tumor Microenvironment



Values above the graphs represent the means and 95% confidence intervals. Methods: biopsies of the injected tumor were collected at screening (prior to dosing) and post-dose. Biopsies were analyzed by the nCounter® PanCancer Immune Profiling Panel (NanoString Technologies, Inc., Seattle WA) to evaluate the immunophenotype of the tumor environment. Nanostring data were analyzed using the nSolver™ Analysis Software

CONCLUSIONS

- The addition of 2 mg/lesion of SD-101 to pembrolizumab appears to increase immune activity in the tumor microenvironment and efficacy compared with 8 mg/lesion in similar patient populations
  - The ORR and PFS were significantly better in the 2 mg/lesion SD-101 group than in the 8 mg/lesion SD-101 group
  - Responses occurred in patients with PD-L1 negative tumors and PD-L1 positive tumors
  - Tumor shrinkage occurred in injected lesions, and non-injected visceral lesions including in the liver and lung
- The combination of SD-101 and pembrolizumab was well tolerated, consistent with previous reports
  - AEs associated with SD-101 were transient, mild to moderate flu-like symptoms that were manageable with over-the-counter medications
  - No increase in immune-related AEs over pembrolizumab monotherapy was observed
- Clinical responses were supported by immunologic data consistent with the mechanism of SD-101
  - Increases in CD8+ cells, NK cells, cytotoxic cells, and Th1 cells in the tumor microenvironment were observed in both SD-101 dose groups but were higher in the 2 mg group and appeared to correlate with enhanced clinical efficacy

DYNAVAX

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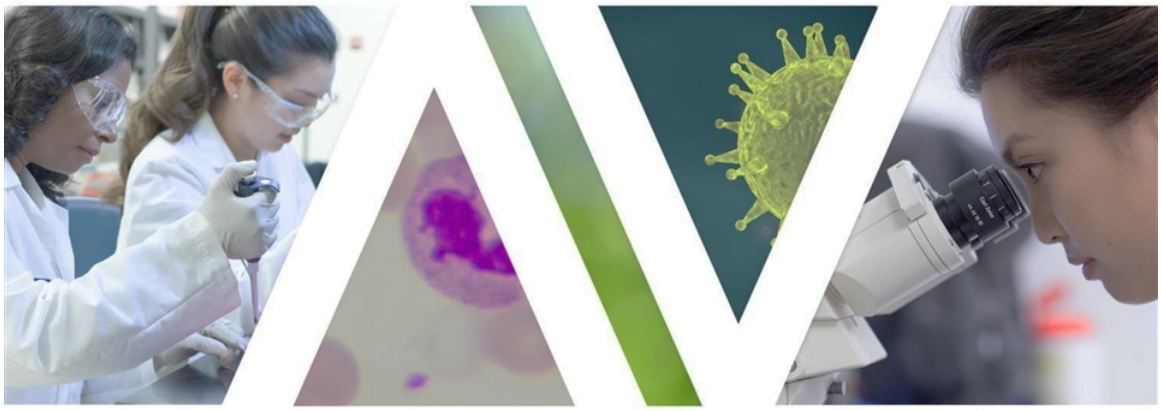


Abstract 3560: Phase 1b/2, Open-Label, Multicenter Study of Intratumoral SD-101 in Combination With Pembrolizumab in Anti-PD-1 Treatment-Naïve Patients With Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma (SYNERGY-001/KEYNOTE-184, NCT02521870)

Ezra Cohen,[1] Alain Algazi,[2] Douglas Laux,[3] Deborah Wong,[4] Asim Amin,[5] Lisle Nabell,[6] Michael Chisamore,[7] Erick Gamelin,[8] Robert Janssen,[8] Sarwan Bishnoi[9]

[1]Moores Cancer Center, University of California San Diego, La Jolla, CA USA; [2]University of California San Francisco, CA USA; [3]University of Iowa, Iowa City, IA USA; [4]Jonsson Comprehensive Cancer Center, UCLA, Los Angeles, CA USA; [5]Levine Cancer Institute, Charlotte, NC USA; [6]University of Alabama at Birmingham, Birmingham, AL USA; [7]Merck & Co., Inc., Kenilworth, NJ USA; [8]Dynavax, Berkeley, CA USA; [9]Adelaide Cancer Centre, Kurralta Park, Australia

RESULTS

Table 1. Demographics and Baseline Characteristics

Characteristics	8 mg (n=23)	2 mg (n=10)
Median age, years (Min, Max)	65 (43, 91)	60 (38, 84)
Male/female sex, %	91/9	50/50
ECOG PS 1, N (%)	22 (84.6)	24 (75.0)
Primary tumor location, n (%)		
Hypopharyngeal	1 (4.3)	1 (10.0)
Nasopharyngeal	1 (4.3)	0
Oral	10 (43.4)	4 (40.0)
Oropharyngeal	5 (21.7)	2 (20.0)
Laryngeal	3 (13.0)	1 (10.0)
Unknown	3 (13.0)	2 (20.0)
0/1/2/≥ 3 prior lines of therapy, n	4/11/5/3	4/6/0/0
Prior radiotherapy, n (%)	18 (78.3)	5 (50.0)
Prior surgery, n (%)	21 (91.3)	8 (80.0)
Prior systemic therapy,* n(%)	19 (82.6)	6 (60.0)

ECOG PS = Eastern Cooperative Oncology Group performance status; HPV = human papillomavirus
* No patient received prior anti-PD-1/L1 or anti-CTLA-4 therapy

RESULTS CONT.

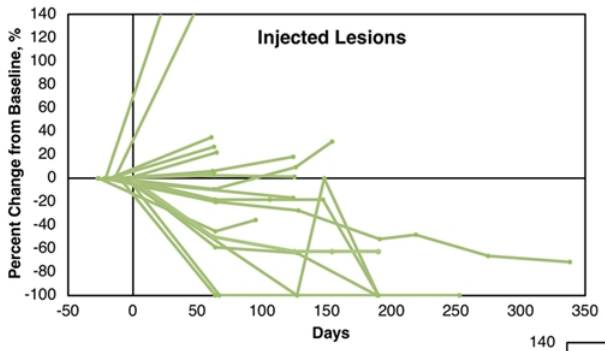
Efficacy

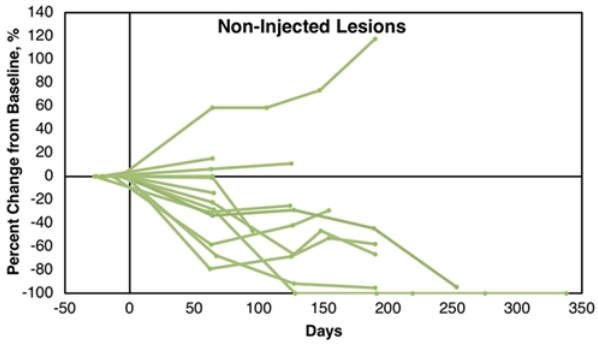
Table 3. Objective Response Rate: SD-101 8 mg or 2 mg/injection

	8 mg	2 mg
mITT patients, n*	22	2
Objective response rate, n (%)	6 (27.3)	
95% confidence interval	(16, 56)	
Best overall response, n (%)		
Complete response	0	
Partial response	6 (27.3)	
Stable disease	4 (18.2)	2 (100)
Progressive disease	10 (45.5)	
Time to response (months)		
Median	2.1	
Min, max	(2.0, 4.2)	
Duration of response (months)		
Median	3.6+	
Min, Max	(0.0, 6.9)	

* mITT = excluding patients on treatment but did not yet have their first CT scan and tumor assessment

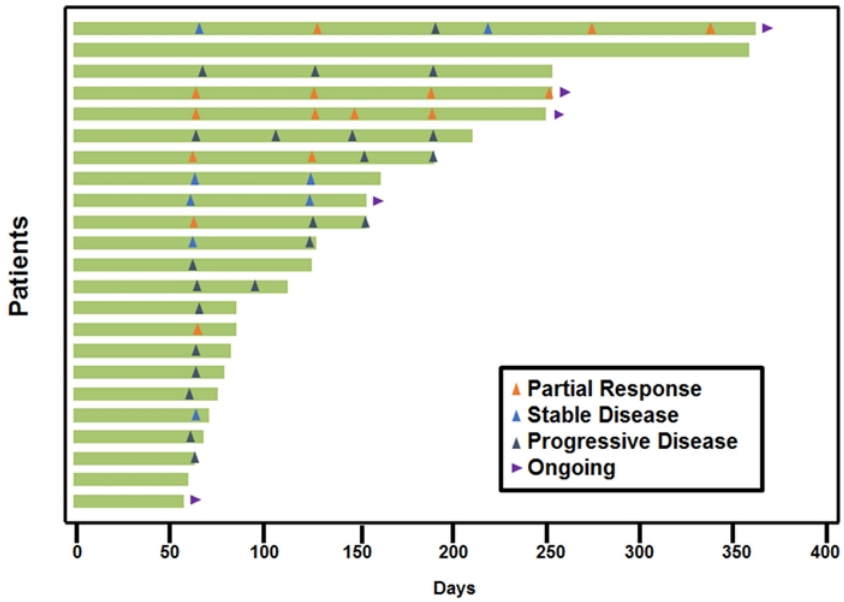
RESULTS CONT.





RESULTS CONT.

Figure 4. Current Patient Status with SD-101 8 mg



HNSCC CONCLUSIONS

- The combination therapy showed encouraging efficacy in patients with HNSCC, with an ORR of 27%
  - Median DOR has not been reached.
  - Some prolonged responses
  - Responses observed in both SD-101 injected and non-injected lesions

SD-101 + PEMBROLIZUMAB CONCLUSIONS

- Why we think SD-101 adds meaningful clinical benefit to pembrolizumab therapy
  - SD-101 in combination with local low dose radiation induced abscopal responses in 80% of patients with indolent non-Hodgkin's lymphoma
  - 8 mg of SD-101 induces responses in anti-PD-1/L1 refractory and resistant melanoma tumors in 21% of patients
  - In 2 similar patient populations with melanoma naïve to anti-PD-1/L1 therapy treated with the same dose of pembrolizumab, the difference in the groups was the dose of SD-101 they received. In this setting, 2 mg/lesion of SD-101 induces a significantly higher ORR and longer PFS than 8 mg/lesion
  - With responses in PD-L1 negative tumors
  - And biomarker activity that suggests 2 mg is the biologically optimal dose in melanoma compared with 8 mg.
  - In HNSCC, 8 mg of SD-101 appears to induce a higher ORR than pembrolizumab monotherapy
- SD-101 adds little additional toxicity to pembrolizumab

SD-101 + PEMBROLIZUMAB CONCLUSIONS

- Moving forward:
  - Currently recruiting patients to receive 2 mg in 1 to 4 lesions:
    - Advanced melanoma who have tumors that are refractory or resistant to anti-PD-1/L1 therapy
    - Recurrent or metastatic HNSCC with no prior anti-PD-1/L1 therapy

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