



ImmVirX

Receptor Targeted Oncolytic
RNA Immunotherapies

BioShares Conference Presentation

August 8 2025

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First-in-Class Clinical Stage Oncolytic Immunotherapy Company

Early signals for IVX037 in major cancer indications



Targeting the most prevalent cancer types globally



Pipeline of oncolytic RNA candidates

IVX055 targeting entry into clinic in Q1 2026 in lung cancer. Other approaches in development.



Lead drug candidate IVX037 in Phase 1a/b solid tumor trial

Induced notable tumour reductions in monotherapy now early signals of activity across 2 indications in Phase 1b in combination with PD-1 inhibitor



Highly experienced management team with proven track record

Developed Viralytics' CAVATAK through to acquisition by Merck & Co.



Recent Industry / Investor interest in oncolytic virus immunotherapies

CG Oncology with market cap of \$2Bn and suite of top tier global shareholders



Well-funded with cash into Q1 2027

Strong institutional investor register (Acorn, OneVentures, others)

Significant Unmet Need Across Solid Tumor Indications

Indication	Forecast Deaths per Annum		Checkpoint Clinical Response	
	USA ¹	China ²	ICI ORR ³ (KEYTRUDA)	Study Identifier (KEYNOTE)
Colorectal	53,010	240,010	4%	028
Ovarian	12,740	32,646	9%	100
Gastric	10,880	400,415	17%	224
Hepatocellular Carcinoma (Liver Cancer)	29,840	316,544	16%	224 (cohort 2)
Lung Cancer	125,070	733,291	18%	010
Melanoma Skin Cancer (CAVATAK™ Lead Target Indication)	8,290	5,385	33%	006

Substantive patient population in major markets

Immune checkpoint therapies effective in only minority of patients with advanced solid cancers - potential for combination with oncolytic immunotherapies to enhance efficacy

Big Pharma facing major pipeline challenges - 2025 through to 2028 drugs with combined annual sales of \$277bn estimated to lose patent protection ⁴

1 National Cancer Institute, 2024 estimates - <https://seer.cancer.gov/statfacts/html/colorect.html>
2. Global Cancer Observatory, International Agency for Research on Cancer (IARC), <https://www.iarc.who.int/>
3. Immune Checkpoint Inhibitor Overall Response Rate
4. Evaluate "World Preview 2023: Pharma's Age of Uncertainty"

Indication Spotlight: Colorectal Cancer (CRC)

3rd most common cause of cancer worldwide¹ with **~1.9M** new cases diagnosed annually

2nd leading cause of cancer-related deaths worldwide² with **>900,000** deaths per year

Despite advances in treatment of CRC, long term survival remains low³

3-year relative OS for patients with metastatic CRC is

~30–35%

5-year relative OS for patients with metastatic CRC is

~15%

CRC is increasing in people under 50 in US: **#1 cause of cancer deaths in men under 50 and #2 cause in women under 50** ⁴

Most early onset CRC patients are too young for routine cancer screening

Often diagnosed at advanced stages when treatment options are limited



1. Sung H et al. CA Cancer J Clin 2021
2. World Health Organization, July 2023
3. Wang J et al. Cancer Med. 2020
4. "More Young People Than Ever Will Get Colorectal Cancer This Year," New York Times, March 27, 2024

Experienced Team Driving ImmVirX Forward



Malcolm McColl, MBA
CEO & CO-FOUNDER



Prof. Darren Shafren, PhD
CSO & CO-FOUNDER



Jeannie Joughin, PhD
NON-EXECUTIVE DIRECTOR



Leonard Post, PhD
NON-EXECUTIVE DIRECTOR



Robert Routley
NON-EXECUTIVE DIRECTOR



Robert Vickery
CO. SEC & CFO



COHESIVE TEAM WITH RECORD OF SUCCESS

- ex-Viralytics team members responsible for discovery, preclinical and clinical development of investigational oncolytic immunotherapy CAVATAK
- McColl, Shafren led Viralytics acquired by Merck for **A\$502M**. Specialist biotech investors included OrbiMed, Baker Bros, Cormorant
- Deep regulatory knowledge with extensive interactions with FDA
- GMP manufacturing and quality systems experience
- **27 strong R&D team** in facility at Hunter Medical Research Institute
- **Global networks of clinicians and KOLs** to facilitate clinical program
- Leonard Post – Leading role in three successful oncolytic virus companies (VLA, Biovex - acquired by Amgen, CG Oncology)
- Robert Vickery – CFO of Clarity Pharmaceuticals through 2021 IPO process

Excellent Operations Team (ex Viralytics, Merck)

Strong Bench to Clinic Capability

ImmVirX 



Min Quah, PhD
DIRECTOR
DISCOVERY & PRE-CLINICAL
RESEARCH



Bronwyn Davies
DIRECTOR
CMC



Susanne Johansson, PhD
DIRECTOR
QUALITY MANAGEMENT



Yvonne Wong, PhD
DIRECTOR
MANUFACTURING SCIENCE



Jennifer Rosenthal, PhD
DIRECTOR
QUALITY & REGULATORY
AFFAIRS



Oksana Zdanska, MD
MEDICAL DIRECTOR

PROVEN ONCOLYTIC IMMUNOTHERAPY DEVELOPMENT TEAM

- Preclinical development and translation of Viralytics' CAVATAK into clinic
- Established advanced preclinical models to assess immunotherapy combinations
- Manufacturing experience across US/AU/UK
- Managed multiple clinical trials across US/AU/UK sites ~300 CAVATAK patients
- Tech transfer to Merck from 2018–2019

Collaboration with Innovent Bio – expanded in Apr 2025

Leading Biopharma Company in China



Innovent Bio

- **HKEX code:** 1801
- **Mkt Cap:** USD\$22bn
- Leading Chinese biopharma addressing cancer, cardiovascular and metabolic, autoimmune and eye disease.
- 11 products in the market plus 5 new drug applications under regulatory review.
- Partnering with 30 global healthcare companies including Eli Lilly, Sanofi and Incyte.



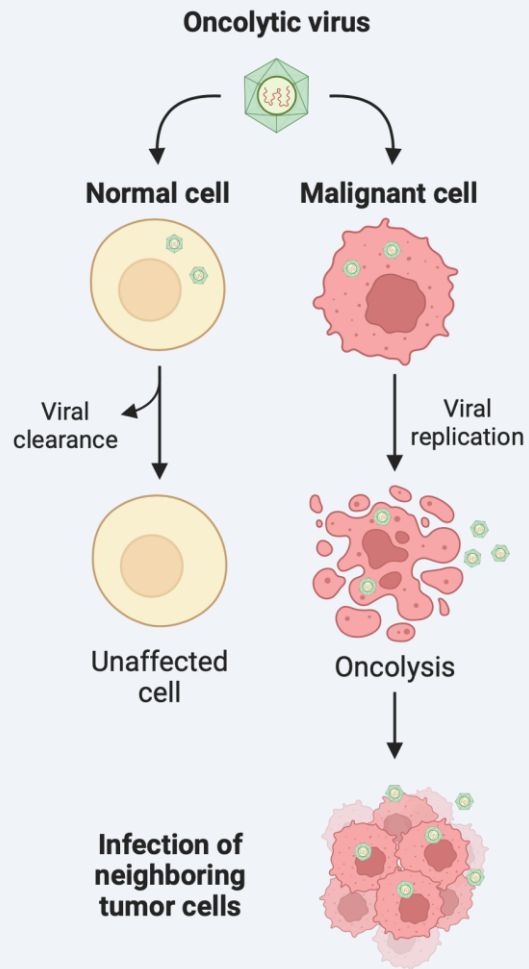
“ImmVirX’s IVX037 with our anti-PD-1 therapy, TYVYT® play **complementary roles** in engaging the immune system **to fight cancer**.

We look forward to seeing **encouraging results** from this study.” ¹

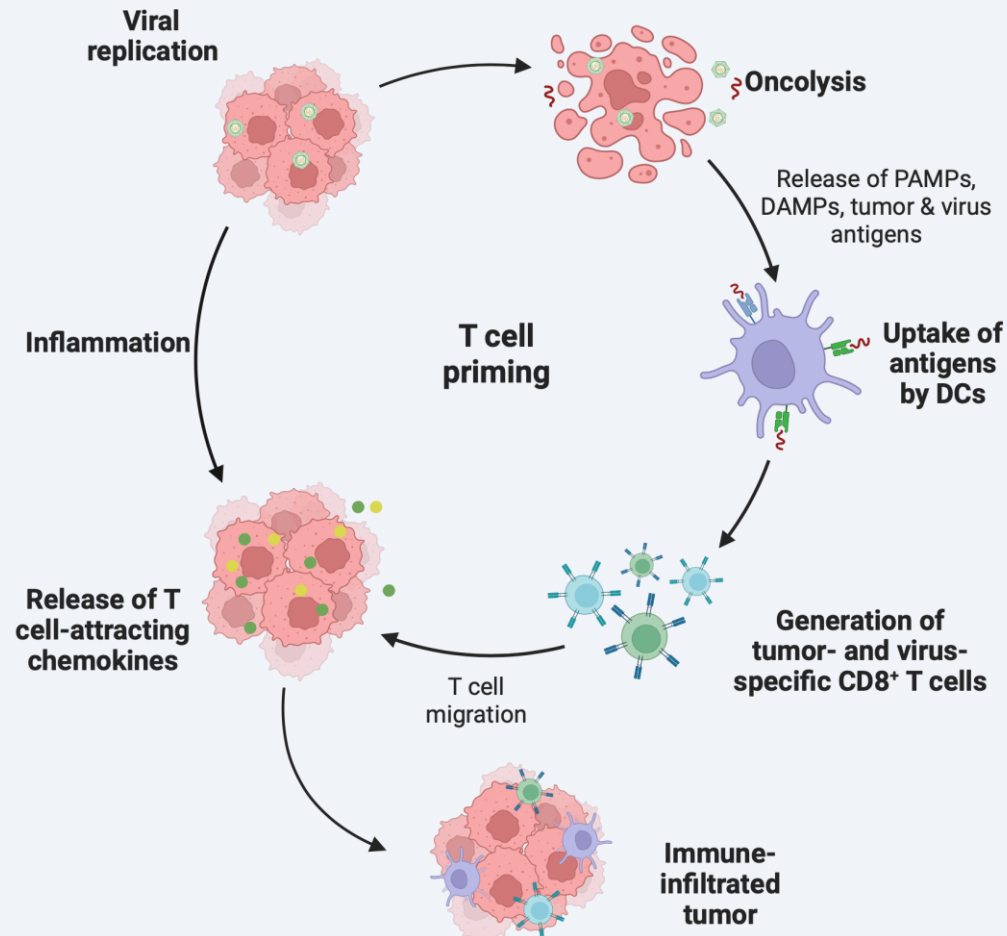
Dr Hui Zhou, Senior Vice President of Innovent.

Oncolytic viruses – Powerful Cancer Cell Killing and Stimulation of Anti-Tumour Immune Response

1. Selective replication in cancer cells






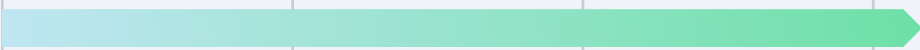


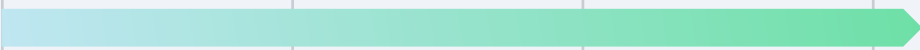






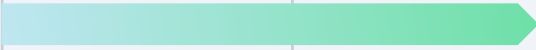

2. Immune activation at tumor site



Triggers **both innate and adaptive immune responses** with immune cell infiltration of tumor at a high level

Highly inflames “cold” tumor types with current low responsiveness to immune checkpoint therapy

Differentiated Oncolytic RNA Immunotherapy Pipeline

Program	Product Overview	Key Indications	Discovery	Preclinical	Phase 1a	Phase 1b Combination with checkpoint inhibitor	Next Milestone
IVX037	Bioselected RNA virus targeting novel receptor #1	Colorectal -IT -IV				 	Initial clinical data in H2 2025
		Ovarian -IT				 	
		Gastric -IT				 	
		Hepatocellular carcinoma -IT				 	
	IVX037 + CAR-T	Solid cancers					Prelim data Q3 2025
IVX055	Bioselected RNA virus targeting novel receptor #2	NSCLC -IT					Preclinical tox Q3 2025
		Second indication (undisclosed)					Preclinical data H2 2025

1 FIP: First in patient

Lead Candidate: IVX037

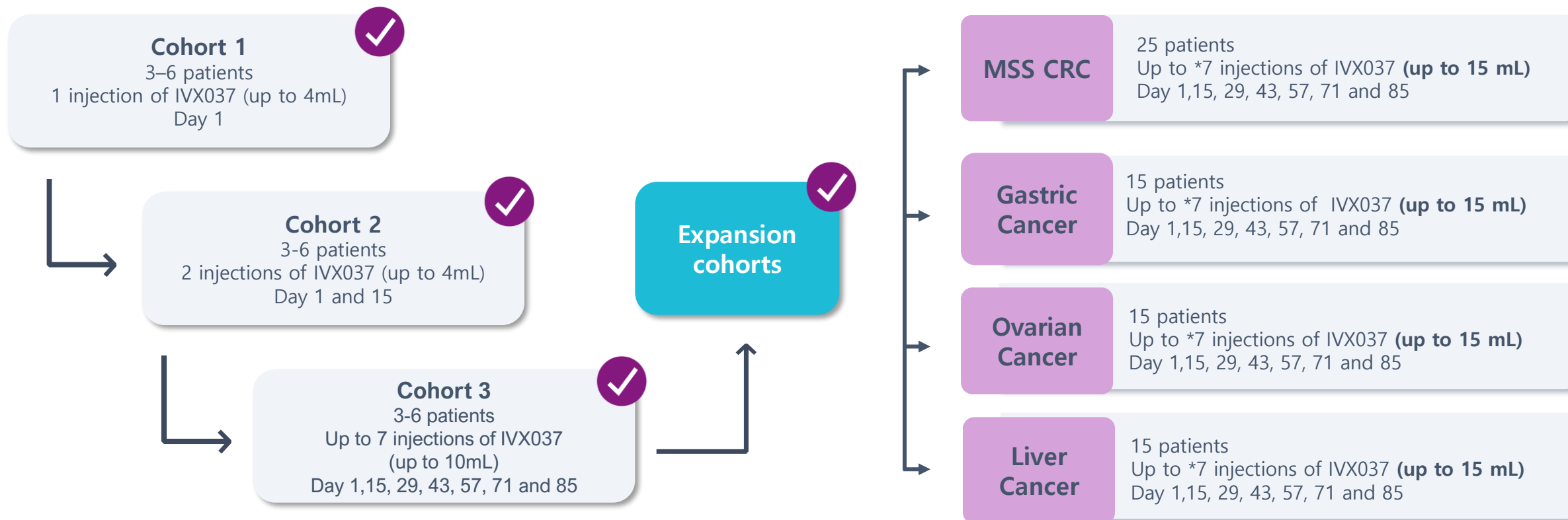
Receptor Targeted

Oncolytic RNA Immunotherapy

Rapid Advancement to Phase 1b – Combination Study Commenced

Phase 1a (intratumoral IVX037)

Phase 1b (combination of IVX037 + Innovent's sintilimab)



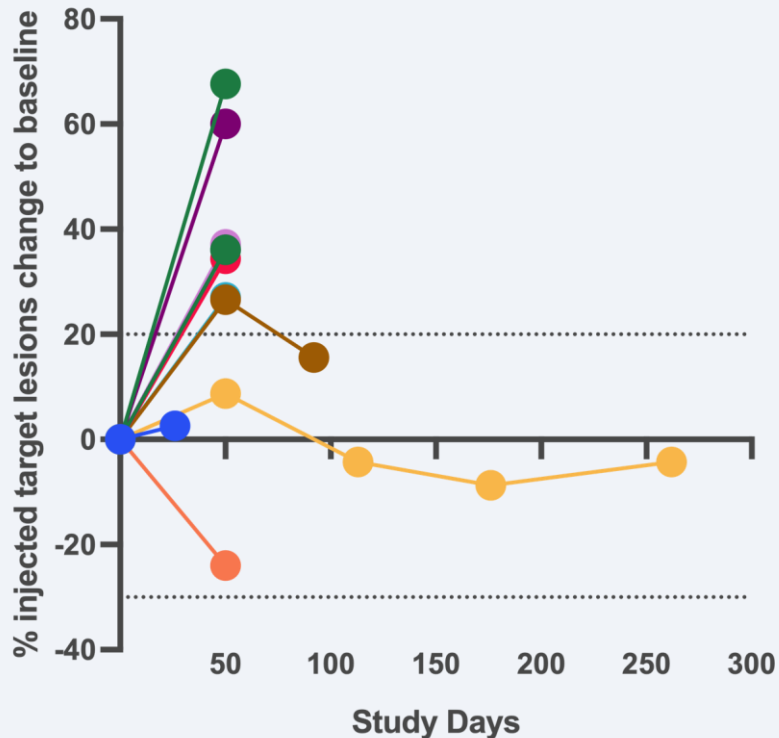
Phase 1b now advancing at 8 sites

Promising Reduction in Injected Lesions

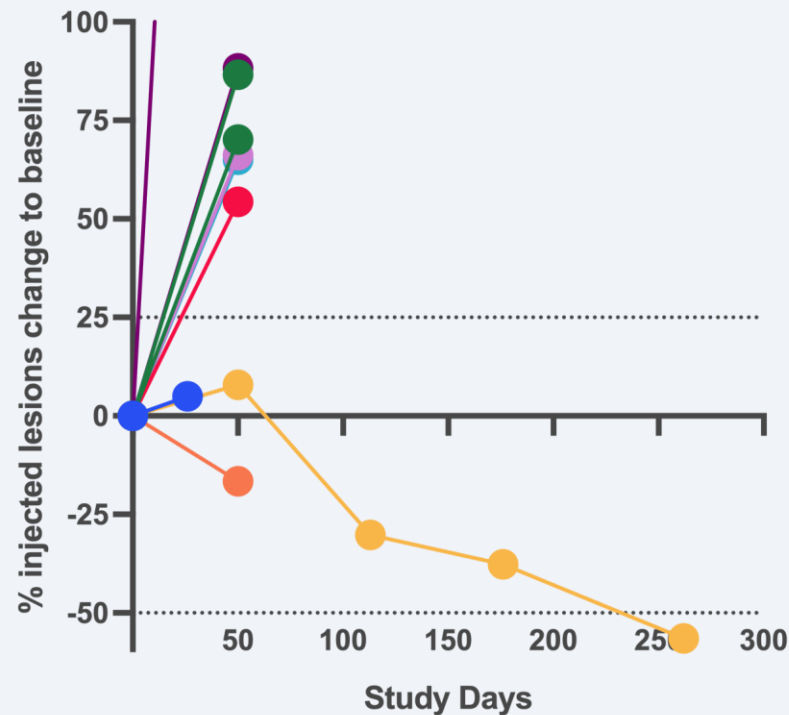
In Cohort Where Standard Care of Therapy Offers CRC <2% Overall Response Rate

Percentage change of injected target lesions change to baseline (Phase 1a data)

RECIST 1.1 criteria



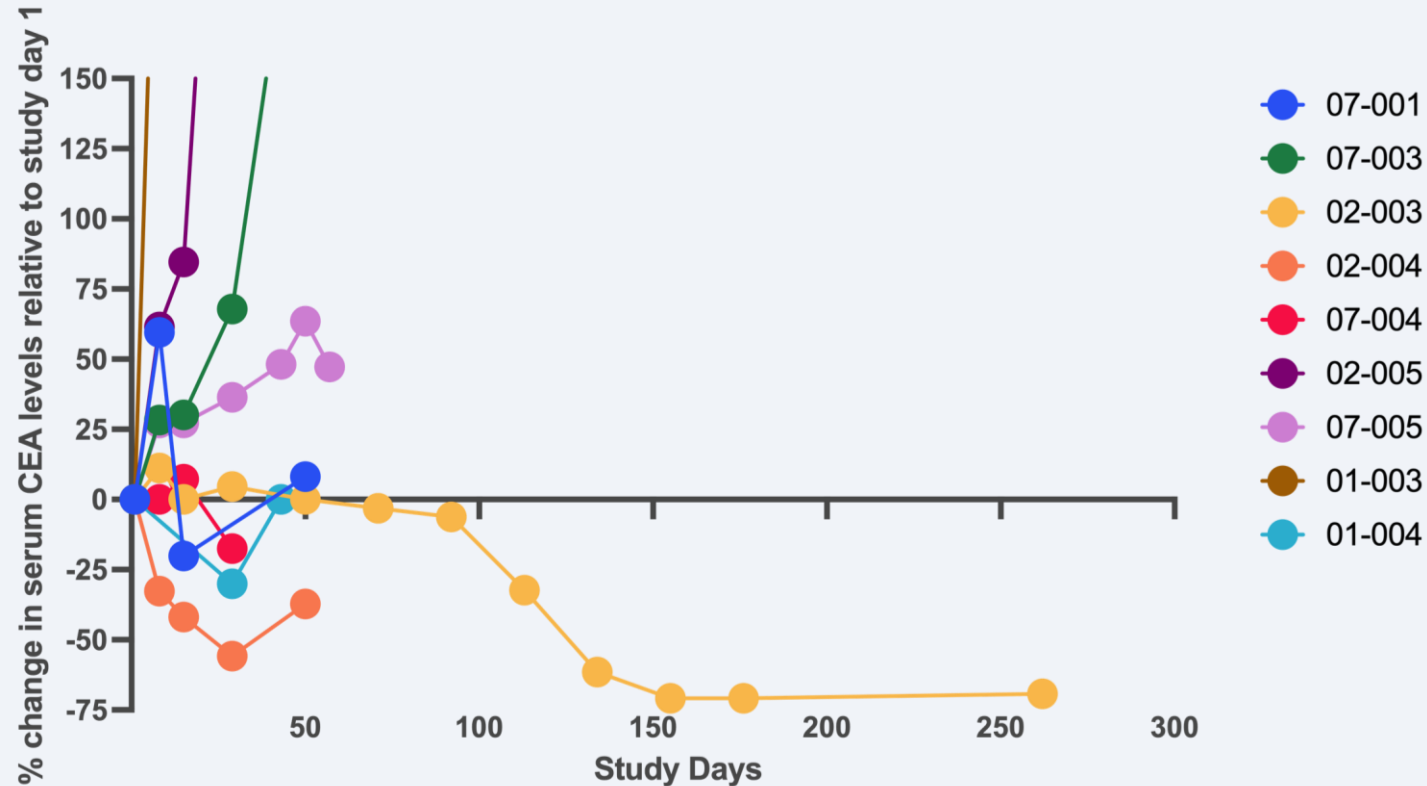
WHO criteria



HIGHLIGHTS

- Promising signals of activity in 2 late-stage patients
- Patient 02-003: complete pathological response in injected target lesion confirmed by histology
- Oncologist considered patient had exceptional response - absence of new metastatic disease (PETscan) for almost two years without additional cancer treatments. Suggestive of IVX037 induced abscopal activity

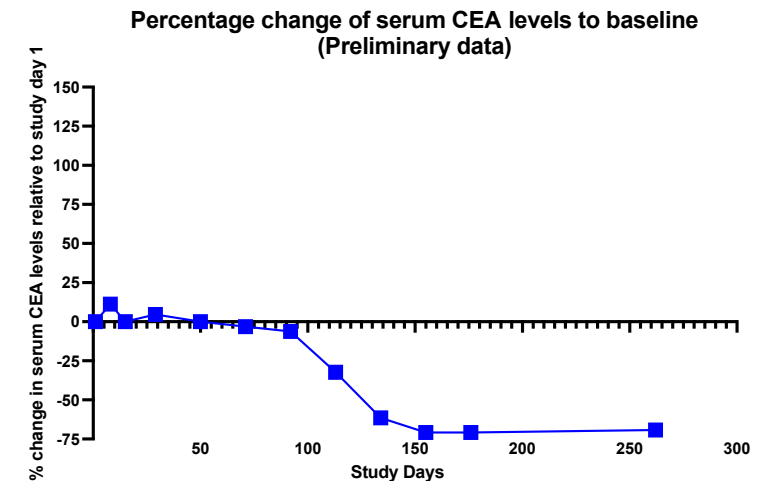
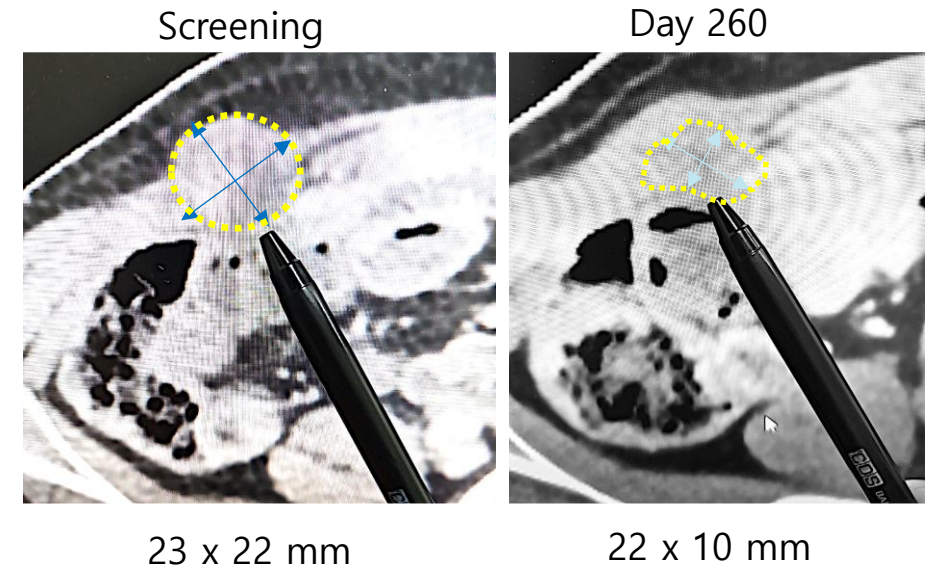
Decline in Key CRC Tumour Marker Reflects Early Signs of IVX037 Activity



- Carcinoembryonic antigen (CEA) is a biomarker that is elevated in patients with colorectal cancer
- Reduction in CEA reflects positive outcomes in IVX037 treated patients
- Positive CEA signal in patients 02-003 and 02-004 also displaying tumor burden reductions

- Both lesions injected with IVX037 - dosing volume: TL 2 ml; NTL 2 ml, trial completed with 5 doses received
- Injected lesions represent 100% of disease burden
- Imaging response: stable disease, corresponding decrease in CEA levels
- **Patient did not require further treatment for 26 months since trial initiation and 20 months since completing the trial treatment => indicative of systemic response and abscopal effect**
- PET-CT scan shows no further disease spread
- Biopsy of both lesions – a few scant cancer cells vs absence of tumor cells (complete response)

Injected target lesion response

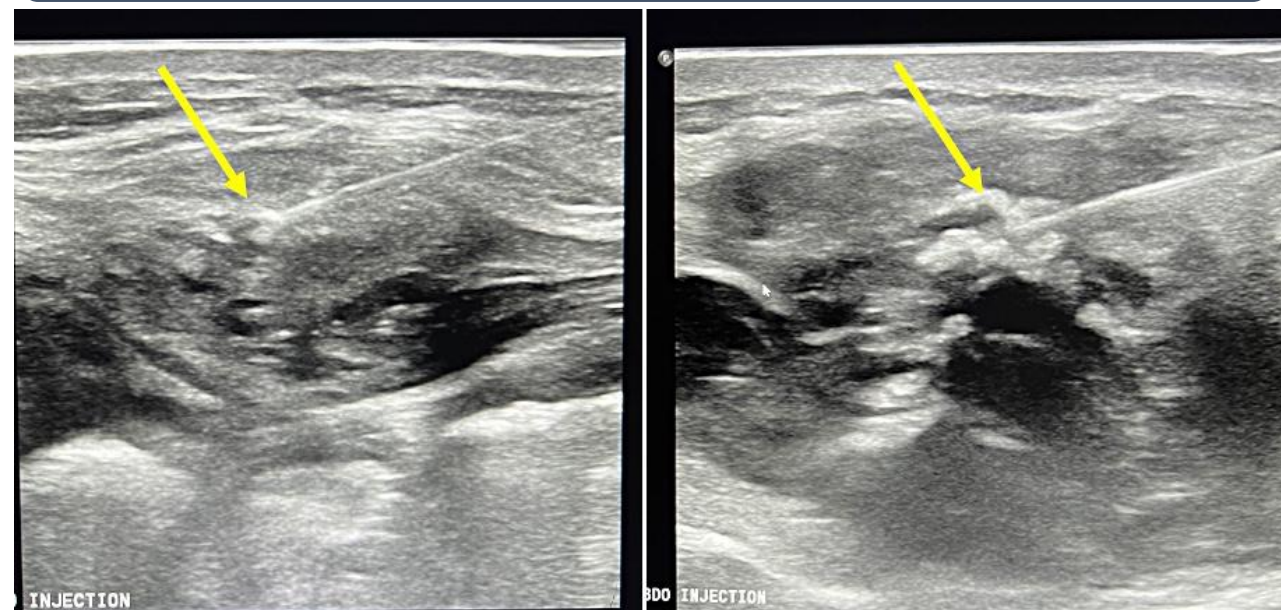


Accessing Lesions For Intratumoral Administration

– A Straightforward Process

- USG / CT guidance – IVX037 can be safely administered repeatedly to liver and other sites of metastases
- Preloaded syringe with IVX037 delivered to radiology rooms, 50 hours life span
- Similar outpatient procedure to biopsy and FNA – local anaesthetic +/- conscious sedation
- 20-minute procedure +/- monitoring for 2-4 hours
- Up to 5 lesions, total volume up to 15ml (50% of total disease burden)

Ultrasound images of a needle inside a tumour delivering IVX037



Current Landscape in MSS CRC:

Poor Response Rate With Significant Toxicity



Agent	Overall Response Rate	Study	Adverse Event profile
Stivarga® (regorafenib)	1.0%	CORRECT	54% ≥ G3 TRAE (hand-foot skin reaction, fatigue, diarrhoea, hyperbilirubinemia, hypertension)
Lonsurf® (trifluridine/tipiracil)	1.6%	RECOURSE	69% ≥ G3 TRAE (haematological: neutropenia, leukopenia, anemia; gastrointestinal: diarrhoea, nausea, vomiting)

IVX037 is Well-Tolerated With a Favorable Safety Profile

- A total of 14 pts have been dosed on the study, 2 gastric cancer pts, 12 MSS CRC
- IVX037 IT administration has been well tolerated with a favorable safety profile
- No dose limiting toxicities have been observed during phase 1a

MOST COMMON TREATMENT RELATED ADVERSE EVENTS (TRAEs) GRADE 2 (moderate)

- Fatigue 14.3%
- Rheumatoid arthritis 7.1%
- Injection site pain 7.1%

MOST COMMON TRAEs GRADE 1 (mild)

- Injection site pain 42.9%
- Intermittent fever 35.7%
- Nausea/anorexia/chills/fatigue/abdominal tenderness 14.3%



Promising Initial Findings from first 2 patients in Ovarian Cancer

Phase 1b IVX037 in combination with sintilimab

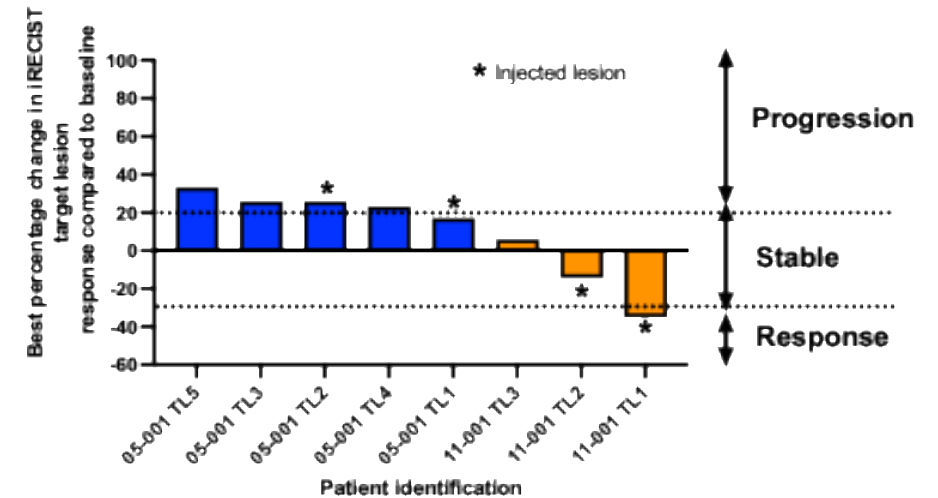
05-001 – 82yo female with high grade serous ca (HGSC)

- 3 prior lines of treatment in advanced/metastatic setting, substantial disease burden
- 3 injections, 2 liver lesions injected
- 24% increase at D43, no new lesions

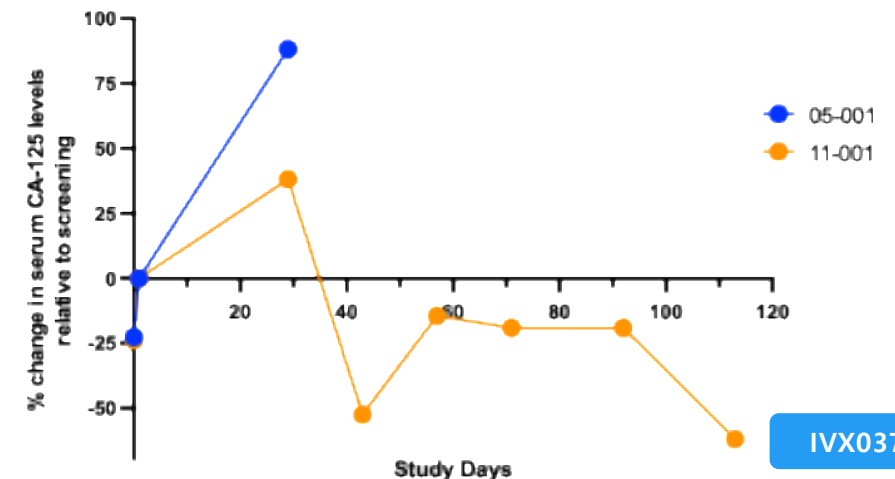
11-001 – 75yo female with high grade serous ca (HGSC)

- 2 prior lines of treatment in advanced/metastatic setting, substantial disease burden
- 7 injections, 2 abdominal wall lesions injected, 35% decrease in TL1 at D92
- TLs 16% decrease at D92, no new lesions
- CA-125 decrease by >60% at D113

Best individual target lesion response iRECIST
Ovarian cancer (CT IVX001)



Percentage change of serum CA-125 levels to baseline
(Preliminary data)



Second Candidate: IVX055

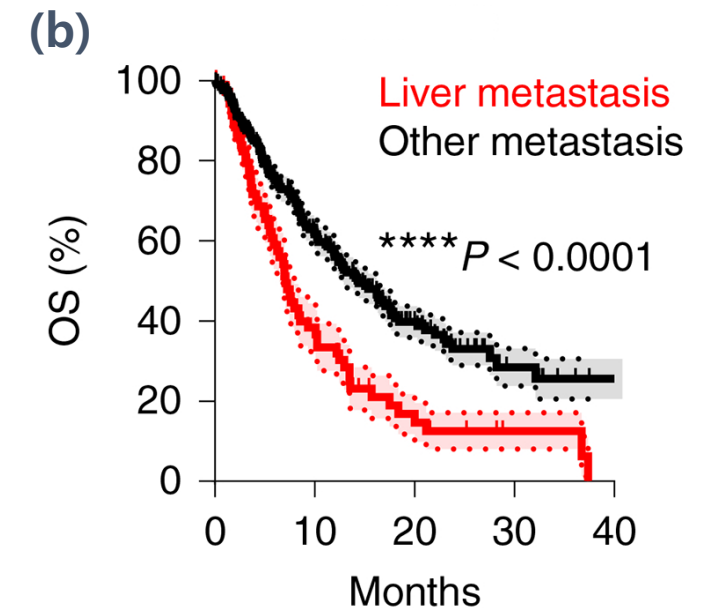
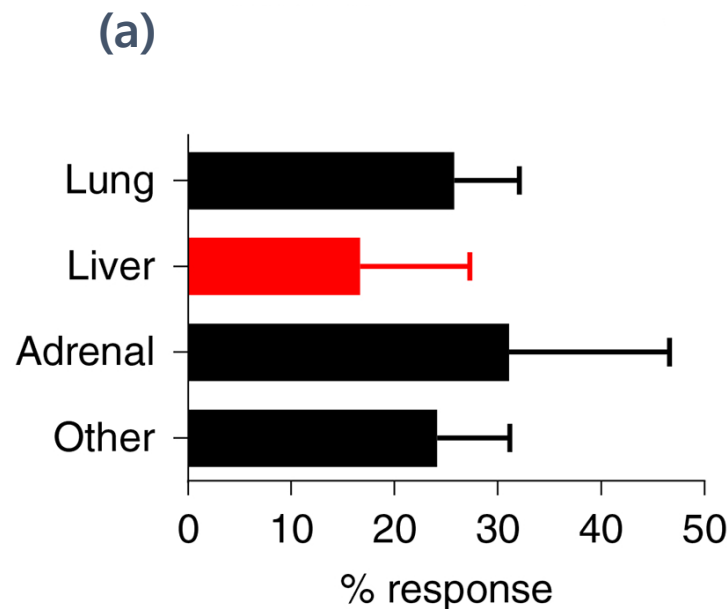
Receptor Targeted

Oncolytic RNA Immunotherapy

Lung Cancer

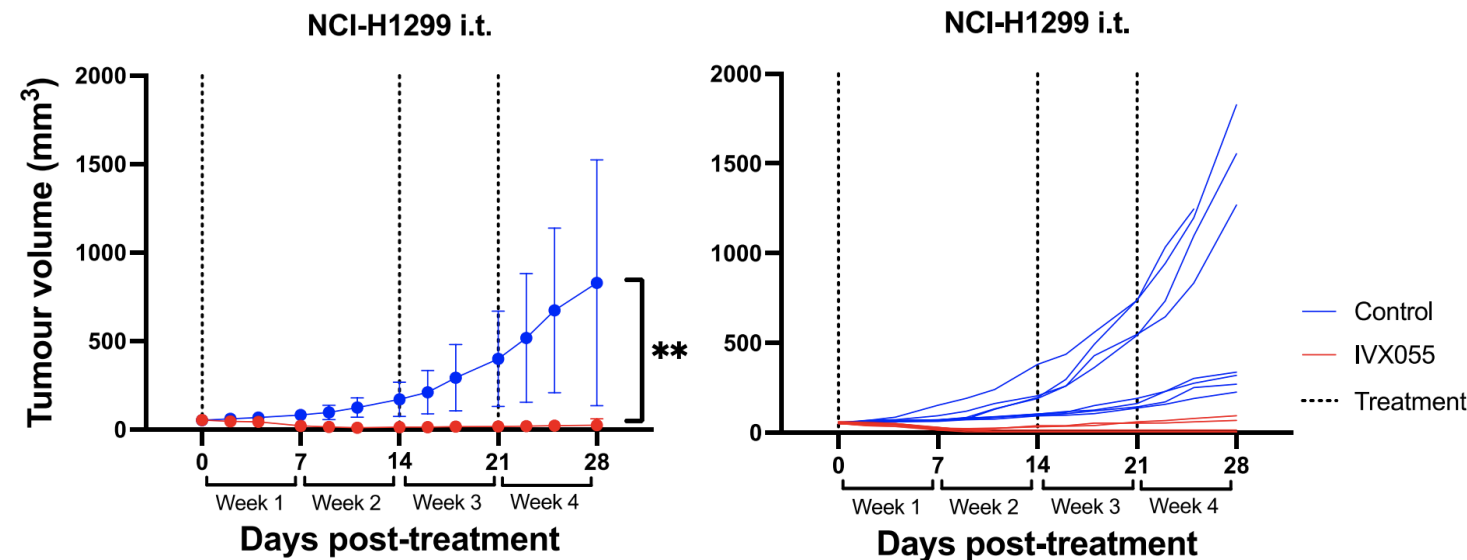
- Lung cancer number one global cause of cancer death
- Approximately 20% of late-stage NSCLC patients with liver metastases
- High unmet need in NSCLC with liver metastases
- Liver metastases significantly worsen prognosis
- Lower response rates and survival in patients with liver lesions.
- IVX055 bioselected to target receptors over expressed on NSCLC.

Best objective response rates and overall survival in patients with metastatic NSCLC who received immunotherapy stratified by (a) baseline disease distribution & (b) presence of liver metastasis



- Three intratumoural doses of IVX055 were well tolerated, with **tumour reduction evident within one week**
- IVX055 inhibits tumour growth in NSCLC xenograft
- Effective oncolytic activity at minimal viral challenge

Tumour Measurements





Pipeline of receptor targeted Oncolytic RNA immunotherapies

Transformative opportunity in most globally prevalent cancers with high unmet need

- Focused on tumour types with **accessible metastatic lesions**, such as CRC, HCC, gastric, ovarian and lung
- **Early signals** seen in cold tumor types, such as MSS CRC and ovarian cancer
- Pathway to randomized controlled trials or expansion of single arm trials for **approval**



Lead Oncolytic RNA immunotherapy candidate IVX037

- **Phase 1a:** Well tolerated with **promising early signals of targeted monotherapy activity**
- **Phase 1b** with promising early signals of activity **across colorectal and ovarian cancer**
- Successful GMP manufacture of IVX037 by US contract manufacturer

Bioselected second asset, IVX055, targeting **lung cancer** using proprietary platform



Catalyst Rich 2025

IVX037

- Readouts and expansion of phase 1b
- Addition of liver cancer to phase 1b
- Upcoming ESMO conference clinical presentation

IVX055

- Complete preclinical tox
- Prepare package enabling FIH study

CAR-T (IVX037 Combination)

- Preclinical data in solid cancers

Strong cash position

A\$20.3M (30th June 2025)

Well-funded - cash to Q1 2027



Receptor Targeted Oncolytic
RNA Immunotherapies

Thank you

Malcolm McColl

Chief Executive Officer and Co-Founder

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