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 4, 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 June 4, 2018, Dynavax Technologies Corporation, a Delaware corporation ("Dynavax"), issued a press release and presented a corresponding poster and investor presentation announcing 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 & Co., Inc. (known as MSD outside the United States and Canada) in patients with advanced melanoma at the 2018 American Society of Clinical Oncology Annual Meeting, in Chicago, IL. A copy of the press release, the poster and the investor 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 June 4, 2018
99.2	Poster presented at the 2018 American Society of Clinical Oncology Annual Meeting on June 4, 2018
99.3	Analyst and Investor Presentation presented at the 2018 American Society of Clinical Oncology Annual Meeting on June 4, 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: June 4, 2018

By: /s/ STEVEN N. GERSTEN

Steven N. Gersten
Vice President, General Counsel and
Chief Ethics and Compliance Officer

Exhibit 99.1

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

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 4, 2018 – 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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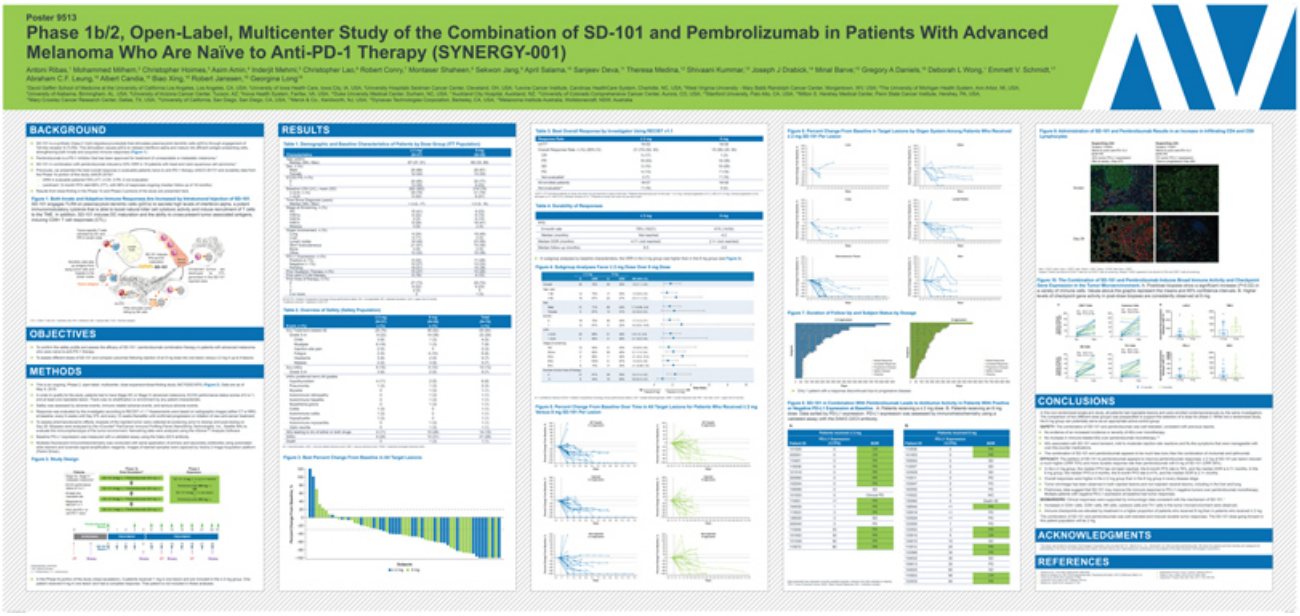

Poster 9513

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 (SYNERGY-001)

Antoni Ribas,[1] Mohammed Milhem,[2] Christopher Hornes,[3] Asim Amin,[4] Inderjit Mehra,[5] Christopher Lao,[6] Robert Conry,[7] Montaser Shaheen,[8] Sekwon Jang,[9] April Salama,[10] Sanjeev Deva,[11] Theresa Medina,[12] Shivaani Kummar,[13] Joseph J Drabick,[14] Minal Barve,[15] Gregory A Daniels,[16] Deborah L Wong,[1] Emmett V. Schmidt,[17] Abraham C.Y. Leung,[18] Albert Candia,[18] Biao Xing,[18] Robert Janssen,[18] Georgina Long[19]

[1]David Geffen School of Medicine at the University of California Los Angeles, Los Angeles, CA, USA; [2]University of Iowa Health Care, Iowa City, IA, USA; [3]University Hospitals Seidman Cancer Center, Cleveland, OH, USA; [4]Levine Cancer Institute, Carolinas HealthCare System, Charlotte, NC, USA; [5]West Virginia University - Mary Babb Randolph Cancer Center, Morgantown, WV, USA; [6]The University of Michigan Health System, Ann Arbor, MI, USA; [7]University of Alabama, Birmingham, AL, USA; [8]University of Arizona Cancer Center, Tucson, AZ; [9]Tulsa Health System, Fairfax, VA, USA; [10]Duke University Medical Center, Durham, NC, USA; [11]Auckland City Hospital, Auckland, NZ; [12]University of Colorado Comprehensive Cancer Center, Aurora, CO, USA; [13]Stanford University, Palo Alto, CA, USA; [14]Milton S. Hershey Medical Center, Penn State Cancer Institute, Hershey, PA, USA; [15]Mary Crowley Cancer Research Center, Dallas, TX, USA; [16]University of California, San Diego, San Diego, CA, USA; [17]Merck & Co, Kenilworth, NJ, USA; [18]Dynavax Technologies Corporation, Berkeley, CA, USA; [19]Melanoma Institute Australia, Wollstonecraft, NSW, Australia

BACKGROUND

OBJECTIVES

METHODS

RESULTS

CONCLUSIONS

ACKNOWLEDGMENTS

REFERENCES

DYNAVAX

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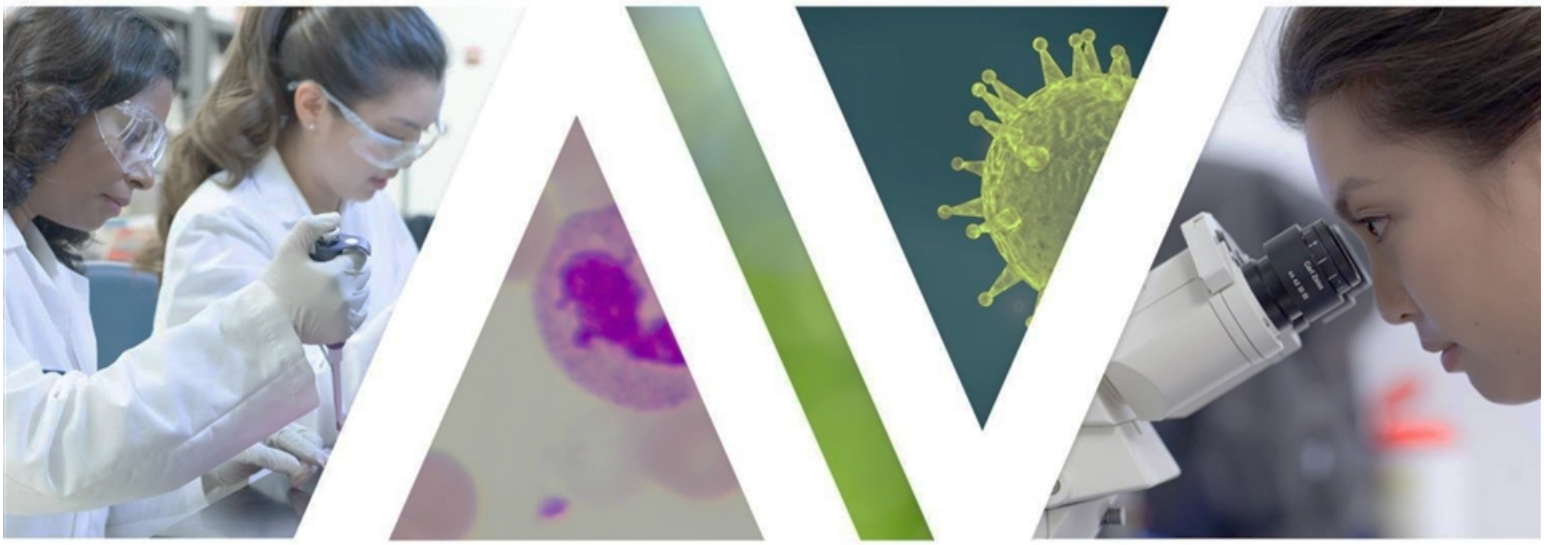


Analyst & Investor Presentation

June 2018

Forward Looking Statement

This presentation 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 presentation 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.

Presenters

COMPANY

- **Eddie Gray** – Chief Executive Officer
- **Robert L. Coffman, PhD** – Chief Scientific Officer
- **Rob Janssen, MD** – Chief Medical Officer
- **Jean Chang** – VP, Cancer Strategy and Business Development
- **Michael Ostrach** – Chief Financial Officer (available for Q&A)
- **Erick Gamelin** – VP, Clinical Development – Oncology (available for Q&A)

GUEST PRESENTER

Antoni Ribas, MD, PhD

Professor of Medicine, Surgery, Molecular and Medical Pharmacology, Director, Tumor Immunology Program, Jonsson Comprehensive Cancer Center (JCCC);

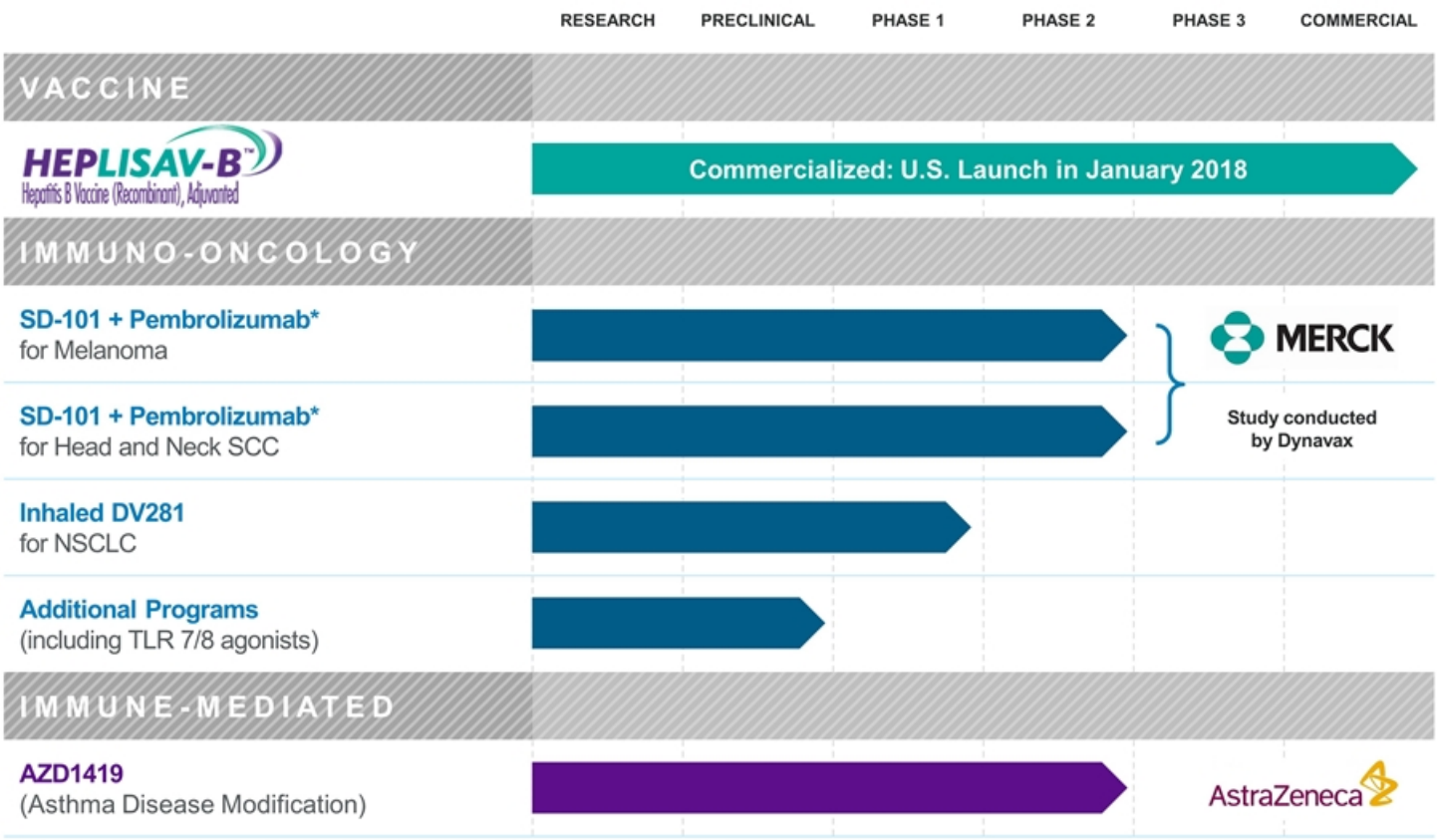
Director, Parker Institute for Cancer Immunotherapy (PICI) Center at UCLA

Chair, Melanoma Committee at SWOG

Agenda

1. TLR9 Agonists for Cancer Immunotherapy – Mechanisms
   Robert L. Coffman
2. Resistance to PD-1 Blockade Due to Lack of Pre-existing Antitumor immunity
   Toni Ribas
3. Clinical Development – Ph1b/2 Melanoma Data and Additional Programs
   Rob Janssen
4. Maximizing Value of Dynavax's TLR9 Agonist Portfolio in the Evolving Treatment Landscape
   Jean Chang
5. Conclusion
   Eddie Gray

Deep and Growing Clinical Pipeline



* Clinical collaboration with Merck; Dynavax maintains all commercial rights to SD-101

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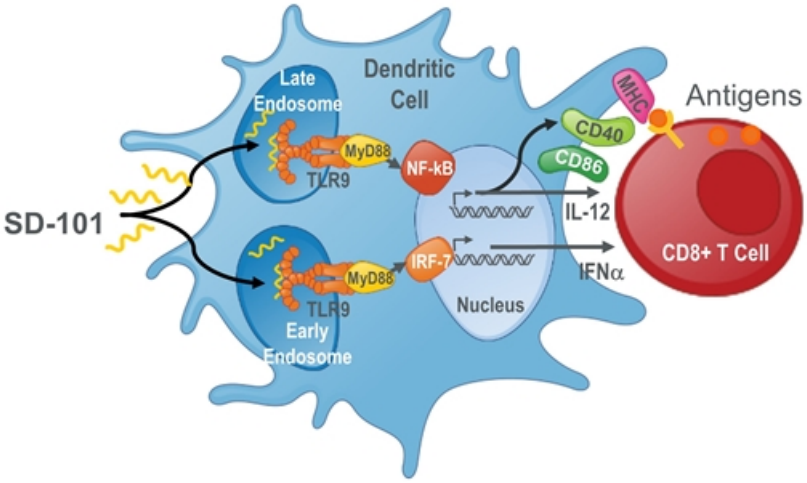
Robert L. Coffman, PhD

SD-101: Optimized TLR9 Agonist for Cancer Immunotherapy

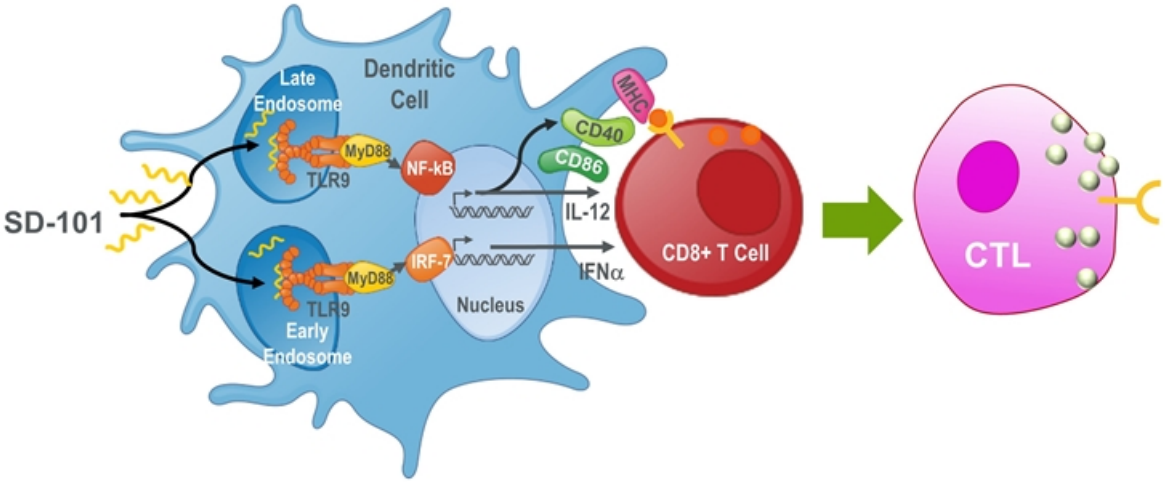
- Synthetic DNA oligonucleotide with TLR9-reactive CpG motifs
- Optimized for two key dendritic cell activation pathways
- TLR9 activation of dendritic cells complements other major classes of immuno-oncology agents.



SD-101: Optimized TLR9 Agonist for Cancer Immunotherapy

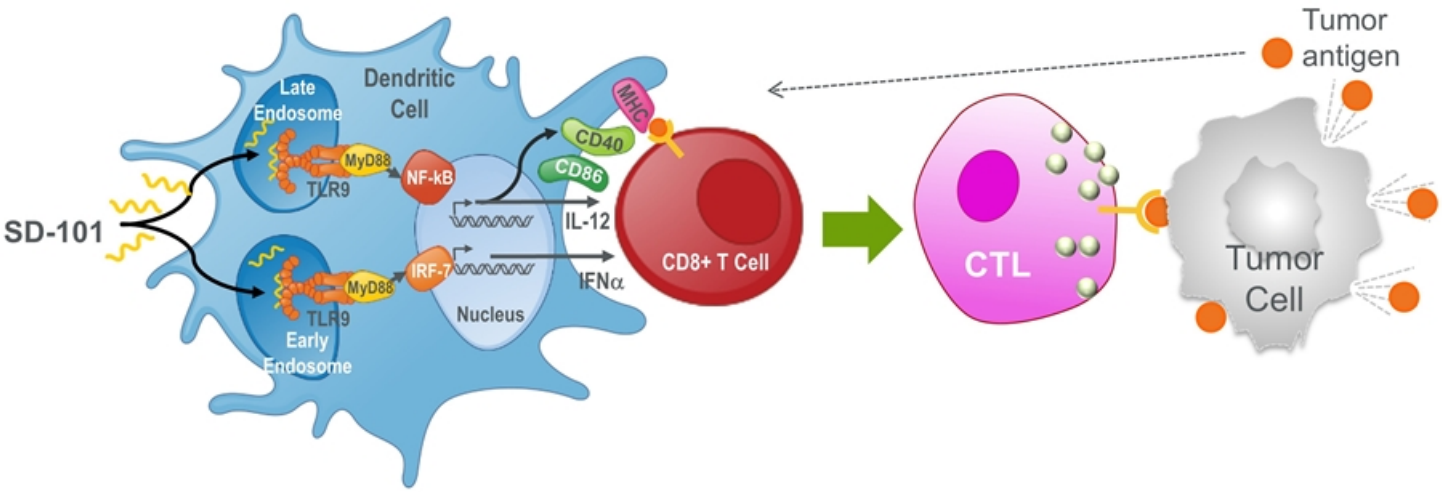
Triggering dual pathways provides more potent response

- Activates dendritic cells to become efficient antigen-presenting cells
- Induces type 1 IFN, leading to development of cytotoxic T cells (CTL)

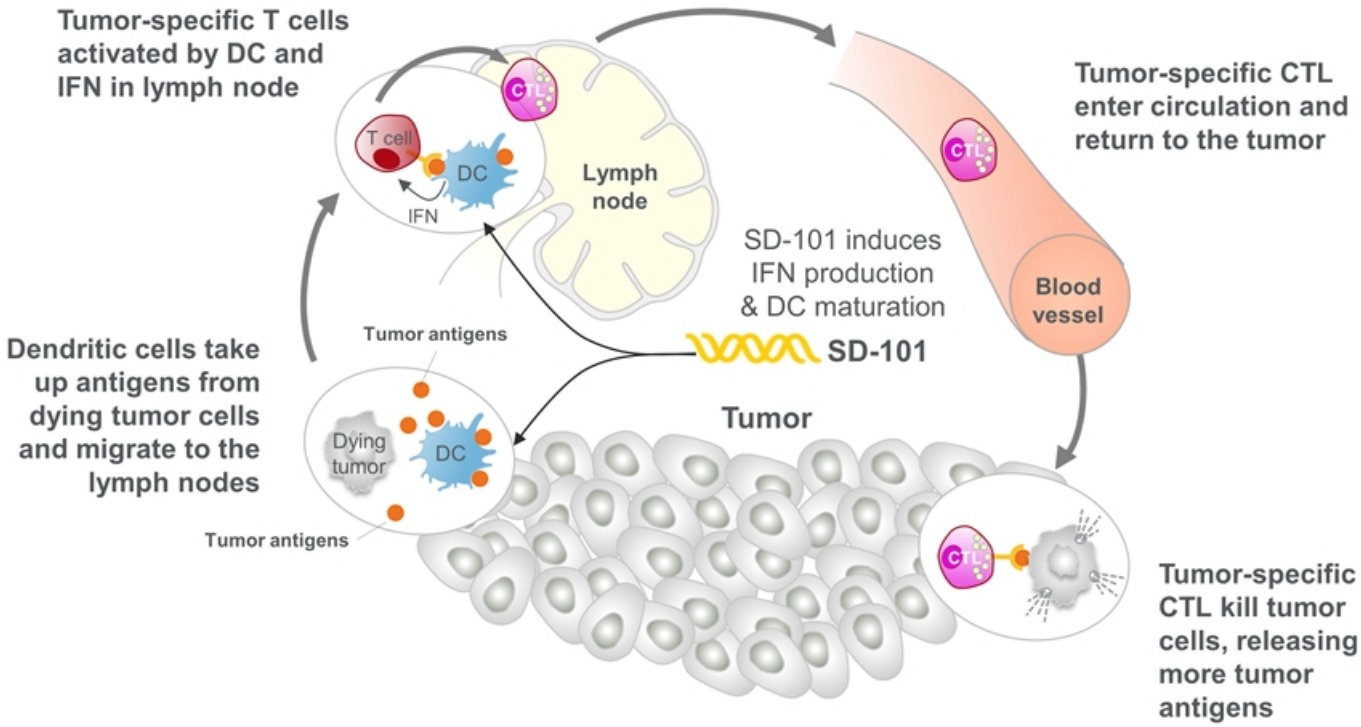


SD-101: Optimized TLR9 Agonist for Cancer Immunotherapy

- Inside tumor, CTL recognize and kill tumor cells, releasing more tumor antigens
- Establishes self-amplifying process leading to control or elimination of malignant cells



Actions of Intratumoral SD-101 in Cancer Immunotherapy



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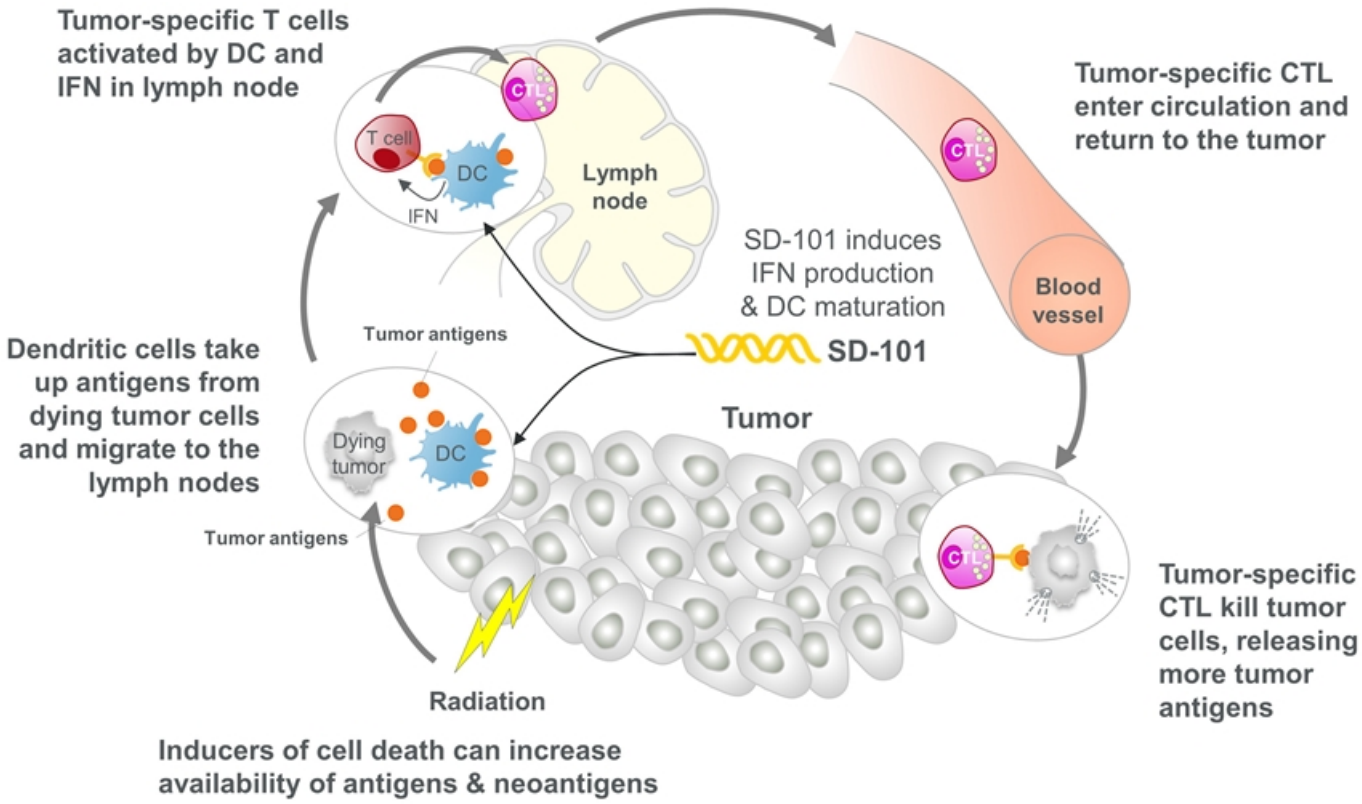

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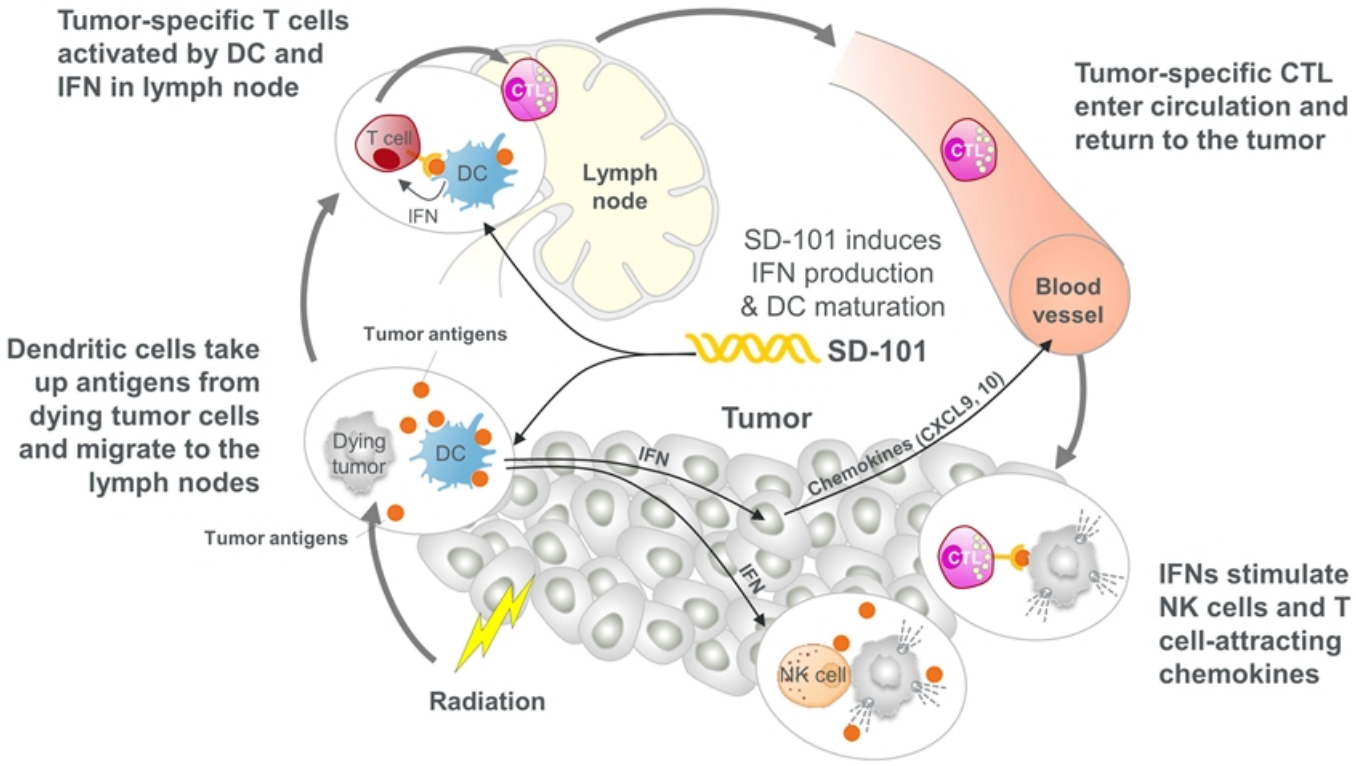
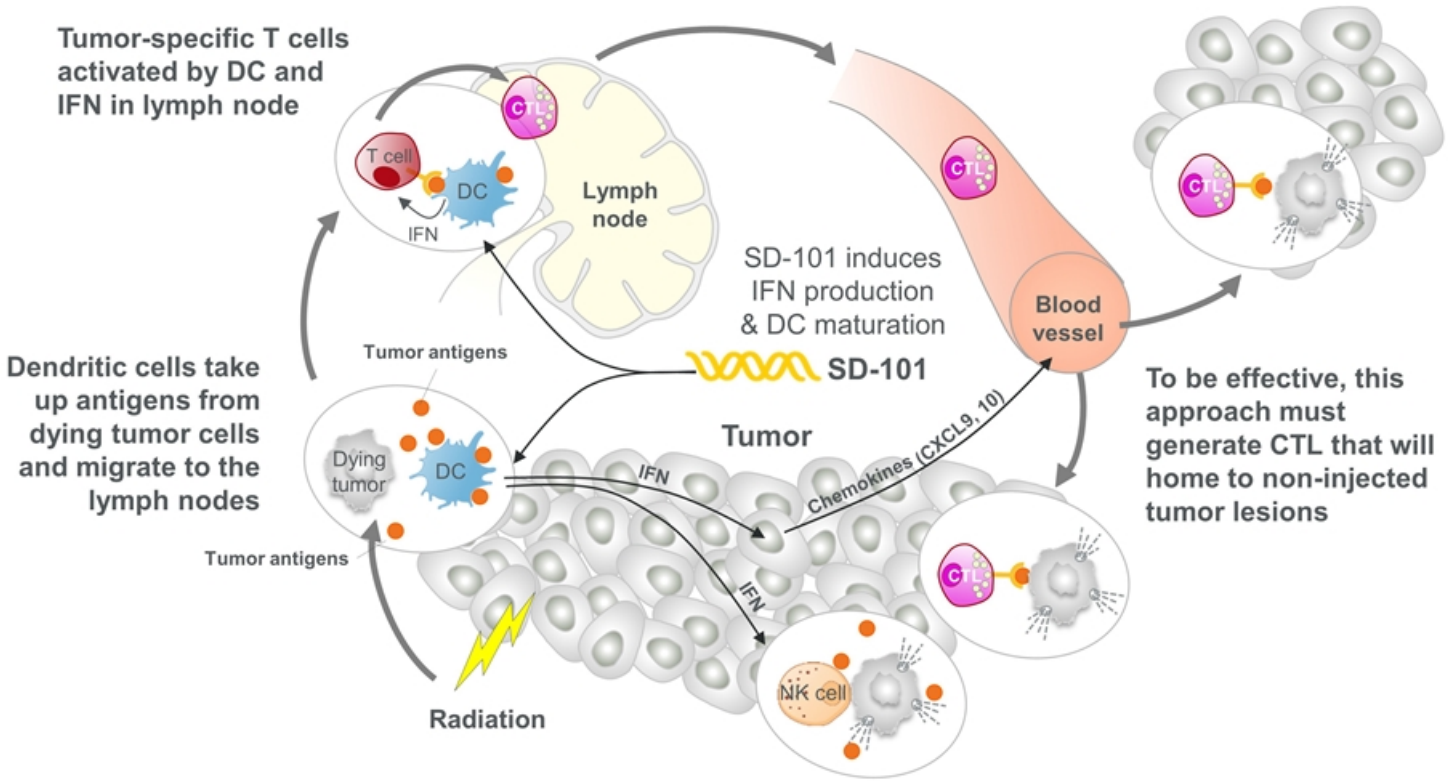
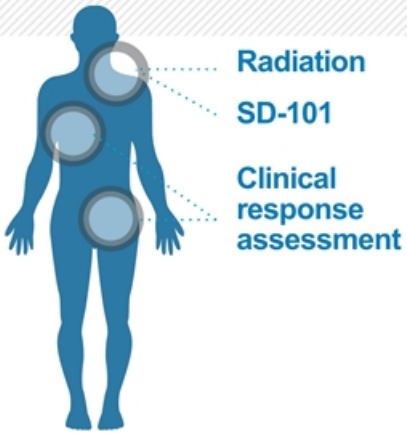


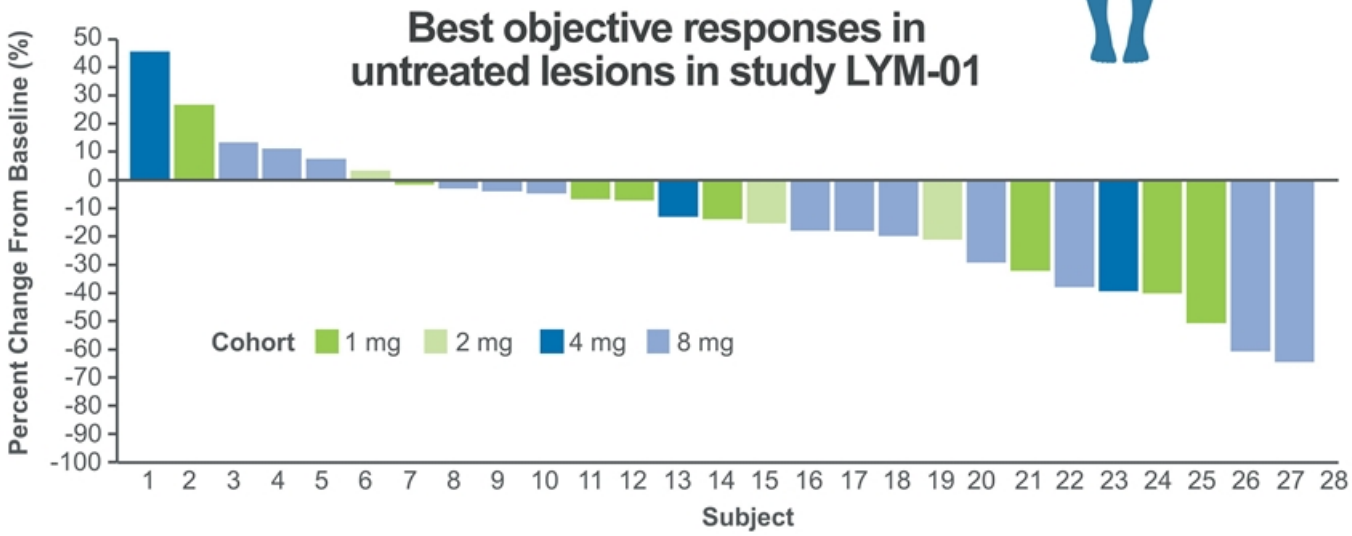
Actions of Intratumoral SD-101 in Cancer Immunotherapy



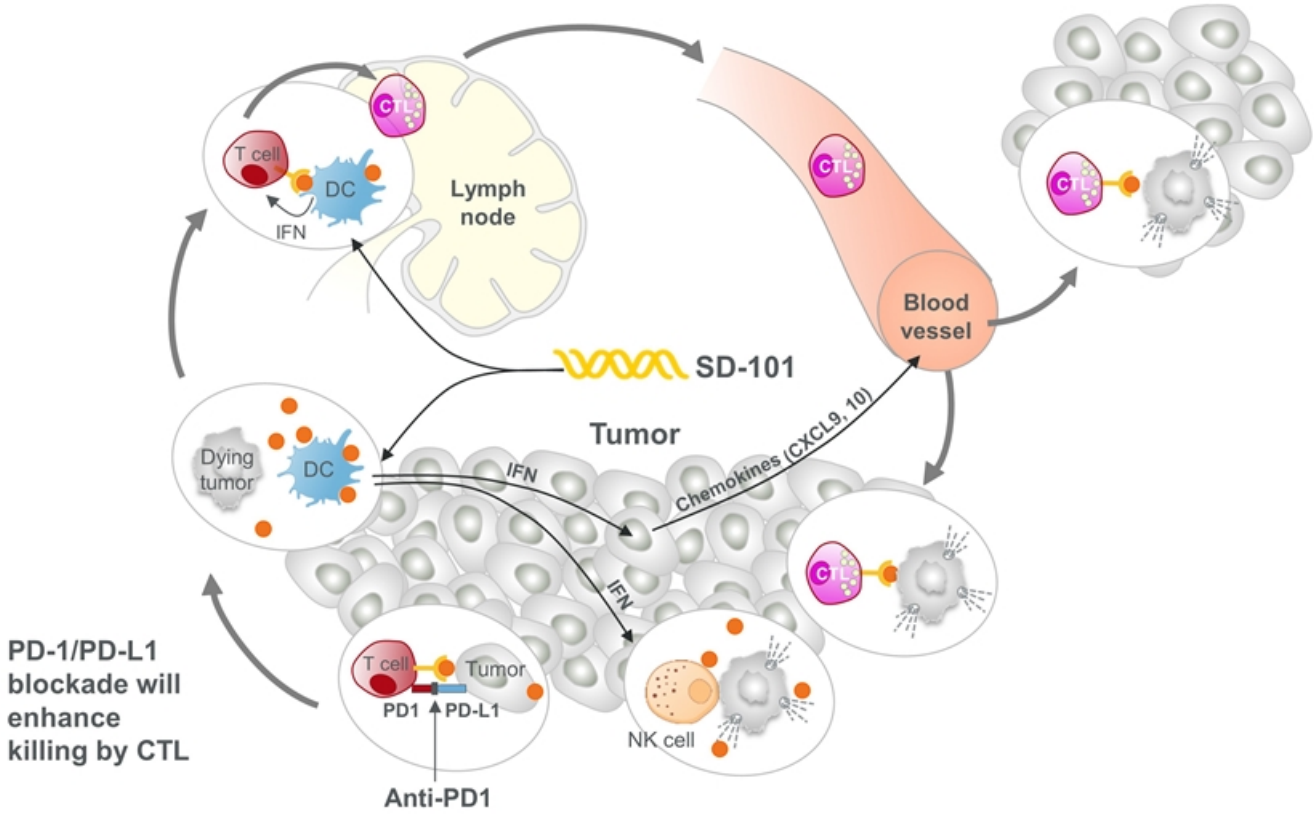
SD-101 + Local Radiation in Lymphoma Leads to Abscopal Response in Many Patients

Previously untreated NHL patients were given low dose radiation (2Gy on days -1 and 0) followed by 5 weekly injections of SD-101 into the irradiated lesion



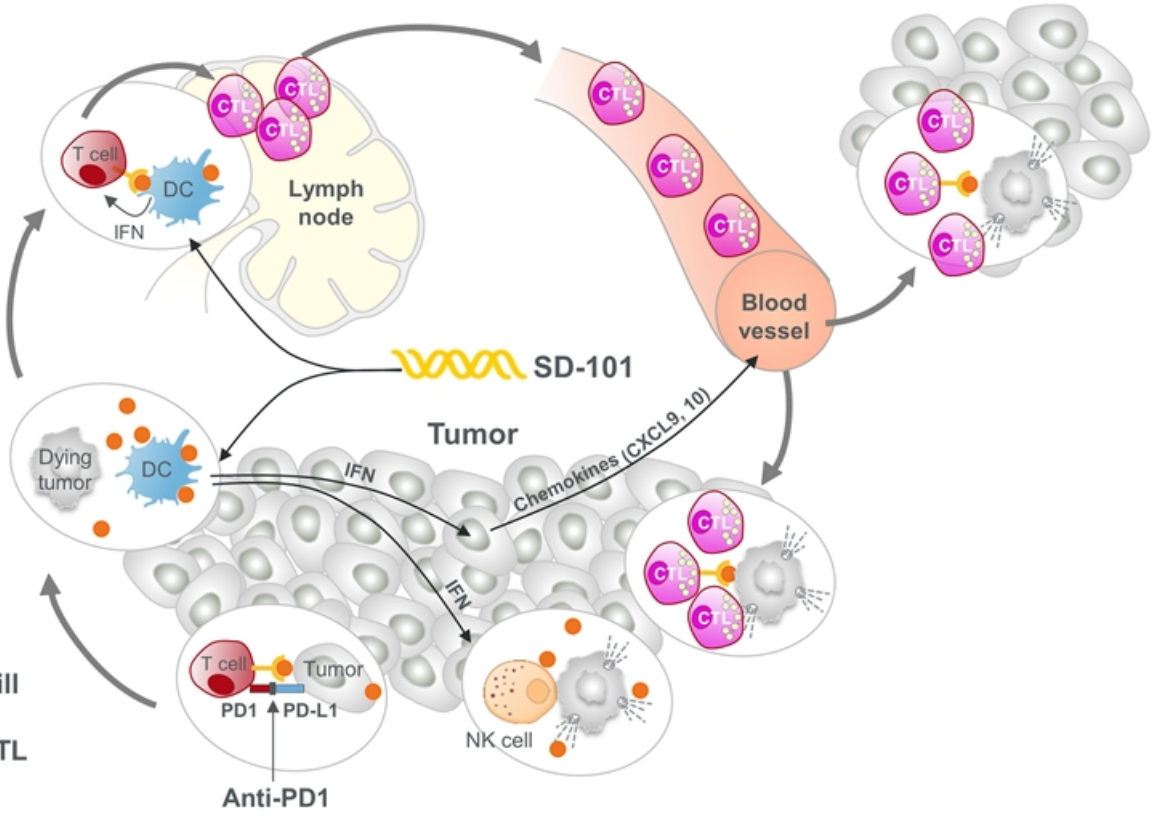


Actions of Intratumoral SD-101 in Cancer Immunotherapy



Combination with Anti-PD-1 Increases Anti-tumor Response

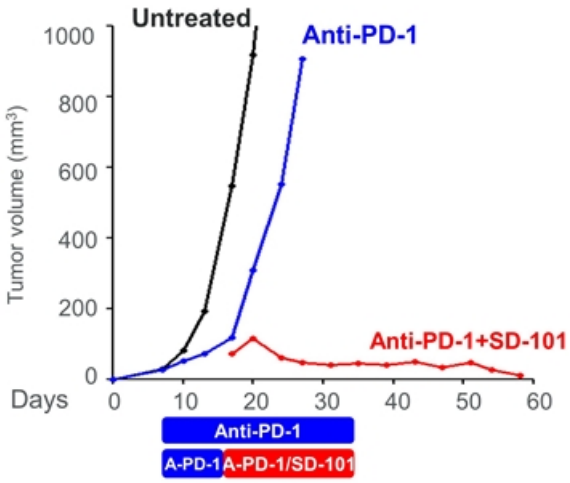
Anti-PD-1 will also increase both the number and cytotoxic activity of CTL in both injected and non-injected tumor lesions

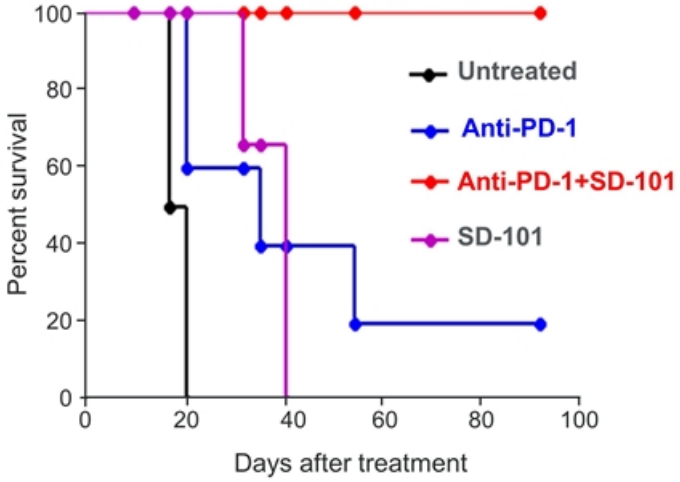


PD-1/PD-L1 blockade will enhance killing by CTL

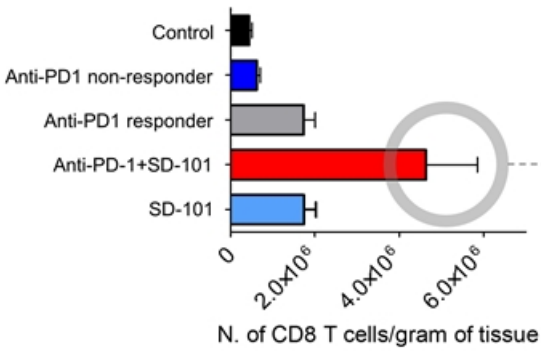
Preclinical Studies in Mice Provide Support for Combining SD-101 With Checkpoint Inhibitors

In preclinical studies, addition of intratumoral SD-101 reverses tumor escape from anti-PD-1 therapy and leads to durable immune-mediated rejection of CT26 tumors

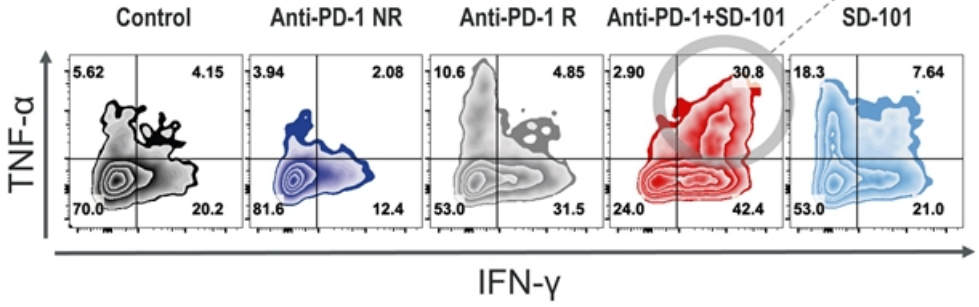




SD-101 and Anti-PD-1 Synergize to Increase Functional CD8+ T Cells in the Injected Tumor

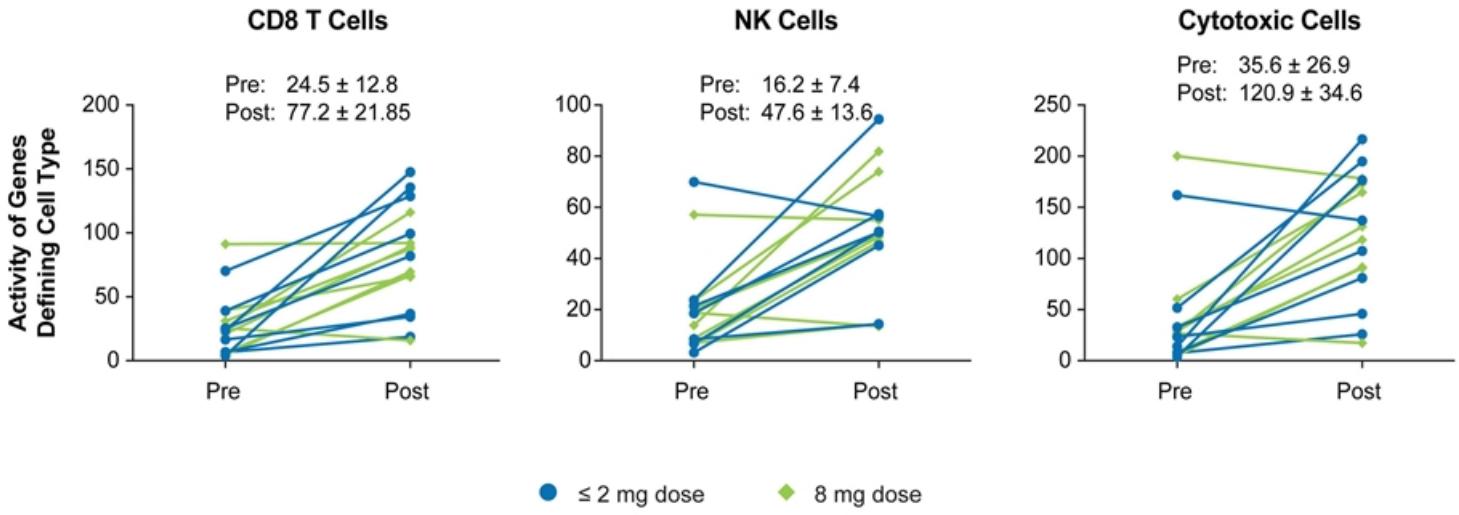


The combination of SD-101 and anti-PD-1 leads to substantial increases in both the **numbers** and **functionality** of the tumor-infiltrating CD8+ T cells



Stimulated CD3+CD8+ T cells

Biomarkers Show Increased Immune Activity with Combination



Cytotoxic T and NK Cells Increase in Melanoma Patients Treated with Intratumoral SD-101 + Pembrolizumab

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Toni Ribas, MD, PhD

Resistance to PD-1 blockade due to lack of pre-existing antitumor immunity

Antoni Ribas, M.D., Ph.D.

Professor of Medicine, Surgery, Molecular and Medical Pharmacology

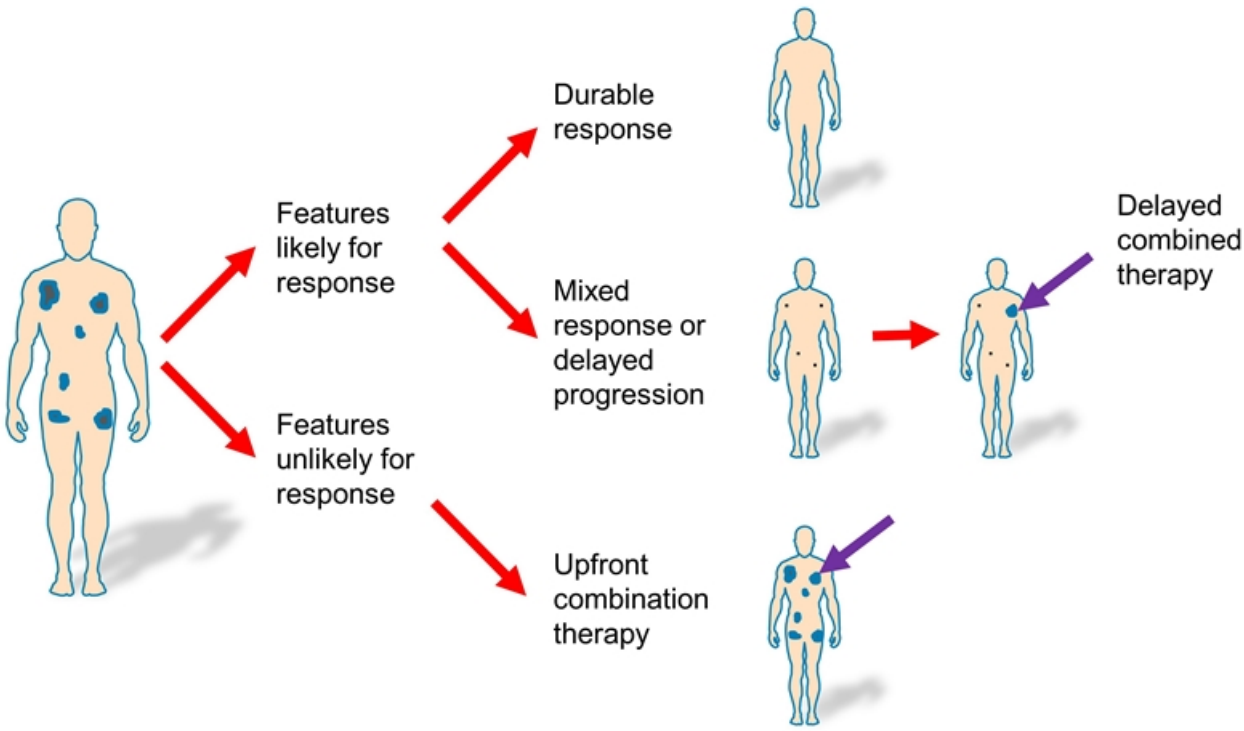
Director, Tumor Immunology Program, Jonsson Comprehensive Cancer Center (JCCC)

Director, Parker Institute for Cancer Immunotherapy (PICI) Center at UCLA

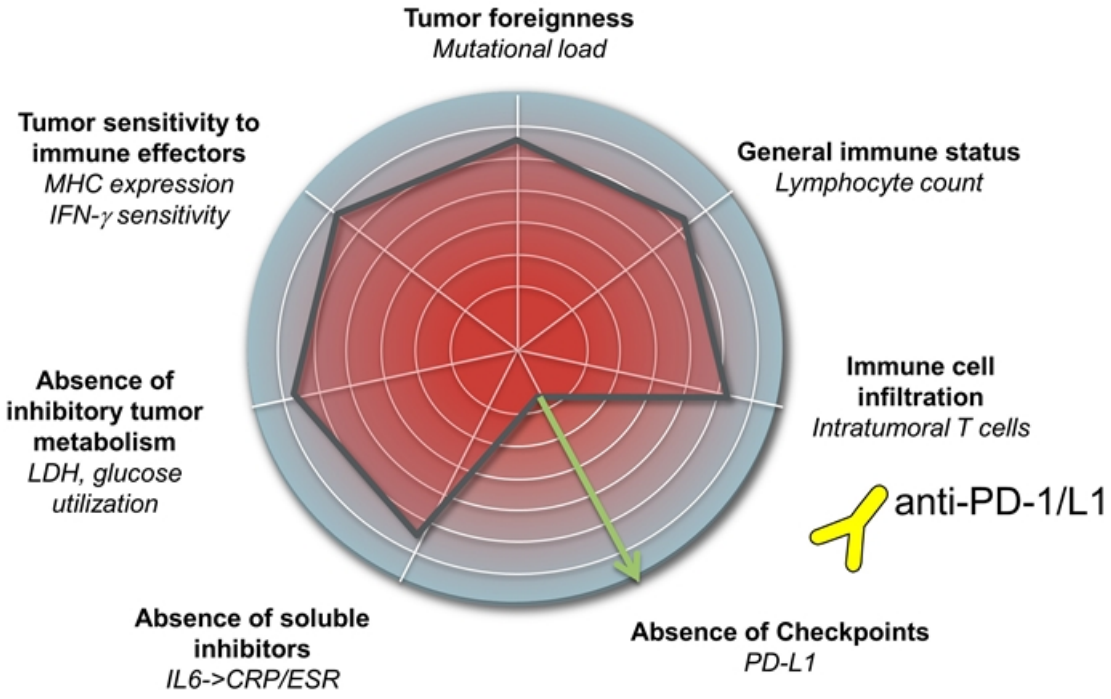
University of California Los Angeles (UCLA)

Chair, Melanoma Committee at SWOG

Management of Cancer in the Anti-PD-1/L1 Era



The Cancer Immunogram



Blank, Haanen, Ribas, Schumacher. Science 2016

Anti-PD-1/L1 Approved Indications and Suspected Mechanism of Action

Group	Indication	ORR	Agents approved*	Main driver of response
High response rate	Hodgkin's disease	87%	Nivolumab, pembrolizumab	PDJ amplicon
	Desmoplastic melanoma	70%	Nivolumab, pembrolizumab	Mutations from chronic sun exposure
	Merkel cell carcinoma	56%	Avelumab, pembrolizumab	Merkel cell virus and sun exposure
	MSI-h cancers	53%	Nivolumab, pembrolizumab	Mutations from mismatch repair deficiency

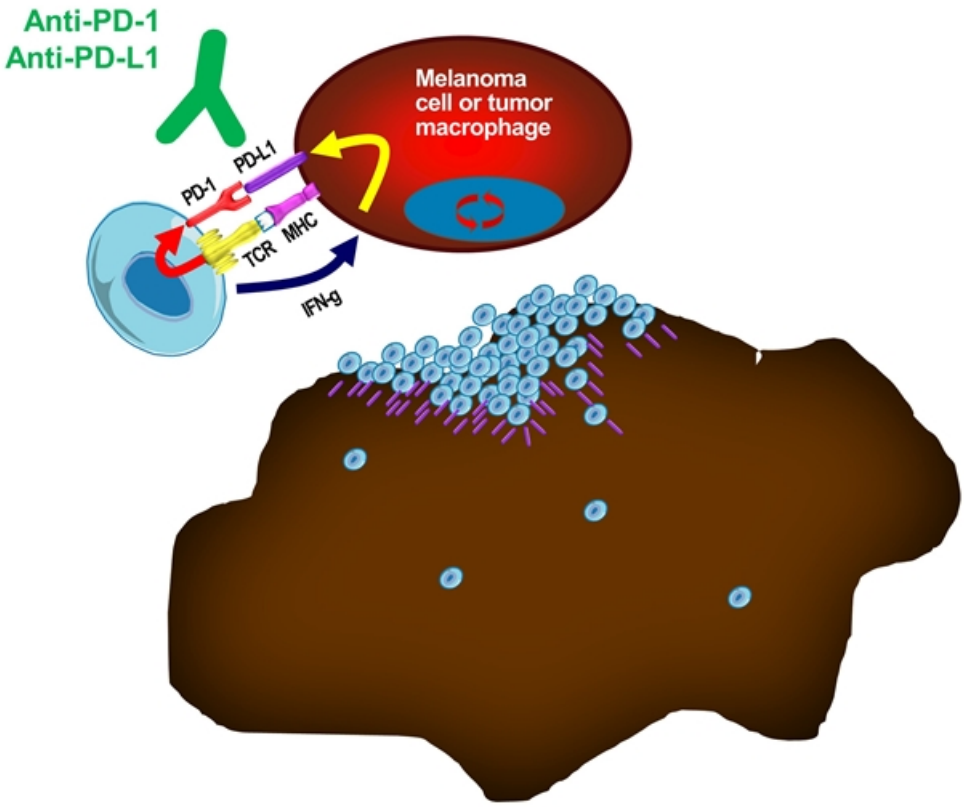
Ribas and Wolchok, Science 2018

Anti-PD-1/L1 Approved Indications and Suspected Mechanism of Action

Group	Indication	ORR	Agents approved*	Main driver of response
High response rate	Hodgkin's disease	87%	Nivolumab, pembrolizumab	PDJ amplicon
	Desmoplastic melanoma	70%	Nivolumab, pembrolizumab	Mutations from chronic sun exposure
	Merkel cell carcinoma	56%	Avelumab, pembrolizumab	Merkel cell virus and sun exposure
	MSI-h cancers	53%	Nivolumab, pembrolizumab	Mutations from mismatch repair deficiency
Intermediate response rate	Skin melanoma	35-40%	Nivolumab, pembrolizumab	Mutations from intermittent sun exposure
	Lung cancer	20%	Atezolizumab, nivolumab, pembrolizumab	Mutations from cigarette smoking
	Head and neck cancers	15%	Nivolumab, pembrolizumab	Mutations from cigarette smoking
	Gastro-esophageal cancer	15%	Pembrolizumab	Mutations from cigarette smoking
	Bladder/urinary tract cancers	15%	Atezolizumab, avelumab, durvalumab, nivolumab, pembrolizumab	Mutations from cigarette smoking
	Renal cell carcinoma	25%	Nivolumab, pembrolizumab	Insertion/deletions (indels)
	Hepatocellular carcinoma	20%	Nivolumab	Hepatitis virus

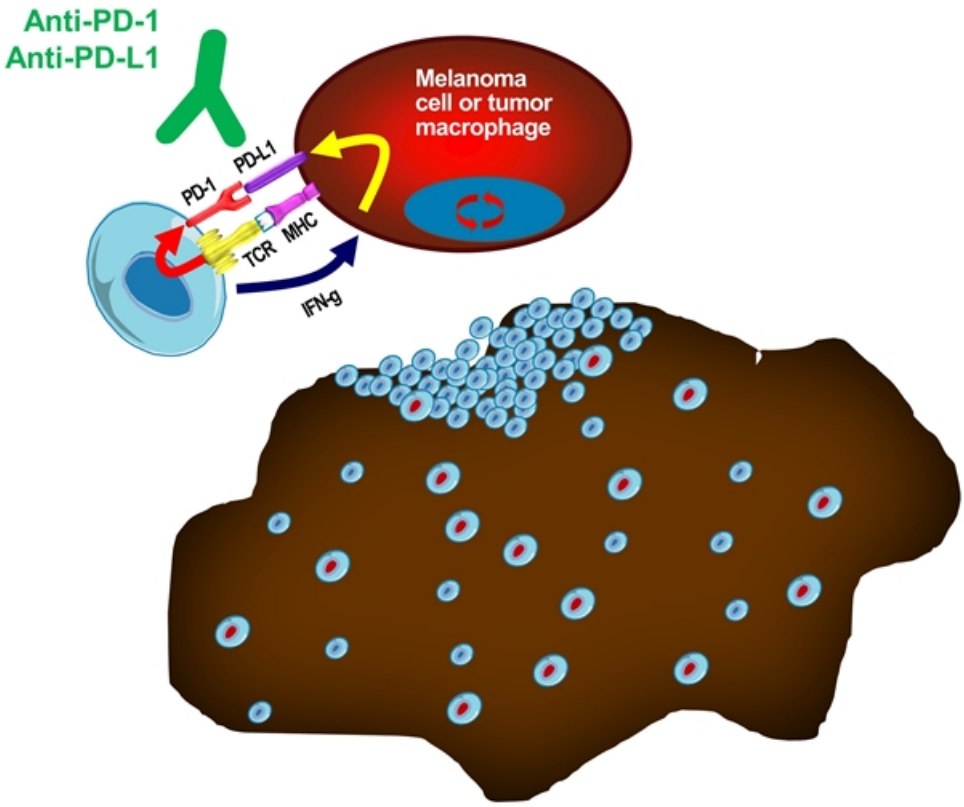
Ribas and Wolchok, Science 2018

Inhibiting PD-1-mediated Adaptive Immune Resistance



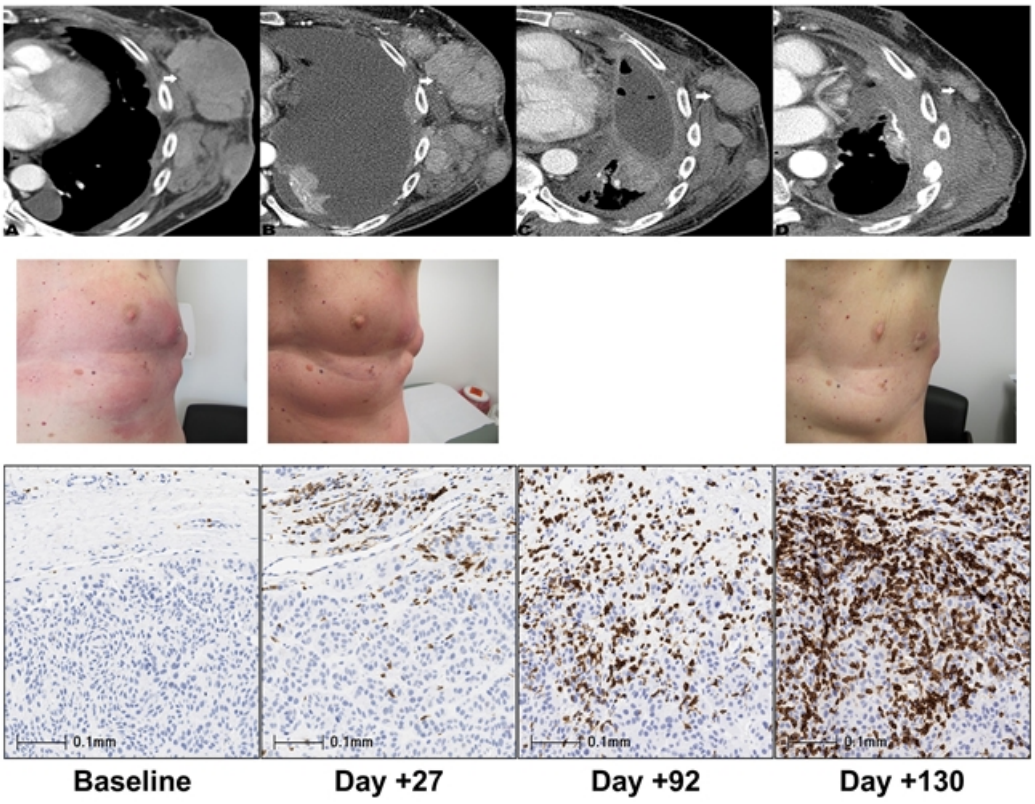
Pardoll, NRC 2012 Taube *et al.* STM 2012 Tumeh *et al.* Nature 2014

Inhibiting PD-1-mediated Adaptive Immune Resistance



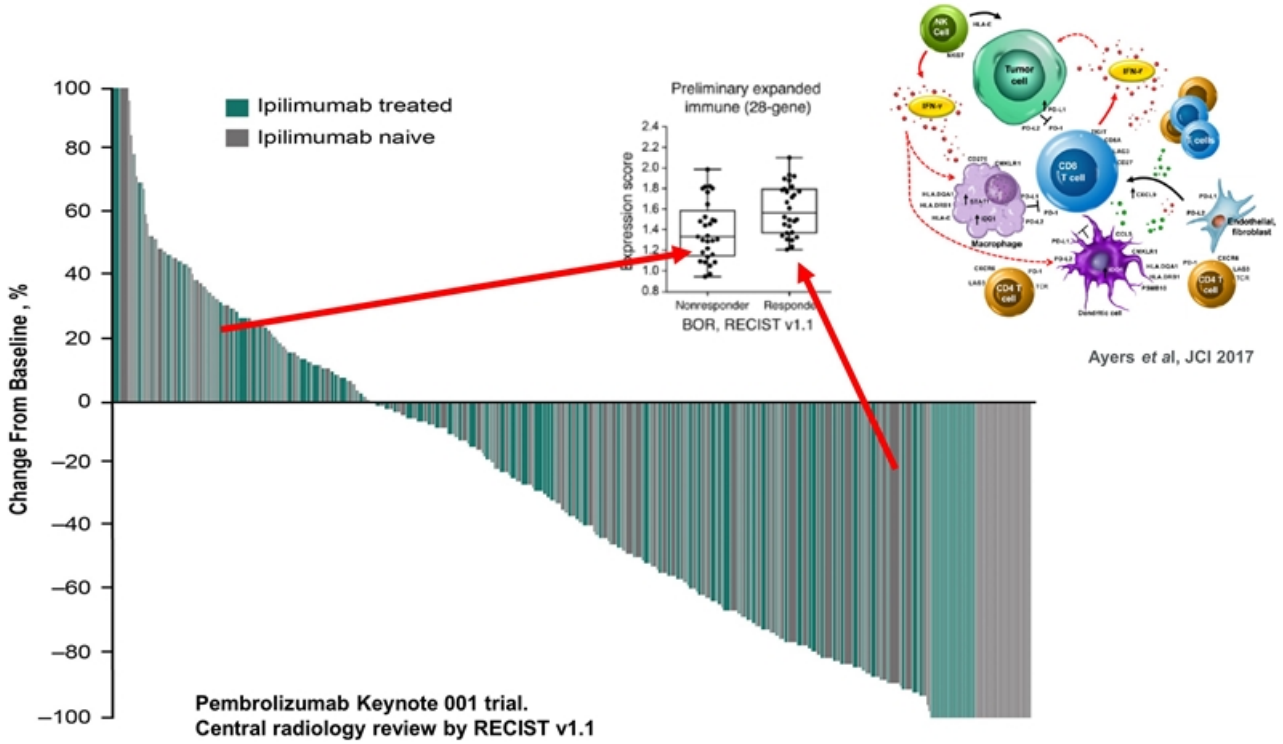
Tumeh *et al.* Nature 2014

Delayed Response to PD-1 Blockade after Transient Progression



Tumeh *et al.* Nature 2014

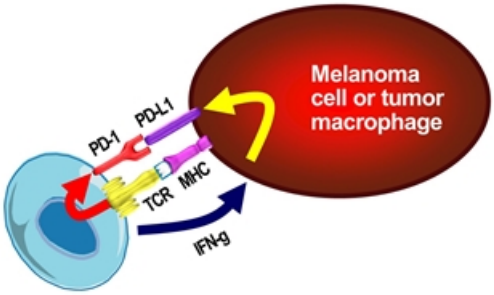
What Differentiates Anti-PD-1-responsive from Non-responding Melanomas?



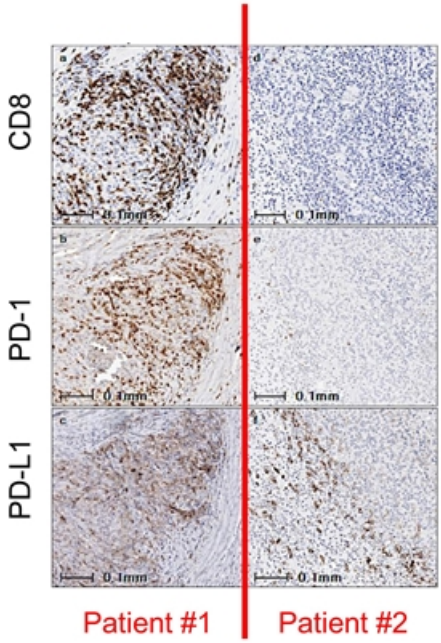
Ayers *et al*, JCI 2017

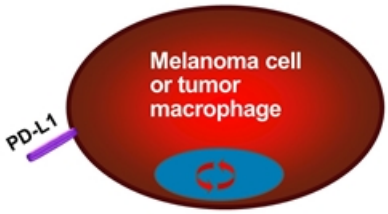
Ribas *et al.* JAMA 2016

PD-1 Blockade Induces Responses by Inhibiting Adaptive Immune Resistance



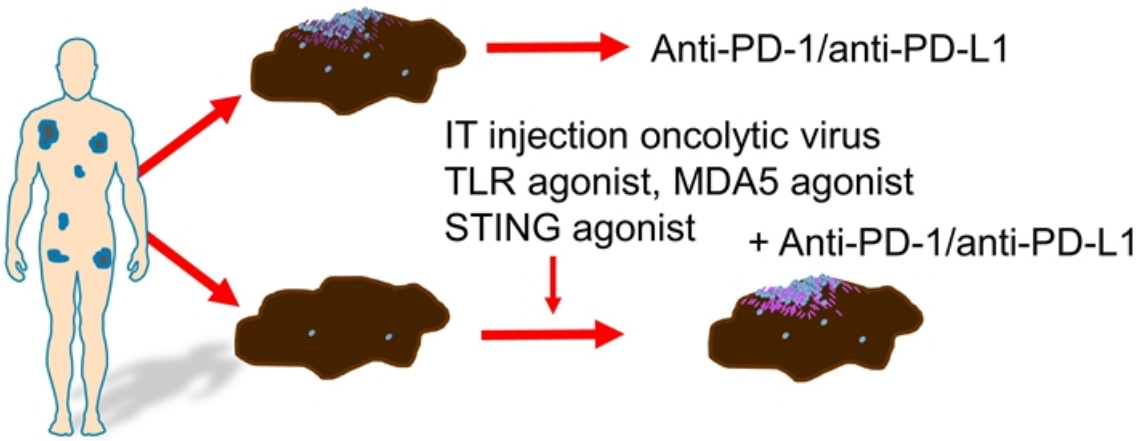
Hypothesis formulated based on quantitative IHC analyses of 46 cases from UCLA





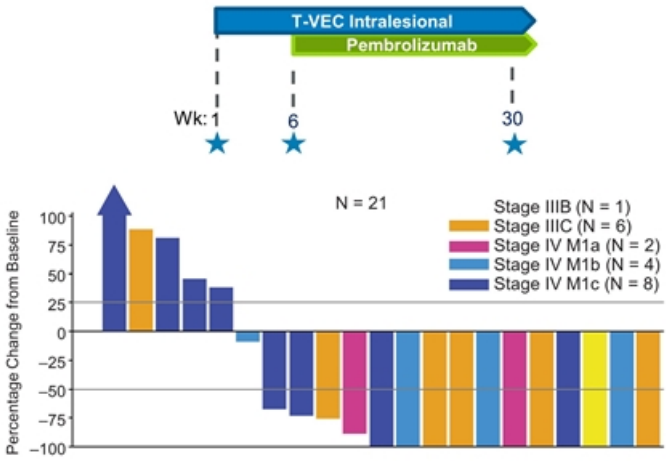
Adapted from Tumeh *et al.* Nature 2014

Reversing T Cell Exclusion with Intra-tumoral Therapies

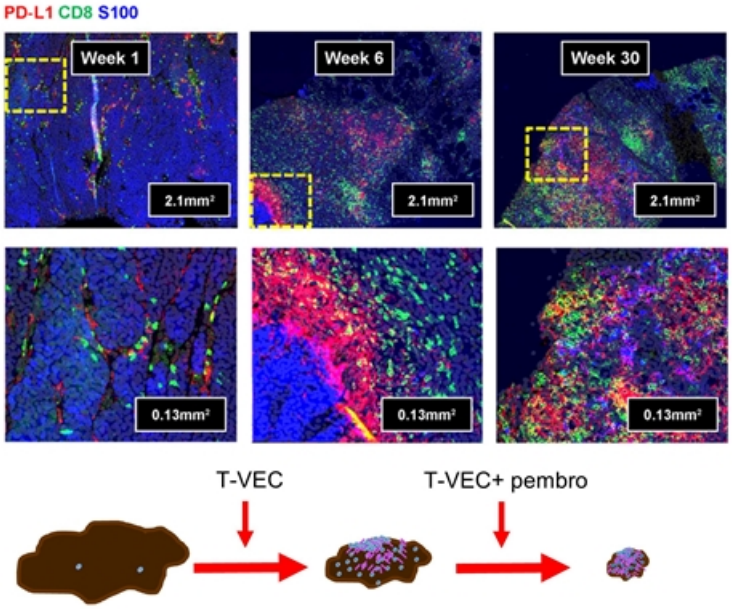


May bring rare antitumor T cells into tumors and improve responds to anti-PD-1/L1 therapy

Intra-tumoral T-VEC (oncolytic virus) Plus Systemic Pembrolizumab Induces High Response Rates by Increases in Tumor CD8 Infiltration



62% objective response rate
33% complete response rate

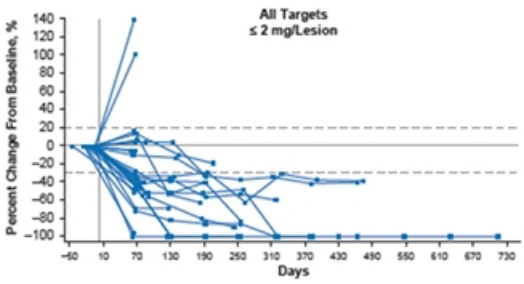


Ribas *et al.* Cell 2017 Sep 7; 170 (6): 1109-1119.e10.

Intra-tumoral TLR9 Agonists Plus Systemic Checkpoint Blockade

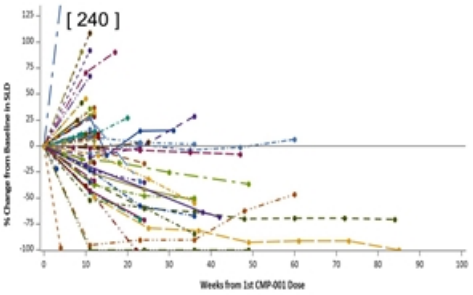
SD101 + pembrolizumab

Anti-PD-1/L1 Naïve

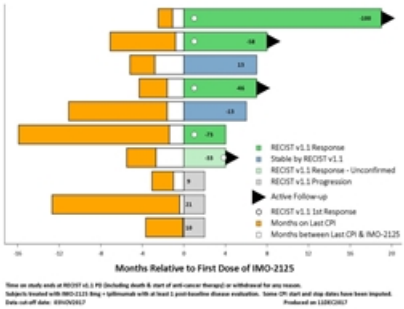


CMP-001 + pembrolizumab

Progressing on prior anti-PD-1/L1



IMO-2125 + ipilimumab



Conclusions

- Inhibiting adaptive immune resistance is the mechanistic basis of the antitumor activity of PD-1 blockade therapies
- Patients without a pre-existing tumor antigen-specific T cell infiltrate inducing reactive PD-L1 expression are unlikely to respond to PD-1 blockade therapy
- Inducing intratumoral infiltration by antigen-specific T cells is likely to potentiate the antitumor activity of PD-1 blockade therapy

DYNAVAX
INNOVATING IMMUNOLOGY

Rob Janssen, MD

SYNERGY-001 (MEL-01)

Phase 1b/2 study of the combination of SD-101 and pembrolizumab in advanced melanoma and head and neck squamous cell cancer

OBJECTIVES:

- Evaluate the safety of the combination
- Evaluate the preliminary efficacy of the combination
- Establish the dose of SD-101 for the Phase 3 trial (2 mg vs. 8 mg)

Understanding Dose Selection

Seeking balance to achieve most potent immune response

SD-101 Mechanism of Action is to stimulate the immune system to respond to specific antigens

- **Efficacy may be most informative** – Looking for "sweet-spot"/the Goldilocks dose. Not too hot, not too cold!
- **Blood PK not informative** – Primary mechanism is local in the tumor and draining lymph nodes
- **Safety may not be informative** – Benign profile may not distinguish between doses—no MTD
- **No biomarkers of CpG-mediated anti-tumor effects established** – Immune stimuli generally stimulate dose-dependent feedback mechanisms complicating interpretation of markers of stimulation

Study Design

Patients

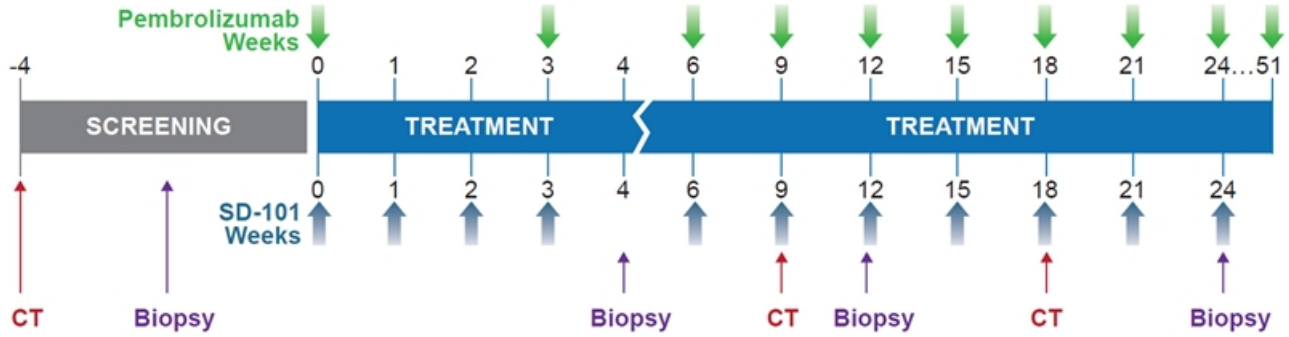
- Stage IIIc, Stage IV metastatic melanoma*
- ECOG performance status of 0 or 1
- At least one injectable site
- Response by RECIST v1.1
- Prior anti-PD-1 or anti-PD-1 naive

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 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.



*Histologically confirmed **DLT period 29 days, i.t. = intratumoral; i.v. = intravenous. 3 patients received 1 mg/lesion

Data cutoff – May 9, 2018

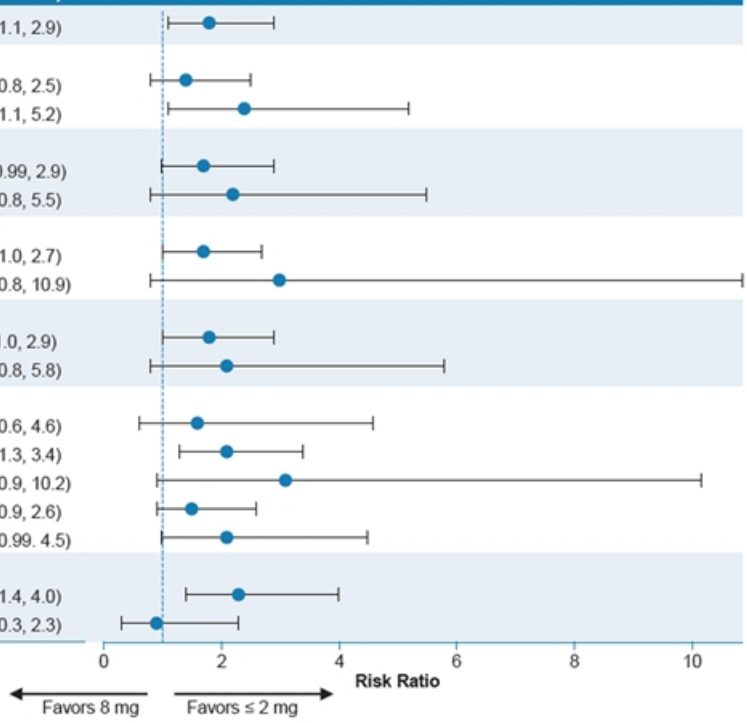
Response Rate Higher in the 2 mg Dose Group

Best ORR	≤2 mg/lesion	8 mg/lesion
mITT*	**(N=30)**	**(N = 39)**
ORR, n (%) (95% CI)	21 (70) (52, 83)	15 (38) (25, 54)
CR	5 (17)	1 (3)
PR	16 (53)	14 (36)
SD	3 (10)	10 (26)
PD	4 (13)	7 (18)
Non-evaluable†	2 (7)	7 (18)
All Enrolled Patients	(N=37)	(N=39)
Non-evaluable**	7**	0

* mITT excludes patients on study with no Day 64 scan yet. † Patients discontinued prior to first scan: ≤ 2 mg—clinical progression (n=1), irAE (n=1); 8 mg—clinical progression (n=2), AE/death (n=1); irAE (n=3), withdrew consent (n=1). ** Patients on study who have not yet had a first scan.

Subgroup Analyses Support 2 mg Dose

	≤ 2 mg		8 mg		
	N	ORR	N	ORR	RR (95% CI)
Overall	30	70%	39	39%	1.8 (1.1, 2.9)
Age, year					
< 65	12	75%	17	53%	1.4 (0.8, 2.5)
≥ 65	18	67%	22	27%	2.4 (1.1, 5.2)
Sex					
Male	21	71%	26	42%	1.7 (0.99, 2.9)
Female	9	67%	13	31%	2.2 (0.8, 5.5)
ECOG					
0	18	72%	30	43%	1.7 (1.0, 2.7)
1	12	67%	9	22%	3.0 (0.8, 10.9)
LDH					
≤ ULN	25	68%	31	39%	1.8 (1.0, 2.9)
> ULN	5	80%	8	38%	2.1 (0.8, 5.8)
Stage at screening					
IIIC	13	54%	9	33%	1.6 (0.6, 4.6)
M1a-c	17	82%	30	40%	2.1 (1.3, 3.4)
M1a	8	88%	7	29%	3.1 (0.9, 10.2)
M1b	1	100%	6	67%	1.5 (0.9, 2.6)
M1c	8	75%	17	35%	2.1 (0.99. 4.5)
Number of prior lines of therapy					
0	21	81%	29	35%	2.3 (1.4, 4.0)
1+	9	44%	10	50%	0.9 (0.3, 2.3)



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

Responses in Patients with PD-L1 Negative or Positive Tumors

- Reponses seen in patients with negative and positive PD-L1 expression at baseline
- 80% (8 out of 10) of PD-LI negative patients responded with 2mg of SD-101

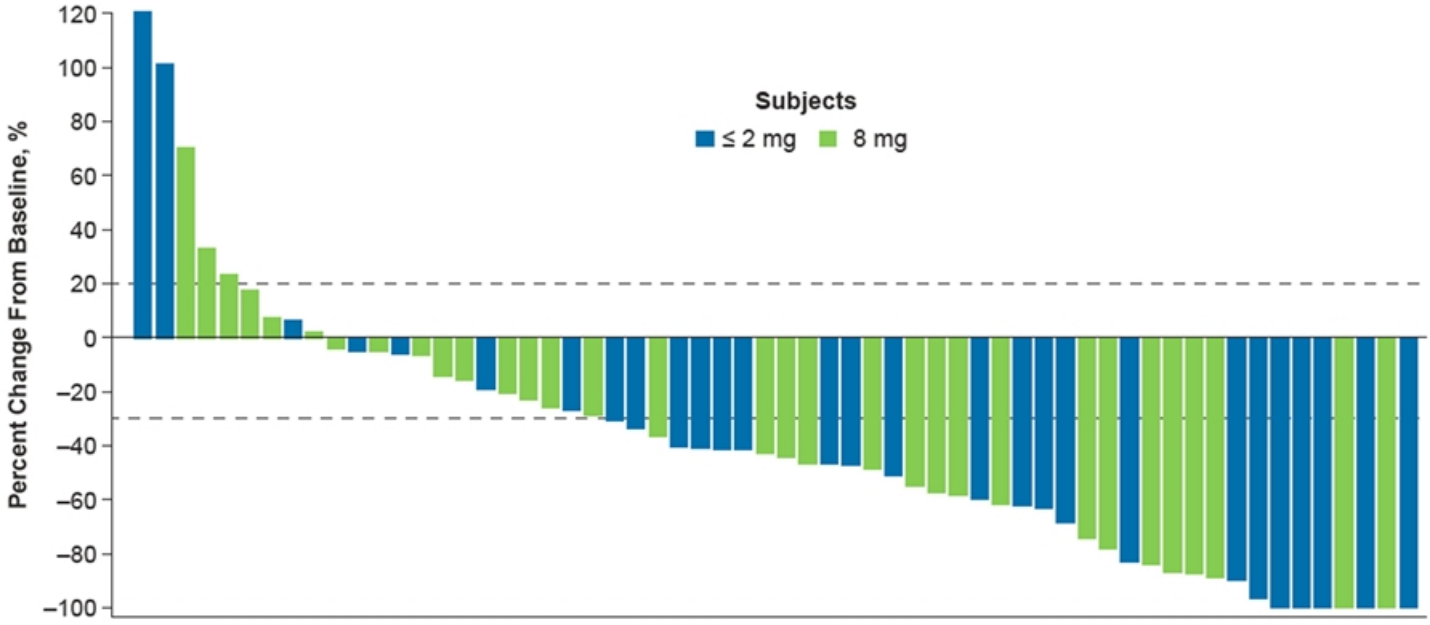
2mg

Pt ID	PD-L1 Expression (%)	BOR
101005	0	CR
305551	0	CR
102004	0	PR
110401	0	PR
101518	0	PR
115538	0	PR
305565	0	PR
108569	0	SD
101003	0	Clinical PD
110501	<1	PR
104530	1	PR
113523	3	PR
126525	3	SD
305545	3	PD
101002	30	PR
110404	30	PR
101539	50	PR
115572	80	PR

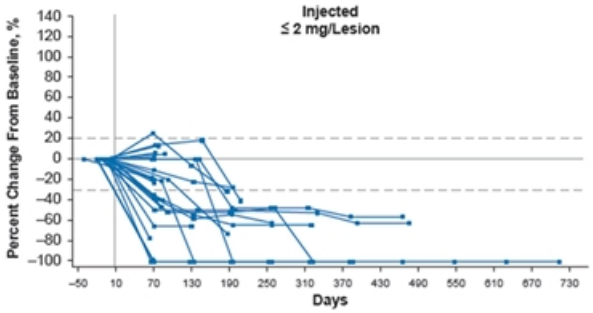
8mg

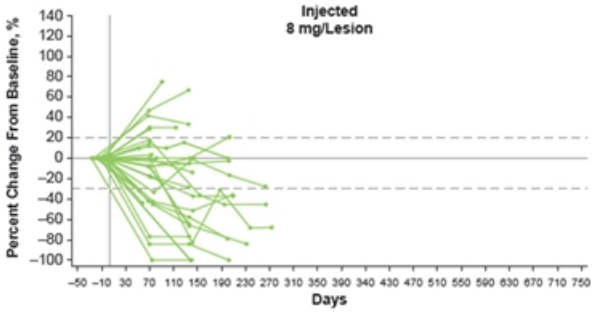
Pt ID	PD-L1 Expression (%)	BOR
110508	0	PR
101553	0	PR
105504	0	SD
112507	0	SD
123528	0	SD
110511	0	PD
133547	0	PD
140550	0	PD
110522	0	n/a
130560	0	n/a
126542	<1	PR
135519	<1	PD
123524	<1	PD
123555	1	PD
123552	2	PR
133510	5	CR
134515	10	SD
110512	25	PR
133566	30	PR
134532	30	SD
109513	30	PD
104520	80	SD
110503	90	CR
123533	90	PR

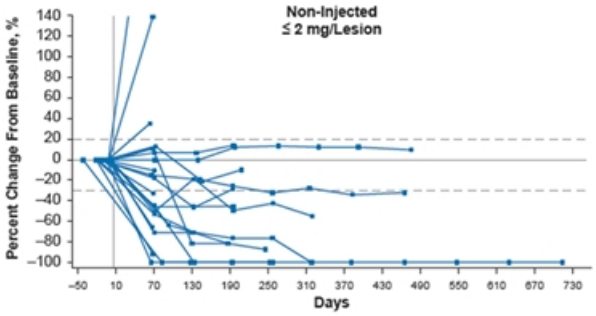
Best Percent Change in Target Lesions

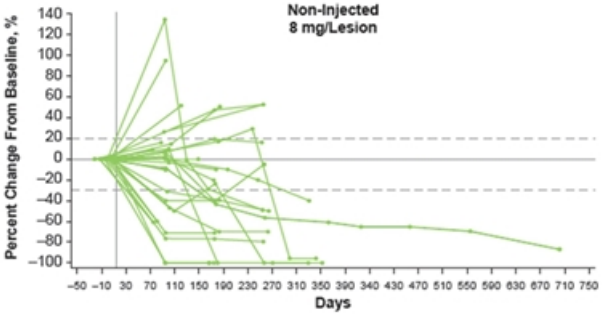


Tumor Shrinkage Seen in Injected and Non-injected Lesions



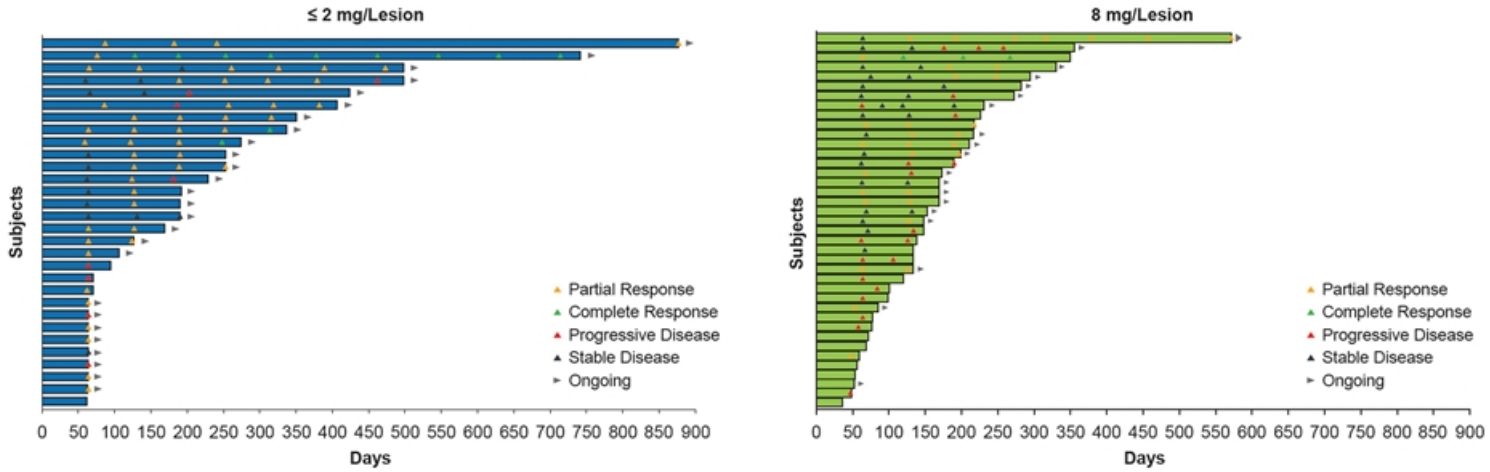






2 mg More Durable than 8 mg

Durability and Time on Study by Dose Group



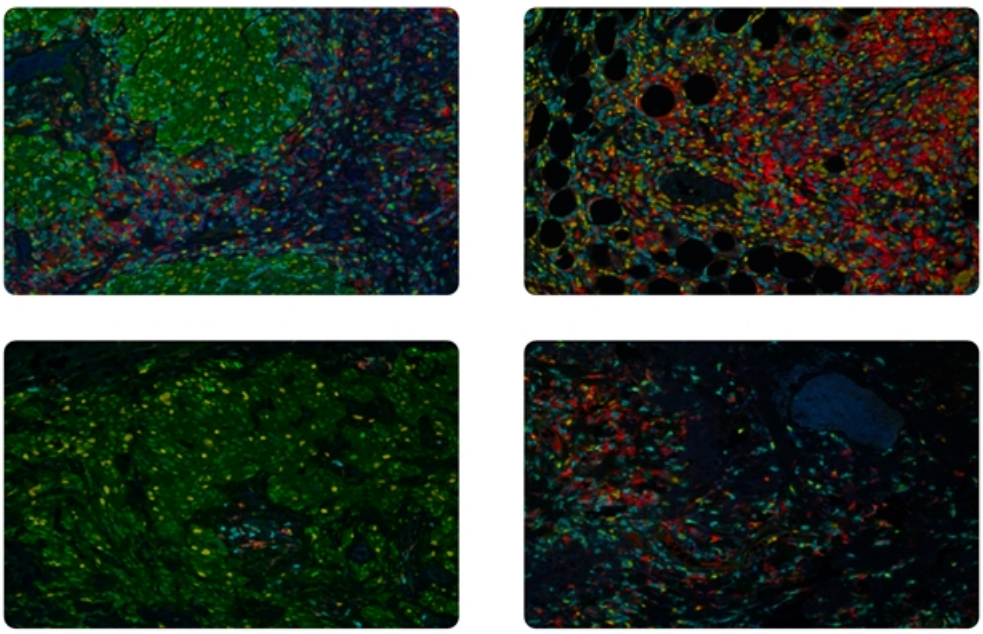
6 month PFS rate = 76%
Median PFS (months) = not reached
Median DOR (months) = 4.7+ (not reached)
Median Follow up (months) = 6.0

6 month PFS rate = 41%
Median PFS (months) = 4.2
Median DOR (months) = 2.1+ (not reached)
Median Follow up (months) = 4.9

Increase in Infiltrating CD4 and CD8 Lymphocytes in the Tumor

Supporting info:
Subject 110404
Naïve to prior anti-PD-1/L1
BOR PR
30% tumor PD-L1 expression
Still on study—Day 473

Supporting info:
Subject 110401
Naïve to prior anti-PD-1/L1
BOR PR
0% tumor PD-L1 expression
Time to progression–Day 463



Red = CD4 T cells; Cyan = CD8 T cells; Yellow = Ki67; Green = S100; Dark blue = DAPI. Subject 110404 was devoid of CD4 T cells but not CD8 T cells at screening. Subject 110401 appeared to be devoid of CD4 and CD8 T cells at screening.

Combination of SD-101 and Pembrolizumab is Well Tolerated

Event	≤2 mg/lesion (N=37)	8 mg/lesion (N = 39)	Total (N=76)
	n (%)	n (%)	n (%)
Any Treatment-related AE	28 (76)	36 (92)	64 (84)
Grade 3-4	8 (22)	14 (36)	22 (29)
Chills	3 (8)	1 (3)	4 (5)
Myalgia	6 (16)	1 (3)	7 (9)
Injection-site pain	2 (5)	0	2 (3)
Fatigue	2 (5)	4 (10)	6 (8)
Headache	3 (8)	2 (5)	5 (7)
Malaise	2 (5)	3 (8)	5 (6)
Any irAEs	6 (16)	4 (10)	10 (13)
Grade 3-4	3 (8)	2 (5)	5 (7)
AEs leading to d/c of either or both drugs	4 (11)	10 (26)	14 (18)
SAEs	9 (24)	12 (31)	21 (28)
Death	0	1 (3)	1 (1)

d/c = discontinuation; irAE = Immune-related adverse event; SAE = Serious adverse event;

Encouraging Early Data in Anti-PD-1/L1 Naïve HNSCC Patients (AACR 2018)

Response Rate	n (%)
Modified ITT*	**N=18**
Objective response rate, n (%)	**6 (33)**
95% confidence interval	**(16, 56)**
Best overall response, n (%)	
Complete response	**0**
Partial response	**6 (33)**
Stable disease	**4 (22)**
Progressive disease†	**8 (44)**
All enrolled patients	**N=22**
Not evaluable**	**4 (18)**
Time to response (days)	
Median	**64**
Min, max	**(62, 128)**

Promising ORR for hard to treat tumor type supports potential breadth of SD-101 in multiple tumor types

*Includes all patients who had a tumor assessment and patients who discontinued the study prior to a scan. Cut-off date, 27 March 2018. Among patients who had a scan, ORR = 38%. †Two patients had clinical disease progression, including one death, prior to a scan on study. **Four patients on study have not yet had a tumor assessment.

SYNERGY-001 Conclusions

Efficacy - addition of SD-101 to pembrolizumab appears to improve pembrolizumab responses

- ≤ 2 mg of SD-101 per lesion induced a higher and more durable response rate than pembrolizumab with 8 mg of SD-101
- ≤ 2 mg dose better than 8 mg dose in all disease stages
- Tumor shrinkage in injected and non-injected lesions including lung and liver
- Responses in patients with negative or positive baseline PD-L1 expression

Safety

- Transient, mild-moderate flu like symptoms
- No increase in frequency or severity of irAEs
- No treatment-related, unexpected safety event

Proceeding to Phase 3

Continue to enroll patients in Phase 2 to receive 2 mg SD-101:

- Melanoma: anti-PD-1/L1 experienced
- HNSCC: anti-PD-1/L1 naïve and experienced

Proposed Phase 3 study design:

- Randomized, double-blind, placebo controlled
  - 2 mg of SD-101 in 1 to 4 lesions
- Unresectable or metastatic melanoma in patients who have not received anti-PD-1/L1 therapy
- Endpoints
  - Primary — PFS
  - Secondary — OS, ORR, safety
- Approximately 600 patients

DYNAVAX
INNOVATING IMMUNOLOGY

Jean Chang

Evolution of Cancer Therapy Landscape

Chemotherapy	Targeted	Checkpoint IO	Combinations
Kills all rapidly dividing cells	Specific genes or proteins in cancer cells	Activate immune system against the tumor by inhibiting tumor's suppressive mechanisms	Hit multiple pathways
Toxicities	Rapid responses	Long lasting responses in multiple tumor types	Improve response rates
Response rates limited	Better tolerated	Minority of patients respond	Durable, longer lasting responses
	Responses not durable		Expand treatment options for refractory and resistant patients

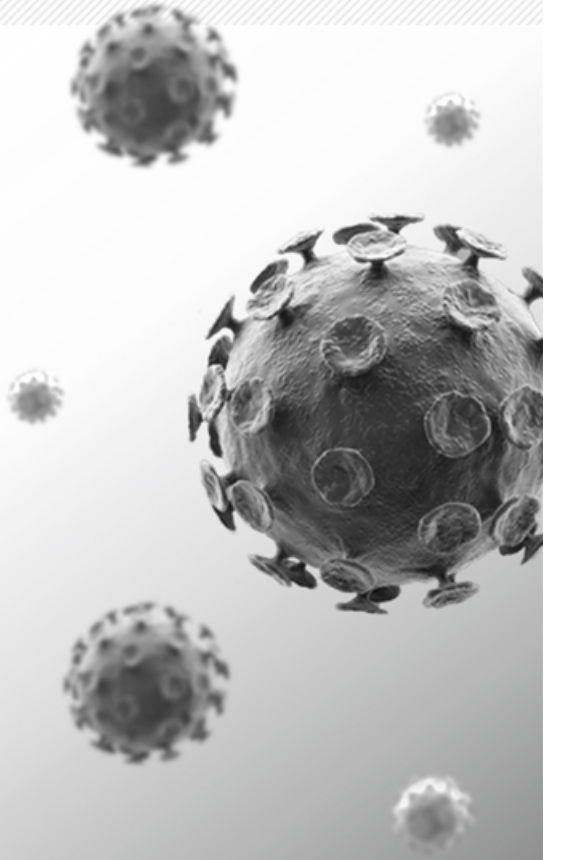
A Range of Combinations Will Emerge Over Time

Immune system is intricate

- Multiple and redundant feedback mechanisms
- Mechanisms maintain immune system balance

Patients are heterogeneous

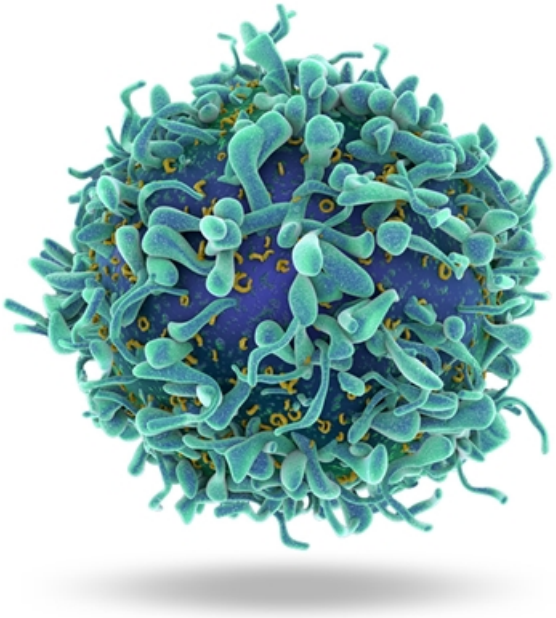
- Prior therapies
- Tumor microenvironment
- Tumor mutational burden



Four Classes of Agents Appear Particularly Well Suited to Complement PD-1 Blockade

Increasing appreciation in IO field that stimulation of innate immune system is required to optimally exploit T cell activation

- Other agents that inhibit or block a checkpoint
- Activate or expand T cells
- Agents that alter the TME
- Innate immune activators
  - TLR9 agonists SD-101, DV281



TLR9 Agonists + Anti-PD1: A Promising Combination

Characteristics of a successful combination treatment

- Robust response
- Durable disease control
- Not reliant on predictive biomarkers
- Minimal additive toxicity burden for patients

Implications

- Earlier use may maximize outcomes, e.g. neoadjuvant setting
- Basis of triplet combinations going forward
- Opportunity for other modes of local delivery
  - DV281 inhaled for lung

SD-101+ Anti-PD1: Development in Melanoma

Neoadjuvant in melanoma

Advance SD-101+ pembrolizumab combination into earlier treatment settings

Unresectable or metastatic melanoma naïve population

Phase 3 SD-101 + pembrolizumab

Unresectable or metastatic melanoma refractory/resistant to anti-PD-1

Phase 2 SD-101+pembrolizumab

Establish SD-101 + pembrolizumab as core combination

SD-101 + Anti-PD1: Leveraging Shift in Melanoma Treatment towards Neoadjuvant Setting

- **Checkpoint blockade, anti-PD1 in particular, is moving into the neoadjuvant setting (earlier is better)**
  - Pembrolizumab is showing early efficacy
- **SD-101 fits well within this shift**
  - TLR9 agonists can improve responses to PD-1 blockade; opportunity to expand upon this
  - Intratumoral injection leverages primary tumor as an antigen source for expansion and activation of T cells; SD-101 orchestrates and primes T cell response
- **Potential benefits**
  - Greater fitness of host immunity
  - Significantly higher proportion of patients amenable to intratumoral injection

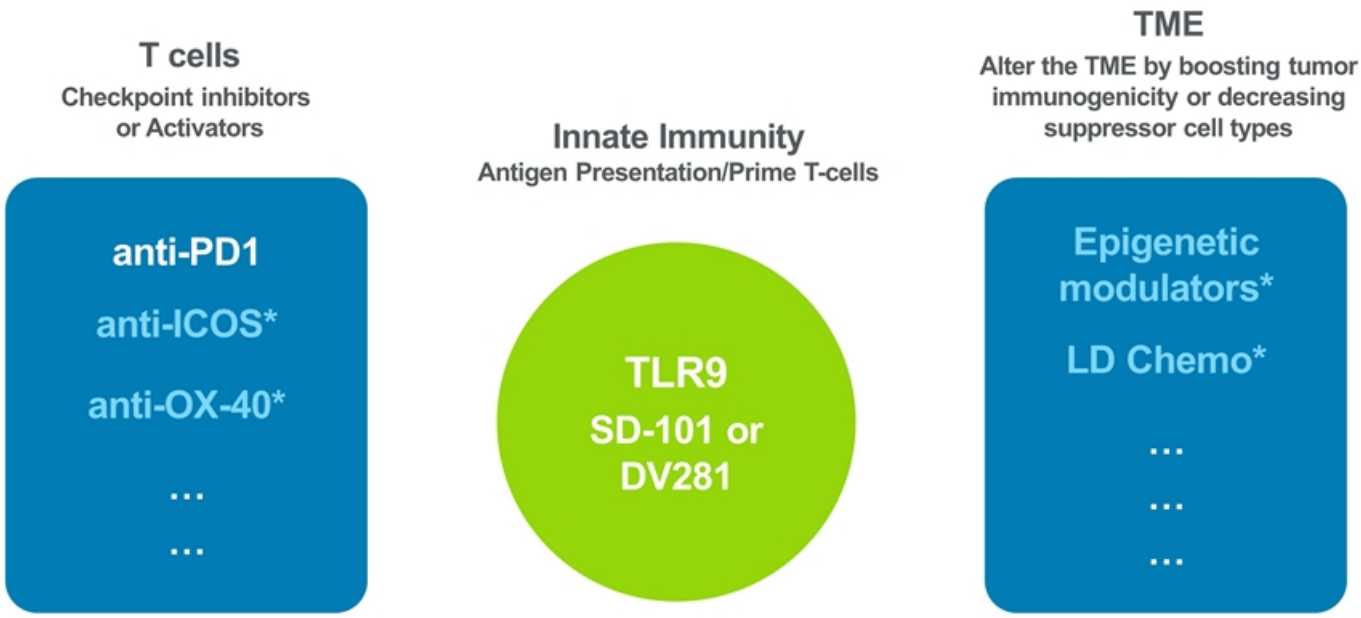
TLR9 Agonists + Anti-PD1: Application to Additional Indications in Neoadjuvant Setting

Criteria for cancer selection

- Stage at diagnosis
- Amenable to series of injections or inhalation
- Evidence of anti-PD1 activity
- Potential to raise the bar for outcomes
  - Clinical response
  - Pathologic complete/major response

Breast cancer SD-101
Lung cancer DV281

Building on the Strength of Dynavax's SD-101 + Pembrolizumab Data: Strong Basis for Additional Combinations



SD-101 + pembrolizumab + X

SD-101/DV281 + X

* Tested pre-clinically for synergistic effect

Dynavax TLR9 Agonists Fill Gap in Pharma Combination Therapy Pipelines

- Pharmaceutical companies continue to build combination optionality across multiple mechanisms
- Considerable opportunity exists within our class of agents
- Dynavax clinical programs can fill Pharma's pipeline gap, creating opportunities for pre-clinical/clinical collaborations and partnerships

Clinical Stage Immuno-Oncology Assets	NVS	AZN	BMS	ROC	CELG	JNJ	MRK	PFE	AMG	GSK	MRK KGaA	SNY	LLY	TAK	BAY	ABV
Checkpoint	II	III	M	M	III†	I	M	III		I	III	II	I			I
Costim	II	I/II	II	I			I	II		I						
Oncolytic virus		I							M							
Cancer vaccine		I/II	III		II	II	I	I		III		M				
Other Cell Therapy	II				I			I**			I					
CAR-T Cells	II				II			I								
Innate Immunity	I	I					I									
Cytokine	M		II	M		M	M				M	M	II	M		
Other IO	I	I	II	I		I			M			I	I	M		

NVS, Novartis; AZN, AstraZeneca/MedImmune; BMS, Bristol-Myers Squibb; ROC, Roche/Genentech; CELG, Celgene; JNJ, Johnson & Johnson; MRK, Merck & Co; PFE, Pfizer; AMG, Amgen; GSK, GlaxoSmithKline; MRK KGaA, Merck KGaA; SNY, Sanofi/Regeneron; LLY, Eli Lilly; TAK, Takeda; BAY, Bayer; ABV, Abbvie

Use Partnering to Make TLR9 Agonists Broadly Available and Integral to Combination Therapy

Goals for collaborations and partnerships

- Maximize breadth across tumor types
- Maximize combination use
  - Doublets or triplets with anti-PD1 treatments
  - Doublets with other T cell agonists, particularly in tumors not responsive to anti-PD1
  - Triplets with T cell agonists and TME targeting agents

Dynavax: Developing TLR-mediated Immune Stimulation in Multiple Cancer Applications

	Discovery	Phase 1	Phase 2/3
TLR9 agonists in combination with anti-PD1 or other	• Pre-clinical assessment of novel combinations • Cancer Vaccine • DV230 Ficoll for liver indications	• NSCLC • Neoadjuvant NSCLC • Lung mets	**Phase 3** • MEL naive **Phase 2** • MEL anti-PD1 refractory/resistant • HNSCC tx-naïve • HNSCC anti-PD1 refractory/resistant • Breast cancer neoadjuvant • MEL neoadjuvant
TLR7/8 agonists	Multiple agonists and delivery strategies in preclinical development		**SD-101 i.t.** **DV281 inhaled**

DYNAVAX
INNOVATING IMMUNOLOGY

Eddie Gray

Concluding Remarks

- **TLR9 agonist technology** has demonstrated encouraging potential in immuno-oncology as a combination agent
- **Growing immuno-oncology database** validates our ongoing studies and expansion of our program
- Positioning ourselves to take advantage of **anti-PD-1 therapy shift** into neoadjuvant setting
- **Upcoming catalysts in 2H18** consist of new data in melanoma and HNSCC, safety data in DV281 (lung), and initiation of Phase 3 in advanced melanoma
- **Business development efforts** focused on partnerships/collaborations to maximize use of SD-101 in tumor types and in combinations