

# Heating Up Cancer Immunotherapy

September 2021



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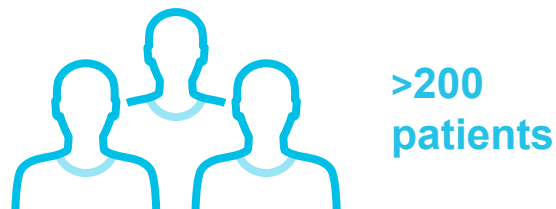
# Investment Highlights

## 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 melanoma<sup>1</sup>; similar magnitude of regression in injected and non-injected lesions
- 70% pathologic response in PD-1 naïve neoadjuvant melanoma and 90% RFS at 1 year<sup>2</sup>
- 17.5% ORR in PD-1 refractory melanoma as monotherapy<sup>3</sup>

## 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



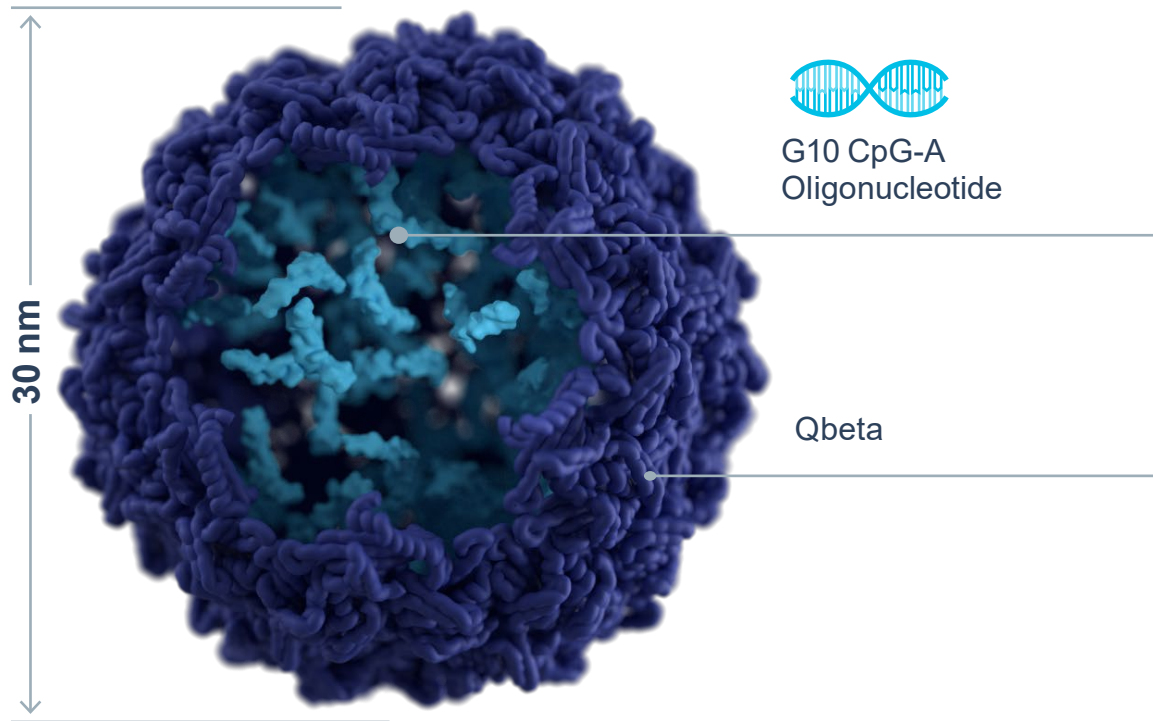
- Melanoma topline data anticipated late 2022/1H 2023
- Head & neck cancer Ph2 data maturing throughout 2022
- Non-melanoma skin cancer interim Ph2 data 2H 2022

<sup>1</sup> Vidutolimod plus pembrolizumab, data cutoff September 30, 2020 (includes post-progression responders); N=98

<sup>2</sup> Davar, SITC 2020, data cutoff October 1, 2020

<sup>3</sup> Vidutolimod monotherapy, data cutoff September 30, 2020; N=40

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



## Potent Type A CpG DNA payload (G10)

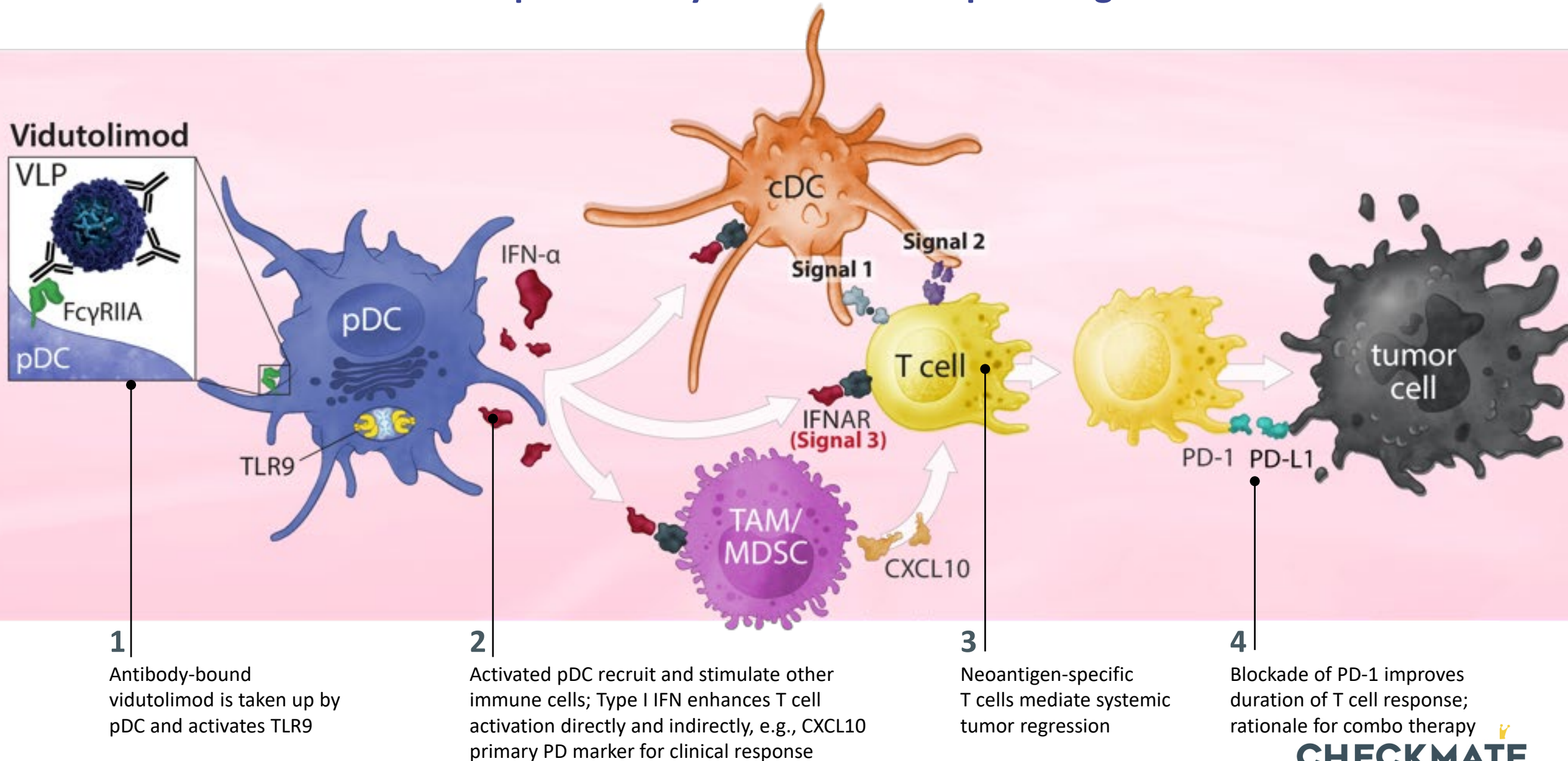
- Mimics viral, retroviral DNAs
- Synthesized on native phosphodiester backbone
- Most potent inducer of type I IFN known, drives T cell immune response

## Immune stimulating virus-like particle (VLP)

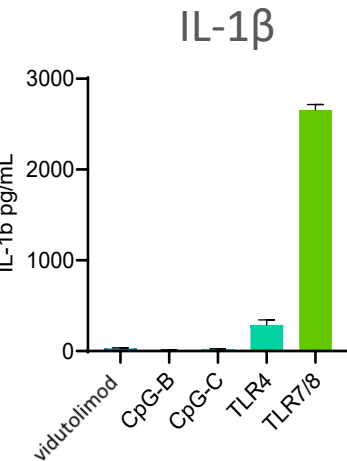
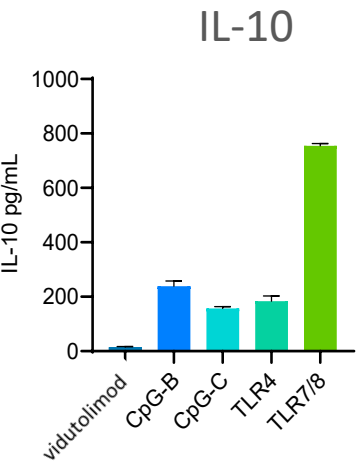
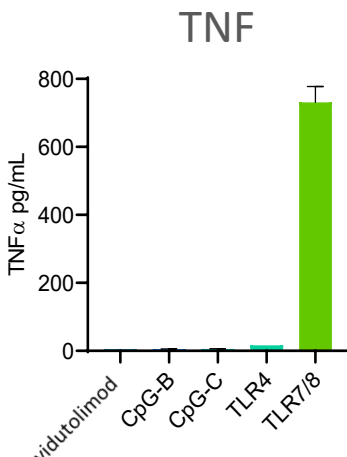
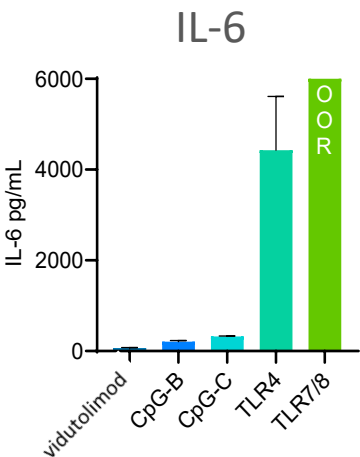
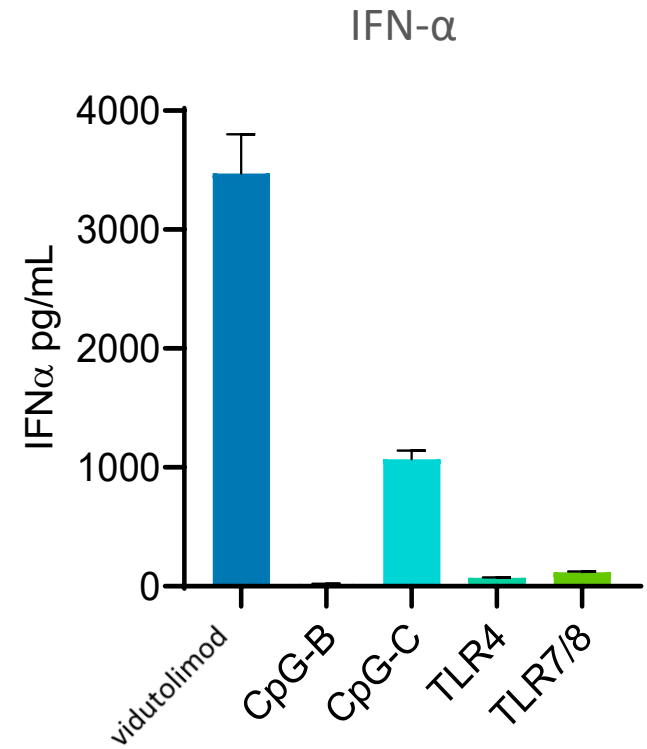
- Stimulates an immune response that causes immune cells to take up the VLP
- *The VLP is not infectious*
- VLP potentiates the systemic activity of G10

Biologic with potential for **12 years**  
**exclusivity** in US (if approved)<sup>1</sup>

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



# 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




# Systemic Effect via Local Activation







- ✓ Local injection into tumors to trigger an antigen-specific anti-tumor T cell response
- ✓ Evidence of systemic effect in non-injected lesions
- ✓ Requires a single lesion accessible for injection
  - Cutaneous or subcutaneous lesions, or palpable lymph nodes
- ✓ Injections performed in clinic by physicians, physician assistants, nurses, and nurse practitioners
  - Often without the need for any imaging
  - Similar to subcutaneous injection, but directly into tumor





# 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 Market<sup>1</sup>

High unmet need in melanoma with continued expected growth

**~1.2 M**

people living with  
melanoma of the skin

**5<sup>th</sup>**

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% ORR<sup>3</sup>**

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

<sup>1</sup>American Cancer Society

<sup>2</sup>Worldwide sales; EvaluatePharma

<sup>3</sup>Keytruda & Opdivo USPI

# Phase 1b Study in PD-1 Refractory Melanoma



## Key elements of study design

1. Evaluate vidutolimod +/- pembrolizumab

Vidutolimod + pembrolizumab (N=159)

Vidutolimod 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)



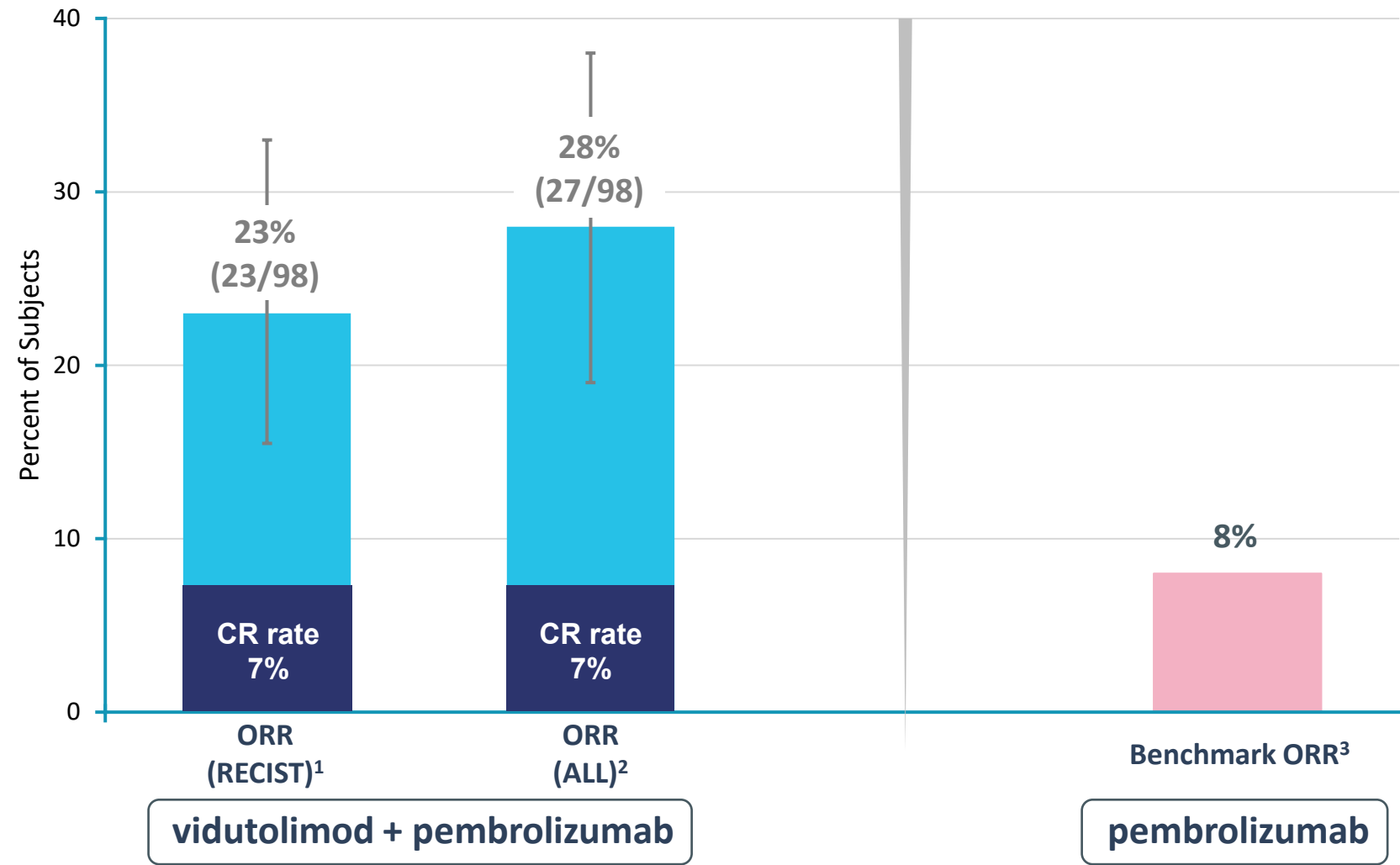
## Baseline patient characteristics (N =159)

<b>Prior cancer therapies</b>	Any PD-1	100%
	Any ipilimumab	47%
<b>Prior PD-1 best response</b>	CR (complete response)	4%
	PR (partial response)	13%
	SD (stable disease)	31%
	PD (progressive disease)	43%
<b>Prior PD-1 last response</b>	SD (stable disease)	3%
	PD (progressive disease)	93%
<b>Baseline disease locations</b>	Skin only	8%
	Lymph nodes ± skin	19%
	Soft tissue ± skin & lymph nodes	13%
	Bone w/o visceral disease	4%
	Any visceral	55%
<b>LDH</b>	High	42%
<b>Target lesion SLD<sup>1</sup></b>	Median measurement	6.8 cm
<b>ECOG status</b>	0	65%
	1	35%

Data cutoff September 30, 2020

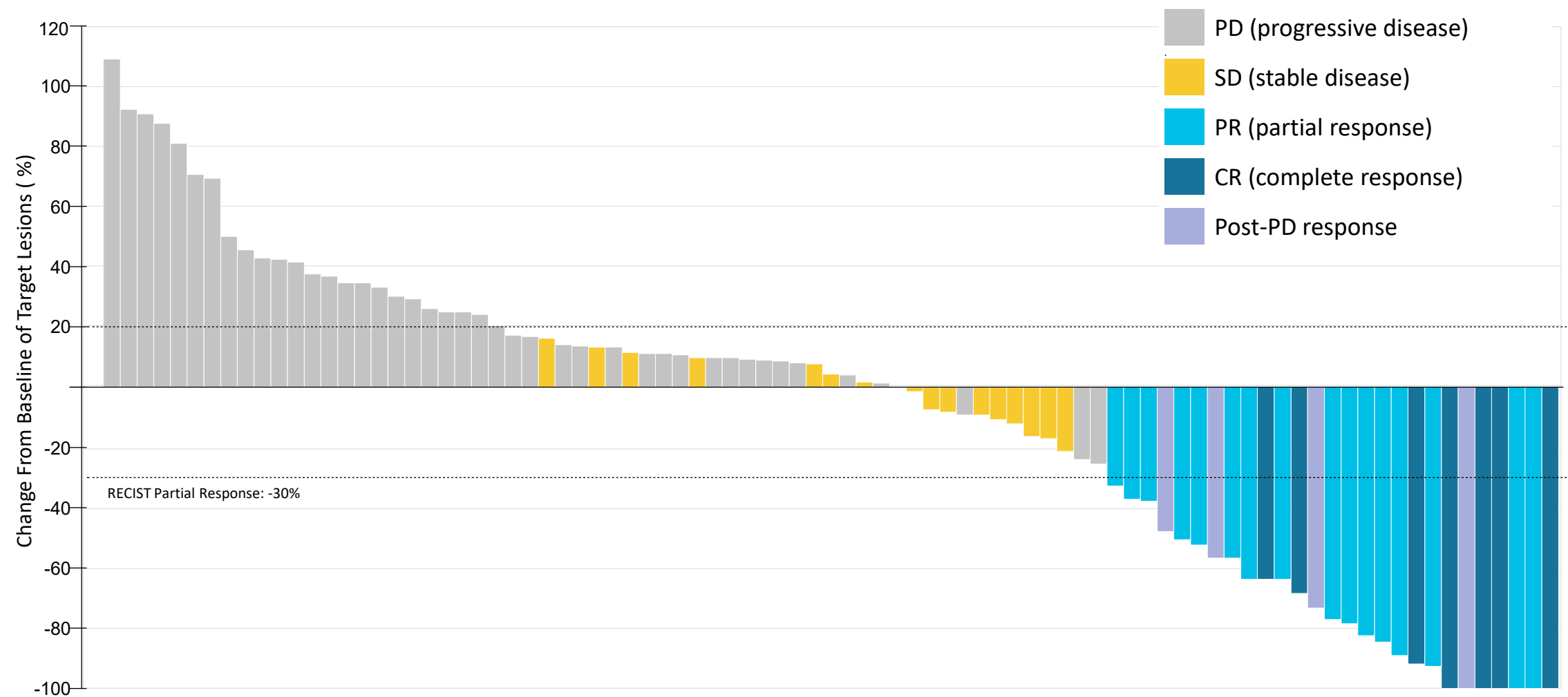
<sup>1</sup> Luke et al. AACR 2021

# Clinically Meaningful Response in Refractory Patient Population



<sup>1</sup>RECISTv1.1, Data cutoff September 30, 2020  
<sup>2</sup>RECISTv1.1 plus post-progression responses, Data cutoff September 30, 2020  
<sup>3</sup>Response 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

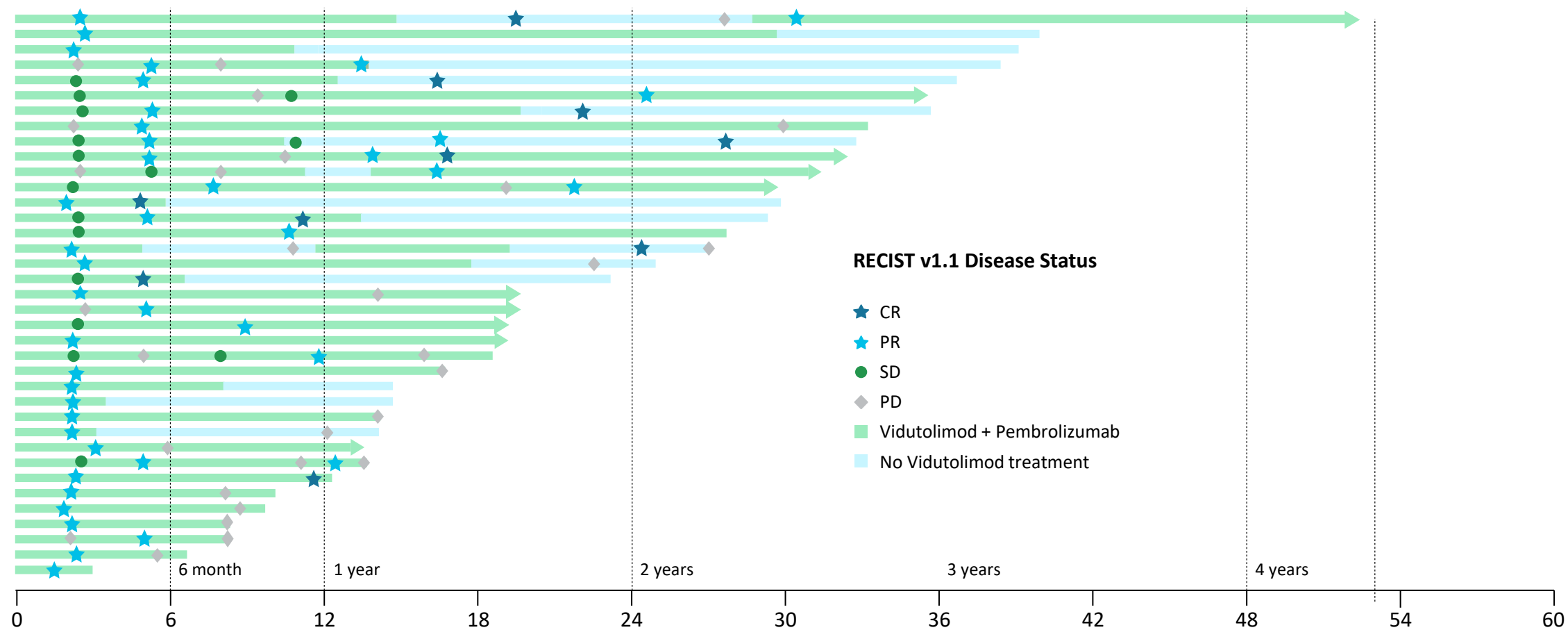
# Robust Depth of Response



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

# Highly Durable Responses

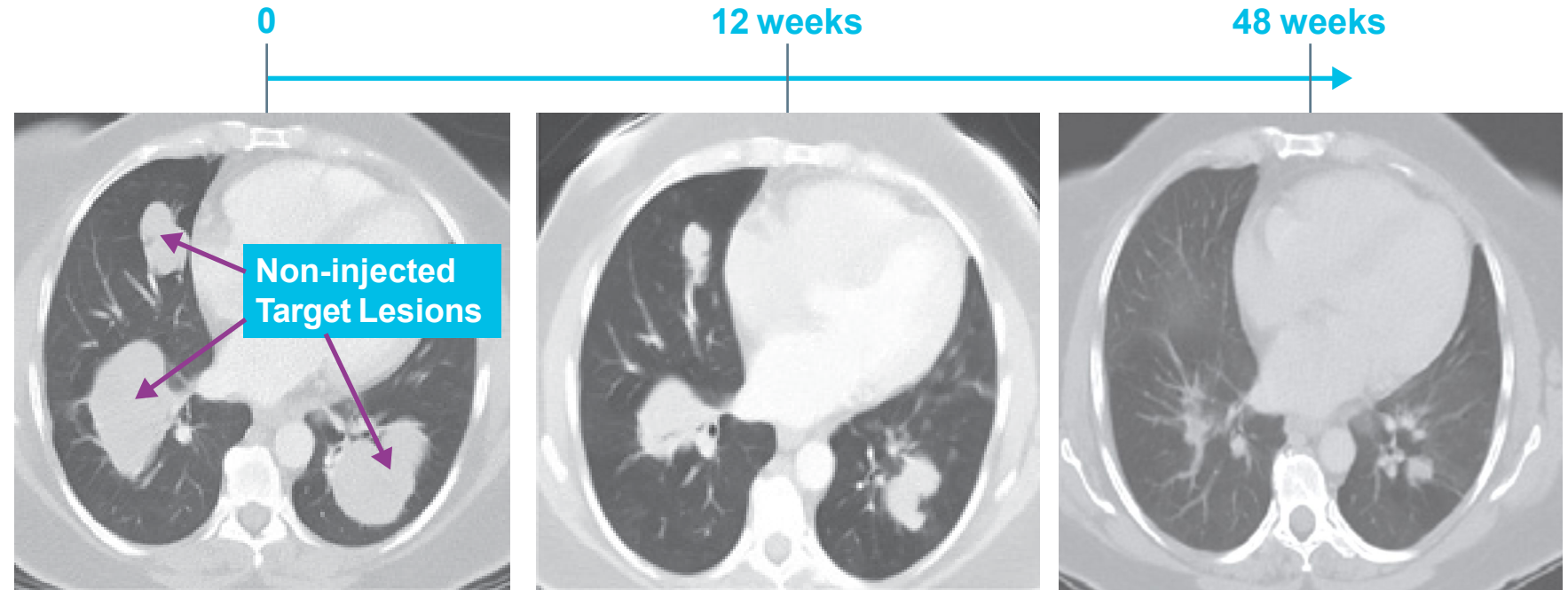
Median duration of response 19.9 months



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

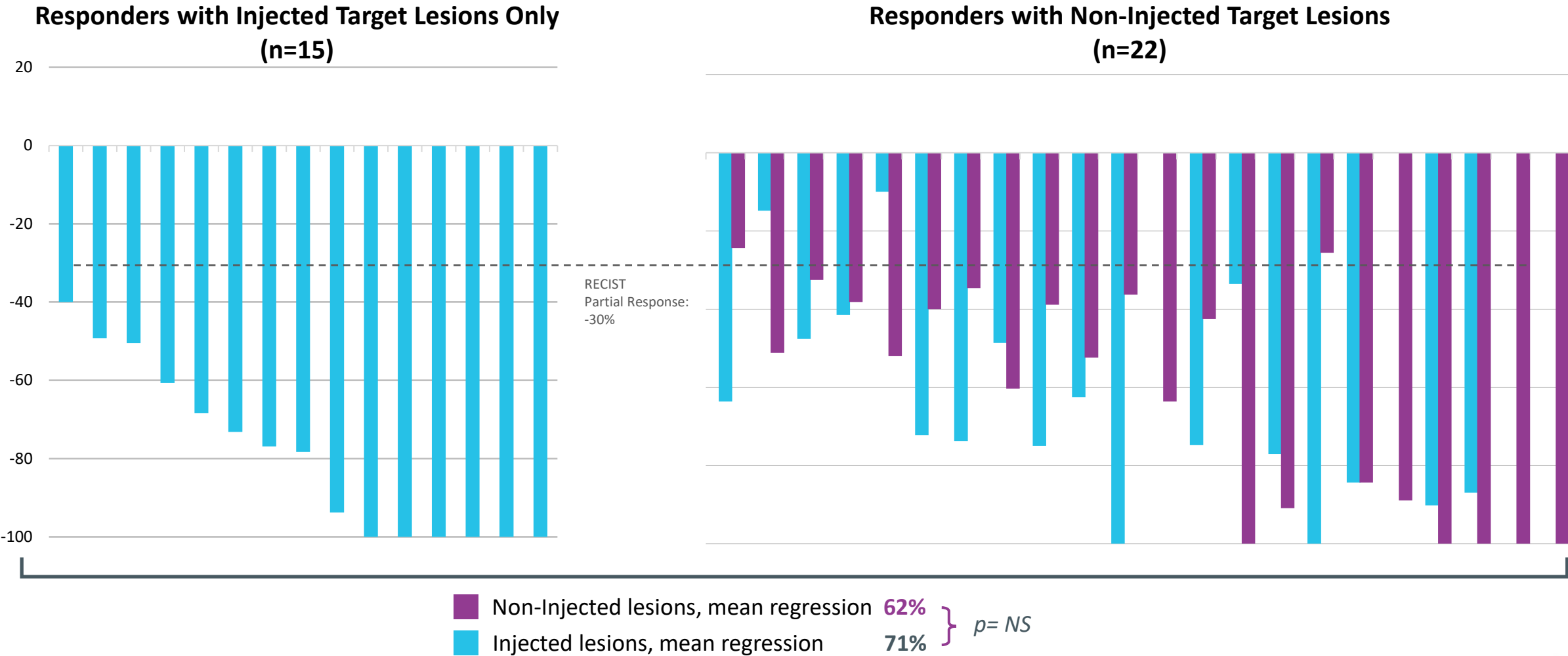
# Systemic (Abscopal) Effect Observed in Distant Visceral Lesions

- 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)



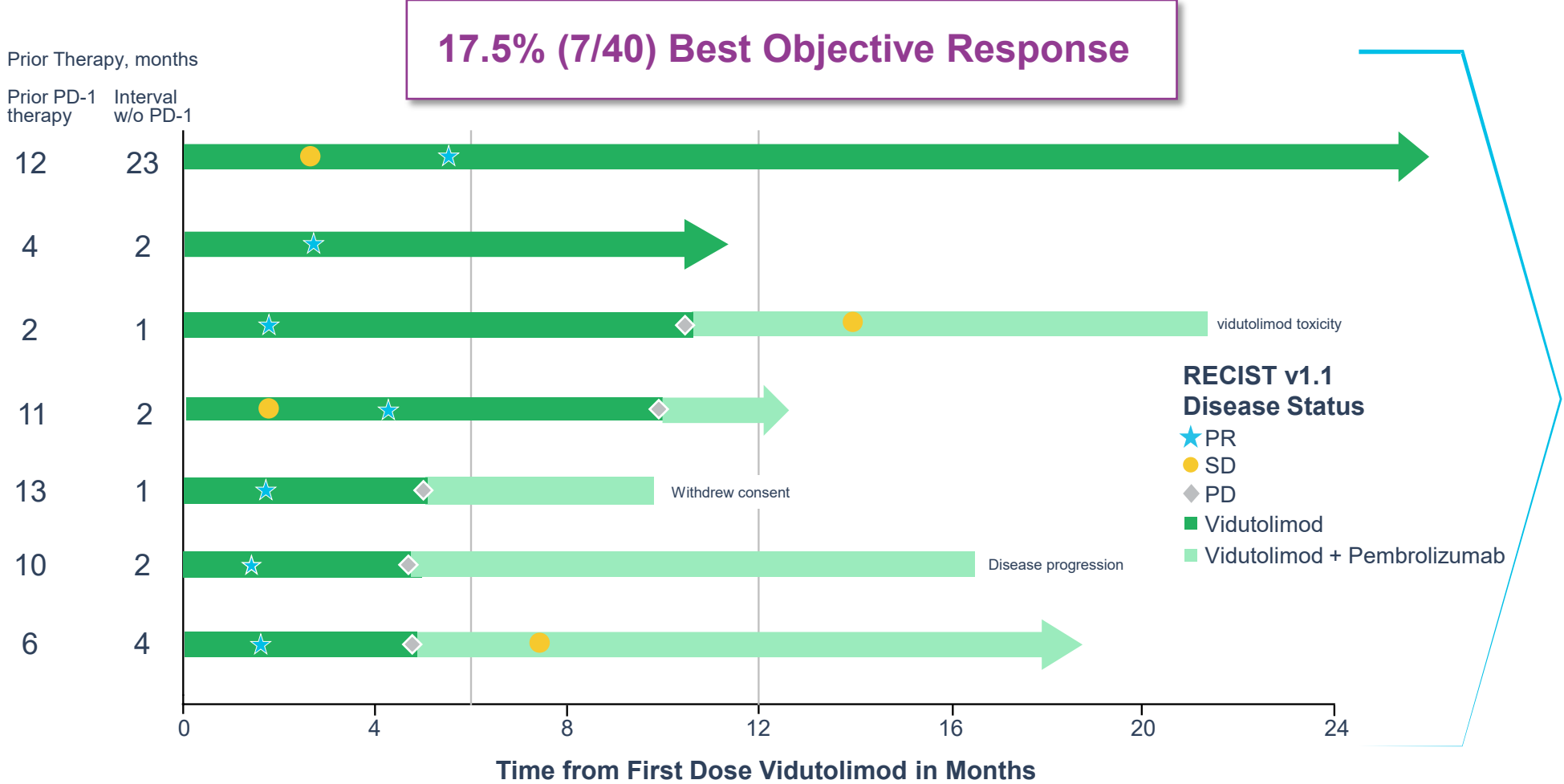
**>70% reduction in distant target lesions with response duration >2.5 years**

# Systemic Effect Observed in Non-Injected Lesions





# Vidutolimod Monotherapy Activity Supportive of Further Development In Combination



- Vidutolimod has shown monotherapy activity
- Median duration of response 5.6 months<sup>1</sup>; substantially shorter than combination therapy
- Supportive of further development in combination

Data cutoff September 30, 2020  
<sup>1</sup> Milhem et al. SITC 2020

# 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 ( $\geq 3$  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  $\geq 3$  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  $\geq 2$  subjects: hypotension (n=2, 5%)

#### Treatment-Related Serious Adverse Events

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

# Neoadjuvant Study Design<sup>1</sup>

## Stage IIIB/C/D melanoma pre- surgery

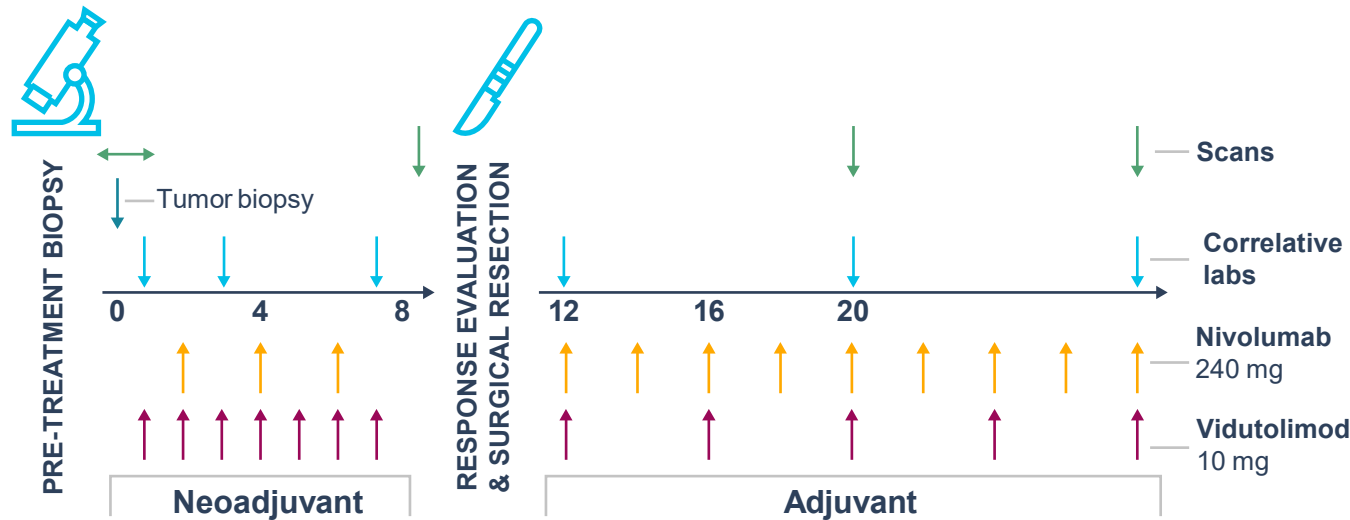
- No active CNS disease
- Deemed surgically resectable
- Accessible tumor for biopsy
- Accessible tumor for CMP-001 injection
- 30 patients

## Primary endpoint:

Major pathological response (MPR) rate by irPRC


## Secondary endpoints:

Relapse-free survival and overall survival

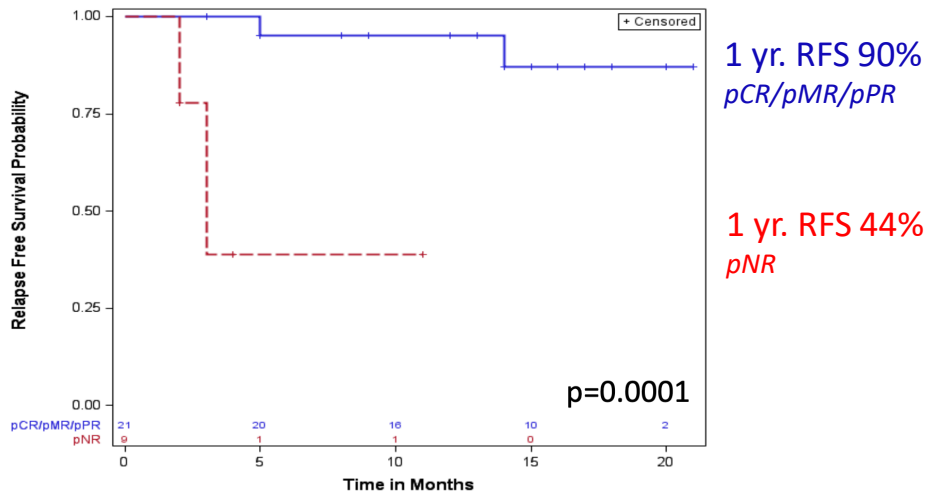


Pathologic Response <sup>2</sup>	Residual Viable Tumor	MPR
Complete Response (pCR)	0%	
Major Response (pMR)	≤10%	
Partial Response (pPR)	>10% & <50%	
Non-Response (pNR)	>50%	

# Compelling Pathologic Response and 1 Year Relapse Free Survival

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

## Pathologic Response is Associated with Improved RFS



**Benchmark<sup>5</sup>:** ~25% pCR with single agent anti PD-1 therapy

<sup>1</sup>Davar et al, SITC 2020; Data cutoff: October 1, 2020

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

<sup>3</sup>MPR = major pathologic response

<sup>4</sup>PR = pathologic response

<sup>5</sup>Amaria et al., Lancet Oncology, 2019, 20:e378

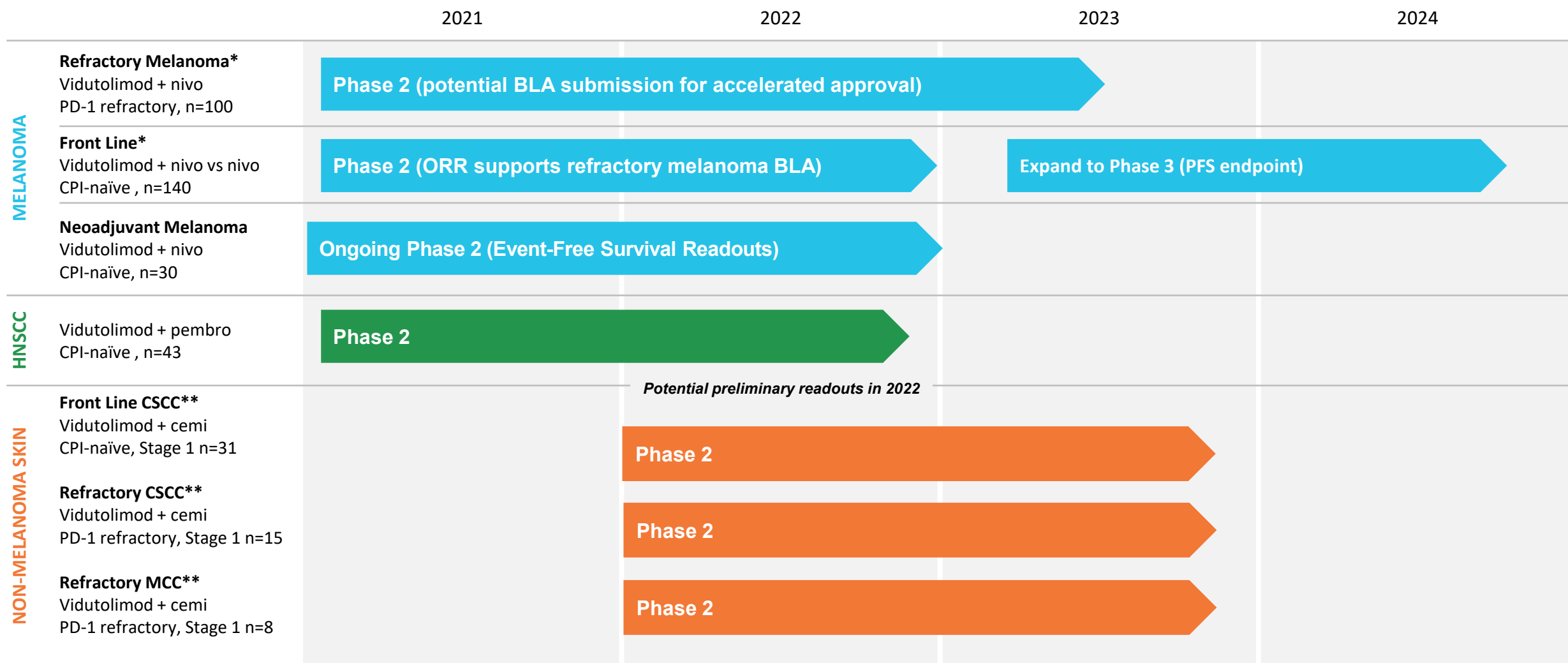
# Treatment-Related Adverse Events Were Generally Manageable



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




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

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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 June 30, 2021
  - Cash and Cash equivalents of \$95.6M
  - Common stock shares outstanding 21.6 million
  - No debt
- Cash runway through end of 2022

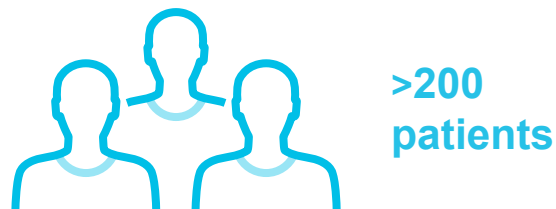
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