

**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): **January 8, 2024**

**REPLIMUNE GROUP, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-38596**  
(Commission  
File Number)

**82-2082553**  
(IRS Employer  
Identification Number)

**500 Unicorn Park Drive  
Suite 303  
Woburn, MA 01801**  
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(781) 222-9600**

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	REPL	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

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 7.01 Regulation FD Disclosure.**

On January 8, 2024, Replimune Group, Inc. (the “Company”) announced updated clinical data of RP1 and RP2 during a presentation at the 42<sup>nd</sup> Annual J.P. Morgan Healthcare Conference. A copy of the presentation slides are furnished as Exhibit 99.1 to this Current Report on Form 8-K and a replay of the webcast will be available on the Company’s website at [www.replimune.com](http://www.replimune.com) under “Investors and Media” for 30 days following the event. The Company undertakes no obligation to update, supplement or amend the materials attached hereto.

The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Item 7.01 and the accompanying Exhibit 99.1 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

**Item 8.01 Other Events.**

The Company preliminarily estimates that as of December 31, 2023, it had approximately \$466 million in cash and cash equivalents and short-term investments. The Company believes that its existing cash and cash equivalents and short-term investments along with its debt commitments will enable it to fund its operating expenses and capital expenditure requirements into the second half of 2026.

This amount is unaudited and preliminary, and does not present all information necessary for an understanding of the Company’s financial condition as of December 31, 2023. The review of the Company’s condensed consolidated financial statements for the three and nine-months ended December 31, 2023 is ongoing and could result in changes to the preliminary estimates due to the completion of financial closing procedures, final adjustments and other developments that may arise between now and the time the condensed consolidated financial statements the three and nine-months ended December 31, 2023 are finalized and publicly released. The Company’s independent registered public accounting firm, PricewaterhouseCoopers LLP, has not audited, reviewed, compiled or performed any procedures with respect to the preliminary financial estimate, and does not express an opinion or any other form of assurance with respect thereto. The preliminary financial estimate presented above has been prepared by and is the responsibility of management. Estimates of financial results are inherently uncertain and subject to change, and the Company undertakes no obligation to update this information. In addition, the estimated balance of cash and cash equivalents and short-term investments as of December 31, 2023 is not necessarily indicative of future performance or any other period, including the results to be achieved for the remainder of the fiscal year ending March 31, 2024 or any future period.

**Item 9.01 Financial Statements and Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Company Presentation dated January 8, 2024</a>
104	Cover page interactive data file (formatted as Inline XBRL)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**REPLIMUNE GROUP, INC.**

Date: January 8, 2024

By: /s/ Philip Astley-Sparke  
Philip Astley-Sparke  
Chief Executive Officer

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# Igniting a Systemic Immune Response to Cancer

**JP Morgan**  
January 2024



## Safe harbor



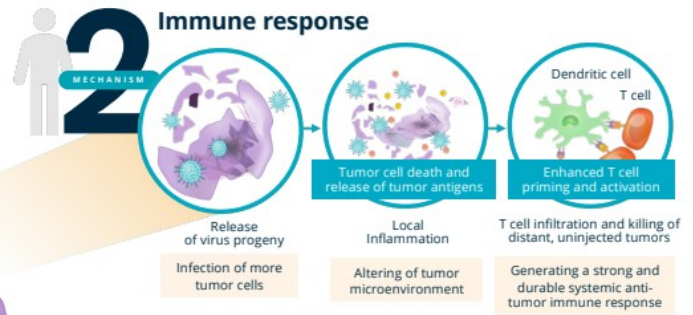
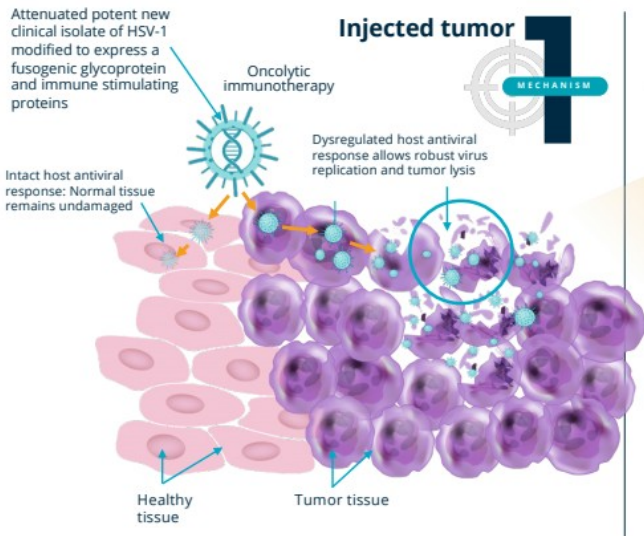
Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the advancement, timing and sufficiency of our clinical trials, patient enrollments in our existing and planned clinical trials and the timing thereof, the results of our clinical trials, the timing and release of our clinical data, statements regarding our expectations about our cash runway, our goals to develop and commercialize our product candidates, our expectations regarding the size of the patient populations for our product candidates if approved for commercial use and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to generate positive clinical trial results for our product candidates, the costs and timing of operating our in-house manufacturing facility, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, political and global macro factors including the impact of the SARS-COV-2 coronavirus as a global pandemic and related public health issues, the ongoing military conflict between Russia and Ukraine and the impact on the global economy and related governmental imposed sanctions, and other risks as may be detailed from time to time in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and other reports we file with the Securities and Exchange Commission. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

- **RP1 – activity across multiple skin cancers supports broad skin cancer strategy**
  - 140 patient registrational IGYTE study in anti-PD1 failed melanoma
    - ~ **1 in 3 patients demonstrating durable response**
      - 100% of responses >6 months with median DOR >24 months
    - **BLA filing planned 2H 2024**
  - 211 patient 1L CSCC randomized controlled CERPASS study; primary analysis reported December 2023
    - Missed significance at  $P < 0.025$  for dual endpoints (ORR/CRR)
      - However, clear clinical benefit for RP1+cemiplimab was demonstrated
        - **CRR vs. cemiplimab alone (38.1% vs 25.0%,  $p=0.040^1$ )**
        - Duration of response increased
    - Strong data in hard-to-treat solid organ transplant patients as **monotherapy**
    - Potential for the portfolio to deliver commercial revenues beginning in late 2025
- **RP2 has shown compelling monotherapy and combination activity**
  - Uveal melanoma RCT study in planning -> **potential for a rare cancer franchise**
- **Strong balance sheet** ~ \$466m <sup>(1)</sup> as of 31 December 2023; runway into H2 2026

<sup>(1)</sup> Unaudited estimate

<sup>1</sup>Per the protocol  $p < 0.025$  is required for formal statistical success in CERPASS for CRR or ORR alone. <sup>\*</sup>SOT=solid organ transplant







# Oncolytic immunotherapy - mechanism of action





# RPx positioning: Platform designed to address a range of tumor types with an optimal balance of potency & tolerability



	 RP1	 RP2
<b>Payloads</b>	GALV-GP R-, GM-CSF	GALV-GP R-, anti-CTLA-4, GM-CSF
<b>Target</b>	Immunologically responsive tumor types, including anti-PD1 failed	Less immunologically responsive tumor types
<b>Intended indication(s)</b>	Skin cancers (CSCC inc. SOT*, anti-PD1 failed melanoma, anti-PD1 failed CSCC, other NMSCs, etc)	Rare cancers and neo adjuvant ; uveal melanoma registration study planned
<b>Clinical activity in anti-PD1 failed patients demonstrated</b>		
<b>Good tolerability and Safety profile demonstrated</b>		
<b>Injection location</b>	Superficial, nodal & visceral	Superficial, nodal & visceral
<b>Systemic activity</b>	<b><i>Clear systemic effects seen in responding patients (un-injected tumor responses, responses are generally highly durable)</i></b>	
<b>Other design considerations</b>	Designed for more I-O sensitive tumor types with excellent safety profile alone & in combination	Increased I-O systemic activity, also with excellent safety profile alone & in combination

\*SOT=solid organ transplant



# RPI: Establishing a major skin cancer franchise

## AGENDA

# IGNYTE RPI + nivolumab in anti-PD1 failed melanoma registrational study data

Consistent ORR benefit across all subgroups



BOR n (%)	All patients (n=156)								
	Prior cohort (n=16)	Anti-PD1 failed cohort (n=140)	All patients (n=156)	Prior single agent anti-PD1 (n=84)	Prior combination anti-PD-1 & anti-CTLA-4* (n=72)	Stage IIIb/IIIc/IVa (n=76)	Stage IVb/c/d (n=80)	Primary resistance to anti-PD1 (n=91)	Secondary resistance to anti-PD1 (n=63)
CR	2 (12.5)	17 (12.1)	19 (12.2)	14 (16.7)	5 (6.9)	15 (19.7)	4 (5.0)	12 (13.2)	6 (9.5)
PR	4 (25.0)	26 (18.6)	30 (19.2)	16 (19.0)	14 (19.4)	14 (18.4)	16 (20.0)	19 (20.9)	11 (17.5)
SD	2 (12.5)	29 (20.7)	31 (19.9) <sup>^</sup>	21 (25.0)	10 (13.9)	18 (23.7) <sup>^</sup>	13 (16.3)	15 (16.5) <sup>^</sup>	16 (25.4)
PD	8 (50.0)	68 (48.6)	76 (48.7)	33 (39.3)	43 (59.7)	29 (38.2)	47 (58.8)	45 (49.5)	30 (47.6)
ORR	6 (37.5)	43 (30.7)	49 (31.4)	30 (35.7)	19 (26.4)	29 (38.2)	20 (25.0)	31 (34.1)	17 (27.0)

- 1 in 3 patients experienced a response
  - 26.4% ORR in hard-to-treat Ipi+Nivo failed patients (approx. 50% of the overall study population)
  - 100% of responses lasted >6 months, with median DOR >24 months

BOR=best overall response

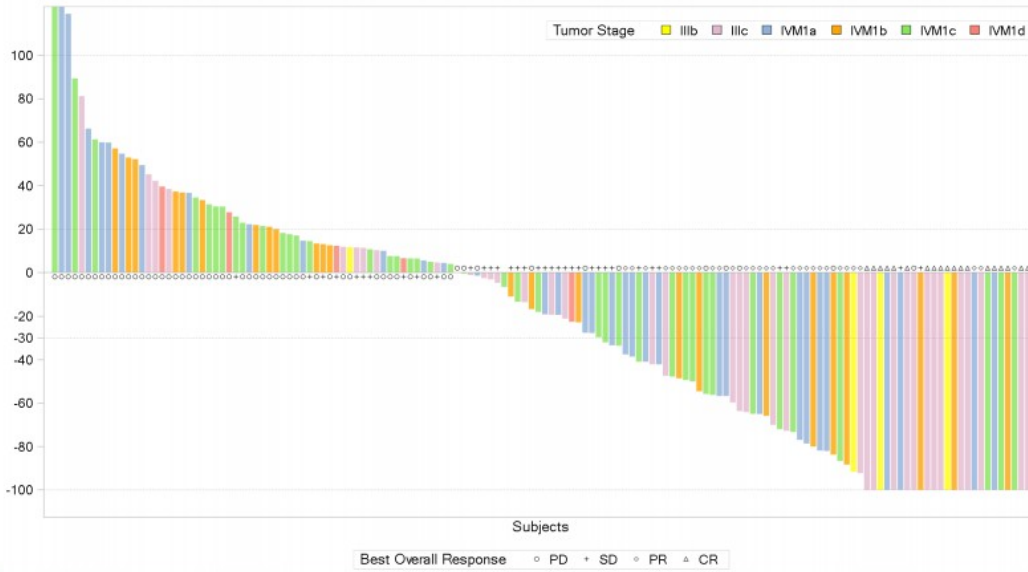
<sup>^</sup>Includes 1 patient with a unconfirmed PR (uPR). There are 5 patients still on study with the opportunity for response. Response data presented is by investigator assessment; the primary analysis from the study will be by blinded, independent central review.

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# Depth of response n=156

Maximum change in target lesions; patients with at least one follow up assessment



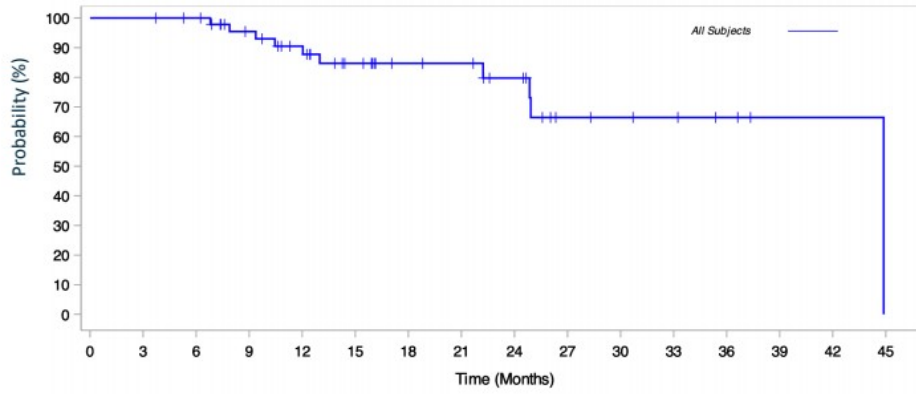
### Key Takeaways

- Target tumor reduction is seen in >50% of patients
- Responses were seen across disease stages, including complete responses in patients with stage IVM1b/c disease

Patients with at least one post baseline assessment – target lesion response for each patient

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# Duration of response (time from baseline to end of response for responders)



**Key Takeaway**  
Responses are highly durable, with median DOR >24 months

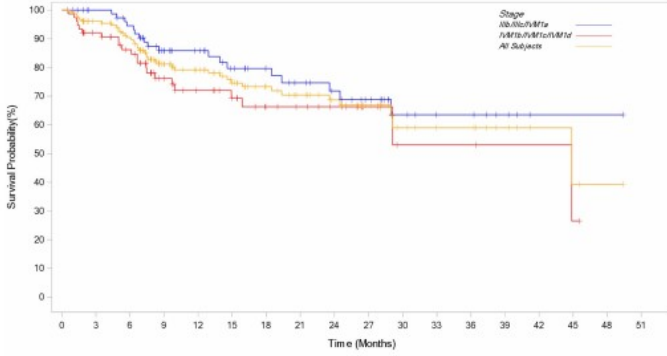
>6 months	>12 months	>18 months	>24 months
100%	90.5%	84.7%	79.7%

All patients have at least 6 months follow up, median follow up is 88.21 weeks

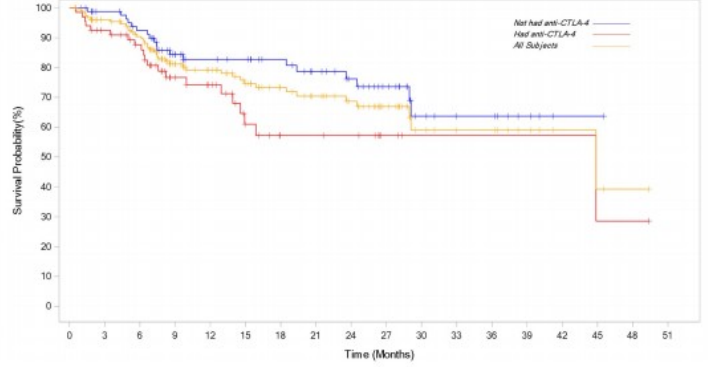
# Promising OS is seen across disease subsets, including those with the greatest unmet need



Stage IIIb/IIIc/IVM1a vs Stage IV M1b/c/d



Prior anti-CTLA-4+anti-PD1 vs prior anti-PD1 alone



All patients have at least 6 months follow up, median follow up is 88.21 weeks

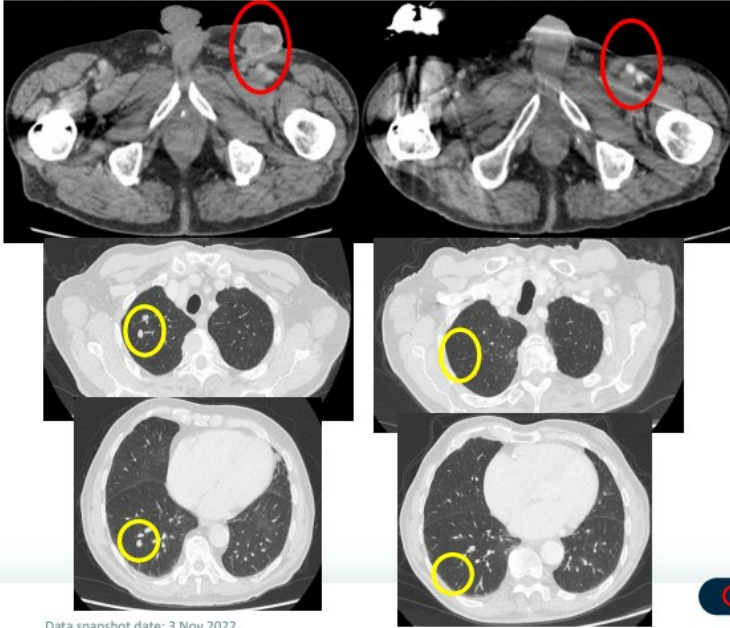
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**Patient 4401-2021: Prior Tafinlar/Mekinist, Keytruda**  
Prior BRAF/MEK as well as progressed on anti-PD1 Stage IVM1c



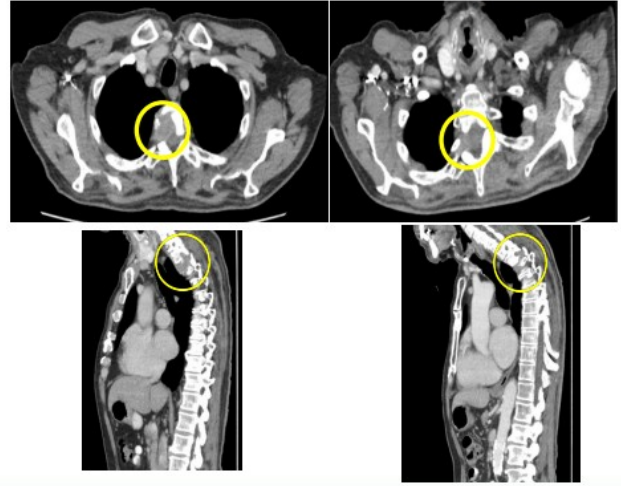
12JAN2021/Baseline

15FEB2022/Day 368



12JAN2021/Baseline

15FEB2022/Day 368



● Injected    ● Un-injected

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Data snapshot date: 3 Nov 2022

29 JUL 2021 / Screening



20 APRIL 2022



 Injected     Un-injected

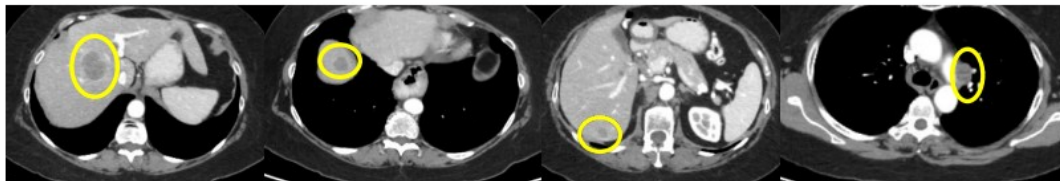


# Patient 1121-2011 Cont'd:

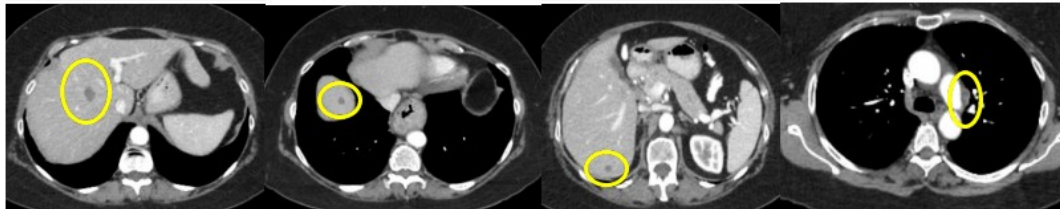
Prior Opdivo (adjuvant) and Keytruda (first line for metastatic disease), Stage IVM1c



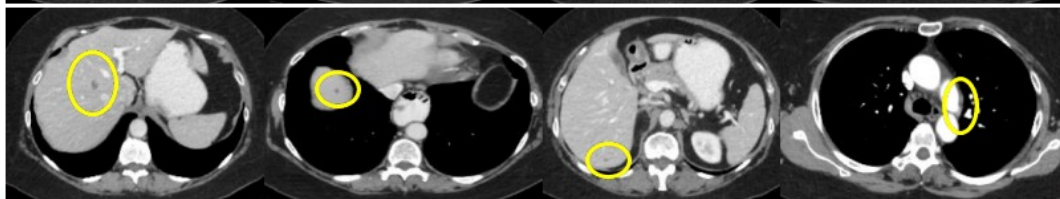
22 Jul 2021/  
Baseline



22 Sep 2021/  
Day 57



29 Dec 2021/  
Day 155



● Injected    ● Un-injected

### IGNYTE

#### **IGNYTE FDA Type C meeting on anti-PD1 failed melanoma**

- The FDA acknowledged that the IGNYTE population is one of unmet need
- The FDA agreed with a 2-arm randomized trial design in anti-PD1 failed melanoma with physician's choice as a comparator arm in the study population
  - The study should be underway at time of BLA submission
- A BLA submission for anti-PD1 failed melanoma is planned for 2H 2024 pending
  - Centrally reviewed data by RECIST v 1.1
  - All patients followed for at least 12 months (which is the per protocol primary analysis timepoint)
  - All responding patients followed for at least 6 months from response initiation

# CSCC disease characteristics and typical patient presentation

- **Second most common skin cancer** with ≈700,000 patients annually in the U.S.<sup>1</sup>
- **Approximately 7,000-15,000 US deaths** annually<sup>1-3</sup>
  - 80% of patients die from locoregional progression, not metastatic disease<sup>4,5</sup>
- Usually develops from precursor lesions (actinic keratosis) but may be *de novo*; **majority (80-90%) occur on the head and neck**
- **CSCC is a predominately outward growing disease with large, painful, superficial tumors which can impact quality of life and contribute to social isolation**
  - Disfiguring, painful
  - Foul smelling drainage
  - Delay in seeking medical care
- Anti-Pd1 SOC ~ **50% ORR**, ~ **15-25% CRR**.



<sup>1</sup>Rogers et al JAMA Dermatol 10 2015;

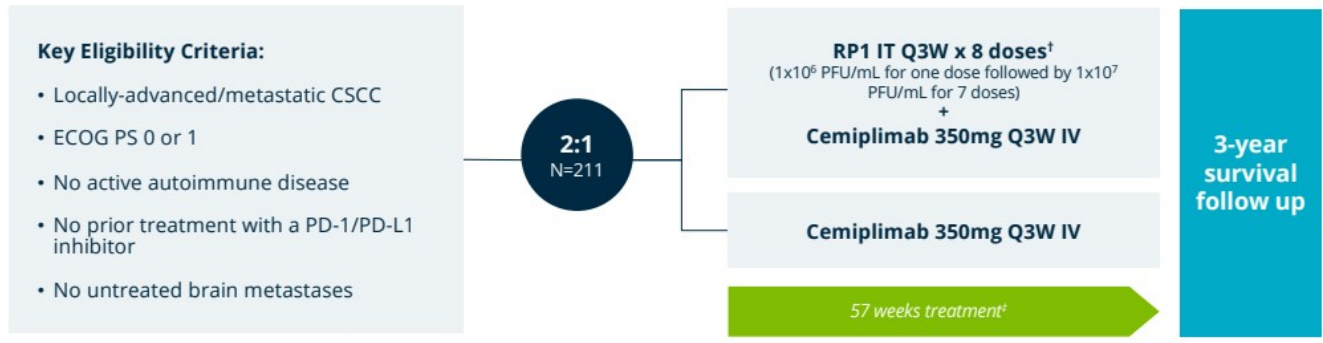
<sup>4</sup>Schmults et al JAMA Dermatol 149 2013;

<sup>2</sup>Clayman et al JCO 23 2005;

<sup>5</sup>Motaparthy et al Adv Anat Pathol 24 2017

<sup>3</sup>Mansouri et al J Am Acad Dermatol 153 2017;

# CERPASS registration-directed Ph2 study in CSCC



**Key Endpoints**

- **Dual independent primary endpoints: Complete Response Rate & Overall Response Rate\***
  - Approx. 15% absolute difference in CRR and/or ORR required
- Secondary endpoints: DOR, PFS, OS, disease-specific survival, safety/tolerability

*\*Note  $p \leq 0.05$  is required if both dual primary endpoints hit for statistical success, if only one of the dual endpoint hits need a  $p \leq 0.025$  is needed*

<sup>†</sup>First dose of RP1 to be given as monotherapy with cemiplimab to be given with second dose of RP1  
<sup>‡</sup>57 weeks treatment for the combination arm; treatment duration for cemiplimab-only arm is 54 weeks

## Confirmed ORR & CRR (ITT population)



BOR (confirmed response)	All N=211	
	Cemiplimab n=72	RP1+ cemiplimab n=139
n/%		
PR	19 (26.4)	20 (14.4)
SD	14 (19.4)	18* (12.9)
PD	12 (16.7)	27 (19.4)
<b>OR</b>	<b>37 (51.4%)</b>	<b>73 (52.5%)</b>
	P=0.692 <sup>1</sup>	
<b>CR</b>	<b>18 (25.0%)</b>	<b>53 (38.1%)</b>
	P=0.040 <sup>1</sup>	

BOR (confirmed response)	Locally advanced CSCC n=83		Metastatic CSCC n=128	
	Cemiplimab n=31	RP1+ cemiplimab n=52	Cemiplimab n=41	RP1+ cemiplimab n=87
n/%				
<b>OR</b>	<b>18 (58.1%)</b>	<b>33 (63.3%)</b>	19 (46.3%)	40 (46.0%)
<b>CR</b>	<b>7 (22.6%)</b>	<b>25 (48.1%)</b>	11 (26.6%)	28 (32.2%)

### Key Takeaways

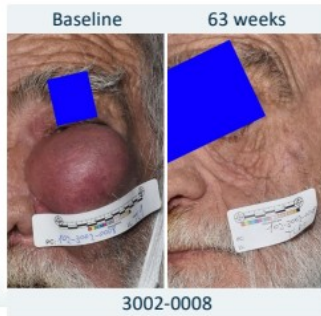
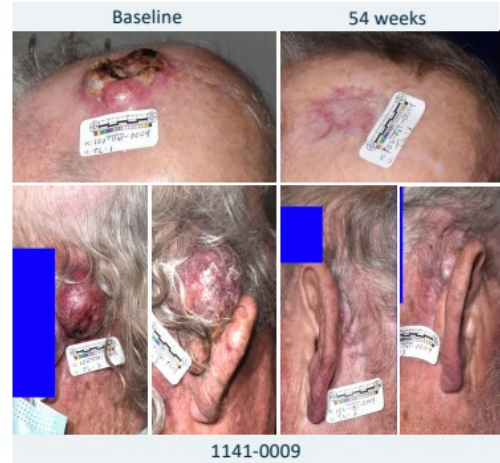
- While ORR was similar between the arms, the number of patients who achieved a CRR was substantially increased with RP1+cemiplimab (P=0.04)
- In LA CSCC, there was a more than doubling of the CR rate for RP1+cemiplimab vs cemiplimab alone (48.1% vs 22.6%)
- CRs are the key driver of long-term clinical benefit in CSCC

\*One patient shown as SD was a CR due to the confirmatory assessment happening 21 days rather than later 28 days as required per protocol (CRR if included = 38.8%; p=0.031); \*\*Nominal p value 0.013

<sup>1</sup>Per the protocol p≤0.025 is required for formal statistical success in CERPASS for CRR or ORR alone and p≤0.05 if both endpoints were met  
BOR=best overall response



# Five of the most visually impactful CRs with RP1+cemiplimab

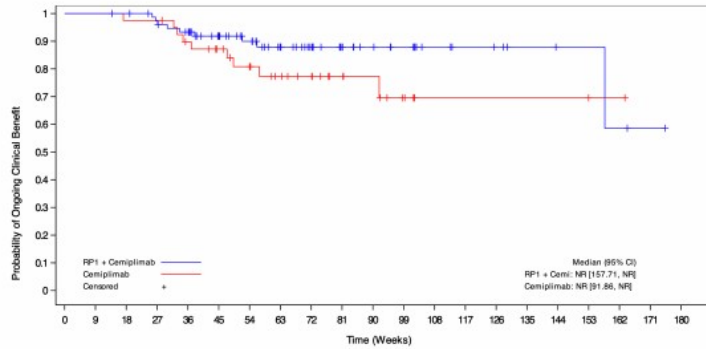


# Duration of response (immature data)

Time from baseline to end of response for responders



## All responding patients



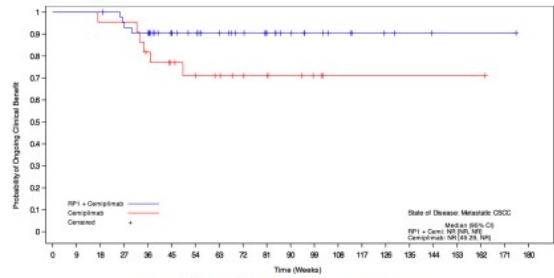
Number of subjects at risk:

	0	9	18	27	36	45	54	63	72	81	90	99	108	117	126	135	144	153	162	171	180
RP1 + Cemi	78	76	77	73	68	58	48	37	29	22	17	14	9	7	6	4	3	3	2	1	0
Cemiplimab	40	40	39	39	34	29	25	20	17	12	10	6	2	2	2	2	2	2	2	1	0

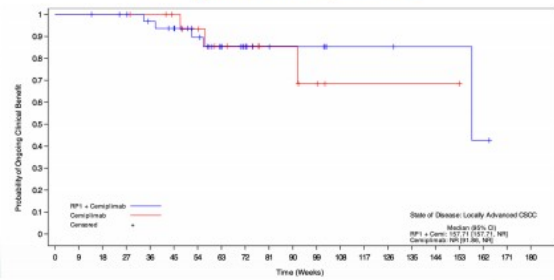
### Key Takeaway

Duration of response was improved with RP1+cemiplimab as compared to cemiplimab alone (HR 0.45 immature data). While the improvement is clear in metastatic disease, locally advanced patient data is currently too immature to draw conclusions. The study will continue to allow all endpoints to further mature, in particular for DOR, PFS & OS

## Metastatic patients



## Locally advanced patients





### CERPASS

- CERPASS missed its primary endpoints while demonstrating treatment effects suggesting clinical benefit
  - CR rate
  - Duration of response
- All time-based endpoints are immature (DOR, PFS and OS) and will be followed to maturity
- Mature data required to determine whether any filing or compendia listing strategy is warranted

### ARTACUS STUDY

- Treatment of high risk immune compromised populations who develop skin cancers
- Anti-PD1 use can lead to loss of graft
- **RP1 monotherapy; 35% ORR (N=23)**

### IGNYTE anti-PD1 failed NMSC

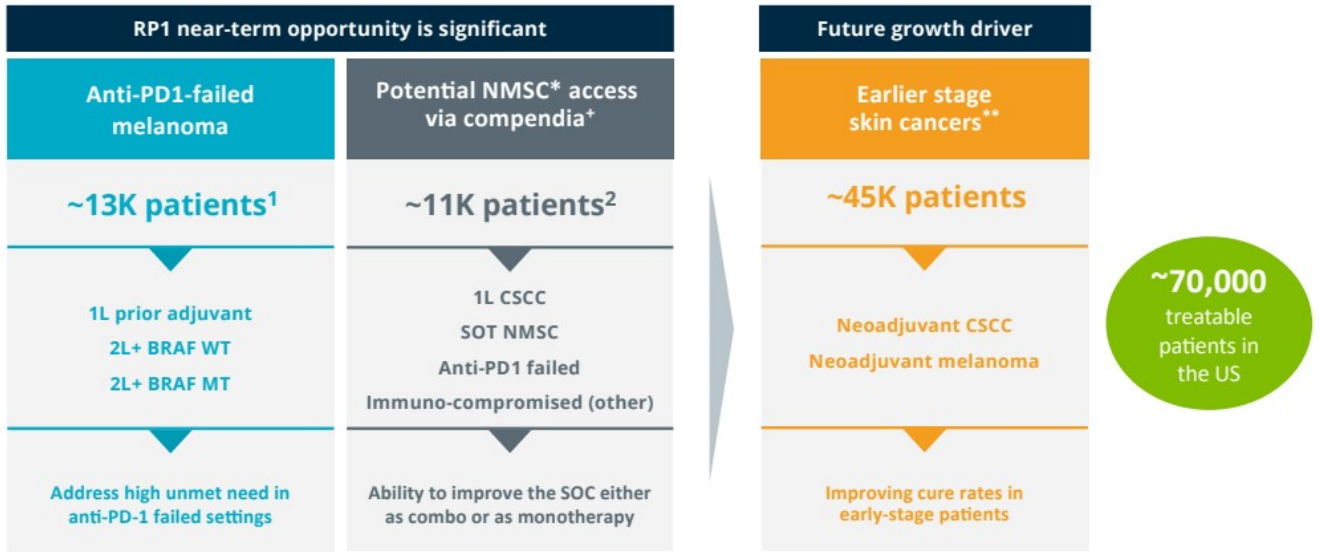
- No FDA approved options for anti-PD1-failed CSCC/NMSC; ~ 70% of treated patients still ultimately progress
- **RP1 + nivo 30% ORR (N=30)**

<sup>1</sup>Lam JKS, et al. Head Neck. 2018;40:985-992.  
<sup>2</sup>Friman T, et al. Int J Cancer. 2022;150(11):1779-91.  
<sup>3</sup>Marin-Acevedo et al Cancers 2023, 15(12), 3180

# RP1 Commercial Opportunity

## AGENDA

# Significant opportunity to establish a broad skin cancer franchise built upon strong foundation in melanoma



**"Opportunity to change the treatment paradigm and ensure all appropriate patients can benefit from RP1"**

\*Spontaneous use will not be promoted

Source: <sup>1</sup>Melanoma US treated patient population for 2030 based on CancerMPact® Patient Metrics, Cerner Enviza (available from www.cancermpact.com Accessed 15 Oct 2023), with adjustments to future 2L+ treatment rates based on primary market research. <sup>2</sup>CSCC US treated patient population for 2030 based on IQVIA claims, primary market research, and company data. <sup>+</sup>NMSC (non-melanoma skin cancers); RP1+ cemiplimab or RP1+ nivolumab or RP1 mono <sup>\*\*</sup>Neoadjuvant CSCC (est. 30K patients) and melanoma (est. 15K patients). SOT=solid organ transplant

## Investment in manufacturing to support full commercialization



### Commercial scale in-house manufacturing established

- 63,000 square foot state-of-the-art facility for GMP manufacturing
  - *RP1-2 technology transfer from CMO successfully completed*
  - *RP1 released to clinic post comparability analysis*
  - *RP1 BLA consistency lot runs complete*
- Scale expected to be sufficient to cover global commercialization of all Replimune's product candidates at full capacity
- Commercially attractive cost of goods & 'off the shelf' product practicality



# RP2 update

# AGENDA



## RP2 leverages Replimune's platform to express anti-CTLA-4



- Anti-CTLA-4 prevents immune blockade at the APC / T cell interface
  - Anti-CTLA-4 is clinically validated; Ipilimumab, tremelimumab
- **RP2 has shown durable mono-therapy responses in multiple immune insensitive tumor types**
  - Salivary gland cancer
  - Chordoma
  - Uveal melanoma
  - Esophageal cancer
- **30% ORR (N=17) in 2L uveal melanoma with impressive duration**
  - Randomized control trial planned ; foundation of rare disease strategy
    - Rare head and neck cancers
    - Sarcomas
    - HPV associated ; vulvar, anal



# Mucoepidermoid carcinoma patient featured in BBC news

Prior carboplatin/paclitaxel, bicalutamide, ceralasertib - ongoing CR>2 years (RP2 monotherapy)



BBC

Home News Sport Business Innovation Culture Travel Earth Video Live



Krzysztof's cancer is no longer detectable

Krzysztof Wojkowski

ICR The Institute of Cancer Research

**"My final lifeline"**

"I had injections every two weeks for five weeks which completely eradicated my cancer. I've been cancer-free for two years now."

1 month

4 months



"It's a true miracle, there is no other word to describe it. I've been able to work as a builder again and spend time with my family, there's nothing I can't do."

Confidential

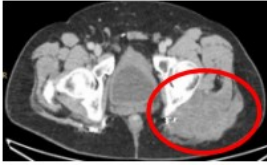
27

# Patient 4401-0029: Chordoma

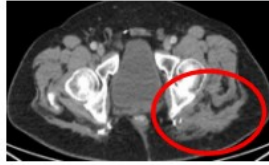
Prior imatinib - ongoing PR at over 8 months (RP2 monotherapy)



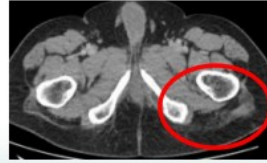
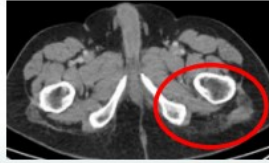
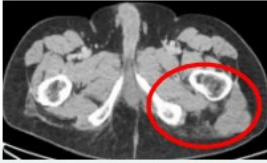
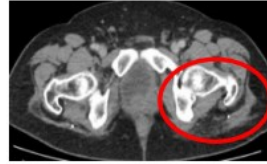
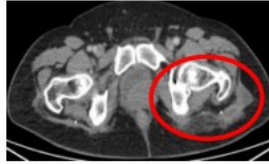
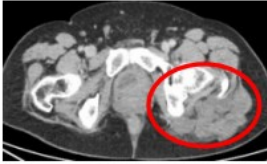
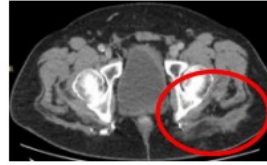
Screening



3 months



6 months



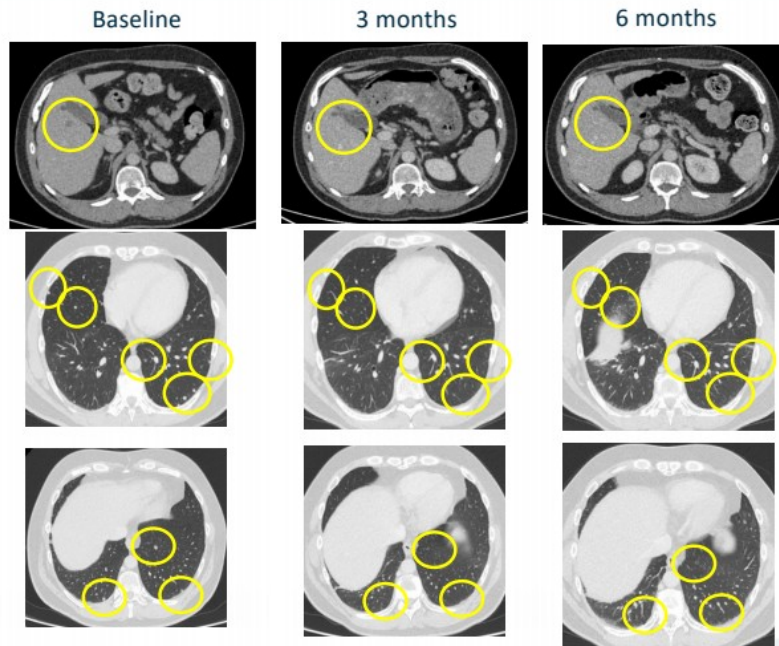
## Pt 4401-0029 - ongoing PR

- Left gluteal muscle injected
- Liver & >50 small lung lesions also disappeared during treatment

● Injected ● Un-injected

# Patient 4401-0029: Chordoma

Prior imatinib - ongoing PR at over 8 months (RP2 monotherapy)

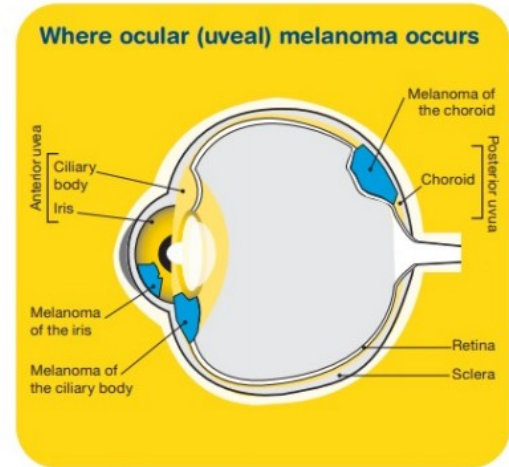


## Pt 4401-0029 - ongoing PR

- Left gluteal muscle lesion injected
- Liver & >50 small lung lesions also disappeared during treatment



- Ocular or “uveal” melanoma is a rare cancer with approx. 1,000 cases in the US per year<sup>1</sup>
  - Originates from melanocytes and can occur in several eye locations
  - The historic median OS is approx. 12 months<sup>1</sup>
- Uveal melanoma **behaves quite differently from skin melanoma**
  - **Mostly metastasizes to the liver** (approx. 70-90% of cases) and once this occurs only about 10% of these patients survive beyond a year
  - **A difficult to treat tumor where CPIs have previously demonstrated limited activity**<sup>2,3,4</sup>
  - Kimmtrak (tebentafusp) is the 1st approved agent in uveal melanoma in HLA-A-02:01-positive adult patients (approx. 50% of the total population)\*
- **Unmet need for uveal melanoma patients remains high, including improved efficacy/tolerability, effective options for HLA negative patients, and options for Kimmtrak and anti-PD1 failed patients**

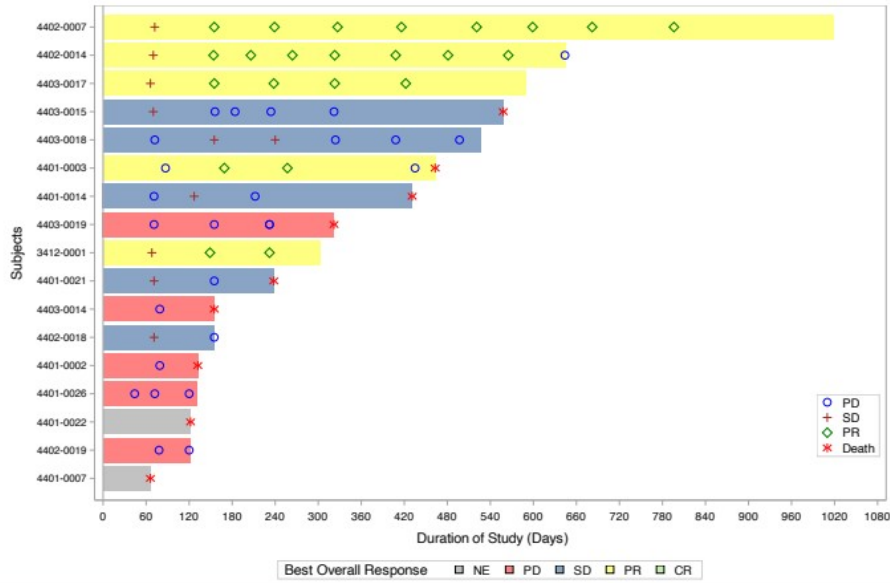


<sup>1</sup>Carvajal RD et al. Br J Ophthalmol 2017; <sup>2</sup>Nathan P et al. N Engl J Med. 2021;385(13):1196-1206; <sup>3</sup>PelsterMS et al. J Clin Oncol. 2021;39(6):599-607; <sup>4</sup>Lukzky J et al SMR 2022;

\* Versus investigator's choice, pembrolizumab, ipilimumab, or dacarbazine

# RP2 Uveal melanoma: Duration of response

Durable responses in small initial dataset, both monotherapy RP2 and RP2 + nivo



### Key Takeaways

- 5/14 (29.4%) evaluable patient responders
- Heavily pre-treated population, with all responders having failed prior CPI

Durable responses represent compelling initial signal

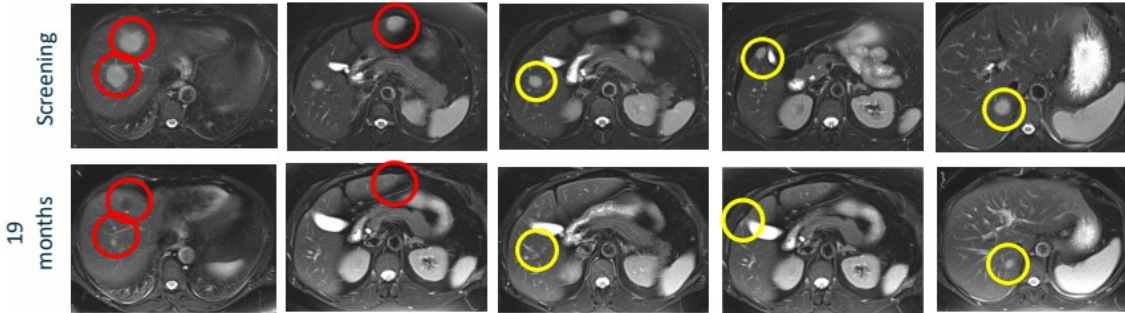
- Longest ongoing response over 24 months

CR, complete response; NE, not evaluable; PD, progressive disease; PR, partial response; SD, stable disease. Data from SMR 2023



# Uveal melanoma patient featured in ITV news

## Prior nivolumab+ ipilimumab – PR (RP2+nivolumab)



Pt 201-4403-0017 – ongoing PR

- Liver metastases
- Patient has ongoing PR at 19 months



"This trial has given me hope in the treatment, the trial, my care, and I'm happy. I don't think about dying anymore at all"

ITV, 03 November 2023



Confidential

3 2



### **RP1 in skin cancer**

- Initial snapshot of data from all 156 anti-PD1 failed melanoma patients demonstrate that RP1+nivolumab maintains transformative potential in this high unmet need setting
  - BLA submission planned for 2H 2024
- While CERPASSS missed its primary endpoints at  $P > 0.025$ , a clinically meaningful benefit in CRR ( $P = 0.04$ ) and DOR in CSCC was demonstrated
- Other skin cancer data in hard-to-treat settings such as solid organ transplant recipients & anti-PD1 failed melanoma & NMSC demonstrate compelling clinical activity



### **Mid-stage pipeline**

- Strong data with RP2 in uveal melanoma
- Planning for a randomized controlled pivotal study in uveal melanoma underway
  - Plan to investigate other rare cancer opportunities



### **Strong cash position**

- Strong balance sheet; \$466m <sup>(1)</sup> as of 31 December 2023
- Cash Runway into H2 2026

<sup>(1)</sup> Unaudited estimate





# THANK YOU

## MISSION

To enable tumor directed oncolytic immunotherapy (TDI) to become a cornerstone in the treatment of cancer

## VISION

To deliver **transformational** results for patients **across cancers** using tumor directed oncolytic immunotherapy to induce a powerful and durable systemic anti-tumor immune response resulting in **quality survival** and a **chance for a cure**

