Society for Immunotherapy of Cancer

SITC 2026

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#SITC26







STEALTH-001: A Phase 1 Study of VET3-TGI, an Oncolytic Vaccinia Virus Encoding TGFb Inhibitor and IL-12, for the Treatment of Advanced Solid Tumors
ABSTRACT #572

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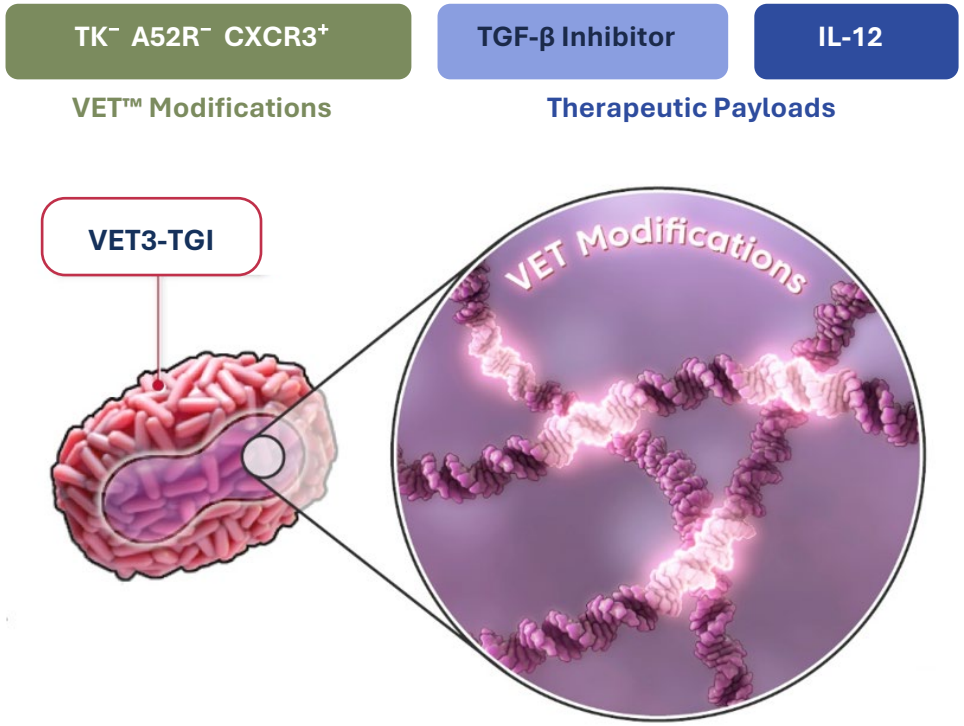
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Disclosures

- Consultant/Advisor: BMS, IDEAYA, Immunocore, Merck, Novartis, Pfizer, Replimune, Sun Pharma, Therakos
- Research Funding (to institution): BMS, Merck, Pfizer, Replimune, Sun Pharma
- Speaker’s Bureau: Immunocore, Pfizer

VET3-TGI: Three Complementary Mechanisms Engineered into a Single Backbone

Western Reserve Vaccinia Engineered with VET™ Modifications and Dual Therapeutic Transgenes



VET3-TGI Construct: Full deletion of the viral TK and A52R genes, CXCR3 insertion for tumor homing, and two encoded payloads expressed locally in the tumor

VET™ BACKBONE MODIFICATIONS

1 Tumor Lysis · TK (J2R/VACWR094), A52R (VACWR178)

Full deletion of viral thymidine kinase and the A52R NF-κB inhibitor gives selective replication in tumor cells, destroying them and releasing tumor antigens with increased selectivity and safety

2 Targeted Delivery - CXCR3

Chemokine receptor engineered into the backbone for targeted systemic delivery to CXCL9-, CXCL10- and CXCL11-expressing tumors

THERAPEUTIC PAYLOADS

3 IL-12 Expression

Potent, pro-inflammatory type 1 cytokine that induces and enhances cell-mediated anti-tumor immunity at the tumor site

4 TGF-β inhibition

Novel inhibitor binds the endogenous TGF-β type II receptor and blocks TGF-β signaling (e.g., a suppressive pathway linked to immune exclusion and reduced antitumor T-cell function)

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STEALTH-001 Study Design

First-in-human, open-label Phase 1/1b of intratumoral VET3-TGI

PATIENTS

Failed or refused standard of care

Tissue for biopsy

ECOG 0–1

Not immunosuppressed with adequate end organ function

Other Information:

All comer solid tumors dose escalation with an emphasis on cutaneous malignancies

PHASE 1

Dose escalation

MONOTHERAPY

1×10^8 → 3×10^8 → 1×10^9 → 3×10^9

3+3 design 28-day DLT window

Mono MTD/MFD

IN PARALLEL

COMBINATION DOSE Phase 1

VET3-TGI + atezolizumab
At/below highest monotherapy dose

Combo MTD/MFD

PHASE 1b

Dose expansion

MONOTHERAPY EXPANSION

Up to 15 additional patients focused on cutaneous malignancies

COMBINATION EXPANSION

Up to 15 additional patients

ENDPOINTS

Safety and activity

PRIMARY

Safety / DLTs
RP2D

SECONDARY

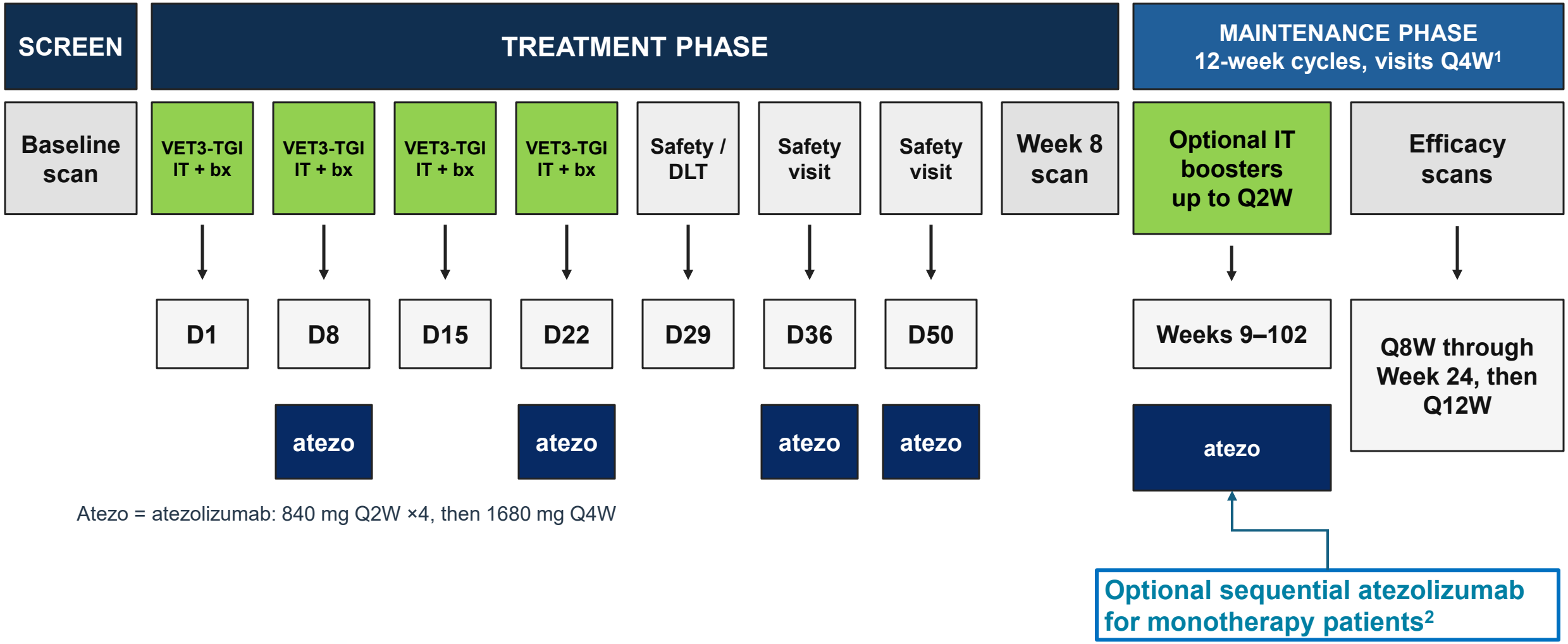
Tumor response
Survival
Viral / immune activity

EXPLORATORY

Viral kinetics / shedding
Additional biomarkers

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STEALTH-001: Intratumoral Treatment Schema



Atezo = atezolizumab: 840 mg Q2W ×4, then 1680 mg Q4W

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1. Maintenance visits: cycle Days 1, 29 and 57 (every 4 weeks). Optional IT boosters may occur up to every 2 weeks.
2. Eligible monotherapy patients may add atezolizumab during maintenance with sponsor and investigator approval.

Baseline Characteristics

As of data cut-off, 20 IT patients dosed (16 monotherapy + 4 combination)

Characteristic	IT Mono Solid Tumor (N = 12)
Demographics	
Age, median (range), yrs	65.5 (44 – 78)
Male, n (%)	5 (41.7%)
ECOG PS 0, n (%)	6 (50.0%)
Tumor type, n	
Advanced melanoma	3
Merkel cell carcinoma	3
Other cutaneous: CSCC	1
Non-cutaneous: [sarcoma, thyroid, gallbladder, NSCLC]	5

Characteristic	All-Comers (N = 12)	Cutaneous (N = 7)
Prior therapy		
Prior lines, median (range)	3 (1-9)	3 (1-9)
Prior anti-PD-(L)1, n (%)	8 (66.7%)	7 (100%)
Prior CTLA-4 + anti-PD-(L)1	3 (25.0%)	3 (42.9%)
IO refractory	11 (91.7%)	7 (100%)
Disease burden		
Stage IV	8 (66.7%)	4 (57.1%)
LDH > ULN, n (%)	8 (66.7%)	6 (85.7%)
Visceral metastases, n (%)[2]	8 (66.7%)	4 (57.1%)

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1. EPP- evaluable patient population; defined as having a BICR-reviewed scan
2. Based on local radiology lesion identification

ECOG PS = Eastern Cooperative Oncology Group performance status; ULN = upper limit of normal; CPI = checkpoint inhibitor.
Data cleaning and monitoring are ongoing; some data remains unmonitored. September 2026 data cut-off.

Preliminary Efficacy Readout: IT Basket vs. Cutaneous Indications

ORR Based on Independent Central Radiology Review

	IT Solid Tumor (N=12)[1]	Cutaneous Indications (N=7)[1]
Objective Response Rate, n (%)	**5 (42%)**	**5 (71%)**
Complete Response	1 (10%)	1 (14%)
Partial Response	4 (30%)[2]	4 (57%)[2]
Stable Disease ≥ 8 weeks	4 (80%)	0 (0%)
Progressive Disease	3 (25%)	2 (29%)
Disease Control Rate, n (%)	9 (75%)	5 (71%)
Duration of Response, months	**NR**	**NR**

Responses seen across multiple dose levels: 1e8 to 1e9

- 3 MCC; 1 CR, 2 PR[2]
- 3 Melanoma; 2 PR, 1PD
- 1 cSCC; 1 PD

KEY TAKEAWAYS

- Deep, durable responses
  - All responders remain on study treatment (range: 10-19 months)
  - Responses remain durable and continue to deepen in some patients
- IT monotherapy and combo expansion ongoing in Phase 1

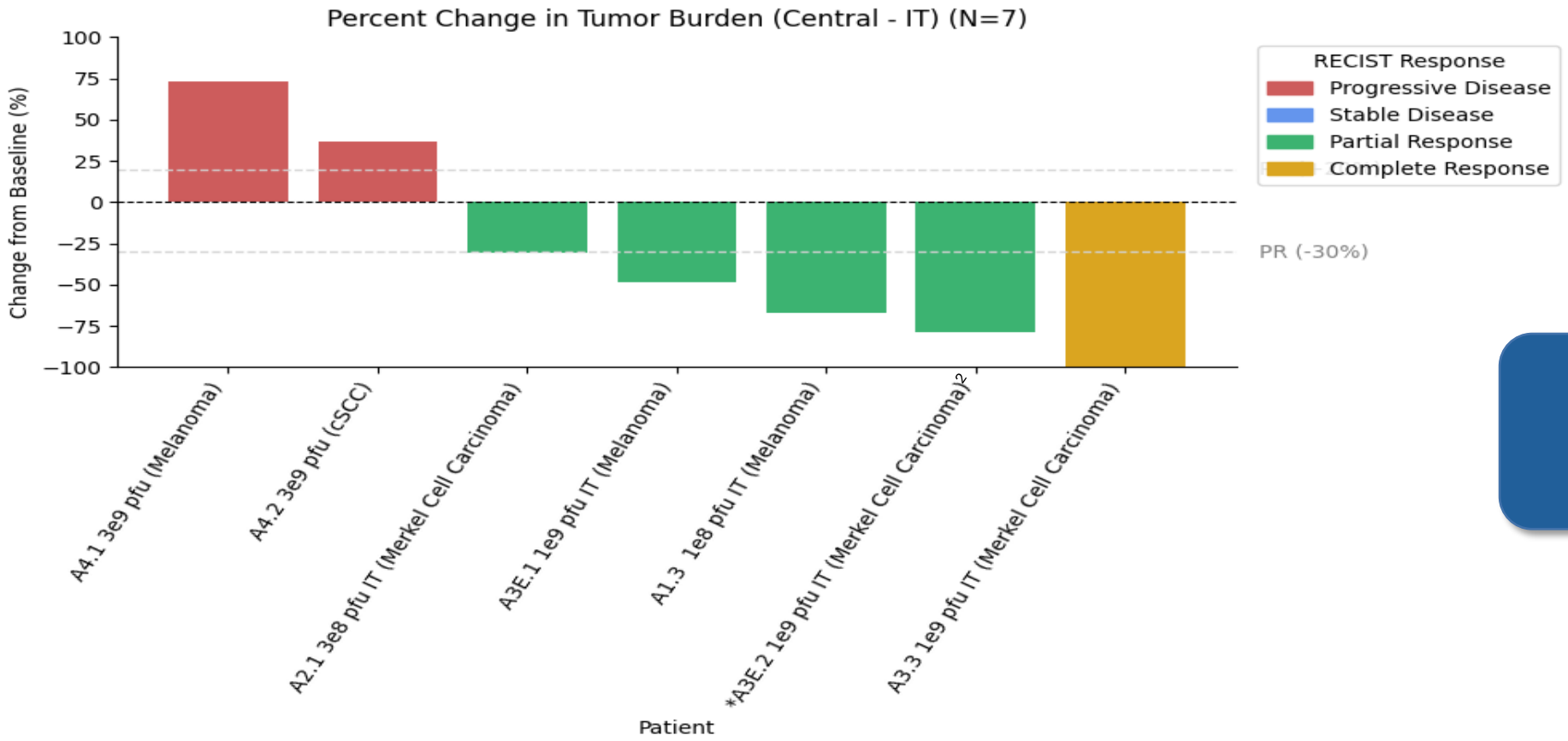
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1. Evaluable patients defined as having a BICR assessment. Patients who have not yet reached W8 or who withdrew consent prior to W8 are not included.
2. MCC #3- PR at week 16 and beyond after addition of atezolizumab at Week 14: -42.6% change at Week 16 vs Baseline, -36% at Week 16 vs wk 8; -79% wk 36 vs BL; and 50% wk 36 vs wk 8. PD at wk 8 based on new lesion, conservatively, as CT failed to capture thigh window at BL.

Information based on an independent RECIST 1.1 assessment performed by a blinded, central radiologist at the imaging core lab. PFU = Plaque Forming Units; DOR = Duration of Response; DLT = Dose-Limiting Toxicities. Data cleaning and monitoring are ongoing; some data remains unmonitored. September 2026 data cut-off.

Broad Antitumor Activity of IT Monotherapy in Cutaneous Disease[1]

Best Overall Response and % Change in Target Lesion by BICR (RECIST 1.1)



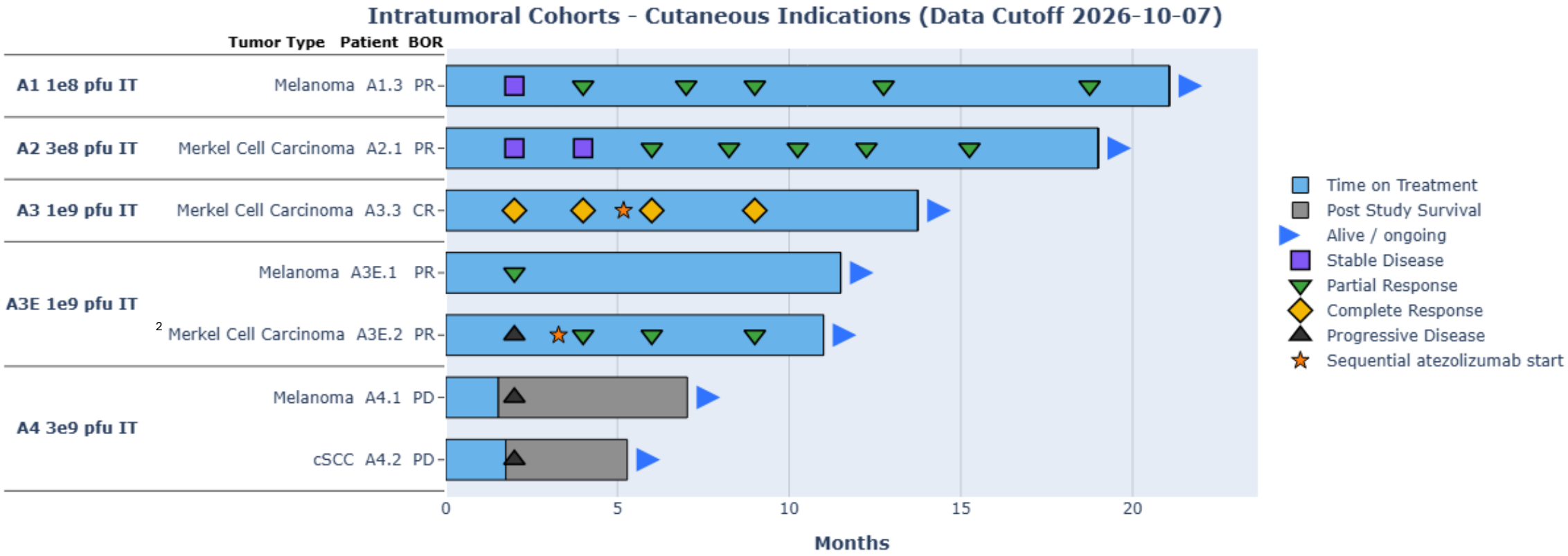
Cutaneous Disease Cohort: ORR: 71%

1. Evaluable patients defined as having a BICR assessment. Patients who have not yet reached W8 or who withdrew consent prior to W8 are not included.
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Information based on an independent RECIST 1.1 assessment performed by a blinded, central radiologist at the imaging core lab. SLD = sum longest diameter
Data cleaning and monitoring are ongoing; some data remains unmonitored. September 2026 data cut-off.

Durability By Patient: Study Disposition & Overall Survival [1]

Reponses have been durable and continues to deepen in several patients



1. Evaluable patients defined as having a BICR assessment. Patients who have not yet reached W8 or who withdrew consent prior to W8 are not included.
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Single-Injection Complete Response In Merkel Cell Carcinoma

- Failed 1 Prior Line (Multiple Resections Followed by Recurrence on the Leg)

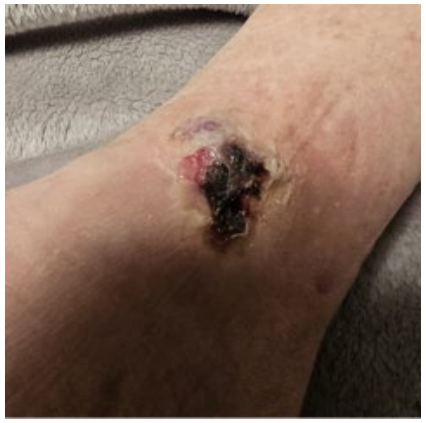
Target Lesion (Day 1)



Target Lesion (Day 8)



Target Lesion (Day 13)



Weeks 8–9: post-debridement





Latest visit: Oct 2026



Complete Response (CR)

Cancer History for Metastatic Disease

- Failed 1 prior line of systemic therapy: Pembrolizumab for 14 months- PD
- Multiple resections (4x) and radiation followed by recurrence on the leg

VET3-TGI Trial Experience

- Received 1 IT injection into one superficial lesion on the leg
- Was unable to receive additional IT injections due to inflammation and necrosis
- Debridement procedure occurred at Week 8 after the CT staging scan. Only necrotic tissue found with normal wound healing post-procedure
- PET CT scan confirmed CR with NED
- Patient remains on study as a CR
- Started sequential atezolizumab ~Week 16 for MRD

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CR = Complete Response. Information based on an independent RECIST 1.1 assessment performed by a blinded, central radiologist at the imaging core lab. Data cleaning and monitoring are ongoing; some data remains unmonitored. September 2026 data cut-off.

Partial Response (PR) in Merkel Patient (IT at 3e8 pfu)

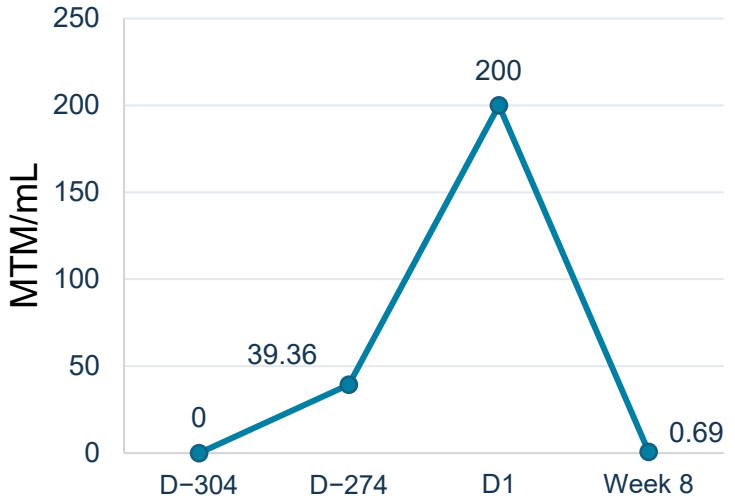
Continued Shrinkage Observed through at least Week 60 with no treatment between W3 and W16

Injected lesions: forearm targets 3 and 4, non-injected lesions 1 and 2

Timepoint	Baseline	Week 8	Week 16	Week 24	Week 60
Size (mm)	81.4	70.0	61.8	56.2	61.8
Target size (% change from BL)	—	−14% (SD)	−24.1% (SD)	−31.0% (PR)	−24.1% (PR)
Non-target / new	+	+*	+*	+*	+*
Overall response	—	**SD**	**SD**	**PR**	**PR**

*Two subcentimeter non-target lesions followed; one disappeared completely (CR).

ctDNA response via Signatera



Early biochemical response predicted future radiographic response (SD→PR)

Prior Therapy: Failed 3 prior regimens

Pembrolizumab (BOR: PD)
Avelumab (BOR: PD)
Nivolumab + Ipilimumab (BOR: PD)

VET3-TGI Trial Experience

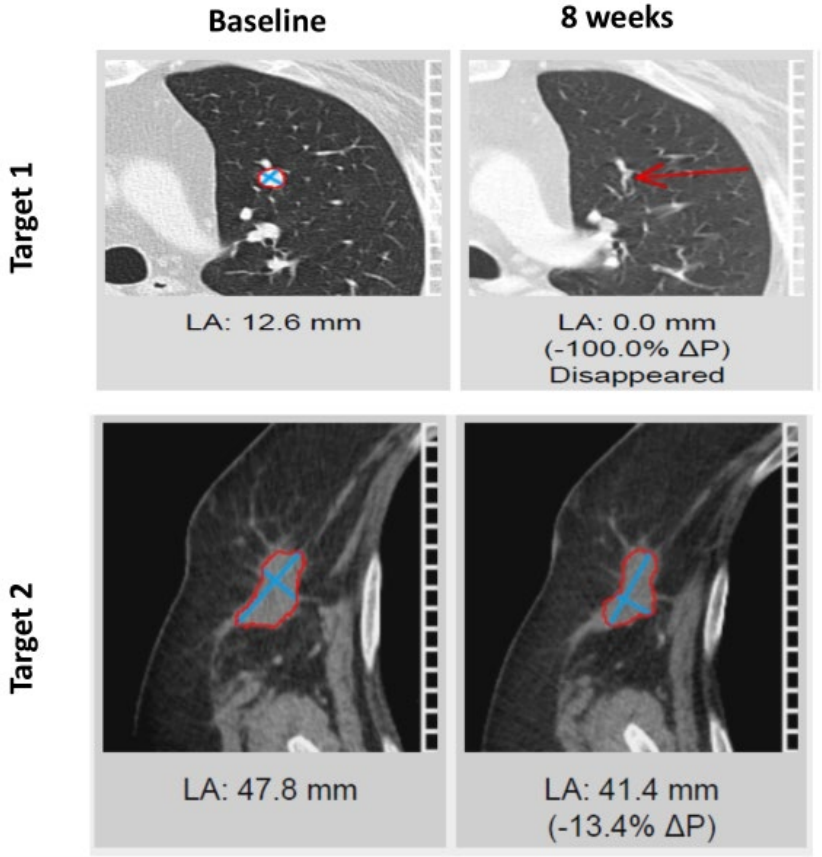
- Received IT injections into two of 4 target lesions on Days 1, 8, 15, and 22
- 85-day treatment gap with dosing resuming at Week 16
- SD maintained despite no treatment: W3- W16
- Continues in maintenance with boosters
- Insufficient tumor tissue present in biopsies to complete immunofluorescence (IF)

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Independent, blinded central RECIST 1.1 review. BL = baseline. SD = stable disease. PR = partial response. CR = complete response. Preliminary data. September 2026 efficacy cutoff. Data cleaning and monitoring are ongoing; some data remain unmonitored.

Partial Response (PR) in Melanoma #2 (IT at 1e9 pfu)

Resolution of non-injected lesion within the lung



Clinical photographs

Screening / Day 1



11-Month post Day 1



Timepoint	Baseline	Week 8
Size (mm)	**60.4**	**41.4**
Target size (%Δ BL)	–	**-31.5% (PR)**
Non-target / New	–	**None**
Final response	–	**PR**

Cancer history for metastatic disease

4 prior lines of therapy

- Pembrolizumab: no response
- Dabrafenib + trametinib: toxicity
- Encorafenib + binimetinib: toxicity
- Nivolumab + relatlimab: PD

VET3-TGI trial experience

- Received 4 IT injections into two lesions (superficial chest and abdominal wall) – Target #2 and a Non-Target lesion.
- Booster injections on hold due to insufficient tumor available for injection

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PR = Partial Response. Independent RECIST 1.1 assessment by a blinded central radiologist at the imaging core lab.
Data cleaning and monitoring are ongoing; some data remain unmonitored.

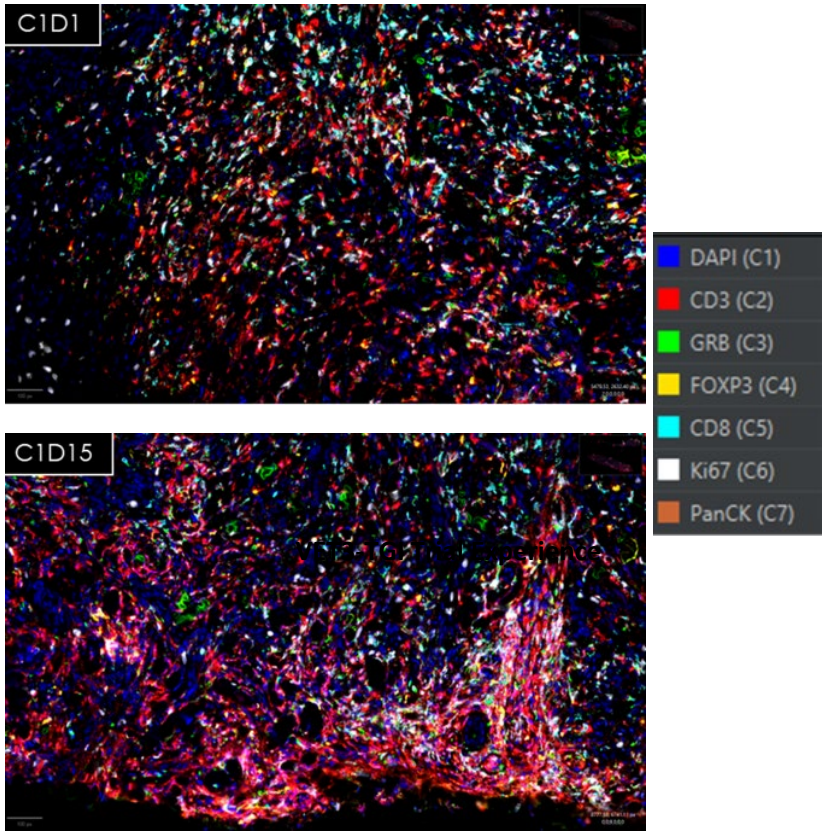
Durable Partial Response (PR) in Melanoma Patient (IT at 1e8 pfu)

Heavily pre-treated patient- PR beginning at Week 16 following SD and ongoing beyond Week 72; continues to deepen, with all lesions too small to measure. Target lesions are non-injected.

Four target lesions, all non-injected

Timepoint	Baseline	W8	W16	W24	W36	W48	W60	W72
Size (mm)	60.5	65.6	39.5	24.8	23.8	20.0	NE*	20.0
Change from baseline	—	**+8.4%**	**−34.7%**	**−59.0%**	**−60.7%**	**−66.9%**	**NE***	**−66.9%**
Non-target / new	—	Present / No	Present / No	Present / No	Present / No	Present / No	CR / No	CR / No
Overall response	—	**SD**	**PR**	**PR**	**PR**	**PR**	**NE***	**PR**

Non-injected lesion biopsy



2.5× CD8+ **2.4×** CD8+GRB+ **4.8×** CD8+Ki67+

Prior Therapy: Failed 5 prior regimens

- Peginterferon alfa-2b
- Ipilimumab + T-VEC
- Nivolumab + ipilimumab
- Ipilimumab + pembrolizumab
- Pembrolizumab + brentuximab

VET3-TGI Trial Experience

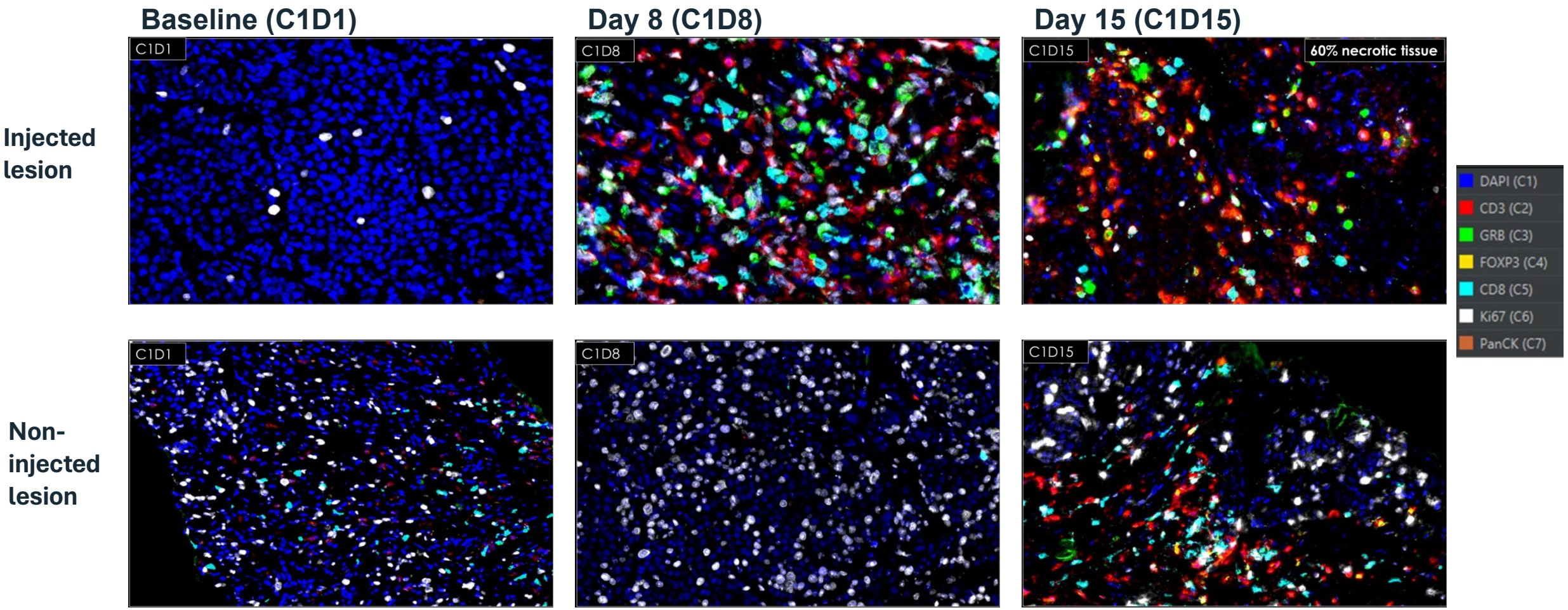
- Received IT injections into **non-target** lesions on the left leg on Days 1, 8, 15, and 22
- Continues in maintenance with boosters every 4 to 8 weeks
- Ongoing past Week 84 – with a deepening response
- Non-injected lesion with increased T-cell infiltration and activation (see IF images)

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*Week 60: imaging artifact made target lesions T01–T03 non-evaluable. PR = partial response. SD = stable disease. NE = non-evaluable. Preliminary data. September 2026 cutoff. Data cleaning and monitoring are ongoing; some data remain unmonitored.

Melanoma: immune changes in paired lesion biopsies

Low baseline immune staining, with post-treatment increases in both lesions



Clinical response: Non-Evaluable. Patient declined further travel.

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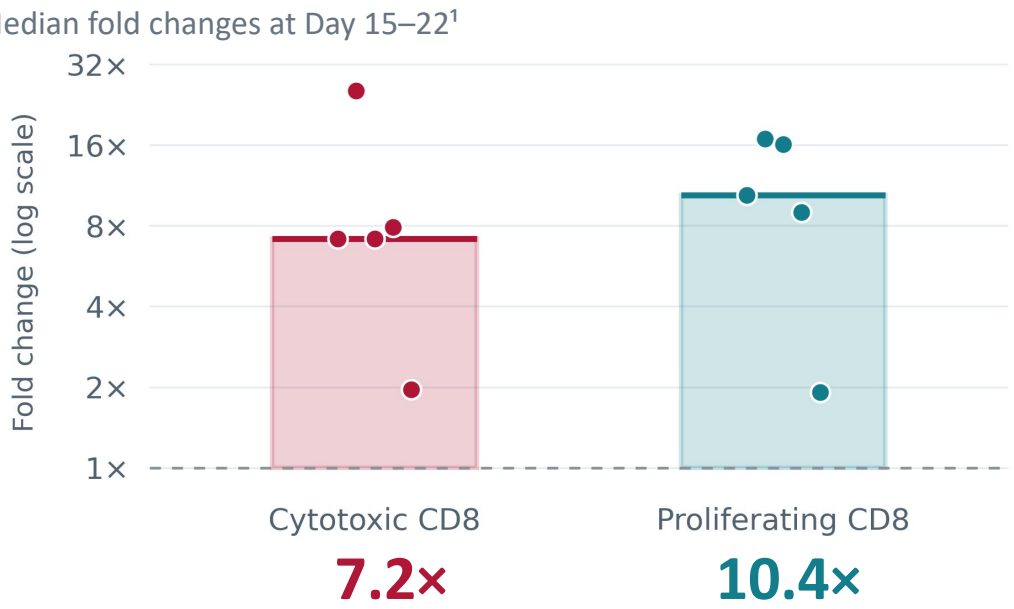
Data cleaning and monitoring are ongoing; some data remains unmonitored. September 2026 data cut-off.

Early Translational Data: A More Active Tumor Immune Environment

Consistent increased infiltration of cytotoxic and proliferating CD8+ T-cells in treated and untreated tumors

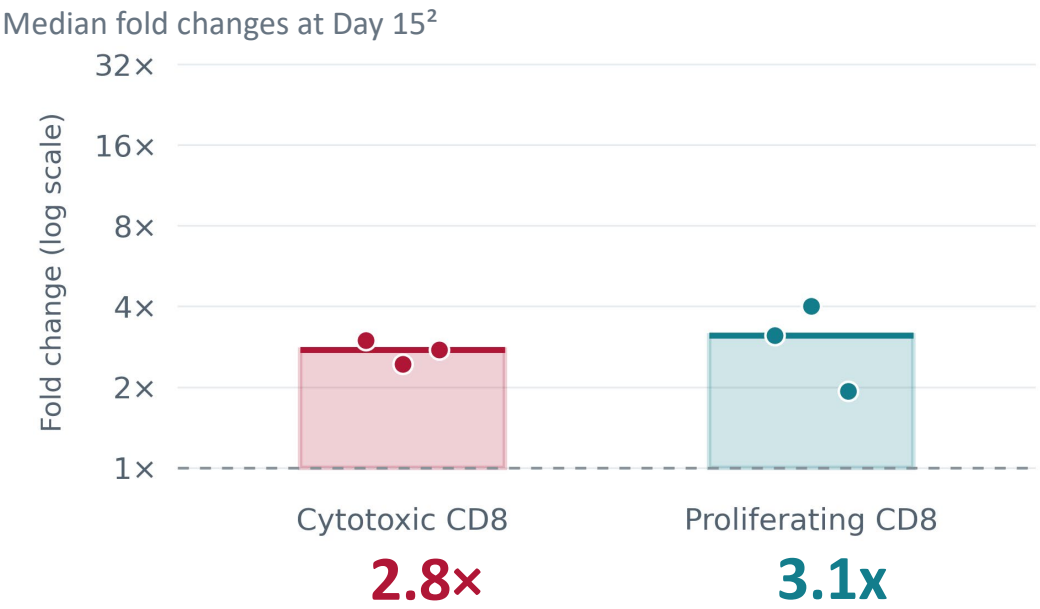
Injected lesions (n=5)

5/5 Paired biopsies with increased immune activity



Non-injected lesions (n=3)

3/3 Paired biopsies with increased immune activity



Translational Readouts Describe a MOA that Converts Immunologically "Cold", CPI Refractory Tumors "Hot"
Biological Basis for Durable Clinical Responses, Not Just a Transient Injection-site Effect

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[1] Latest paired injected biopsy per patient, Day 15–22 (n=5). [2] Paired non-injected biopsy, Day 15 (n=3). Bars show medians, dots show individual patients. Shared log scale, 1× = baseline.
Cytotoxic CD8 = CD8+GRB+ T-cells; Proliferating CD8 = CD8+Ki67+ T-cells. Preliminary descriptive findings, markers do not establish tumor-specific immunity.
Tumor types: Injected lesions = Rhabdomyosarcoma (PD), Leiomyosarcoma (SD), Melanoma (PR), Medullary Thyroid (SD), Gallbladder (SD); Non-injected lesions = Colorectal (NE), Melanoma (104-002- PR), Melanoma (104-004-NE)

Related Adverse Events in Safety Evaluable Cohort– All Dose Levels[1]

No Dose-Limiting Toxicities have been reported – escalation completed in doses up to 3e9 pfu

Preferred Term	Grade 1	Grade 2	Grade 3	Grade 4	All Grades
Cytokine release syndrome	4 (20)	6 (30)			10 (50)
Chills	2 (10)	6 (30)			8 (40)
Nausea	3 (15)	4 (20)	1 (5)		8 (40)
Vomiting	3 (15)	3 (15)	1 (5)		7 (35)
Lymphocyte count decreased		1 (5)	2 (10)	2 (10)	5 (25)
Anaemia		3 (15)	1 (5)		4 (20)
Fatigue	3 (15)	1 (5)			4 (20)
Hyponatremia	2 (10)	1 (5)	1 (5)		4 (20)
Hypophosphataemia	2 (10)	2 (10)			4 (20)
Injection site reaction	2 (10)	2 (10)			4 (20)
Alanine aminotransferase increased	2 (10)		1 (5)		3 (15)
Influenza like illness	3 (15)				3 (15)
Pyrexia	1 (5)	2 (10)			3 (15)
White blood cell count decreased	2 (10)			1 (5)	3 (15)

1. Data for events occurring in 10% or more of patients (N=20) treated as of 30Jun2026
Data cleaning and monitoring are ongoing; some data remains unmonitored. September 2026 data cut-off.

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Preliminary Conclusions & Key Takeaways

1	**TOLERABILITY**	Well tolerated as monotherapy and in combination, with no dose-limiting toxicities through the maximum feasible dose.
2	**LOCAL & SYSTEMIC ACTIVITY**	Initial evidence of responses in injected and non-injected lesions across cutaneous tumor types.
3	**RESPONSE DURABILITY**	Tumor responses remain durable, with some exceeding 18 months.
4	**MECHANISTIC VALIDATION**	Preliminary translational analyses reveal consistent TME remodeling, supporting an immunological shift from “cold” to “hot” in both injected and non-injected lesions.
5	**NEXT DEVELOPMENT STEP**	Additional studies planned to confirm clinical activity in cutaneous tumors.

Acknowledgements

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