

ImmVirX

Receptor Targeted Oncolytic
RNA Immunotherapies

Bell Potter Healthcare Conference

November 20 2024

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First-in-Class Clinical Stage Oncolytic Immunotherapy Company

Early signals for IVX037 administered as a monotherapy in major cancer indication



Targeting the most prevalent cancer types globally

New therapeutic options urgently needed



Pipeline of oncolytic RNA candidates

Inflame "cold" tumours; validated bioselection platform; next candidate IVX055 targeting entry into clinic in mid-2025 in lung cancer



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

IVX037 has induced notable tumour reductions and clinical observations of abscopal activity. Study now progressed to Phase 1b anti PD-1 combination arm in collaboration with Innovent Biologics



Highly experienced management team with proven track record

Developed Viralytics CAVATAK through to acquisition by Merck in 2018



Recent Industry / Investor interest in oncolytic virus immunotherapies

CG Oncology (Bladder Cancer)	Mkt cap US\$2.4B - 90% up on 2024 IPO
Replimune (Melanoma)	Mkt cap US\$800m – 30% up since 1 Jan 2024

Leading US specialist investors active in the space



Well-funded with cash into mid 2026

Strong institutional investor register including OneVentures, Acorn, Perennial and Karst Peak

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"

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
- 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



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



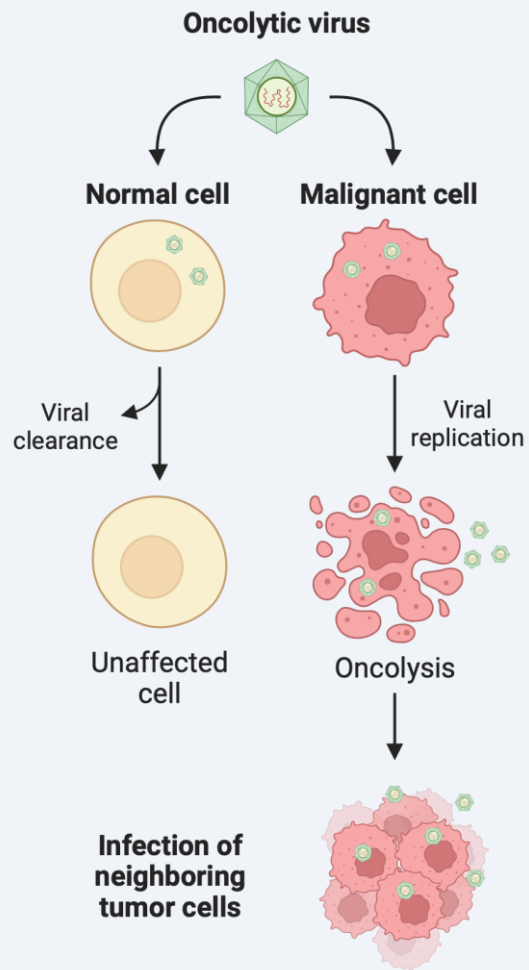
Oksana Zdanska, MD
MEDICAL DIRECTOR

PROVEN ONCOLYTIC IMMUNOTHERAPY DEVELOPMENT TEAM

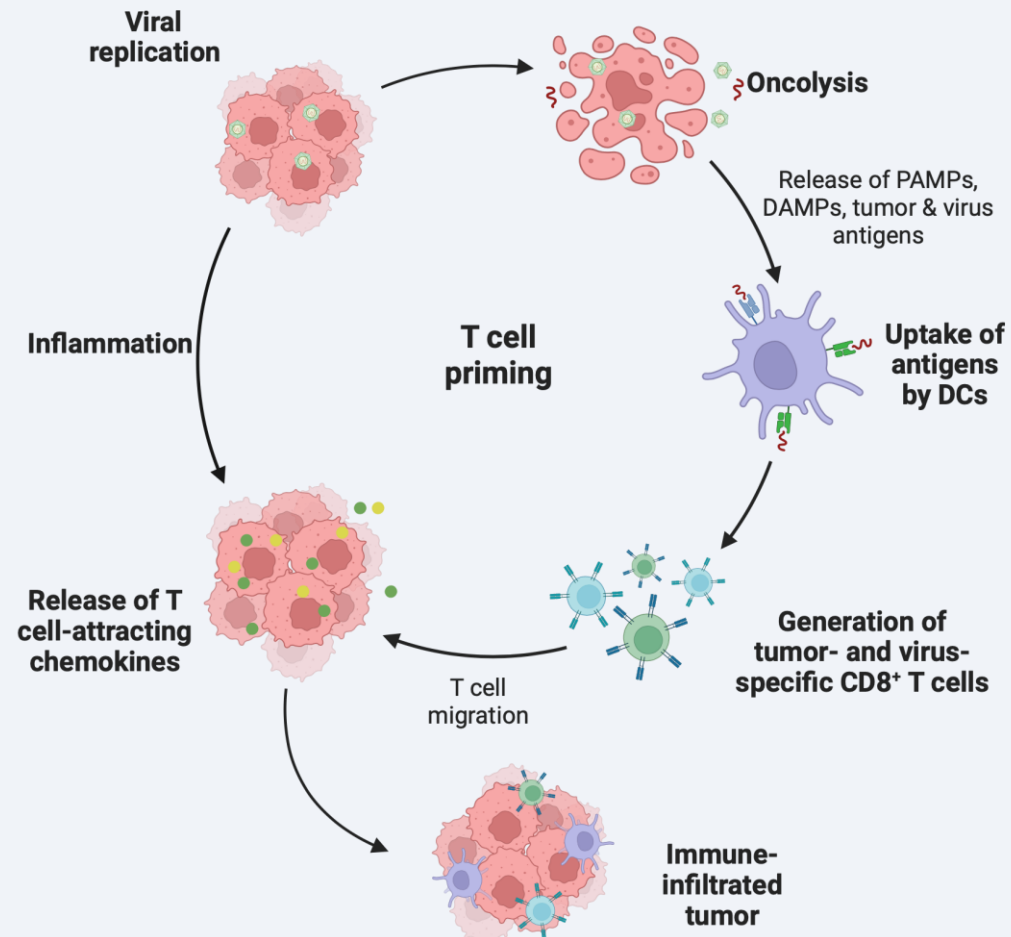
- Preclinical development and translation of Viralytics' CAVATAK into clinic
- Established advanced preclinical models to assess immunotherapy combinations
- Manufacturing experience across US/AU/UK
- Managed multiple clinical trials across US/AU/UK sites ~300 CAVATAK patients
- Tech transfer to Merck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

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

Lead Candidate: IVX037

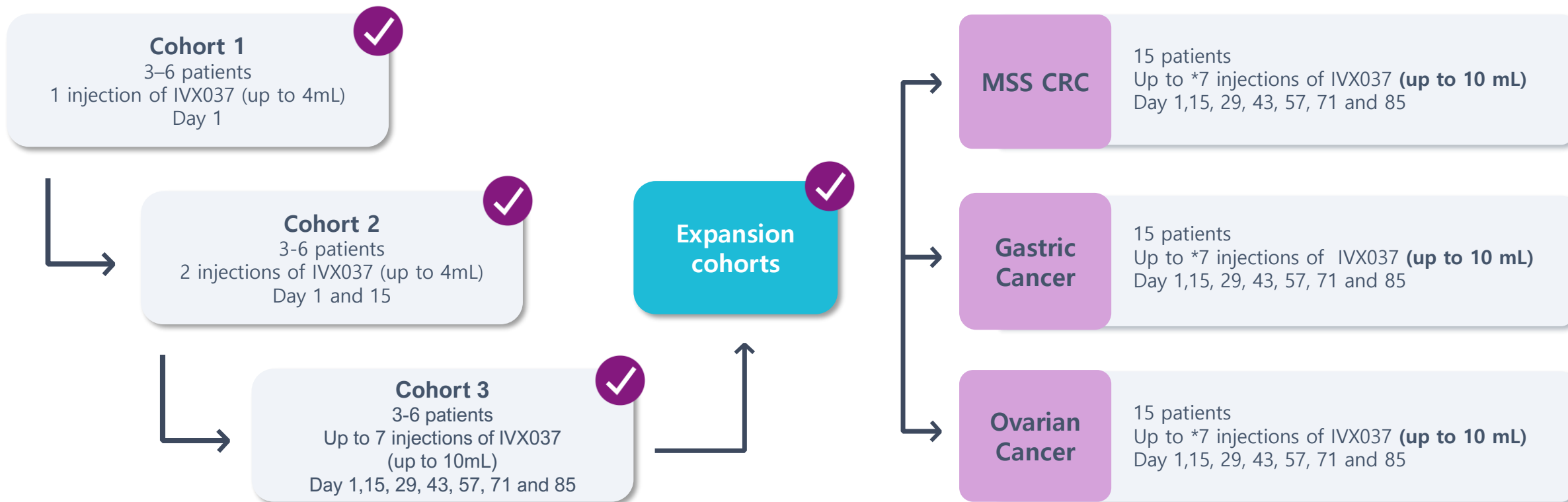
Receptor Targeted

Oncolytic RNA Immunotherapy

Rapid Advancement to Phase 1b – Combination Study Commenced

Phase 1a (intratumoral IVX037)

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

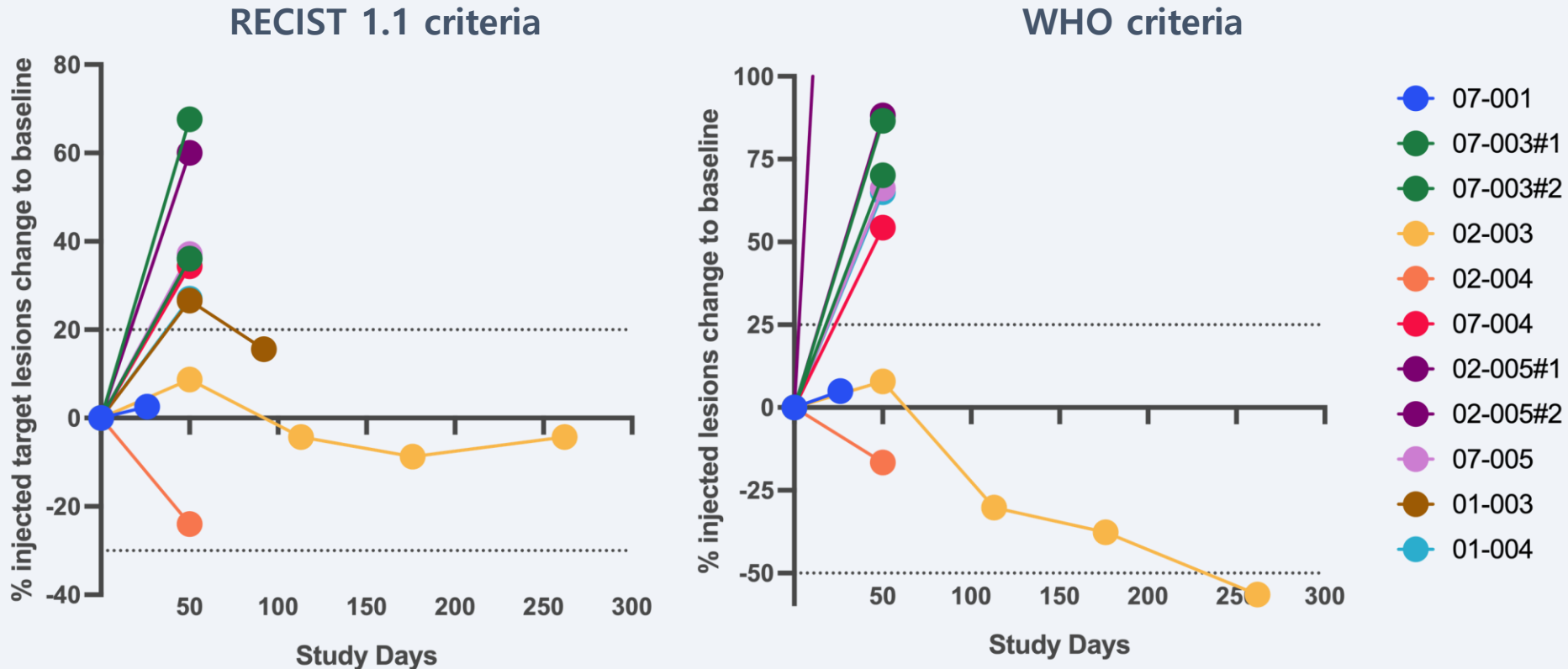


**Phase 1b now underway
with active participants on the study**

Promising Reduction in Injected Lesions

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

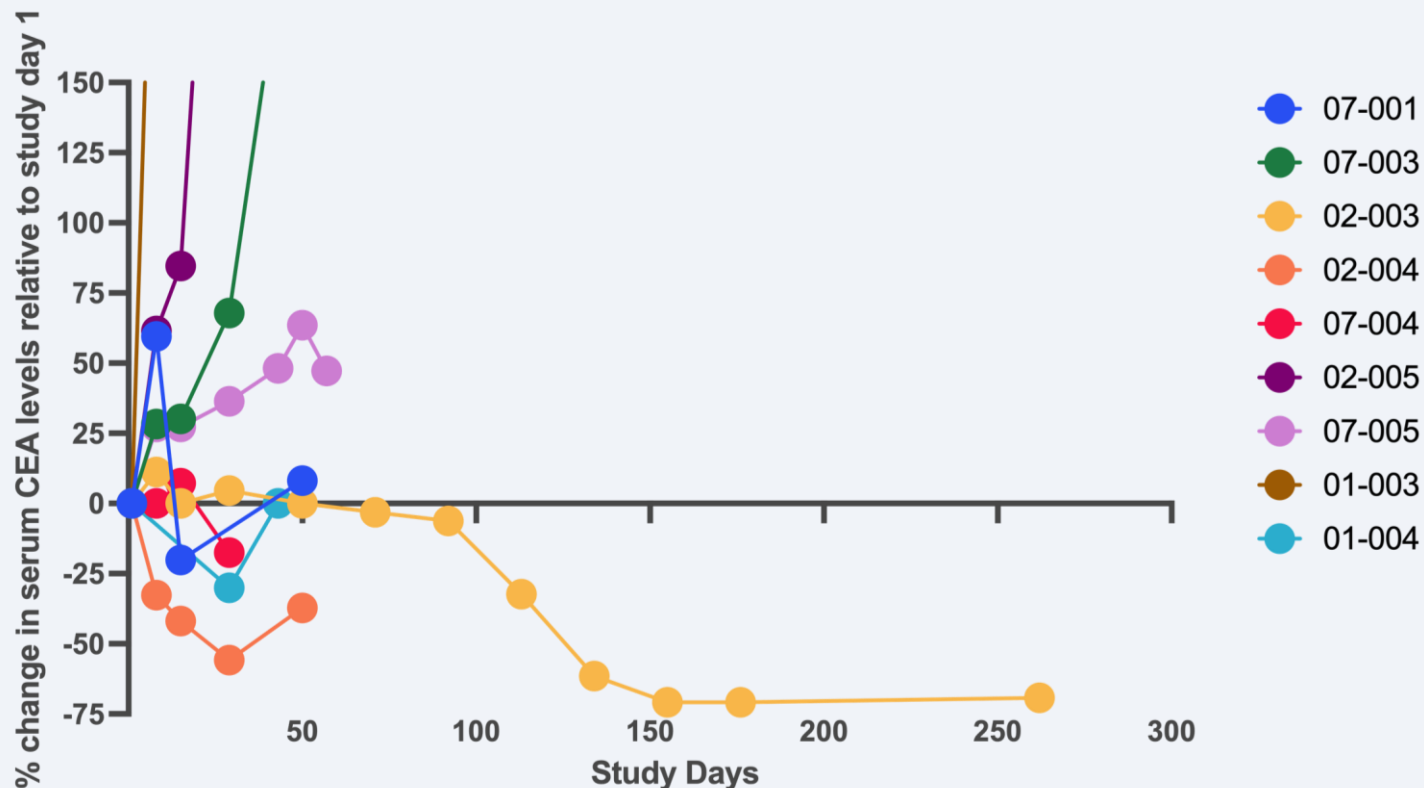
Percentage change of injected target lesions change to baseline (Phase 1a data)



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 over a year without additional cancer treatments. Suggestive of IVX037 induced abscopal activity

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

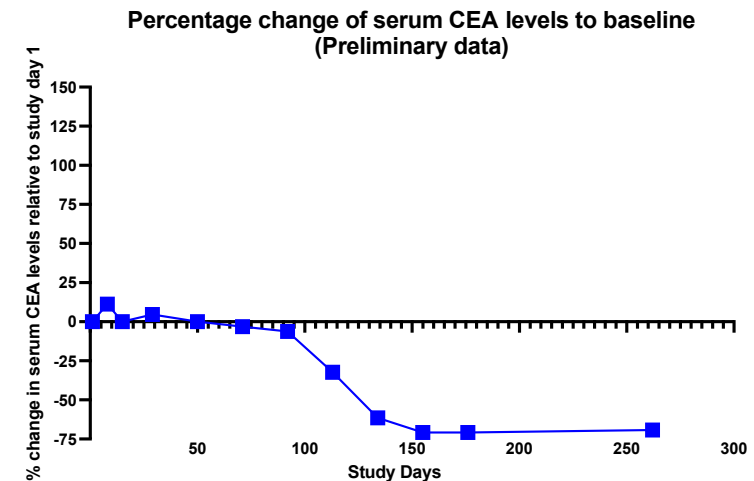
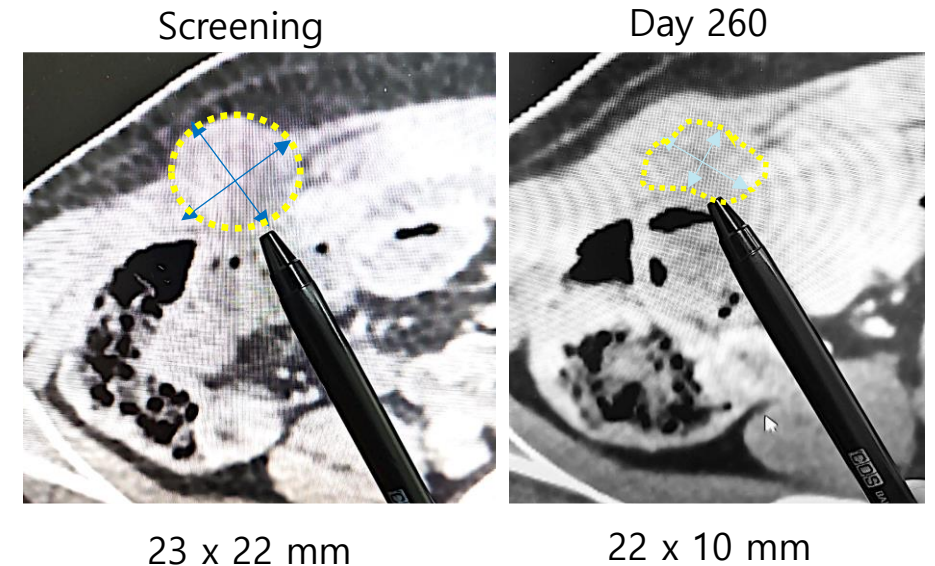


HIGHLIGHTS

- 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

- Consent for CP-IVX001 in June 2023 cohort 1
 - Target lesion dimensions 23x22mm
 - 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 14 months since trial initiation and 8 months since completing the trial treatment => indicative of systemic response and abscopal effect**

Injected target lesion response



Apr 2024 biopsies of both abdominal wall lesions

DIAGNOSIS

A. Superior abdominal wall lesion, core biopsy:

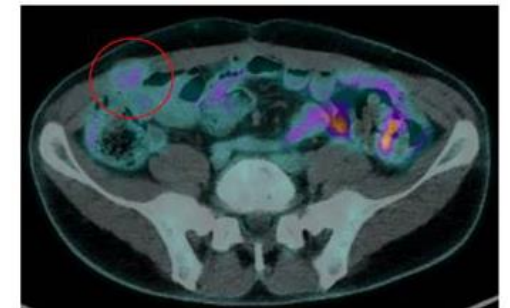
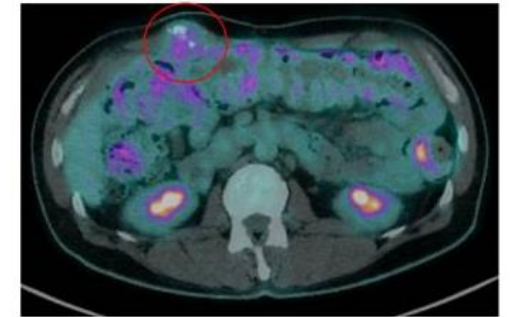
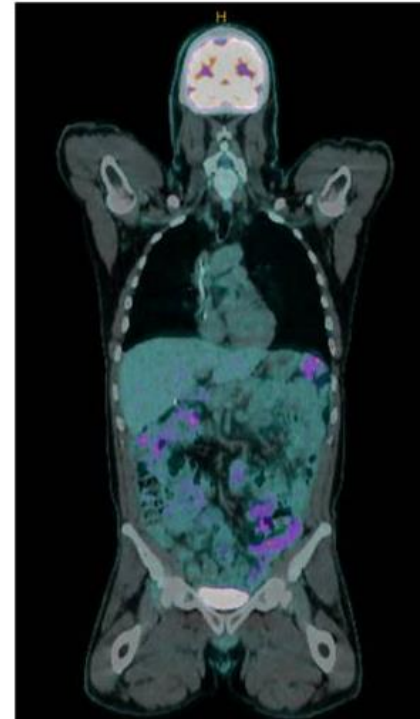
- Scant atypical epithelium within extracellular mucin pools.
- Consistent with **metastatic mucinous adenocarcinoma**.

=> very few scant cancer cells showing a small volume of residual disease

B. Inferior abdominal wall lesion, core biopsy:

- **Acellular mucin pools** within partly necrotic fibrosclerotic stroma.

=> absence of tumour cells confirming complete response

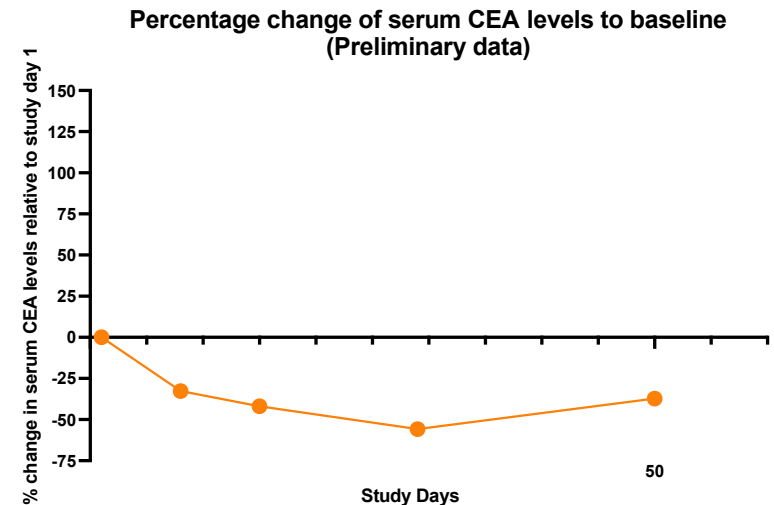
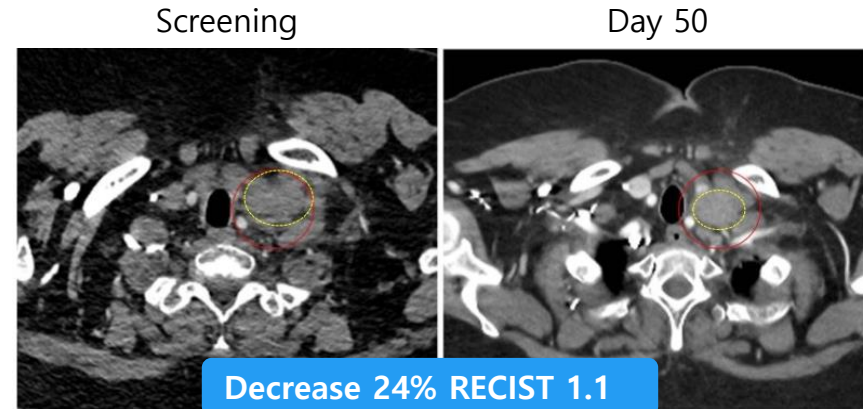


PET-CT scan shows no further cancerous spread

- MSS CRC pt ID 02-004; 57yo Asian female
- Consent and screen for CP-IVX001 in July 2023, cohort 2
- Original diagnosis of caecal carcinoma in Aug 2020; T3 N2 M0
- 1 injected lesion; dosing volume: TL lymph node 2 ml, total of 2 doses received

- Near response in target lesion - 24% decrease in injected lesion (25mm to 19mm); corresponding decrease in CEA levels
- Patient was diagnosed with underlying rheumatoid arthritis requiring steroids

Injected target lesion response

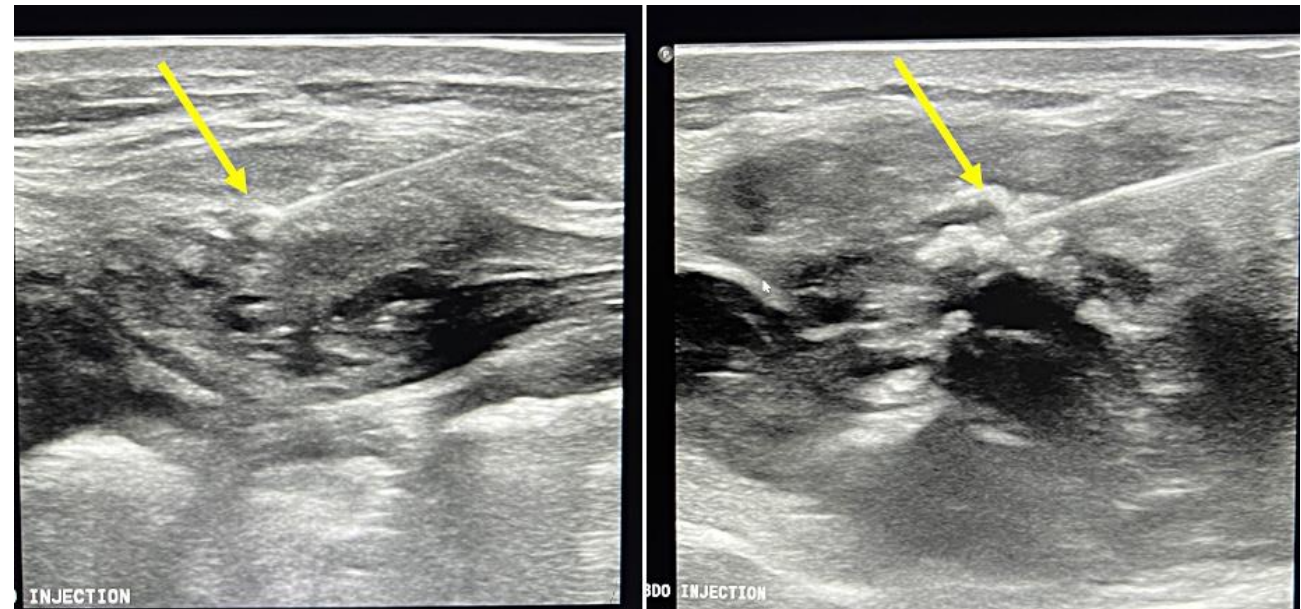


Accessing Lesions For Intratumoral Administration

– 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, 5 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 10ml (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)
Favezelimab/pembrolizumab	6.3% phase 2 Failed phase 3	MK-4280A KEYFORM-007	20% ≥ G3 TRAE (pneumonitis, ALT increase, infusion-related reaction, maculopapular rash, fatigue)

- A total of 14 pts have been dosed on the study, 2 gastric ca 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

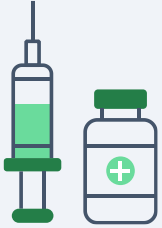
MOST COMMON TREATMENT RELATED ADVERSE EVENTS (TRAEs) GRADE 2 (moderate)

- 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%





IVX037 IT administration has been well tolerated, with all patients exhibiting some level of systemic exposure immediately following injection **with no dose-limiting toxicities**



Three patients displaying injected lesion reduction or stabilization also exhibited **notable decreases** in serum CEA levels



Successful IVX037 administration **to liver, lymph node, and abdominal metastases**



Stable disease maintained for an extended period with no further treatment required



Promising signals of monotherapy activity including **pathological complete response in a CRC target lesion** confirmed by histology. No new metastatic disease (PETscan) for over a year without additional cancer treatments



Serum biomarker analysis indicated IVX037-mediated induction of **potentially beneficial inflammatory cytokines/chemokines**, such as CXCL10

Second Candidate: IVX055

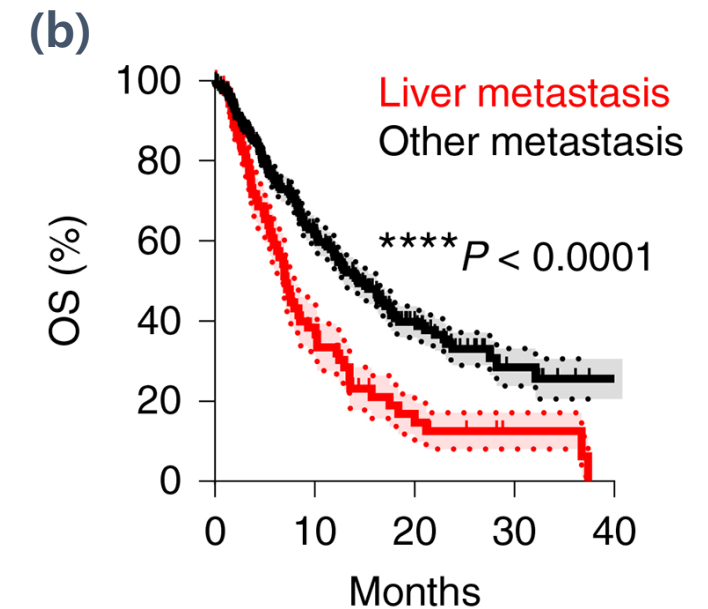
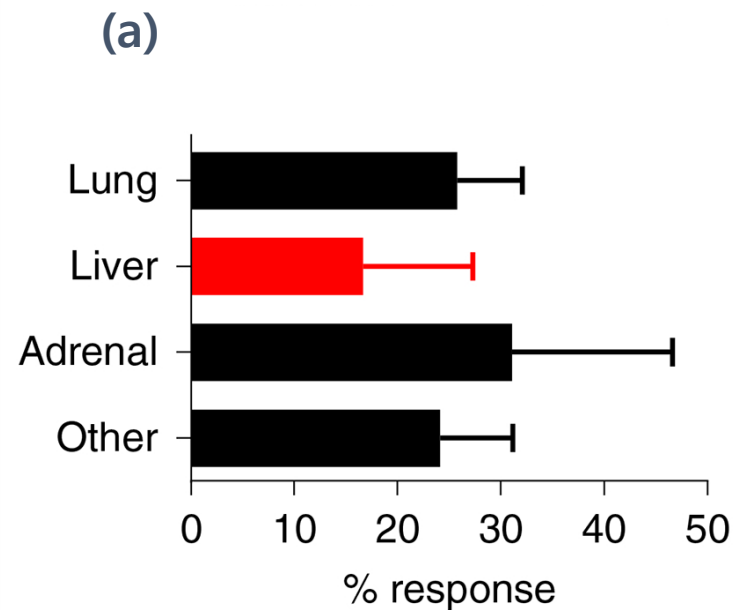
Receptor Targeted

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





Pipeline of receptor targeted Oncolytic RNA immunotherapies

Transformative opportunity in most globally prevalent cancers with high unmet need

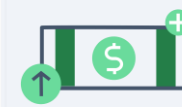
- Focused on tumour types with **accessible metastatic lesions**, such as CRC, HCC, gastric, ovarian
- **Early signals** seen in cold tumor types, such as MSS CRC
- Pathway to randomized controlled trials or expansion of single arm trials for **approval**



Lead Oncolytic RNA immunotherapy candidate IVX037

- **Phase 1a:** Well tolerated with **promising early signals of targeted monotherapy activity**
- **Phase 1b** in combination with Innovent's checkpoint inhibitor across MSS colorectal, gastric and ovarian cancers: now underway
- 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
- File IND

IVX055

- Initiate phase 1a in NSCLC

CAR-T (IVX037 Combination)

- Preclinical data pack

Strong cash position

A\$23.8M (end Sep 2024)

Well-funded - cash to mid 2026

ImmVirX

Receptor Targeted Oncolytic
RNA Immunotherapies

Thank you

Malcolm McColl

Chief Executive Officer and Co-Founder

malcolm.mccoll@immvirx.com