GenVivo

CELL GENE
MEETING ON THE MESA

Defeating Cancer with Off-the-Shelf '*Personalizing*' Cancer Immunotherapy

GenVivo, Inc. ®

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GenVivo Executive Summary – Multiple Short-Term Milestones

Clinical

GEN-2: our latest stage asset with clinical validation: ***off-the-shelf,*** **intravenously** administered**, activates** the patient's own immune system (**'*personalizing*')** to **seek out and destroy** patient's cancer (ongoing expansion phase in **hepatocellular** (**HCC), breast, and melanoma** malignancies)

- ✓ Prodrug activated proprietary enzyme/immunostimulatory cytokine
- ✓ Demonstrated safety & efficacy
- ✓ Ongoing US Phase 1b monotherapy expansion phase with data 2H26
- ✓ Checkpoint inhibitor combination study begins 4Q2025 with data 4Q2026

Pipeline

Versatile vector platform (G-Volve) with advantages over competitors:

- ✓ *in vivo* CAR-T/NK program (GEN-310); file IND in 2026
- ✓ IL-12-encoding vectors (GEN-1013); file IND in 2026
- ✓ Non-integrating vectors

Manufacturing

In-house multiuse cGMP facility:

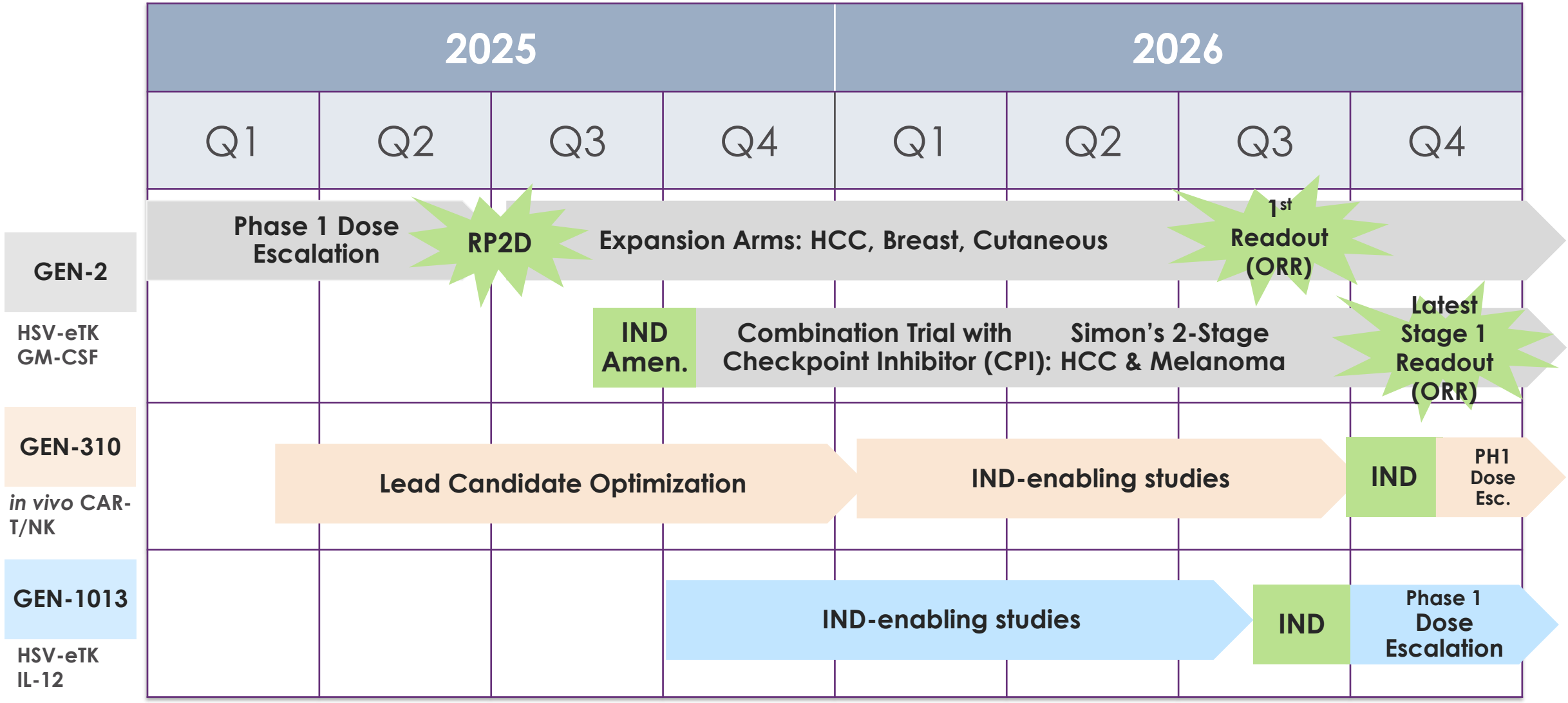
- ✓ Stable suspension cell lines
- ✓ Scalable, consistent, and cost-effective (low COGs)
- ✓ Can produce high quality product to supply through Phase II

GenVivo Pipeline

Building Platform Value Through Diverse Payloads and Target Expansion

Candidate	Indication	Description	Phase
GEN-2	**Solid Tumors (HCC, Breast, Melanoma)**	**Vector encoding HSV-eTK* and GM-CSF dual payloads** *Proprietary Herpes Simplex Virus – enhanced Thymidine Kinase engineered for more potent cell killing	**Phase 1b**
GEN-310	**Liquid Tumors**	***in vivo* CAR-T/NK with targeted vectors**	**Pre-Clinical**
GEN-1013	**Solid Tumors**	**Vector encoding HSV-eTK and IL-12 dual payloads**	**Pre-Clinical**
GEN-0X00	**Solid Tumors**	**Targeted vectors against specific tumor cell surface receptors (Nectin-4, EGFR, HER2)**	**Discovery**

Clinical Development Timeline and Inflection Points

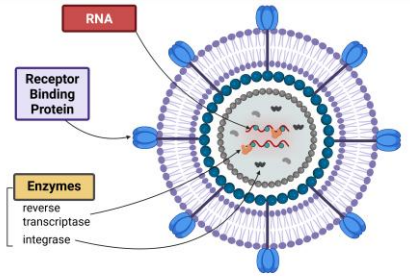


GenVivo's G-Volve Platform

Advantages of Our Versatile, Targeted, Non-Replicating Vector Platform

- **Large capacity** to insert genes (8kb transgene payload capacity)
- **Surface proteins** can be modified to **target** desired cell surface receptors
- **Selectively targets** actively dividing cells
- Expression can be regulated with **suicide gene** and prodrug
- Integrating for cancer
- Non-integrating for autoimmune, vaccines, gene editing
- **Delivered IV** (or IT)
- **Manufacturing**: High potency, scalable, stable, robust and cost effective; in-house cGMP facility

Differentiated from AAV, LNPs, and oncolytic virus platforms



	Vaccinia	HSV	Adeno	Lenti	G-Volve	AAV	LNP
Capacity	190 kb	150 kb	35 kb	9 kb	8 kb	4 kb	2 - 5 kb
Nucleic Acid	DNA	DNA	DNA	RNA → DNA	RNA → DNA	DNA	RNA
Mitotic Selectivity	🔴	🔴	🔴	🔴	🟢	🔴	🔴
Targetability	🔴	🔴	🟡	🟢	🟢	🟡	🟡
Promoter Control	🟡	🟡	🟡	🟢	🟢	🟡	🔴
Genomic Integration	🔴	🔴	🔴*	🟢	🟢	🔴	🔴*
Immunogenicity	🔴	🟡	🔴	🔴**	🟢	🟡	🟡
Manufacturability	🔴	🔴	🟡	🟡	🟢	🟡	🟡
Clinical IV Safety	🟡	🔴	🟡	🟡	🟢	🟡	🟢

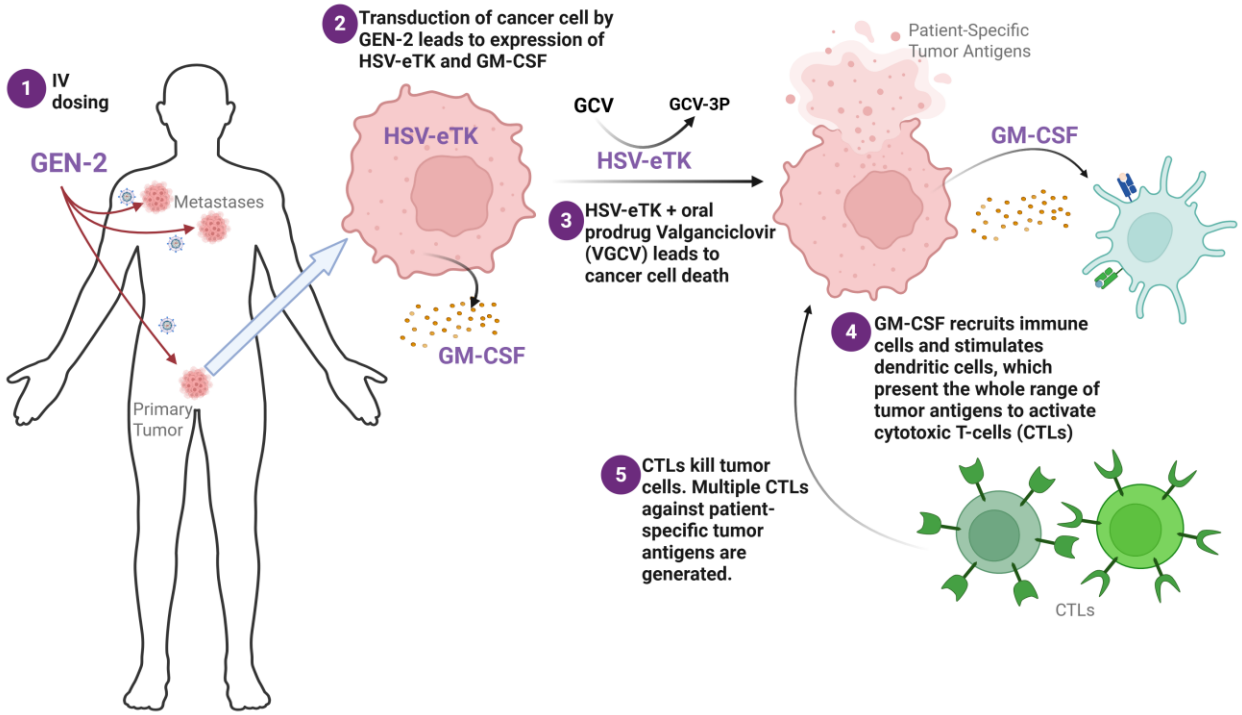
Why GEN-2?

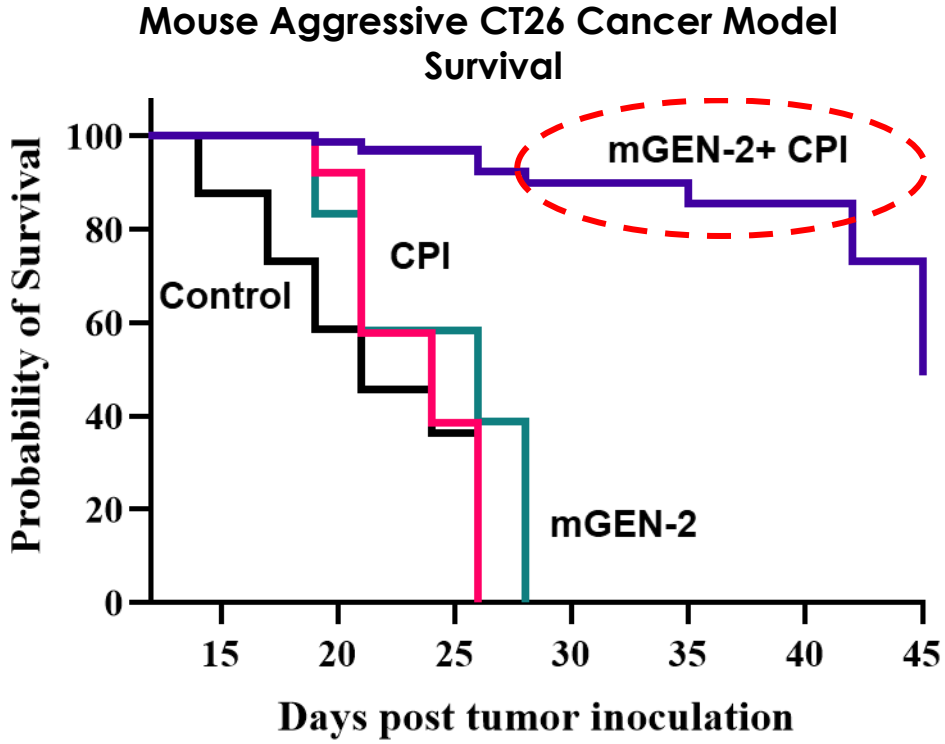
Off-the-shelf, intravenously administered, **activates** the patient's own immune system (**'*personalizing*')** to **seek out and destroy** patient's cancer

Advantages:

- ✓ Off-the-shelf (no time delay; no biopsies, no gene sequencing)
- ✓ Captures all of patient's tumor antigens including neoantigens
- ✓ Repeat dosing to capture new mutations
- ✓ Can be administered IV
- ✓ Very well tolerated
- ✓ Clinical efficacy demonstrated
- ✓ Strong Patent position
- ✓ Consistent, reliable, high quality drug supply; in-house cGMP facility
- ✓ Low COGs

GEN-2 – Dual Mechanism + Checkpoint Inhibitor Synergy





- **Initial cancer-killing mechanism: cytotoxic metabolite;**
- **+ 2nd mechanism: amplified tumor-specific immune killing**

GEN-2 with anti-mPD-1 CPI in CT26 aggressive mouse tumor model

CPI =Checkpoint Inhibitor
mGEN-2 = mouse GEN-2
mPD-1 = mouse PD-1

GEN-2 Asia Clinical Trial Design (EPB-002): NCT04313868

GEN-2 Treatment of Primary Liver Cancer or Liver Metastases

Safety and Efficacy Demonstrated

Recommended Phase 2 Dose (RP2D) not reached:
further dose escalation & RP2D achieved in US trial

Phase 1
Total n= 61

IV – Intravenous n=48	HAI – Hepatic Artery Infusion n=12	IT – Intratumoral n=1
Dosing Schedule	Dosing Schedule	Dosing Schedule
Week 1: Days 1, 2 & 3	Week 1: Days 1,2	Week 1: Day 1

VGCV: Days 8-12
Treatment Holiday: Days 13-21
Cycle Length: 3 weeks

Valganciclovir (VGCV) = prodrug

Inclusion Criteria
Liver involvement, advanced stage malignancy (primary or metastatic)

Dose Range – Week 1
$1.1x10^5$ - $1.0x10^8$ TU/kg (Transducing Units)

Sites
Philippines – 5 sites

Patients treated
61

GEN-2 Asia Phase 1 Trial: Promising Evidence of Efficacy & Safety

Partial Response by RECISTv1.1 in 2 of 6 HCC patients treated by HAI

- One confirmed by follow-up scan
- >50% reduction in a-fetoprotein tumor marker in additional patient with HCC

Stable disease (SD) in 18 of 39 IV patients (46.2%) (dosing was over 3 logs due to concerns about bone marrow toxicity - which was not observed)

- 11 (28.2%%) patients had SD confirmed by a consecutive assessment at least 4 weeks after the first observation.
- 11 SD patients includes: 5 with HCC, 4 w/ HR+ breast cancer, 1 w/ rectal carcinoma, & 1 w/ nasopharyngeal carcinoma

Few Treatment Emergent Adverse Events (TEAEs)

- Possibly related TAEs: Anemia (n=2); Chest pain (n=2); Decreased appetite (n=2)
- Only one Grade 3 Treatment Related Adverse Event (TRAE): Chest pain of one day duration

Well-Tolerated Even at 4 Highest Dose Levels (n=12)

- Median number of cycles: 5.5 (range 2.0 – 28.0) (Cycle = 3 weeks)
- **No Dose Limiting Toxicity** or hypersensitivity reactions observed
- No patient withdrawn for adverse event

RECIST – Response Evaluation Criteria in Solid Tumors
HCC – Hepatocellular carcinoma
HR+ - Hormone Receptor positive
HAI – Hepatic Artery Infusion

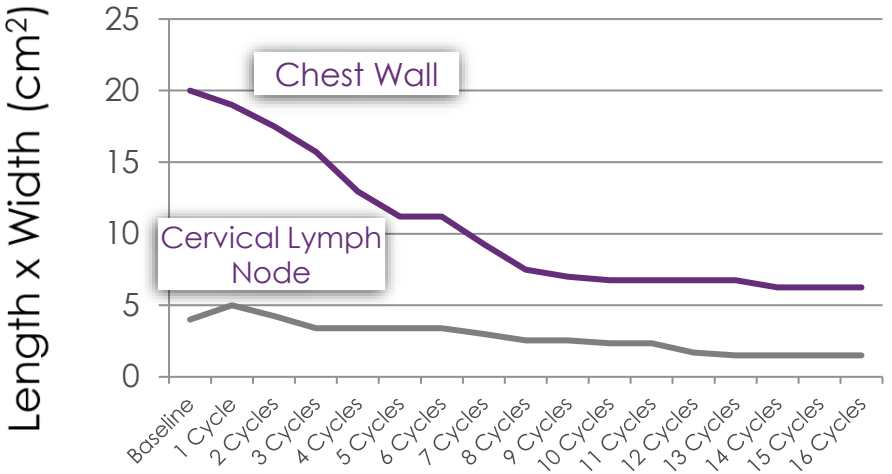
GEN-2 Clinical Benefit - Asia Phase 1 Breast Cancer Patient

One HR+ breast cancer patient with cutaneous response

- 3 prior regimens for metastatic disease (including 2 hormone therapies and paclitaxel/carboplatin)
- 17 cycles of IV GEN-2 at Dose Level 6 (1.0 E+7 TU/kg): Cycle = 3 weeks
- Overall stable disease including liver lesions

(NOTE: Photo size adjusted so that ruler is the same size in all photos)

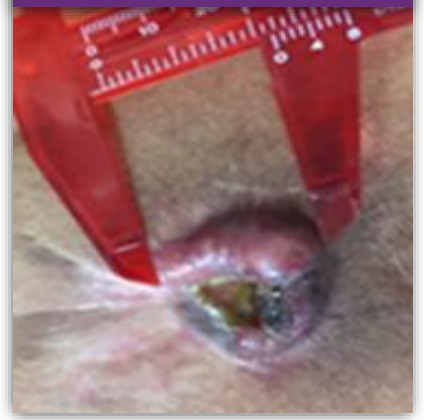
External Lesion Measurements



Prior to GEN-2
5.0 x 4.0 cm

Post 7 Cycles
3.2 x 2.9 cm

Post 10 Cycles
2.7 x 2.5 cm



Post 14 Cycles
2.5 x 2.5 cm

GEN-2 U.S. Phase 1 Ongoing (GVO-1102): NCT06391918

Evaluating GEN-2 monotherapy & combination therapy with immune checkpoint inhibitor

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Protocol

GEN-2: Days 1, 3 & 8
VGCV: Days 12-21
Treatment Holiday: Days 22-28
Cycle Length: 4 weeks

Intravenous Dosing (Main Emphasis)

Eligibility
All solid tumors; progression after 2 lines of FDA-approved therapies

Dose Escalation (COMPLETED)

Monotherapy Expansion (OPEN and RECRUITING)
Three arms of 15 patients each
HCC, breast & cutaneous

Combination: Simon's 2-stage Design with CPI (4Q '25)
HCC and Melanoma

US SITES
USC Norris
City of Hope
NEXT Virginia
Indiana
Sarah Cannon
UCLA
Iowa
+
Additional (TBD)

Intratumoral Dosing (For Comparison)

Eligibility
Selected cutaneous cancers; progression after 2 lines of FDA-approved therapies

Dose Escalation (OPEN and RECRUITING)
Semi-log: 3 + 3 cohorts until first drug related Grade 2 toxicity

Combination: Simon's 2-stage Design with CPI
Melanoma

GEN-2 U.S. Phase 1 (GVO-1102) Protocol Objectives

Primary Objective	Secondary Endpoints
• To determine Recommended Phase II Dose (**RP2D**) (**IV** and IT) in patients with locally advanced or metastatic tumors • To evaluate the **antitumor activity** of GEN-2 in **combination with a Checkpoint Inhibitor**(CPI) in patients with **HCC or melanoma** (**ORR by RECIST 1.1**)	• Relationship between PK and drug effects • Quantification of circulating immune cell subsets and functional activity • ctDNA: serial blood draws for assessment of circulating tumor DNA in the plasma compartment
Secondary Objectives	
Safety and tolerability of GEN-2 + CPI	• Cytokine levels by serial blood draws
Characterize PK properties GEN-2 + CPI	• Paired biopsy sub-study: tumor tissue will undergo other exploratory analyses
Immunogenicity of GEN-2	

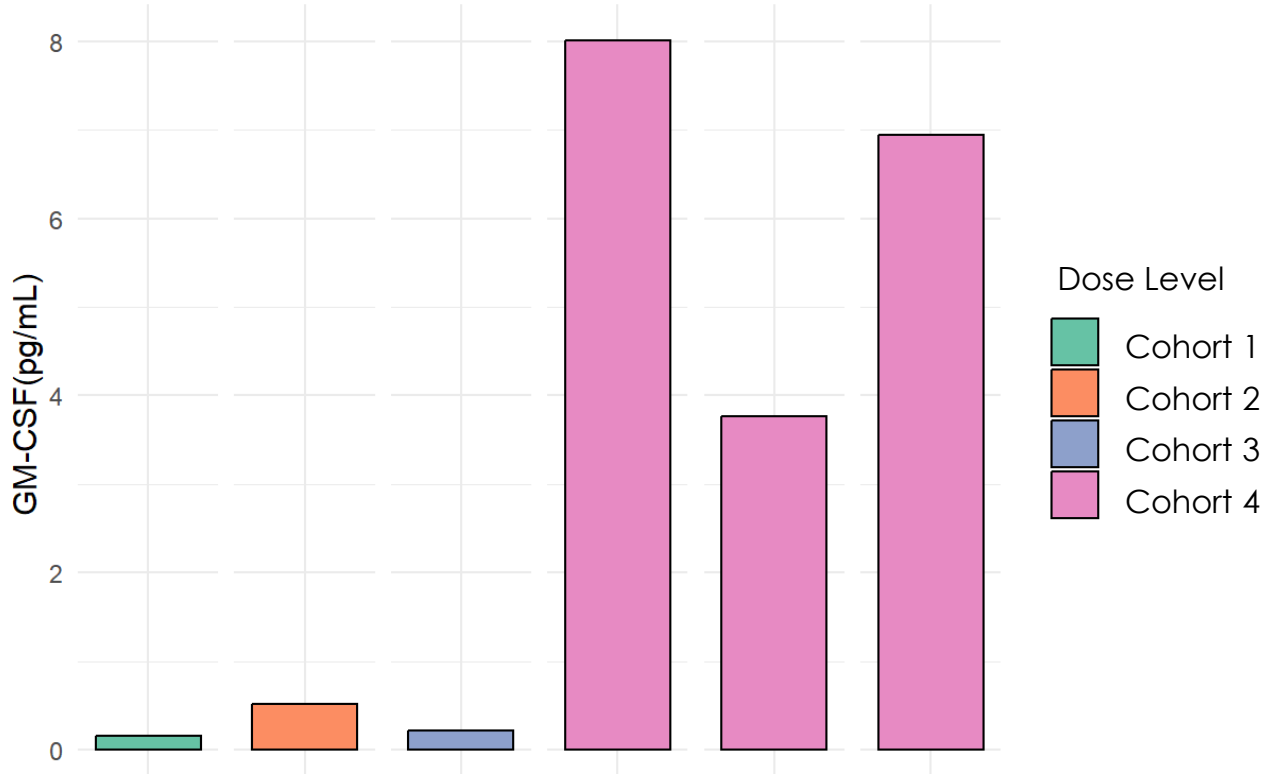
GEN-2 US Phase 1 Data Demonstrates Safety and Signs of Pharmacodynamic Activity

29 patients have been treated (IV)at 5 dose levels starting at 3.4E6TU/kg and reaching 2E8 TU/kg. One patient has been dosed with IT GEN-2 (3E7 TU).

- No DLTs observed over this dose range
- PK data demonstrate an elimination half life 0.6 hours
- Assessment of paired biopsies is pending
- Assessment of cytokines demonstrates consistent increase in GM-CSF by Cycle 1 Day 8
- Consistent pharmacodynamic changes (both vector integration into PBMC DNA and quantitation of GM-CSF in plasma) were observed starting at DL4

GEN-2 Induced GM-CSF Pharmacodynamic Effect

GM-CSF Plasma Concentration After Cycle 1 Day 8 Dose by Dose Level



Assessment of cytokines demonstrates consistent increase in GM-CSF by Cycle 1 Day 8 (third infusion of cycle) for 3 out of 3 evaluable patients enrolled in Dose Level #4 (1E8 TU/kg).

GEN-2 Advantages vs. Competition: IV Administration + Dual Payload

Vectors Using IT and Intravesical Dosing Moving Toward Commercial Approval

Product	CAN-2409	CG0070	RP1	GEN-2
Vector	Adenovector	Adenovirus	HSV	Retrovector
Payload	**HSV-TK**	**GM-CSF**	**GM-CSF**	**HSV-eTK & GM-CSF**
Replication	**No**	Yes	Yes	**No**
Admin	IT	Intravesical	IT	**IV & IT**

GenVivo benefits vs. competition:

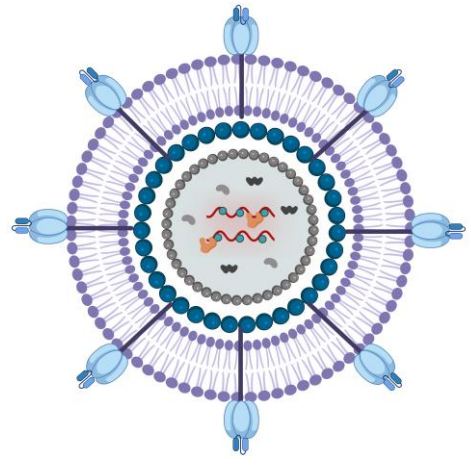
- Capacity for a dual-payload for synergistic potency of HSV-eTK and GM-CSF
- Non-replicating vector to eliminate safety concerns
- IV delivery to reach more tumors while being easier to administer
- Flexibility of dosing route: IV, IT separately, sequentially, or together

In Vivo CAR-T: Advantages of Our G-Volve Platform

GenVivo

GEN-310

- **Intrinsic Selectivity**:
  Selectively transduces active (non-exhausted) T cells
- **Targeting**:
  Engineered envelope can enhance specificity and efficiency
- **Optimized Safety Switch**:
  Inclusion of kill switch provides inherent safety capability
- **Payload Expression:**
  Selective regulatory elements (cell specific promoters, miRNA de-targeting)
- **Drug Supply:**
  Rapid in-house manufacturing with high titer stable cell lines
- **Clinically Proven Platform**:
  Patient data supports transduction and safety *in vivo*



GenVivo is the only company in the *in vivo* CAR-T space focusing on gamma-retrovector, a workhorse for *ex vivo* CAR-T production.

GenVivo CAR Vectors Are Effective at T-Cell Transduction in Human PBMCs

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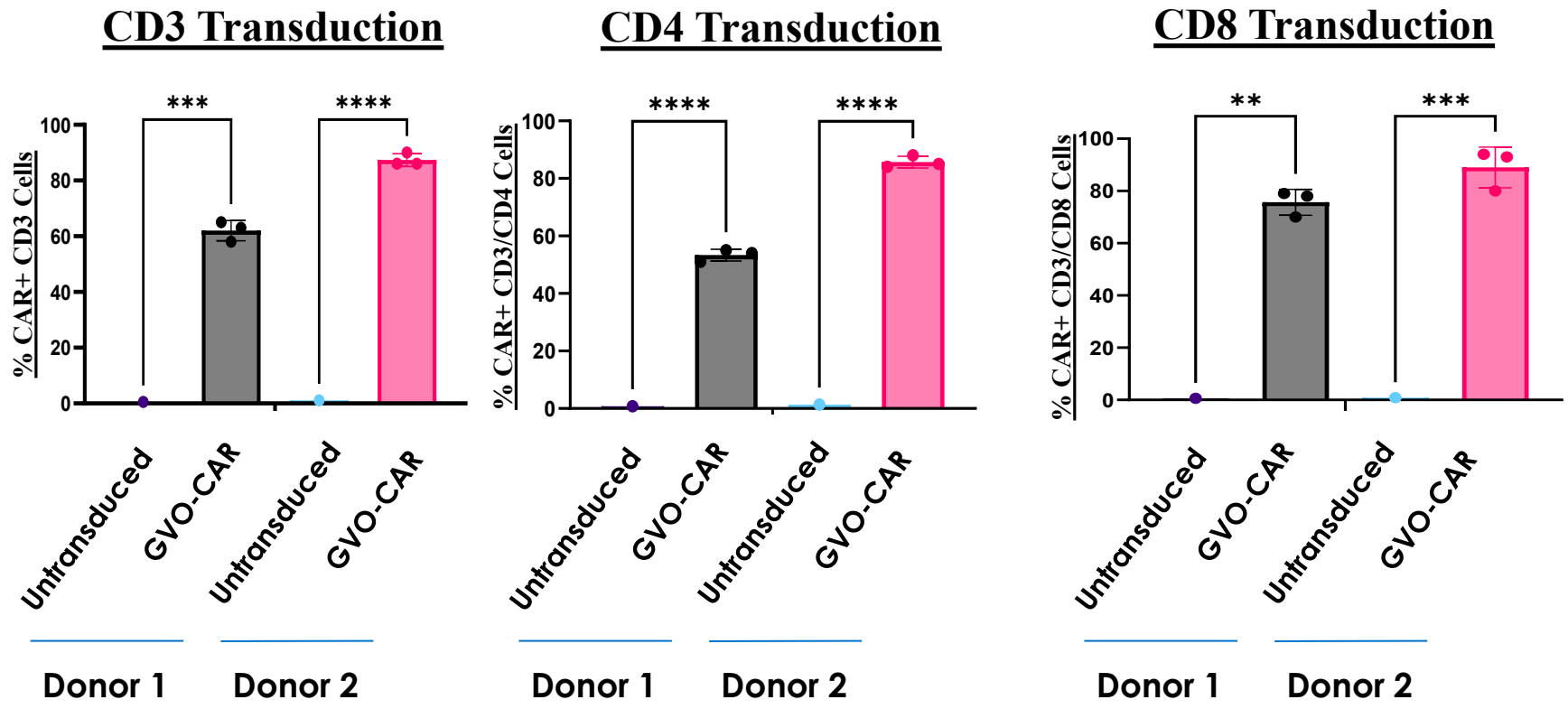
GEN-310

Anti-CD19 CAR



** P<0.01
*** P<0.001
**** P<0.0001

PBMC: Peripheral Blood Mononuclear Cells

CAR vectors transduce and integrate into a majority of actively dividing T cells

GenVivo CAR Vectors Are Effective at B-Cell Depletion in Human PBMC Cultures Post-Transduction

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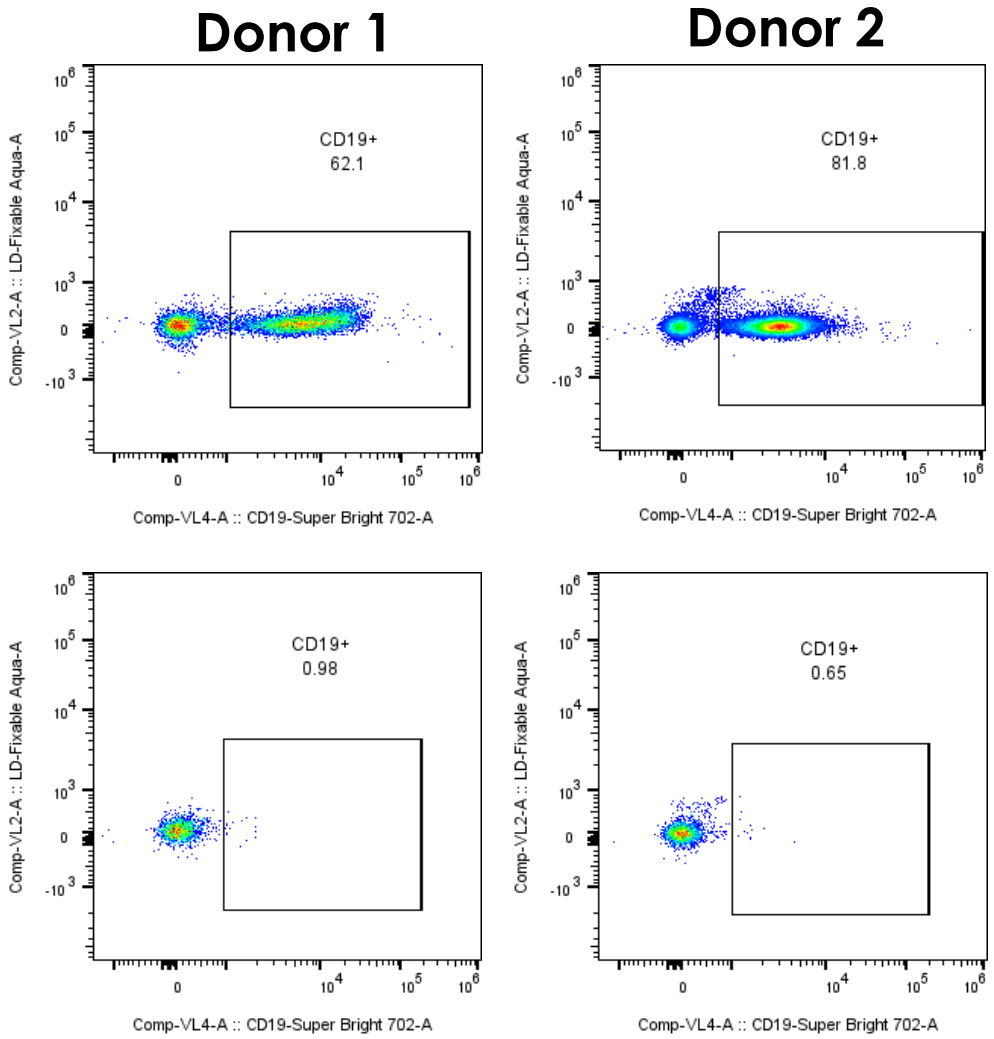
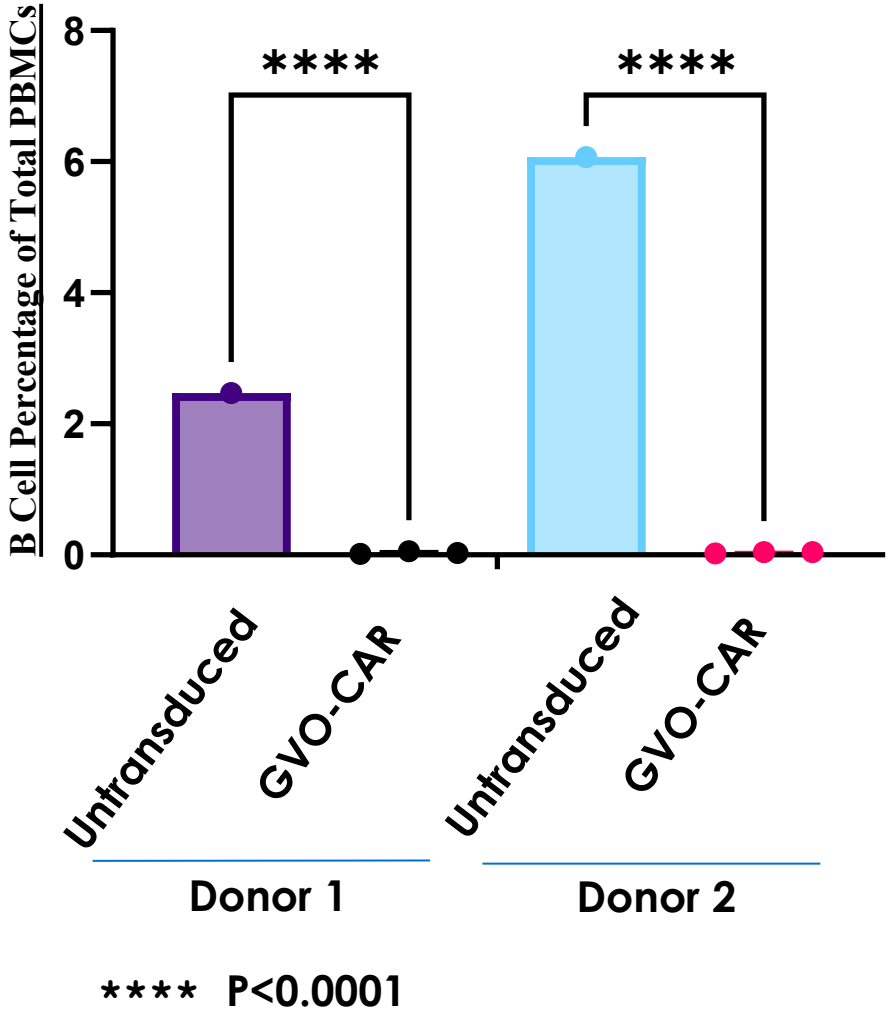
GEN-310





**** P<0.0001

Evidence of PMBC Transduction and Transduced Cell Elimination from GEN-2 Phase 1 Trial

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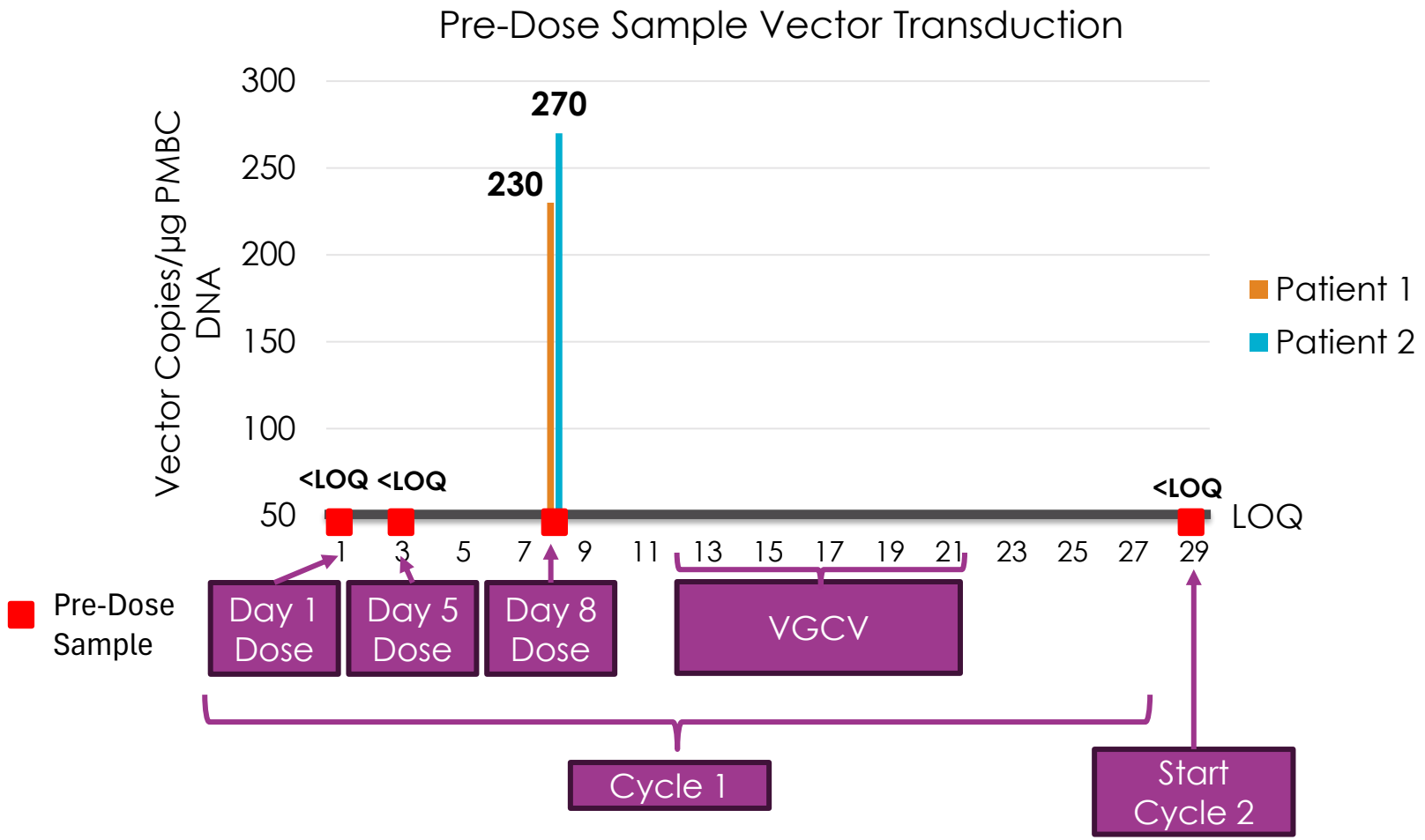
GEN-310

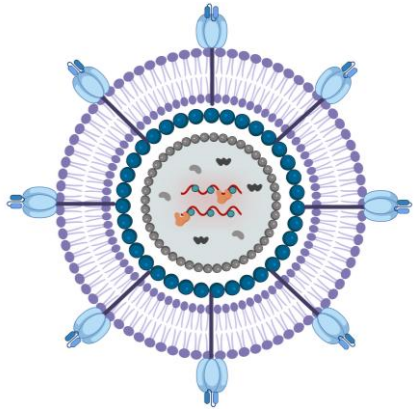


GEN-2 clinical data demonstrates *in vivo* human PBMC transduction and effectiveness of safety switch.

VGCV: Valganciclovir, pro-drug LOQ: limit of quantitation = 50 copies/µg DNA

GenVivo Rapid CAR Development Via G-Volve Platform

Platform Experience



- Clinically Proven Platform
- Multi-payload capacity
- Long-term expression
- In-house cGMP manufacturing

Targeting

Immune Cell Specificity

- Intrinsic selectivity to T cells
- Transcriptional / translational regulatory elements
- Envelope engineering

CAR / other

Seek and Destroy

- Anti-cancer CAR
- TCR, BiTE
- CAR for autoimmune

Immunocytokines

Immune Modulation

- Immune cell activity/durability
- Remodel tumor environment

Safety Switch

Therapeutic Control

- Termination of treatment
- Modulate activity

Identify the best targeted, armored CAR-T/NK candidate for clinical testing

GEN-1013: Harnessing IL-12

A potent, pro-inflammatory cytokine with remarkable antitumor efficacy

GenVivo

GEN-1013

Promotes proliferation and enhances cytotoxicity of Cytotoxic T Cells (CTLs) and Natural Killer (NK) cells

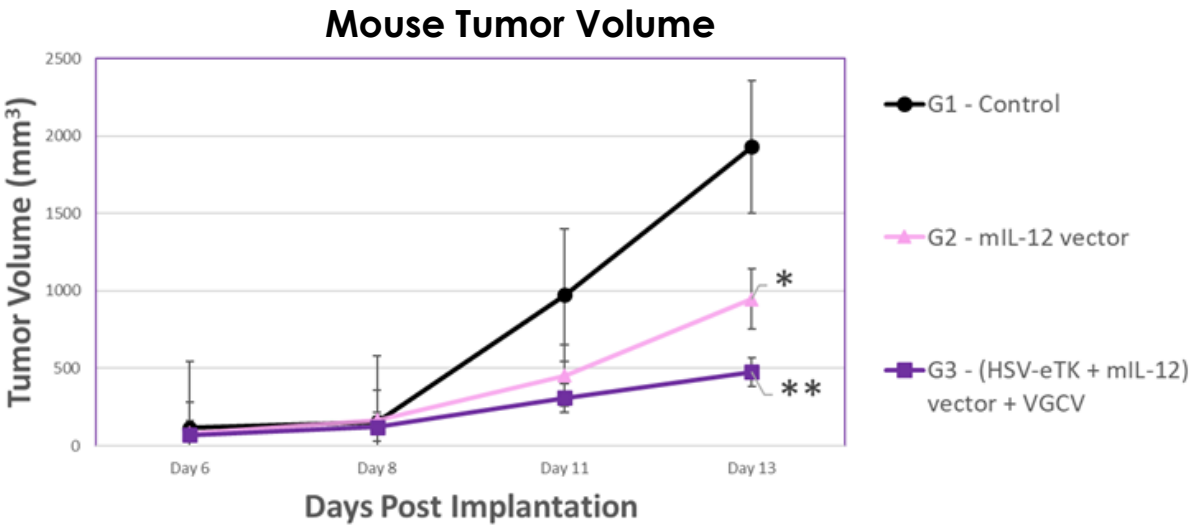
Inhibits or reprograms immunosuppressive cells

Directs immune response to achieve tumor regression

Stimulates Dendritic Cells (DCs) to produce IL-12 and promotes neoantigen presentation

However, IV infusion of IL-12 protein results in severe systemic toxicity in multiple 3rd party clinical studies.

Significant Tumor Growth Inhibition after Systemic Delivery of GenVivo IL-12 Vectors



Two IV infusions of mGEN-1013 in CT26 murine tumor model

T-test p-value compared to G1
* p-value < 0.01
** p-value < 0.001

mGEN-1013 = mouseGEN-1013

[1] Nguyen KG et. al., Localized Interleukin-12 for Cancer Immunotherapy. Front Immunol. 2020 Oct 15;11:575597. doi: 10.3389/fimmu.2020.575597. PMID: 33178203; PMCID: PMC7593768.
[2] Jia Z, et. sl.,. IL12 immune therapy clinical trial review: Novel strategies for avoiding CRS-associated cytokines. Front Immunol. 2022 Sep 20;13:952231. doi: 10.3389/fimmu.2022.952231. PMID: 36203573; PMCID: PMC9530253..

mGEN-1013 Dosing Causes An Increase in Circulating Activated Effector T and NK Cells

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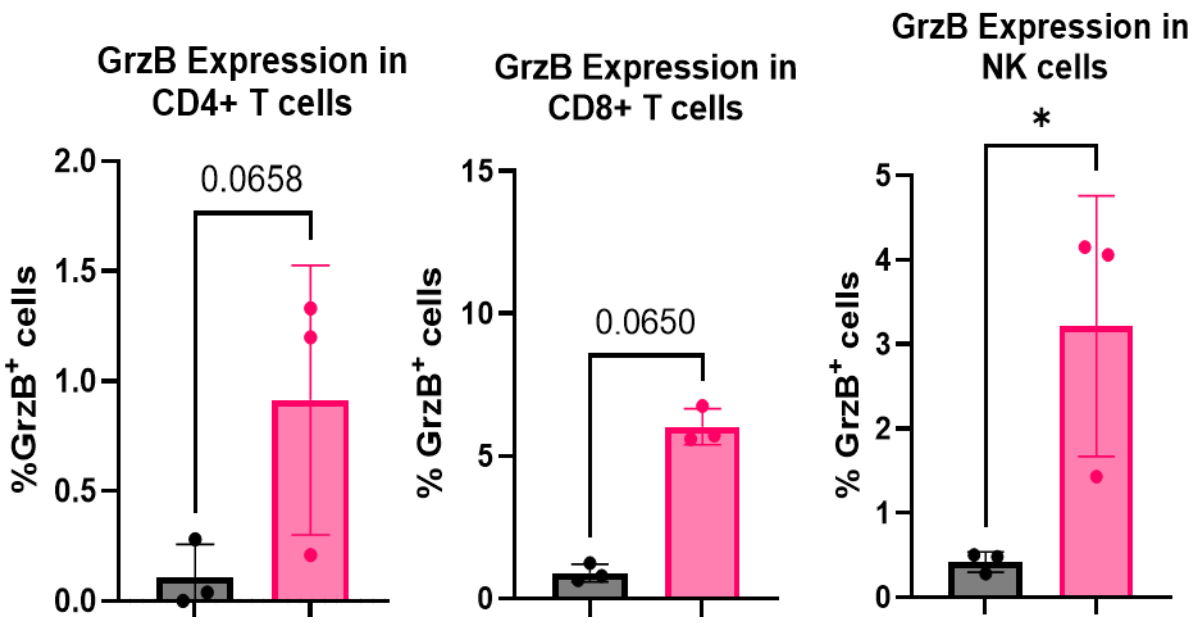
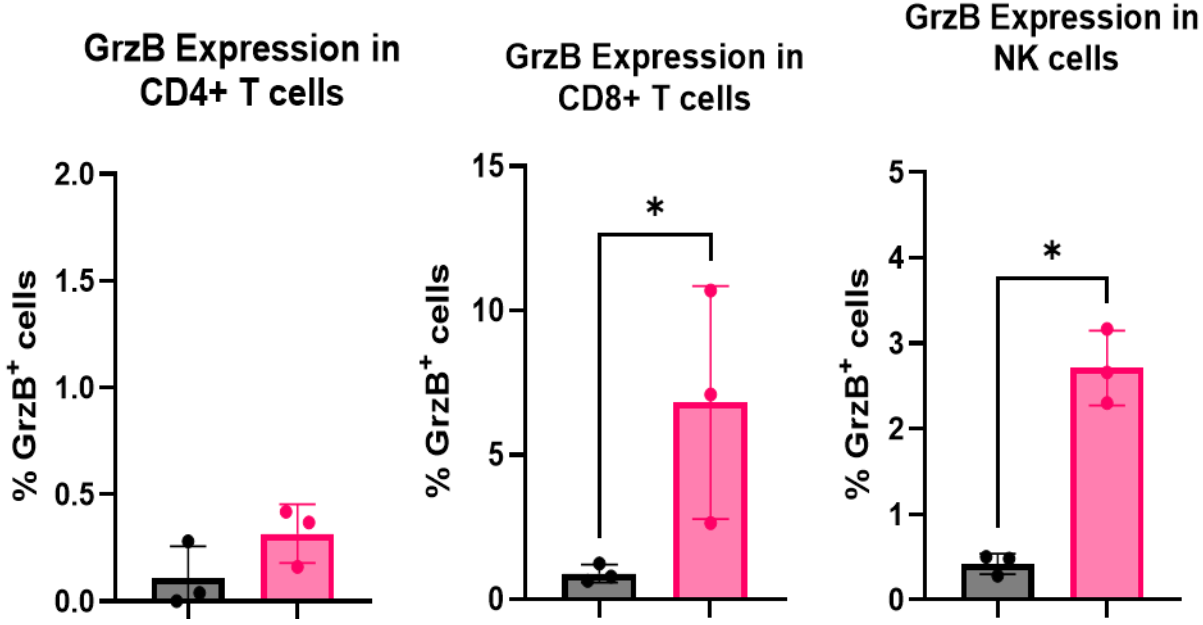
GEN-1013

Intravenous Vector Administration



Intratumoral Vector Administration



Vehicle (IV)

mGEN-1013

Immediate Forward Plan:
Complete pre-clinical animal testing

mGEN-1013 = mouse GEN-1013
GrzB = Granzyme B

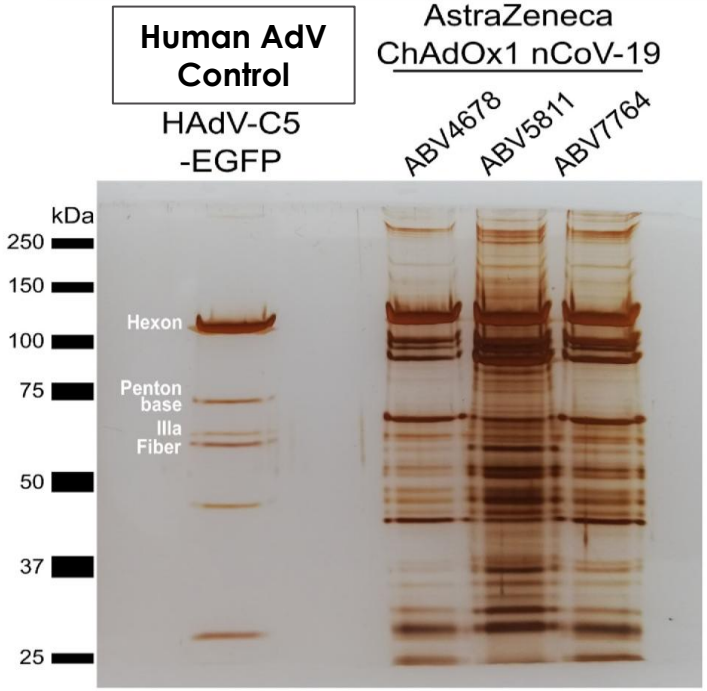
In-House cGMP Manufacturing Capabilities

Scalable, consistent, high quality, cost-effective advantages

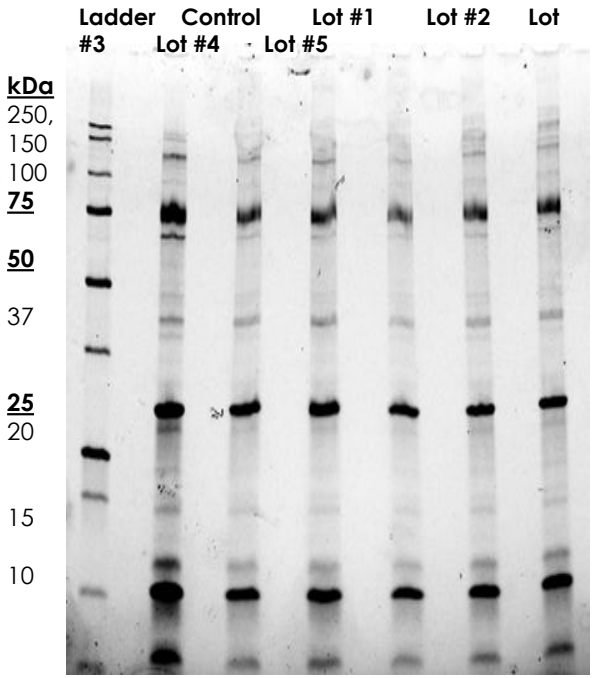
Low COGS: fully loaded cost of GEN-2 vial is ~$200.

Comparison of GEN-2 with a Commercial Vector Product

Commercial COVID vector vaccine

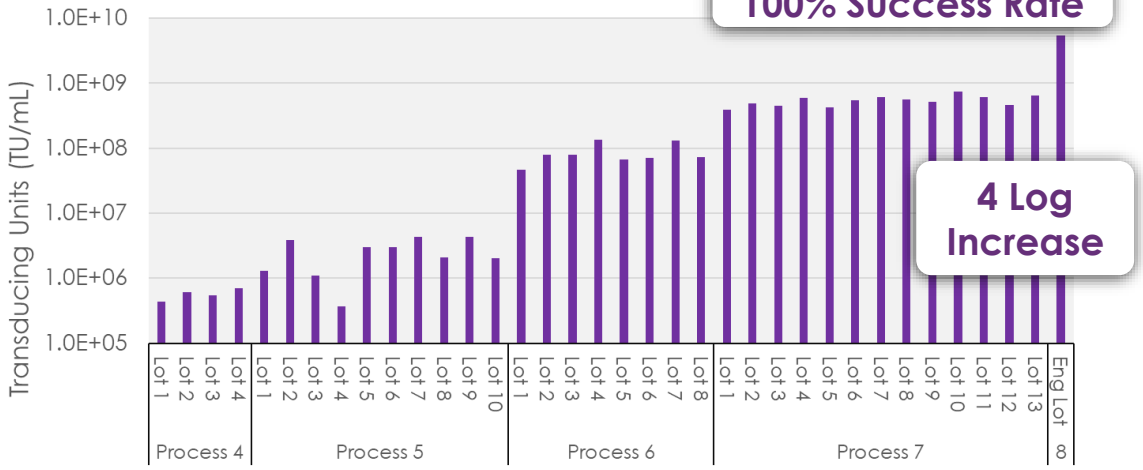


GEN-2



GEN-2 Process Improvements

Recent GEN-2 Mfg.: 100% Success Rate



4 Log Increase

- ISO 7/8 classified space cleanrooms
- Multi-use facility
- Single-use technology
- Quality Systems in place

GenVivo's Strong Patent Portfolio

Broad Range of Issued/Allowed Patents

- **Issued Patents (Composition of Matter)**
  - GEN-2: US/EU/AU/CA/CN/JP/NZ; 2 Continuations in US
  - GEN-1013: US (on-going prosecution in other countries)
  - Integrase Defective Vectors: US (on-going prosecution in other countries)
- **Active Prosecution:**
  - Targeting #1; Deleted Integrase; CAR; CRISPR Vectors
- **Provisional Patents**
  - Targeting #2; GEN-2+CPI; Manufacturing

Key Milestones and Inflection Points

GEN-2

- Establish ORR and DOR in 3rd Line HCC and melanoma
  - Demonstrate activity in CPI refractory patients
  - Simon's 2-stage Design reduces risk
- Clear inflection points
  - Stage 1 Combo Results by 4Q26 a the latest
    - Move to Stage 2 could be earlier due to open label study
  - First Readout (ORR) monotherapy expansion Phase 3Q26

GEN-310 (*in vivo* CAR-T/NK)

- Primate Studies 1H26 (key metrics: lack of CRS, longevity, specificity, efficacy)
- File IND *in vivo* CAR-T 2H26

GEN-1013 (IL-12 Vector)

- Complete pre-clinical testing
- File IND 2H26

Experienced GenVivo Management

David Dornsife
Chief Executive Officer

Herrick USC

Robert Johnson, M.D., Ph.D.
Chief Operating Officer

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Alison L. Hannah, M.D.
Chief Medical Officer

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Victor Constantinescu, M.Eng.
Business & Program Management

Takeda · Baxter

Nori Kasahara, M.D., Ph.D.
Chief Scientific Officer

UCSF · ALLIANCE for CANCER GENE THERAPY · 4DMT

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GenVivo's 'Personalizing' Cancer Immunotherapies

Multiple Near-Term Value Inflection Points

- **GEN-2**: capitalize on the synergy between GEN-2 and CPI in areas of unmet medical need with systemic administration and off-the shelf therapy; Simon's 2-stage design to reduce risk: Readouts 2H26
- **GEN-310**: defining an *in vivo* CAR-T intervention with specificity for T/NK cells: IND 2H2026
- **GEN-1013**: harnessing the power of IL-12: IND 2H26
- **G-Volve platform** technology can be applied to other indications: autoimmune diseases, vaccines, gene editing
- **In-house cGMP** manufacturing: high quality, consistent, cost-effective
- Strong Composition of Matter **patents**