

Heating Up Cancer Immunotherapy

August 2021



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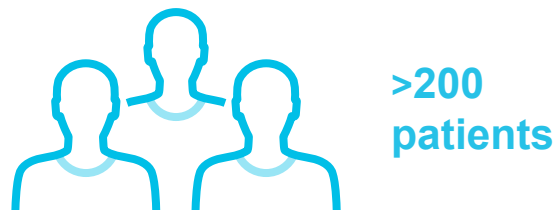
Investment Highlights

Differentiated Therapeutic



- Vidutolimod (CMP-001) is an innate immune modulator with the potential to become a backbone of I/O combinations

Extensive and Consistent Clinical Data



- 28% ORR in PD-1 refractory melanoma¹
- 70% pathologic response in PD-1 naïve neoadjuvant melanoma and 90% RFS at 1 year²
- 17.5% ORR in PD-1 refractory melanoma as monotherapy³

Robust Development Strategy



- Targeting approval in front line metastatic and PD-1 refractory melanoma
- Fast Track and Orphan Drug Designation
- Pursuing head & neck and non-melanoma skin cancers

Multiple Value Driving Catalysts



- Melanoma topline data anticipated late 2022/1H 2023
- Head & neck cancer Ph2 data maturing throughout 2022
- Non-melanoma skin cancer interim Ph2 data 2H 2022

¹ CMP-001 plus pembrolizumab, data cutoff September 30, 2020 (includes post-progression responders); N=98

² Davar, SITC 2020, data cutoff October 1, 2020

³ CMP-001 monotherapy, data cutoff September 30, 2020; N=40

Potential to Extend the Benefits of Cancer Immunotherapy to More Patients



Problem

- Checkpoint inhibitors have revolutionized cancer immunotherapy
- PD-1 checkpoint inhibitors
 - Very effective, when they work
 - Generated >\$20B in WW sales in 2020¹

Unfortunately, effect is largely limited to patients with active T-cell response (“hot tumors”)



Solution

Vidutolimod has the potential to turn “cold tumors” hot

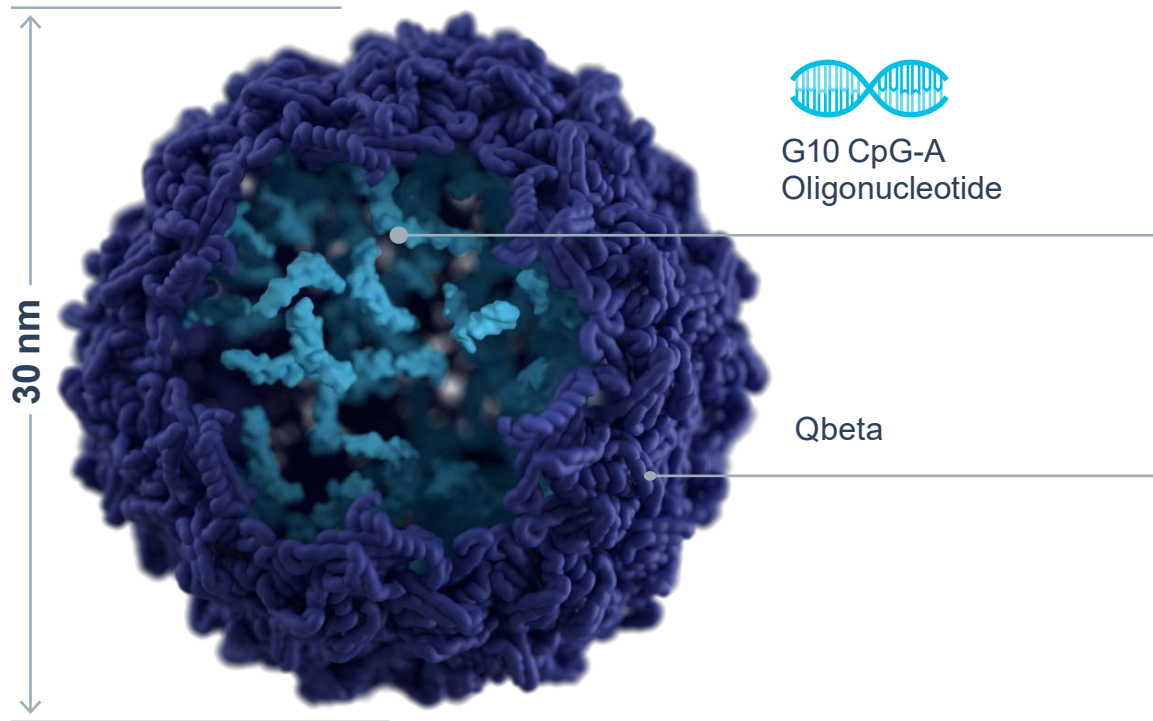
Induced significantly higher levels of type I interferons than other innate immune modulators, potentially leading to a stronger anti-tumor T cell response^{2,3}

¹Source: Evaluate Pharma

²Ribas, A., et al., Cancer Discovery, 2021

³Lemke-Miltner, C.D., et al., J Immunol, 2020. 204 (5): 1386-1394

Vidutolimod (CMP-001) can activate a T cell response



Potent Type A CpG DNA payload (G10)

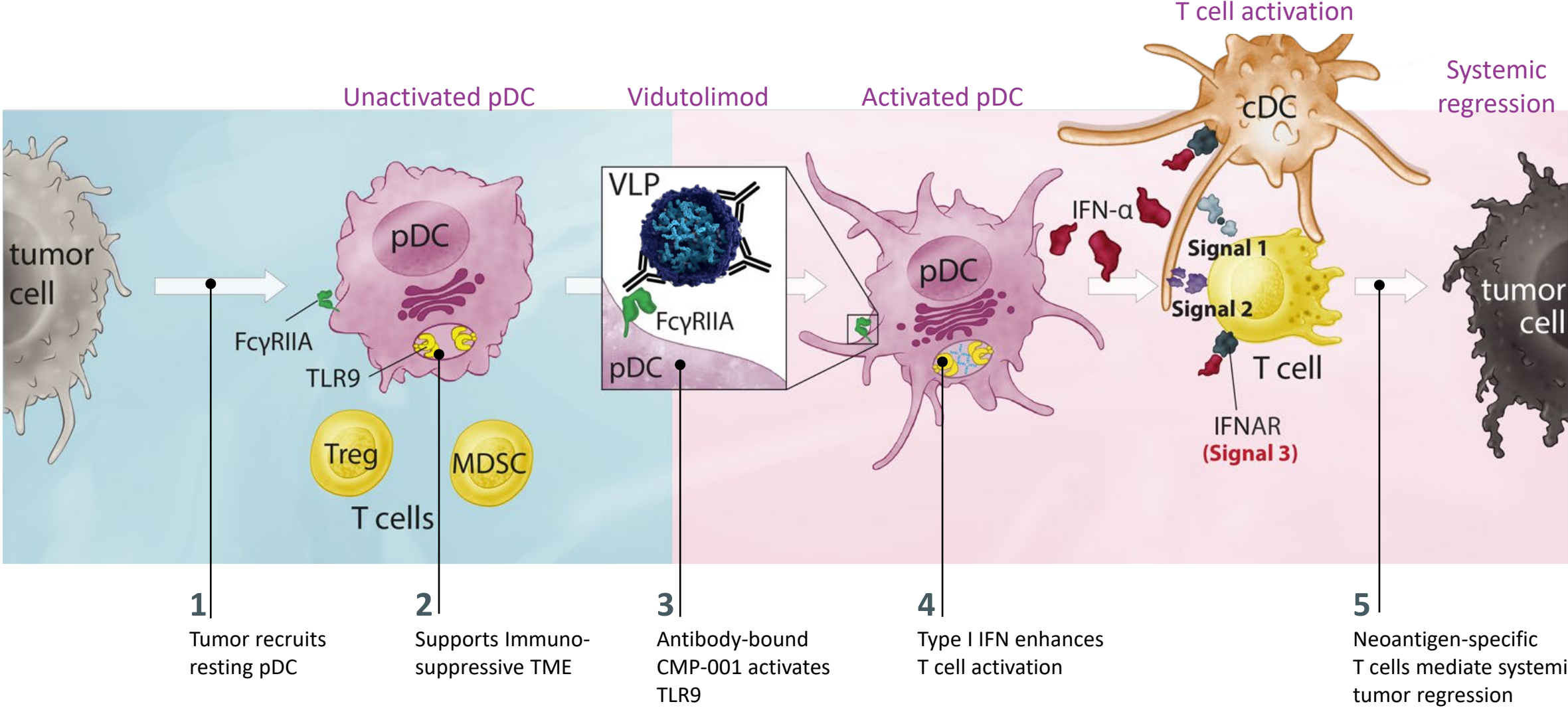
- Mimics viral, retroviral DNAs
- Synthesized on native phosphodiester backbone
- Most potent inducer of type I IFN known, drives T cell immune response

Immune stimulating virus-like particle (VLP)

- Stimulates an immune response that causes immune cells to take up the VLP
- *The VLP is not infectious*
- VLP potentiates the systemic activity of G10

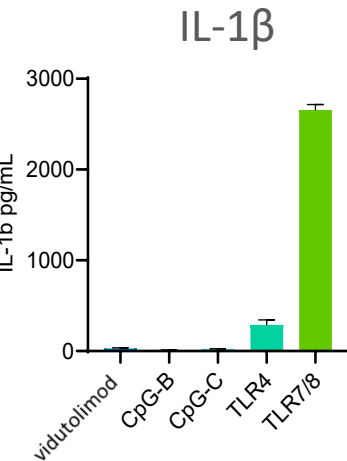
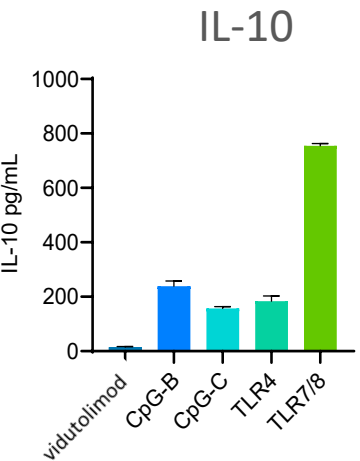
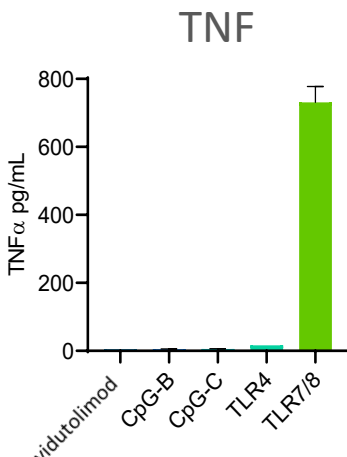
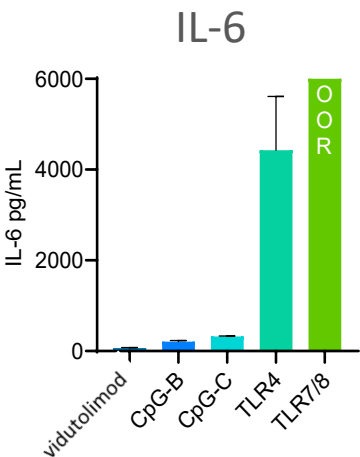
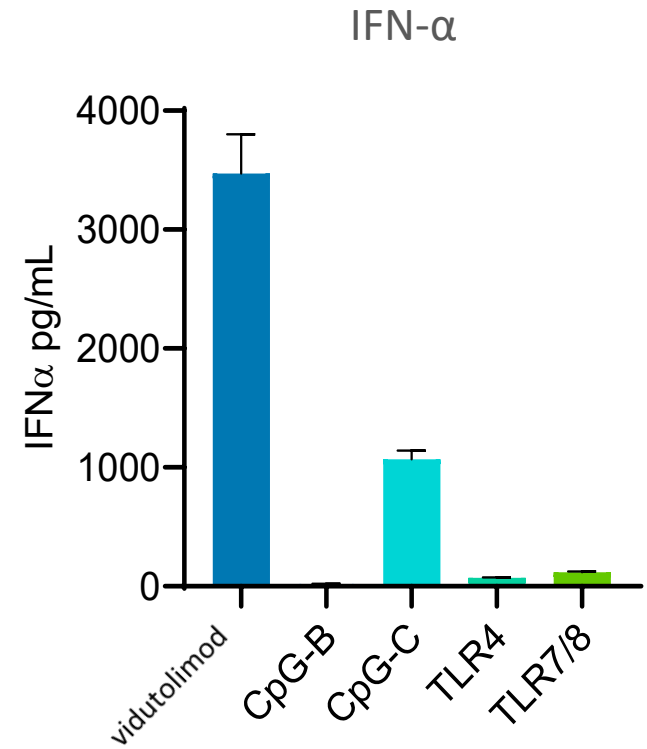
Biologic with potential for **12 years**
exclusivity in US (if approved)¹

Vidutolimod can stimulate a powerful systemic T cell response against a tumor






TME: tumor microenvironment, Treg: regulatory T cell, MDSC: myeloid derived suppressor cells







CPG-A Induces the Highest Type I IFN, and Lowest Inflammatory Cytokine



Luminex cytokine/chemokine multiplex of supernatants from normal human PBMC, performed using optimal conditions and concentrations for each agent at the University of Iowa Cancer Center

Maturing and Expanding Set of Target Indications

-  Previously Reported
-  Currently Enrolling
-  Planned

Indication		Preclinical	Phase 1	Phase 2	Phase 3	Sponsor/Collaborator
MELANOMA	PD-1 Refractory	vidutolimod + pembrolizumab (P1b)		vidutolimod + nivo*		
		vidutolimod Monotherapy (P1b)				
	First-line			vidutolimod + nivo*		
	Neoadjuvant	vidutolimod + nivolumab (P2)				
HNSCC	First-line			vidutolimod + pembro		
NON-MELANOMA SKIN	First-line CSCC			vidutolimod + cemiplimab**		 
	PD-1 Refractory CSCC			vidutolimod + cemiplimab**		
	PD-1 Refractory MCC			vidutolimod + cemiplimab**		

Note: Refractory Melanoma represents Anti PD-1 Refractory Melanoma, 1L Melanoma represents Anti PD-1 Naïve, Metastatic or Unresectable Melanoma, Neoadjuvant Melanoma represents Anti PD-1 Naïve, Neoadjuvant Melanoma, and First Line HNSCC represents Anti PD-1 Naïve, Head and Neck.

* Under clinical trial collaboration & supply agreement with BMS for the supply of Opdivo – full commercial rights retained by Checkmate

** Under clinical trial collaboration & supply agreement with Regeneron for the supply of Libtayo – full commercial rights retained by Checkmate

Large and Growing Market Opportunity in Melanoma

US Market¹

High unmet need in melanoma with continued expected growth

~1.2 M

people living with
melanoma of the skin

5th

most common
cancer in the US

106,110

new diagnoses
per year

7,180

deaths per year

Standard of care

Anti PD-1 (pembrolizumab or nivolumab)



Opportunity

Significant room for improvement vs. single agent anti PD-1 in front-line melanoma

Single agent front-line anti PD-1

34-40% ORR³

No approved therapy for patients who have progressed on anti PD-1 therapy

¹American Cancer Society

²Worldwide sales; EvaluatePharma

³Keytruda & Opdivo USPI

Phase 1b Study in PD-1 Refractory Melanoma

Key elements of study design

1. Evaluate vidutolimod +/- pembrolizumab

CMP-001 + pembrolizumab (N=159)

CMP-001 monotherapy (N=40)



2. Evaluate two schedules:

 **weekly 7 weeks**  **q3 weeks**

 **weekly 2 weeks**  **q3 weeks**



3. Evaluate two formulations:

→ Formulation A (N=98)

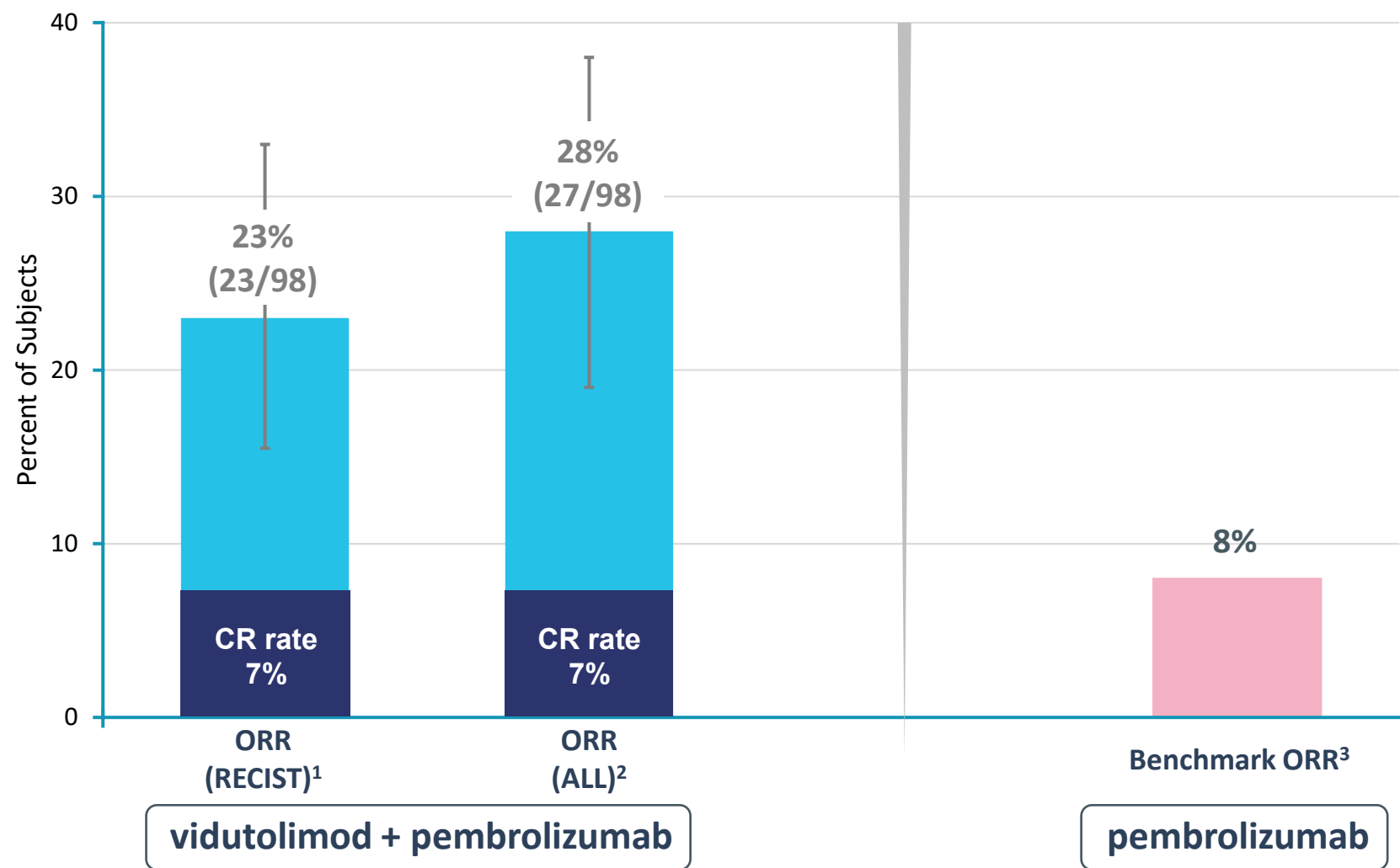
→ Formulation B (N=61)



Baseline patient characteristics (N =159) %

Prior cancer therapies	Any PD-1	100%
	Any ipilimumab	47%
Prior PD-1 best response	CR (complete response)	4%
	PR (partial response)	13%
	SD (stable disease)	31%
	PD (progressive disease)	43%
Prior PD-1 last response	SD (stable disease)	3%
	PD (progressive disease)	93%
Baseline disease locations	Skin only	8%
	Lymph nodes ± skin	19%
	Soft tissue ± skin & lymph nodes	13%
	Bone w/o visceral disease	4%
	Any visceral	55%
LDH	High	42%
ECOG status	0	65%
	1	35%

Clinically Meaningful Response in Refractory Patient Population

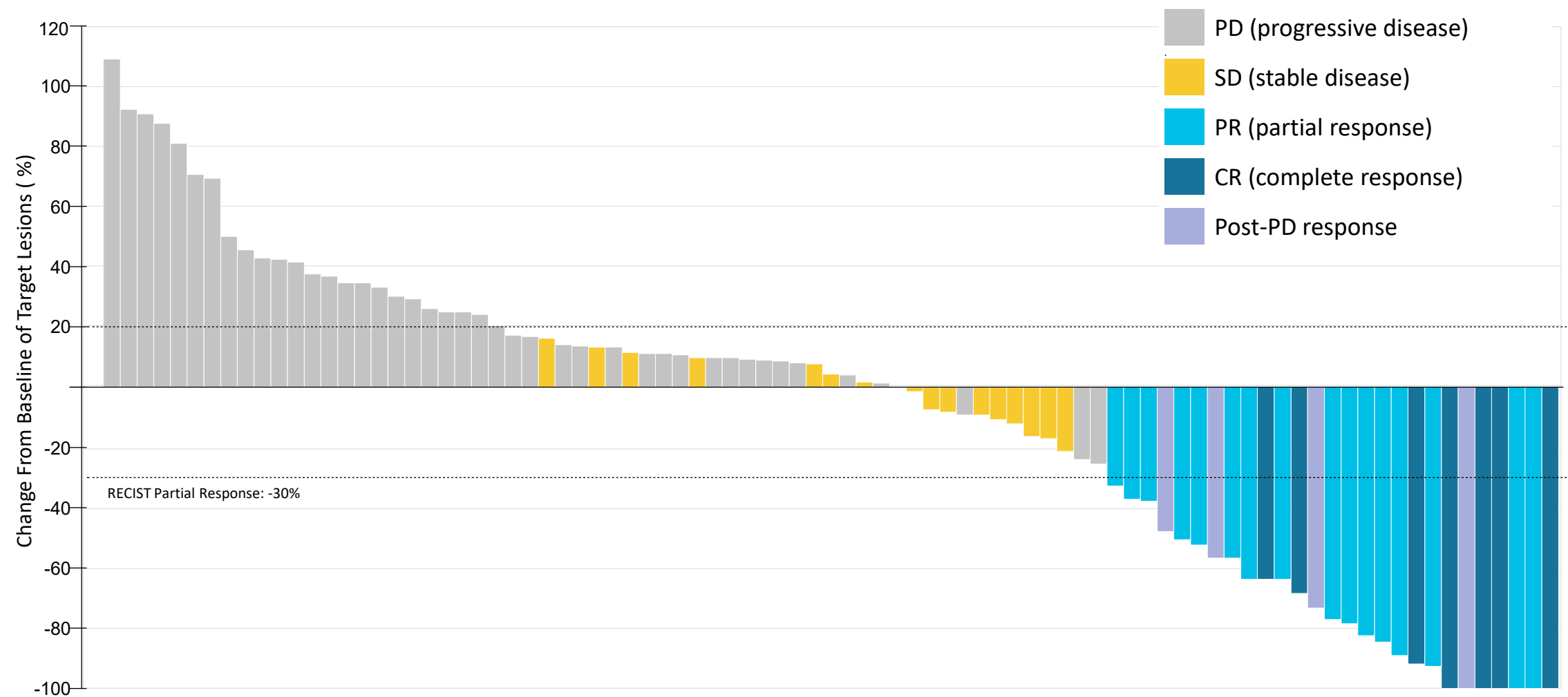


¹RECISTv1.1, Data cutoff September 30, 2020

²RECISTv1.1 plus post-progression responses, Data cutoff September 30, 2020

³Response to treatment beyond progression with anti-PD-1. Ahmed, F.S., et al., Eur Radiol, 2020; 6/78 iPR/iCR after initial PD by RECISTv1.1

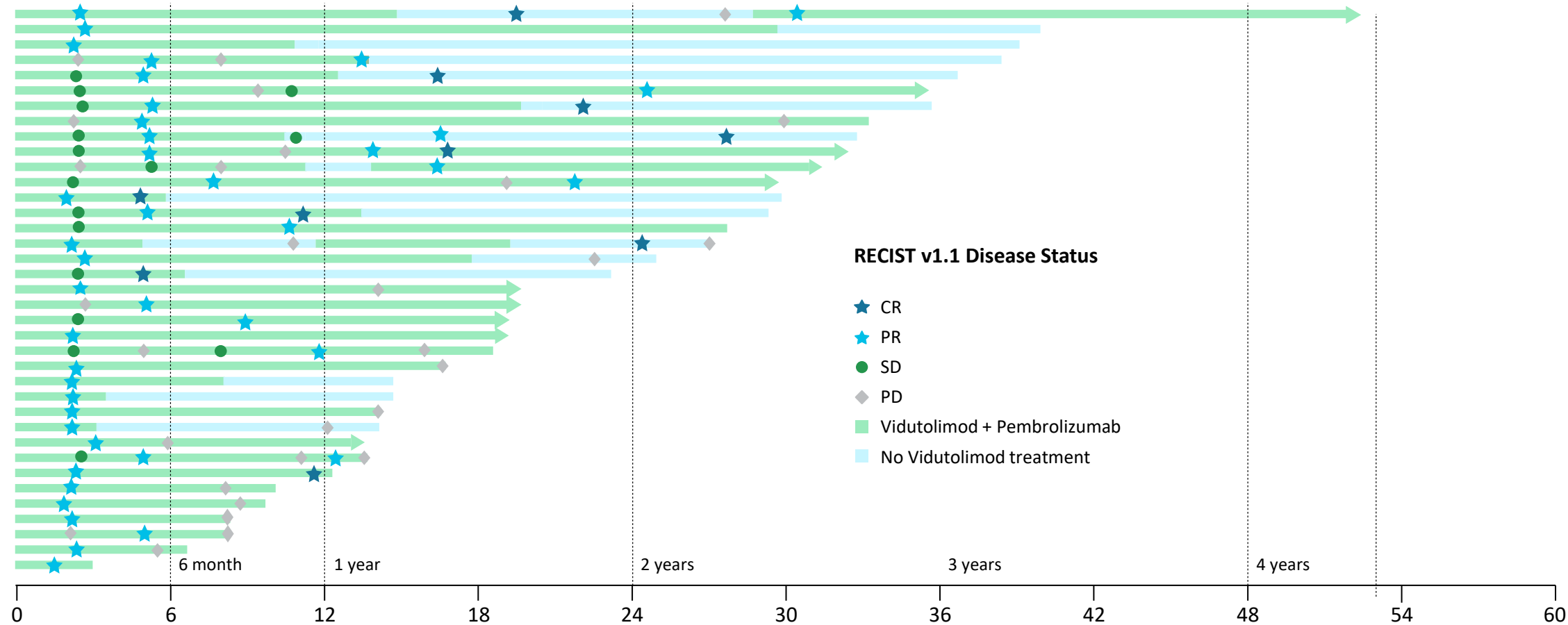
Robust Depth of Response



Note: N=98 subjects who received formulation A, includes all patients with follow-up assessments. Data cutoff September 30, 2020

Highly Durable Responses

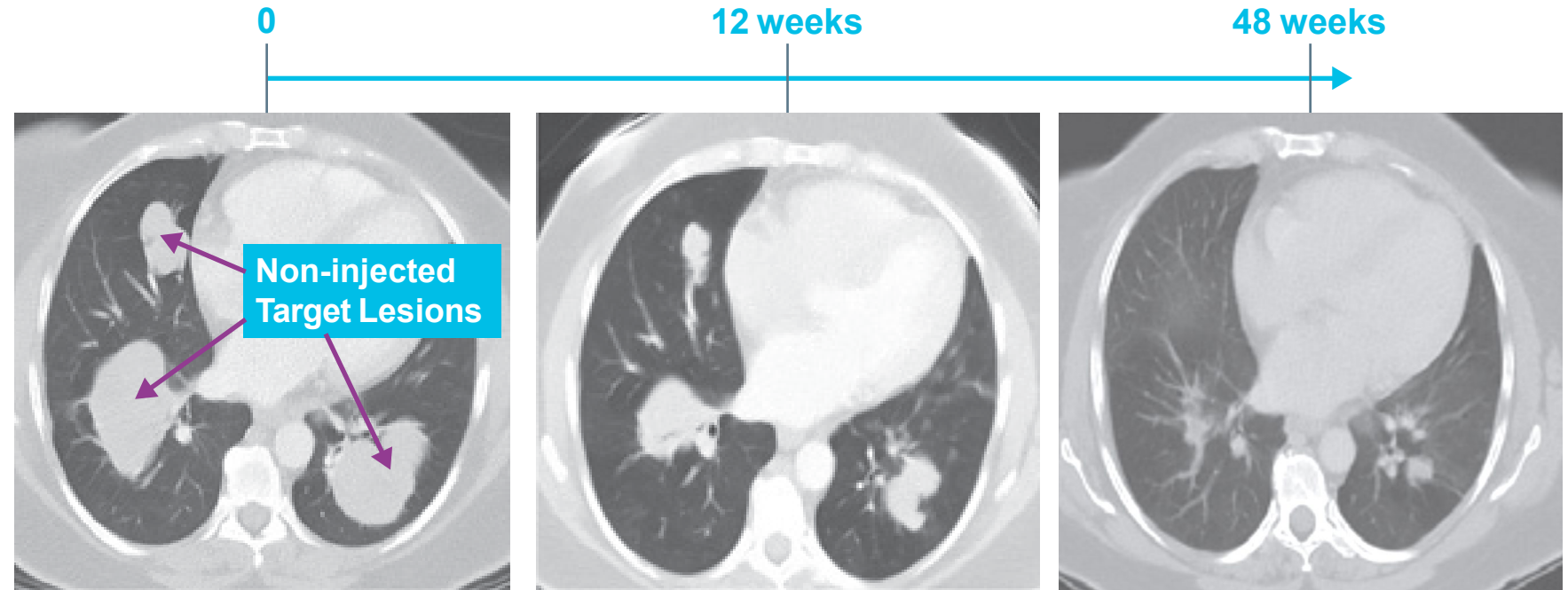
Median duration of response 19.9 months



Note: N=37, RECIST v1.1 responders and Post-progression responders; Data cutoff September 30, 2020

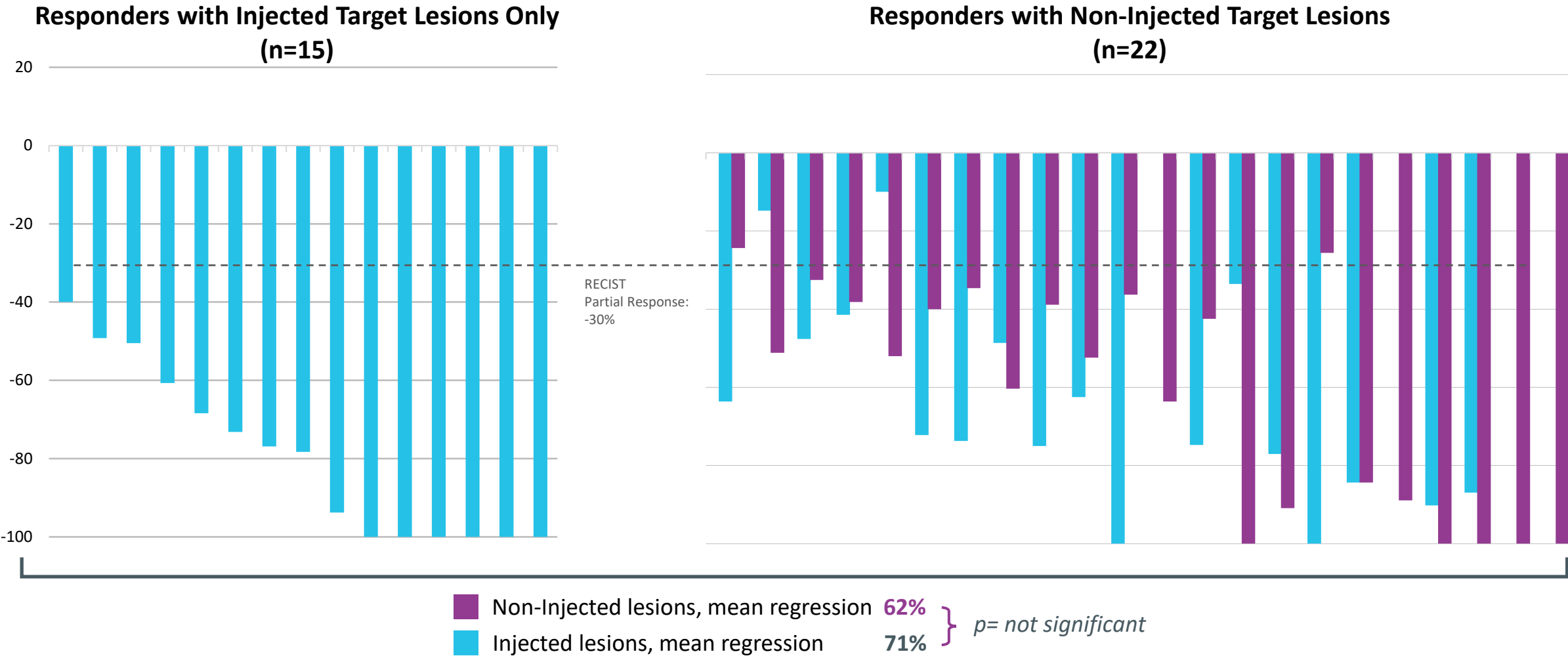
Systemic (Abscopal) Effect Observed in Distant Visceral Lesions

- 48-year-old WF with metastatic bilateral lung disease
- Progressed after prior therapies of ipilimumab (adjuvant), interferon (adjuvant), pembrolizumab, IL-2, aflibercept
- Injection site: right inguinal lymph node (groin)



>70% reduction in distant target lesions with response duration >2.5 years

Systemic Effect Observed in Non-Injected Lesions



Note: N=37, RECIST v1.1 responders and post-progression responders; Data cutoff September 30, 2020

Vidutolimod Monotherapy Activity Supportive of Further Development In Combination

Mono
PD-1 Refractory

17.5% (7/40) Best Objective Response



- Vidutolimod has shown monotherapy activity
- Substantially shorter duration of response than combination therapy
- Supportive of further development in combination

Treatment-Related Adverse Events Were Generally Manageable



PD-1 Refractory

Treatment-Related Adverse Events

- Most were Grade 1 or 2, including flu-like symptoms and injection site reactions
- Severity & frequency decreased over time
- No apparent exacerbation of anti PD-1 toxicity

Vidutolimod + Pembrolizumab (n=159)

Grade 3 or 4 Treatment-Related Adverse Events

- 36.5% (58/159) of subjects
- Most common (≥ 3 subjects): hypotension (n=11, 7%); hypertension (n=8, 5%); chills, back pain (n=5 each, 3%), increased AST, hypoxia, pyrexia (n=4 each, 2.5%); anemia, ALT increased, arthralgia, hypophosphatemia (n=3 each, 2%)

Treatment-Related Serious Adverse Events

- 17% (27/159) of subjects
- SAEs in ≥ 3 subjects: hypotension (n=7, 4%)

Vidutolimod monotherapy (n=40)

Grade 3 or 4 Treatment-Related Adverse Events

- 23% (9/40) of subjects
- No Grade 4 events
- Grade 3 AEs in ≥ 2 subjects: hypotension (n=2, 5%)

Treatment-Related Serious Adverse Events

- 15% (6/40) of subjects
- SAEs in ≥ 2 subjects: hypotension (n=3, 8%)

Neoadjuvant Study Design¹

Stage IIIB/C/D melanoma pre- surgery

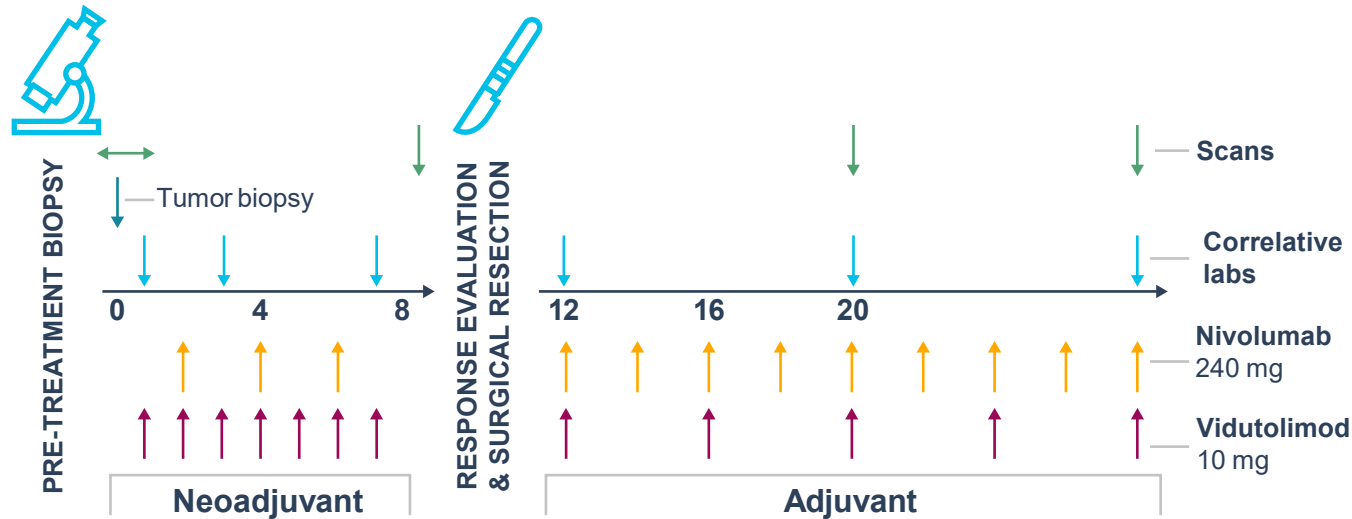
- No active CNS disease
- Deemed surgically resectable
- Accessible tumor for biopsy
- Accessible tumor for CMP-001 injection
- 30 patients

Primary endpoint:

Major pathological response (MPR) rate by irPRC


Secondary endpoints:

Relapse-free survival and overall survival

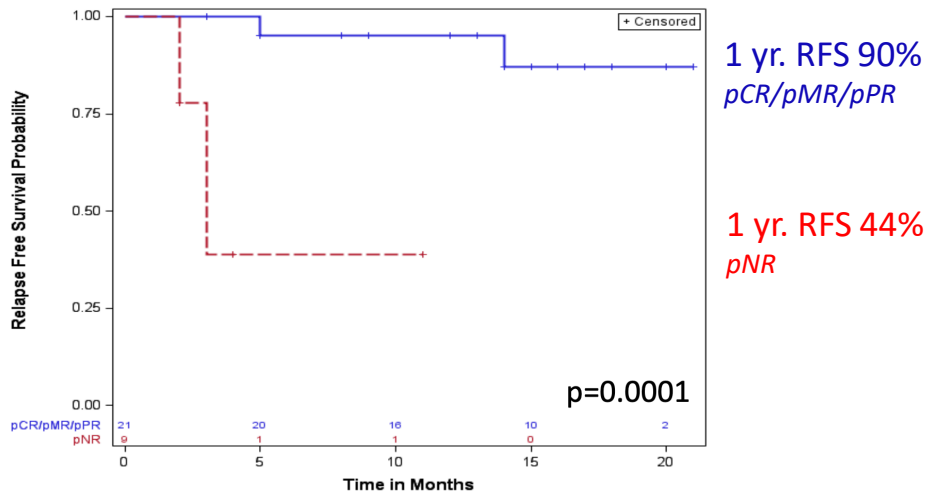


Pathologic Response ²	Residual Viable Tumor	MPR
Complete Response (pCR)	0%	
Major Response (pMR)	≤10%	
Partial Response (pPR)	>10% & <50%	
Non-Response (pNR)	>50%	

Compelling Pathologic Response and 1 Year Relapse Free Survival

Pathologic response ^{1,2}		%	
Complete response (pCR)	15	50%	MPR ³ 60%
Major response (pMR)	3	10%	
Partial response (pPR)	3	10%	
Non-response (pNR)	9	30%	PR ⁴ 70%
Total Evaluable	30		

Pathologic Response is Associated with Improved RFS



Benchmark⁵: ~25% pCR with single agent anti PD-1 therapy

¹Davar et al, SITC 2020; Data cutoff: October 1, 2020

²Tetzlaff Ann Oncol 2018, 29 (8): 1861-1868. [% Residual Viable Tumor: pCR = 0; pMR <10%; pPR 10 - 50%; pNR >50%]

³MPR = major pathologic response

⁴PR = pathologic response

⁵Amaria et al., Lancet Oncology, 2019, 20:e378

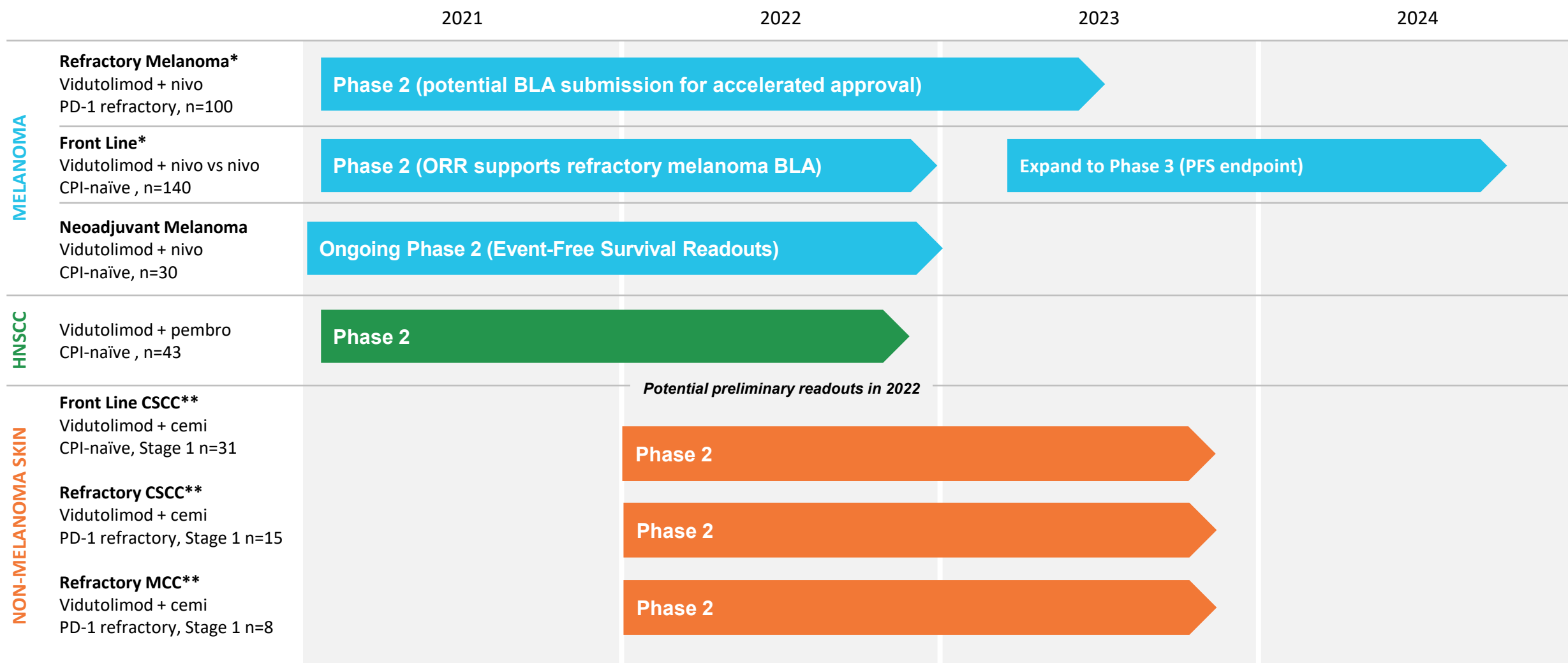
Treatment-Related Adverse Events Were Generally Manageable



No delays or surgical complications related to therapy

AE Term, N (%)	Vidutolimod/Nivolumab (N=31)			
	Grade 1 (n/%)	Grade 2 (n/%)	Grade 3 (n/%)	Grade 4 (n/%)
Hypophosphatemia	12 (38.7)	12 (38.7)	1 (3.2)	0 (0.0)
Flu-like symptoms	14 (45.2)	8 (25.8)	0 (0.0)	0 (0.0)
Fever	14 (45.2)	5 (16.1)	0 (0.0)	0 (0.0)
Hyponatremia	19 (61.3)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue	14 (45.2)	3 (9.7)	0 (0.0)	0 (0.0)
Arthralgia, myalgia	7 (22.6)	6 (19.4)	1 (3.2)	0 (0.0)
Injection site reaction	9 (6.5)	4 (12.9)	0 (0.0)	0 (0.0)
Hypertension	2 (6.4)	5 (16.1)	3 (9.7)	0 (0.0)
Anemia	9 (29.0)	1 (3.2)	0 (0.0)	0 (0.0)
Thrombocytopenia	10 (32.3)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea/vomiting	4 (12.9)	5 (16.1)	0 (0.0)	0 (0.0)
Injection site infection	3 (9.7)	3 (9.7)	1 (3.2)	0 (0.0)
CRS-like reaction* (ECI)	2 (6.5)	3 (9.7)	0 (0.0)	0 (0.0)
Colitis	0 (0.0)	0 (0.0)	1 (3.2)	0 (0.0)

Next Steps for Vidutolimod Development




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Rich Flow of New Data in 2022

- ❑ Head and neck cancer potential interim data readouts beginning 1H 2022
- ❑ Head and neck cancer anticipated full ORR readout 2H 2022
- ❑ Cutaneous squamous cell and Merkel cell carcinomas potential interim data readouts in 2H 2022
- ❑ Melanoma registration program topline data readouts expected in late 2022/1H 2023



Multiple Value
Generating
Milestones in
next 6-18 months

Experienced Management Team



Barry Labinger
Chief Executive Officer



Art Krieg, MD
Founder, Chief Scientific Officer



Kleem Chaudhary, PhD
Chief Business Officer



Robert Dolski
Chief Financial Officer



Katherine Eade
General Counsel



James Wooldridge, MD
Chief Medical Officer



Corporate Highlights

- Headquarters in Cambridge, MA
- Completed IPO in August 2020
- As of March 31, 2021
 - Cash and Cash equivalents of \$111.5M
 - Common stock shares outstanding 21.6 million
 - No debt
- Cash runway through end of 2022

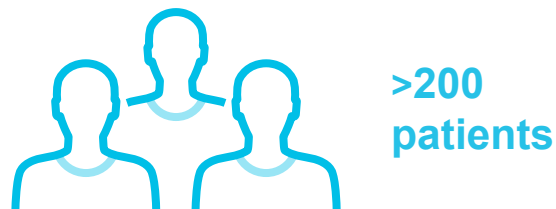
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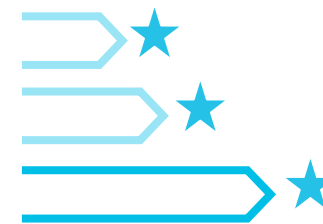
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