GenVivo

***Personalizing,* Off-the-shelf, *Systemic,* Cancer Immunotherapy**

Forward-looking statement

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GenVivo

Mission: Clinically develop innovative, *personalizing*, off-the-shelf, *systemic*, targeted vector-based immunotherapies

Vision: GenVivo will make first- and best-in-class immune therapies that are immediately and easily deployable, highly effective, and which improve survival and quality of life beyond current therapies.

First- & Best-In-Class Solution: GenVivo's technological advantages will induce broad, potent, patient-tumor-specific anti-cancer immune responses, by:

- Enabling precision targeting and direct killing of tumor cells
- Exposing cancer antigens (and neo-antigens), and simultaneously priming the immunological milieu with cytokines
- *Personalizing* activation of a patient's own tumor-killing immune responses for ongoing immune lysis of cancer cells
- Systemic delivery with a clinically demonstrated safety profile
- No time delays or expense usually associated with conventional individualized cancer immunotherapies

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Benefits vs. Other Cancer Vaccine and Immunotherapy Approaches:

- ***Immediate* treatment of patients**
  - No biopsies needed to determine mutations to create patient-specific treatment
  - No tumor gene sequencing needed to identify antigen targets
  - No delays to make the vaccine or grow cells
- **Our vector directly kills the cancer cells <u>and</u> activates the anti-tumor immune response**
  - Initial suicide gene killing is independent of the antigens expressed by the tumor
  - Subsequent cytolytic immune responses target <u>all</u> of the tumor's antigens (hence patient-specific and comprehensive antigenically)
- **Repeat dosing catalyzes new immune responses against any later tumor mutations (neoantigens)**

<u>Dual-mechanisms of lead candidate (GEN2)</u>

HSV-eTK* + GM-CSF synergize:

Personalizing cancer immunotherapy

On-going tumor-specific killing

*eTK (enhanced Thymidine Kinase) is our proprietary more potent version of Thymidine Kinase

GenVivo Highlights

1 Company	**Private, clinical-stage** company with breakthrough, **off-the-shelf vectors** for *personalizing* cancer **immunotherapies**
2 Platform	**Targeted, non-replicating** vectors that can be **dosed systemically** and **repeatedly.** Vectors can be **integrating** or **non-integrating**
3 Mechanisms	**Dual mechanisms: 1) direct killing of tumor cells, 2) generation of immune tumoricidal responses specific for patient's tumor antigens** resulting from cell killing by the suicide gene in the presence of locally-produced cytokines
4 Clinical	US Phase I/1b enrollment **Q2 2024.** Data from **59 patients** in Asia Phase I trial demonstrated safety and tolerability with evidence of **clinical benefit**
5 Manufacturing	**In-house cGMP** facility utilizing suspension cell lines, with production capacity through **Phase II**
6 Pipeline	**Varied mRNA payloads** and **targeted vectors** for specific cancer types

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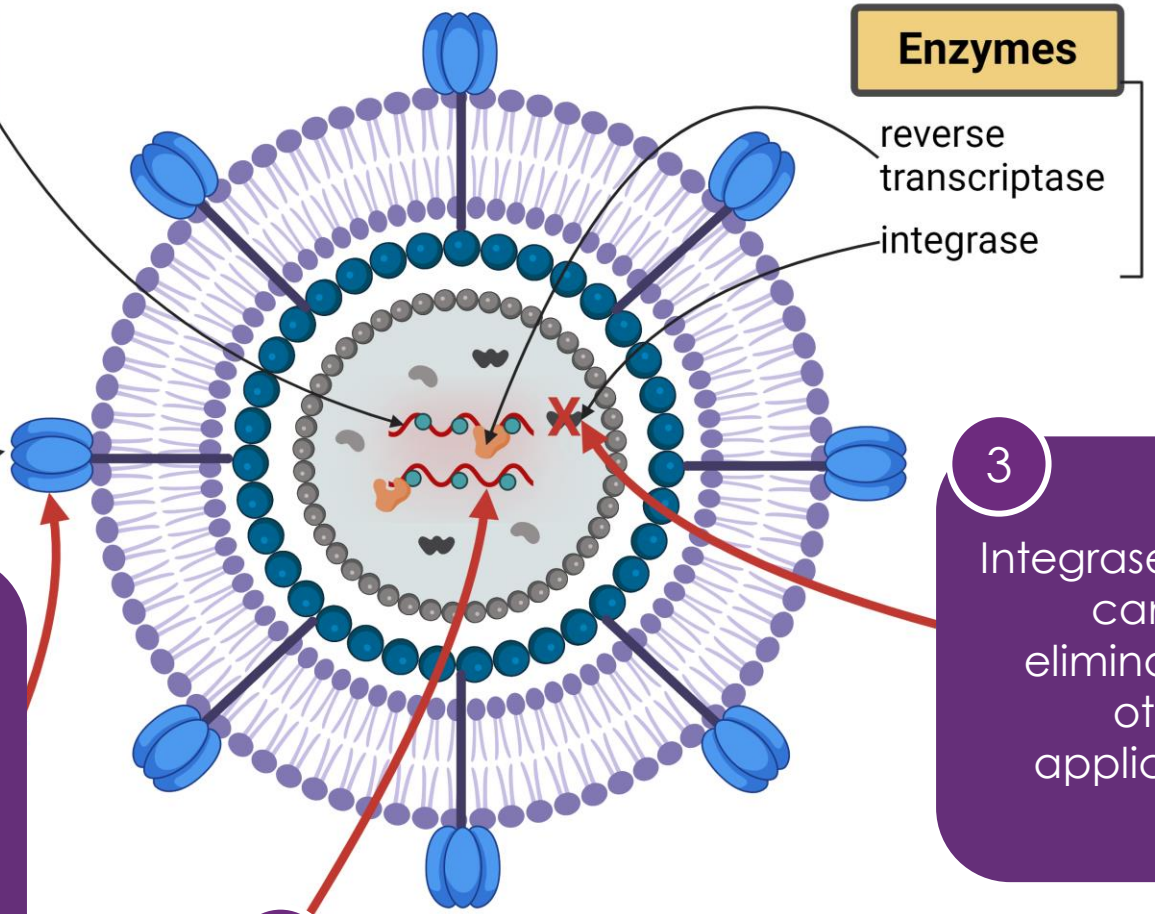
GenVivo's Vector Platform

Advantages of Versatile Targeted, Non-Replicating Vector Platform



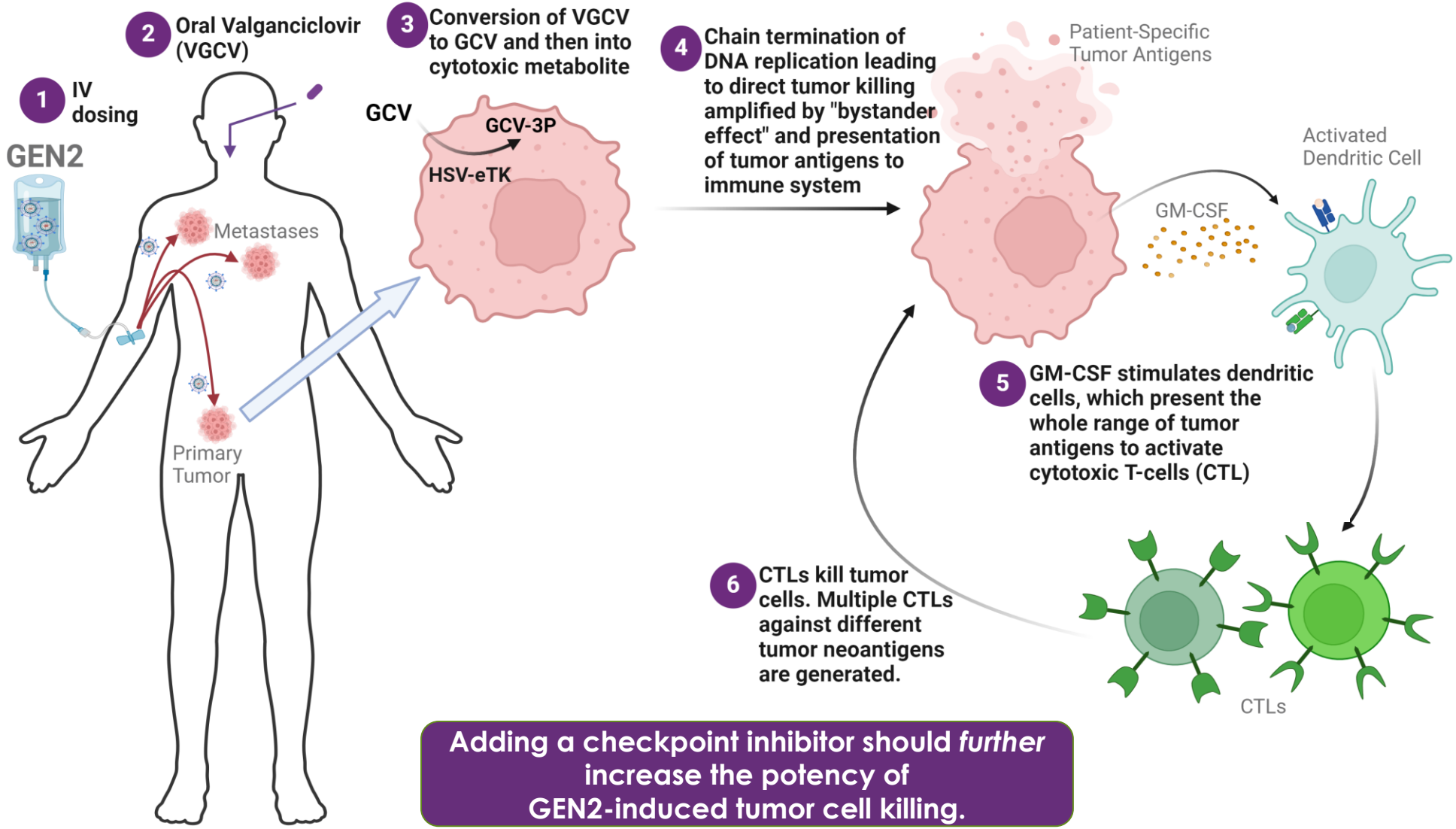
1 Surface proteins can be modified to target desired cancer cell surface receptors.

2 Large capacity to insert gene(s).

3 Integrase function can be eliminated for other applications.

GEN2 – Dual Mechanisms

Initial Cancer-killing Mechanism through Cytotoxic Metabolite and Second Mechanism through Amplified Tumor-specific Immune Killing



Adding a checkpoint inhibitor should *further* increase the potency of GEN2-induced tumor cell killing.

Part 1: Tumors Transduced With GEN2 Generate Tumor-killing Immune Responses Which Eradicate the Tumor

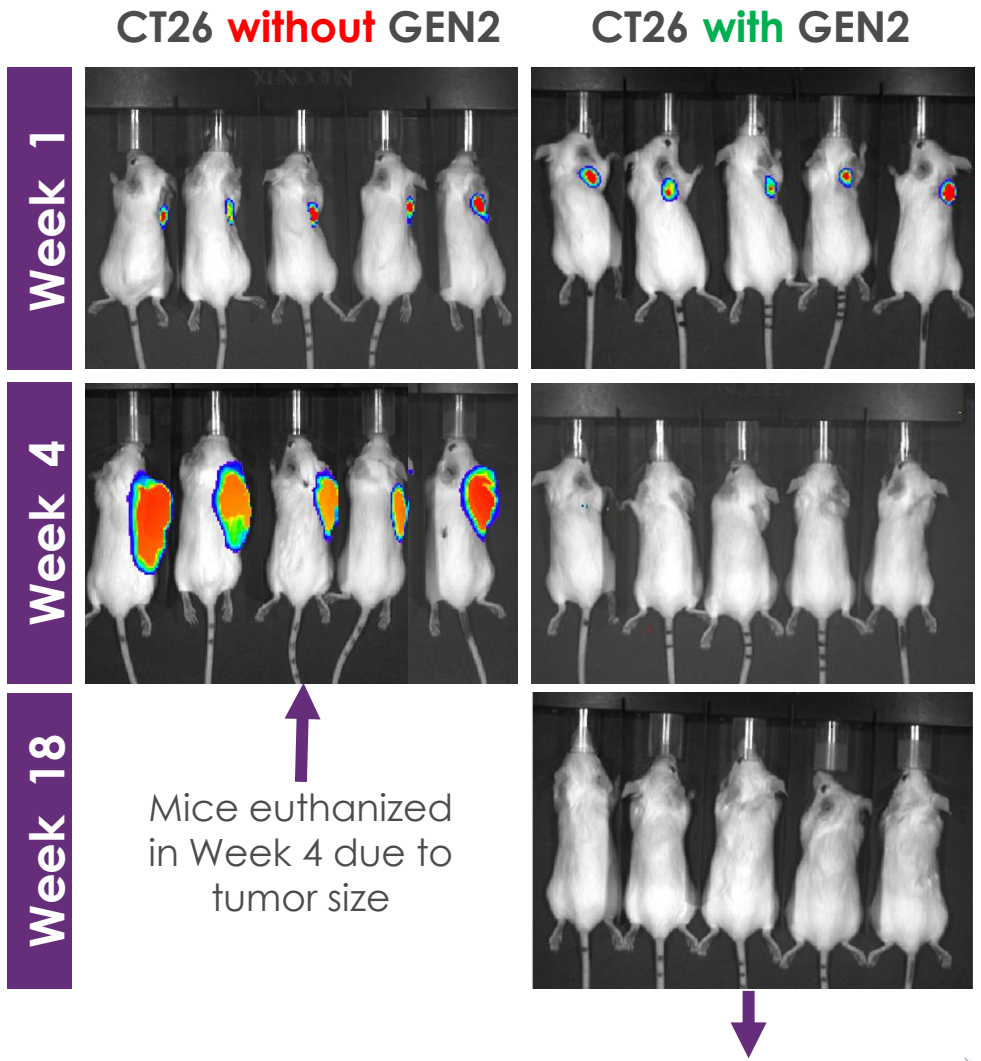
CT26* tumor cells without or with transduced GEN2

Week 0
Implant tumor

Week 1
VGCV
(Oral pro-drug)

Week 18
Imaging

***Mouse colorectal cell line**



Part 2: Re-Implanted CT26 Tumors Rejected in All Mice from CT26-with-GEN2 Group (Cured and Protected)

Re-Implantation of CT26 tumor

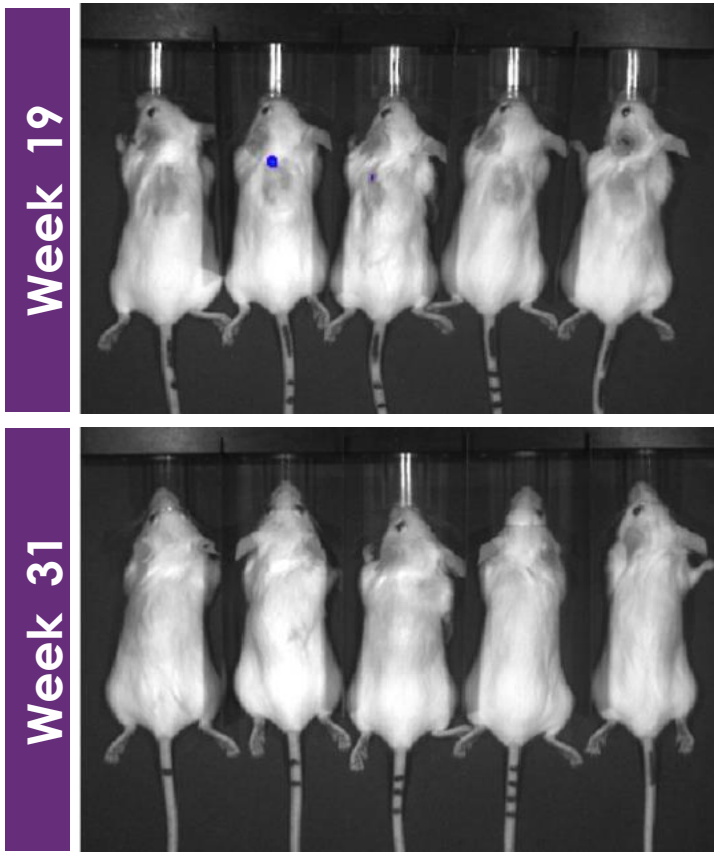
Week 19
Implant new tumor

↓

Monitor until
Week 31

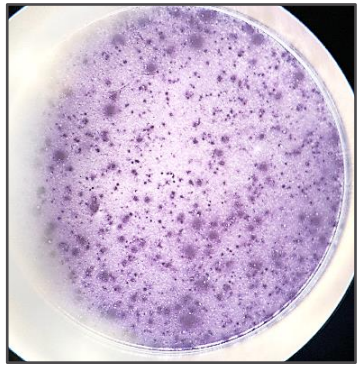
Demonstration of anti tumor T-cell response (IFN-γ)

Post Tumor Re-Implantation

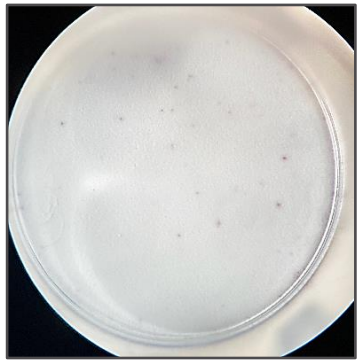


Splenocytes from Mice Implanted with CT26 Transduced with GEN2 Produce IFN-γ (ELISpot Assay)

CT26 cells + Splenocytes from treated mice



CT26 cells + Splenocytes from naïve mice



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Demonstrated Safety of GEN2 in Human Trial With Repeat Dosing (NCT04313868- Asian Study)

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

- Median number of cycles: 5.5 (range 2.0 – 28.0)
- No observations of Dose Limiting Toxicity or hypersensitivity reactions
- No patient withdrawn for adverse event
- Maximum Tolerated Dose not reached

Few Treatment Emergent Adverse Events (TEAEs)

- Possibly related TEAEs:
  - Anemia (n=2)
  - Chest pain (n=2)
  - Decreased appetite (n=2)
- Only one Grade 3 Treatment Related Adverse Event (TRAE)
  - Chest pain of 1 day duration

GEN2 Phase 1 Trial: Promising Evidence of Efficacy

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 in 11 of 39 patients (confirmed by 2 consecutive scans ≥6 weeks later)

- 5 patients with HCC
- 4 patients with HR+ breast cancer
- 1 patient with rectal carcinoma
- 1 patient with nasopharyngeal carcinoma

One HR+ breast cancer patient with cutaneous response (overall stable disease including liver lesions)

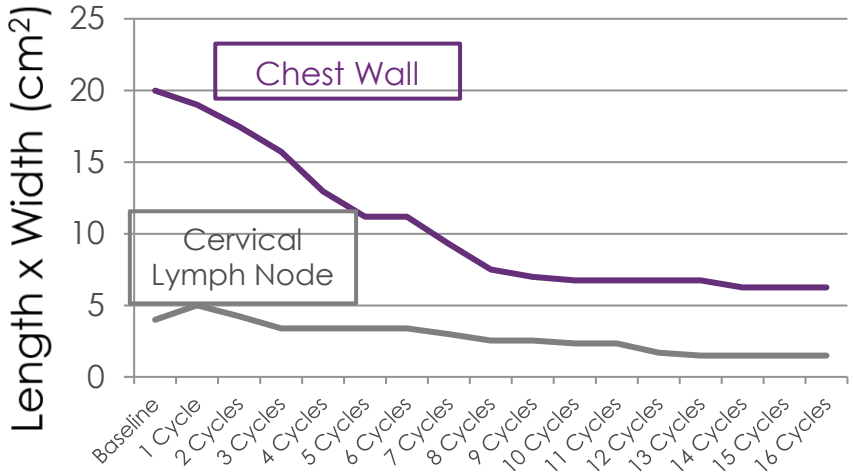
- 3 prior regimens for metastatic disease (including 2 hormone therapies and paclitaxel/carboplatin)
- 17 cycles at Dose Level 6 (1.0 E+7 TU/kg)

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

Clinical Benefit of GEN2 in Phase I Breast Cancer Patient

- 53 y/o Female Breast Ca Pt (ER+, PR+, HER2-)
- Invasive ductal carcinoma
- After radical mastectomy
- Adjuvant therapy – Tamoxifen
- 4 prior standard therapies for advanced disease

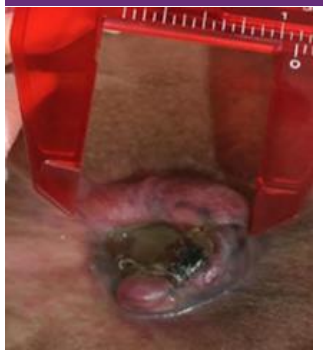
External Lesion Measurements



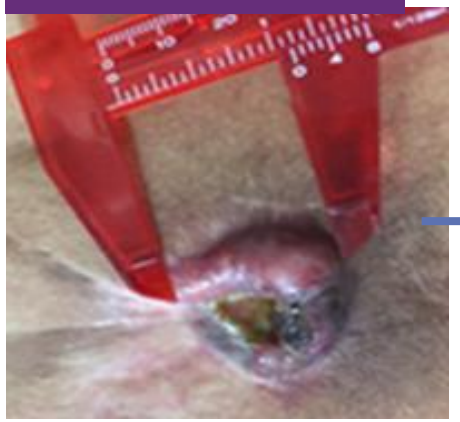
Photos adjusted so that ruler is the same size in all photos

Prior to GEN2

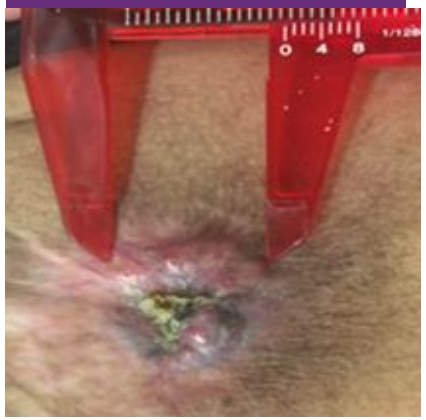
Post 7 Cycles



Post 10 Cycles



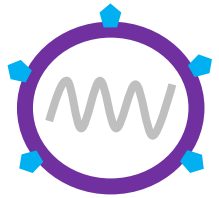
Post 14 Cycles

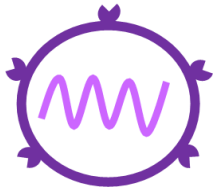


GenVivo Pipeline

Clinical – Phase I/Ib

Pre-Clinical





Product	Indication	Description	
GEN2	Solid Tumors	Platform with HSV-eTK* and GM-CSF mRNA payload	ONCOLOGY
GEN-1013	Solid Tumors	Platform with HSV-eTK and IL-12 mRNA payload	
GEN-0X00	Solid Tumors	Targeted vectors against specific tumor types	
GEN-1045 GEN-4035	Influenza	Non-integrating platform with (antigen) mRNA payloads; platform development for both infectious diseases and other applications	OTHER †

*Proprietary Herpes Simplex Virus – enhanced Thymidine Kinase properties engineered for more potent cell killing

†Other: Vaccines, other cancer approaches (gene editing)

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U.S. Phase I Ongoing: NCT06391918

Intravenous dosing

Protocol

GEN2: Days 1, 3 & 8
VGCV: Days 12-21
Treatment Holiday: Days 22-28
Cycle Length: 4 weeks

Eligibility

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

Dose Escalation

Semi-log: single patient cohorts until first drug related Grade 2 toxicity

Expansion

Three arms of 15 patients each

Sites (Initial)

1. Virginia Cancer Specialists/NEXT Oncology
   – Alex Spira, M.D., Ph.D., FACP
2. City of Hope
   – Daneng Li, M.D.
3. USC Norris Comprehensive Cancer Center
   – Anthony B. El-Khoueiry, M.D.

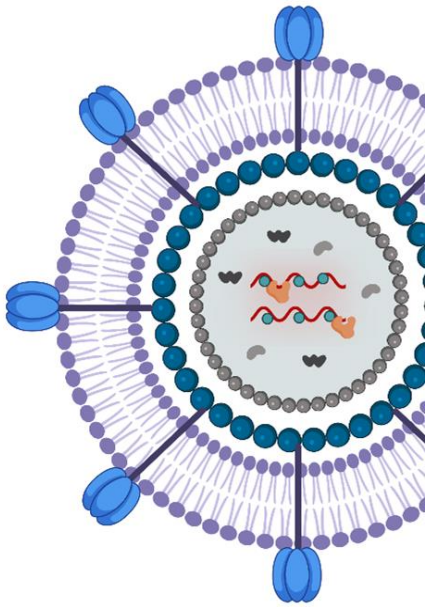
GenVivo Key Strengths

Vector Platform Advantages
- Large gene capacity
- Ability to target specific tumor types
- Integrase-deleted version for additional applications

Clinical Data – Lead Candidate (GEN2)
- Phase I safety demonstrated (59 patients)
- Repeat, systemic dosing boosts immune response
- **Clinical benefit in patients with advanced cancer**

In-house Manufacturing and Controls - CMC
- Manufacturing with high consistency and purity
- Capacity is sufficient through Phase 2

Pipeline
- Additional clinical targets in pre-clinical development



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Thank you

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