ImmVirX

Receptor Targeted Oncolytic Viruses

Bell Potter Healthcare Conference

November 2022

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Overview

AMBITION

To provide durable responses with a high quality of life in patients with some of the most globally prevalent cancer types using our proprietary bio-selected, receptor targeted, RNA oncolytic viruses

APPROACH

- Highly inflame “cold” tumour types with current low responsiveness to immune checkpoint therapy
- Trigger both innate and adaptive immune responses
- Infiltrate tumours with immune cells at a high rate
- Activate immune stimulating genes to create synergy with immune checkpoint and CAR-T therapies
- Offer a favourable safety profile for patients
- Off the shelf therapy / no need for personalisation

Successful Track Record in Oncolytic Immunotherapy

Dr. Malcolm McColl
CEO and Co-Founder
Viralytics
CSL Hospira

Prof. Darren Shafren
CSO and Co-Founder
Viralytics
The University of Newcastle Australia

Robert Vickery
CFO
Viralytics
MERCK

Dr. Leonard Post
Non-Executive Director
Viralytics
Vivace therapeutics BIOMARIN

Robert Routley
Non-Executive Director
Acorn Capital Next Generation Investing

Dr. Jennifer Rosenthal
Director Quality & Regulatory Affairs
Viralytics
Alchemia MERCK

Cohesive Team Leveraging Past Success

- Leadership and scientific team comprised of ex-Viralytics team members responsible for invention, preclinical and clinical development of CAVATAK technology through to acquisition by Merck for $A502M
- Deep regulatory knowledge with extensive interactions with FDA
- GMP manufacturing and quality systems experience
- Global networks of clinicians and KOLs to facilitate clinical programs
- 20 strong R&D team in facility at TUNRA/University of Newcastle Hunter Medical Research Institute
- Completed Series A-1 financing raising $25M
- $16.3M cash at the end of October 2022 with runway to mid 2024

Excellent Operational Team with Viralytics and Merck Experience

Bronwyn Davis

Director
CMC

Dr. Min Quah

Director
Discovery & Pre-clinical Research

Dr. Susanne Johansson

Director
Quality Management

Dr. Yvonne Wong

Director
Manufacturing Science

Dr. Roberta Karpathy

Director
Clinical Science

Mark Grose

Consultant Project Manager
Clinical Operations

Proven OV Development Team

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

MERCK

Viralytics
Developers of Oncolytic Immunotherapies

Oncolytic Viruses: Expanding the Reach and Impact of Immunotherapy

- Immunotherapies including checkpoint inhibitors have been transformative, but only for a subset of patients
- Despite limitations, the cancer immunotherapy market is projected to reach USD$277B by 2030*

Oncolytic virus immunotherapies are an emerging class of combination therapy agents with **big pharma interest** and the potential to **expand the reach** of immunotherapy to **indications not currently responsive** to checkpoint inhibitors

Validating high value oncolytic virus transactions and valuations

Amgen acquisition of Biovex

USD$425M cash upfront, USD$575M future milestone payments

Merck acquisition of Viralytics

A$502M cash upfront

Replimune Valuation

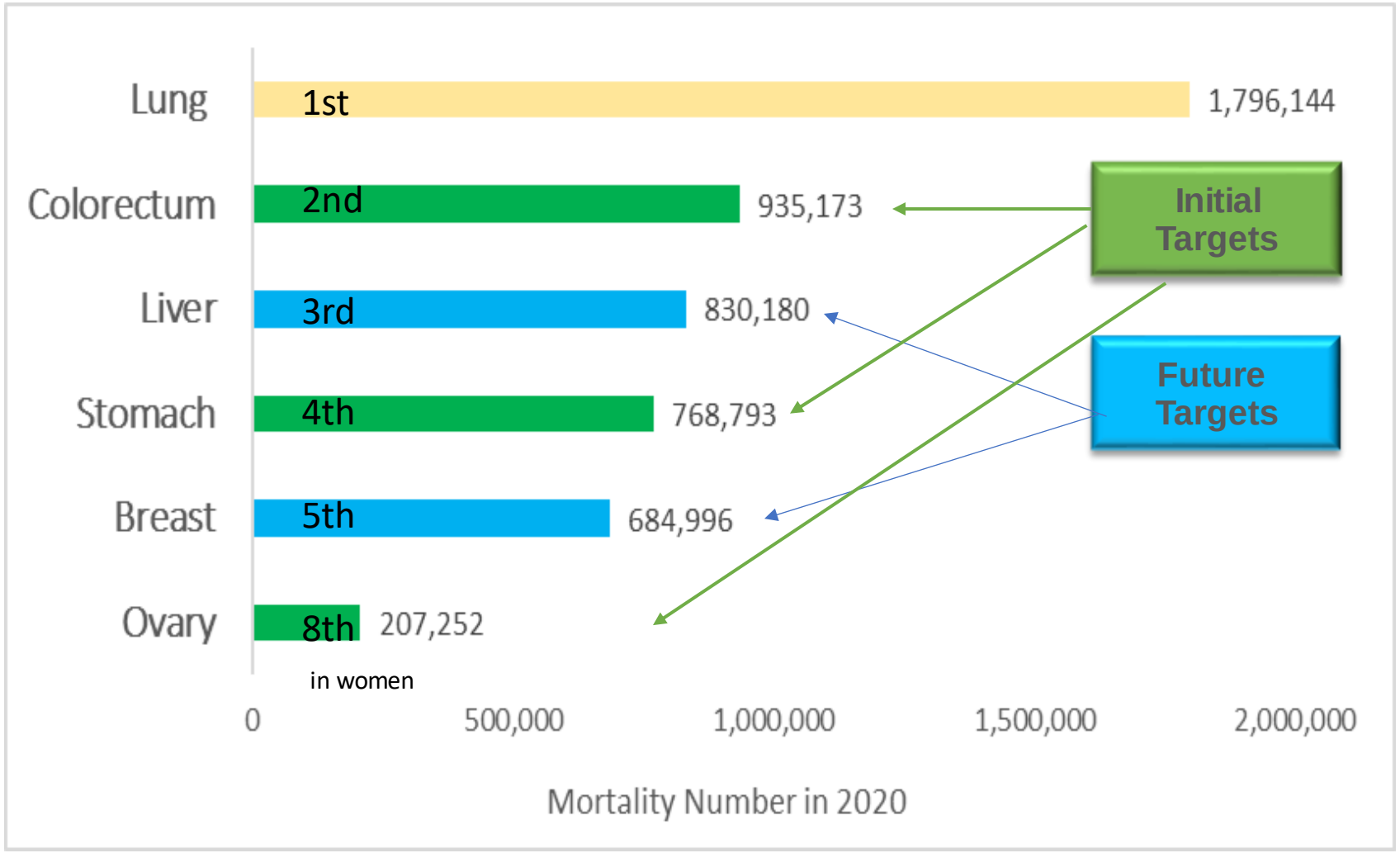
Market cap ~ USD$922M (4th November 2022)

ImmVirX

* Precedence Research Dec 2021

ImmVirX Targeting Substantial Markets

Estimated number of deaths worldwide, both sexes, all ages



International Agency for Research on Cancer
World Health Organization

ImmVirX

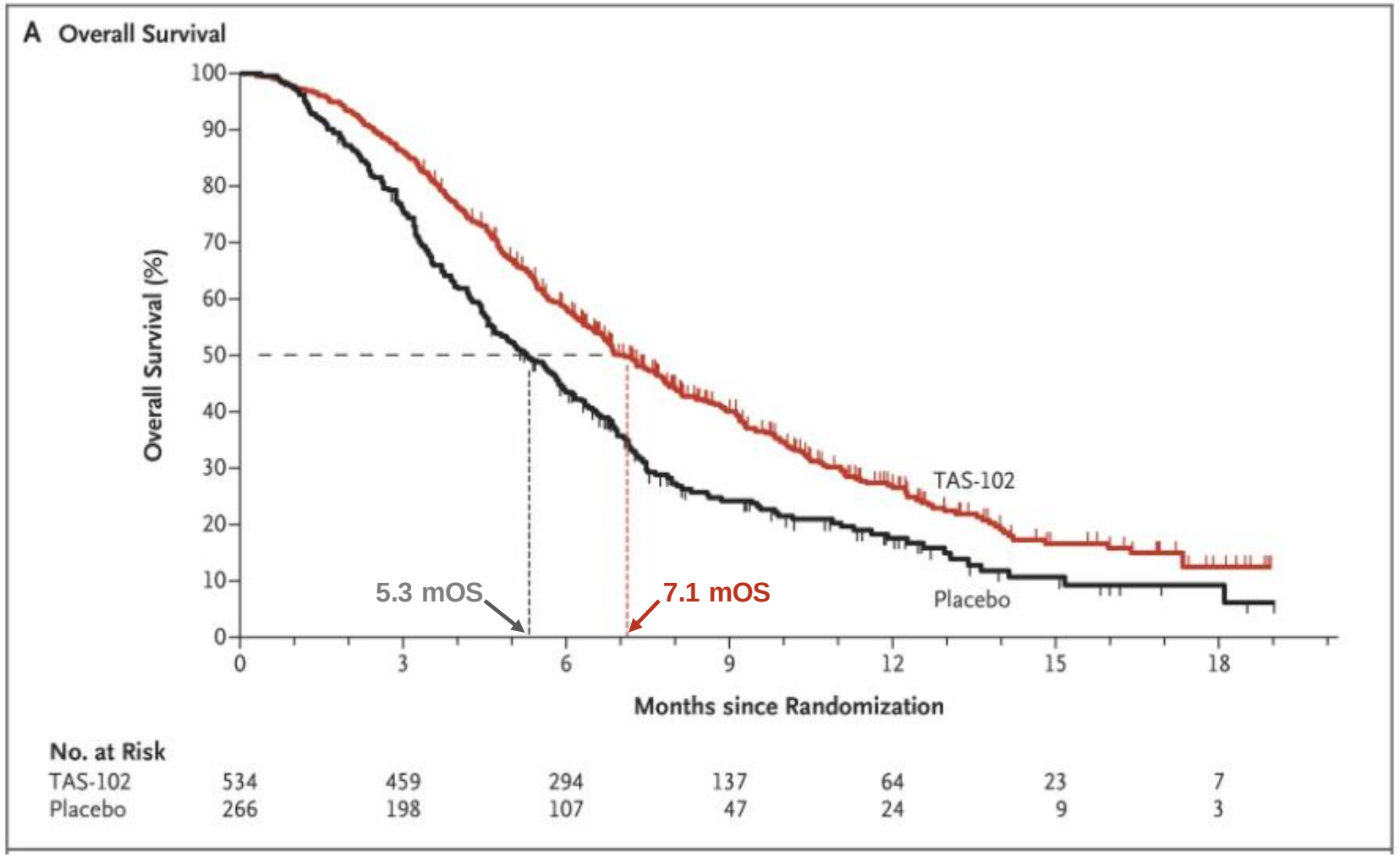
High Unmet Need with Current Treatments

Indication	Forecast Deaths per Annum 2022		Clinical Response	
	USA[1]	China[1]	ICI ORR[3]	Study Identifier
Colorectal[2]	**56,693**	**309,114**	**4% KEYTRUDA**	**KEYNOTE-028**
Ovarian	**14,914**	**39,306**	**9% KEYTRUDA**	**KEYNOTE-100**
Gastric	**11,898**	**400,415**	**17% KEYTRUDA**	**KEYNOTE-224**
Breast	**44,094**	**124,002**	**21% KEYTRUDA in TNBC PD-L1⁺**	**KEYNOTE-086 (cohort B)**
Hepatocellular	**32,332**	**412,216**	**16% KEYTRUDA**	**KEYNOTE-224 (cohort 2)**
Melanoma (CAVATAK™ lead target indication)	7,530	4,369	33% KEYTRUDA	KEYNOTE-006

[1] Chinese Medical Journal 2022; 135(5)
[2] Includes all types of colorectal cancer (CRC). ImmVirX focus on MMRp (Mismatch Repair Proficient) accounting for ~94% of all CRC (Dung et al., Science, 2017; 357 (6349):409-413).
[3] ICI ORR = Immune Checkpoint Inhibitor Overall Response Rate

Limited Efficacy and Significant Toxicity of Therapies in Late-Stage Colorectal Cancer

- TAS-102 is an oral chemotherapy used in late-stage CRC
- Large randomized trial demonstrated that TAS-102 improved median overall survival by 1.8 months
- TAS-102 associated with significant adverse events including neutropenia and leukopenia
- Urgent need for better therapies in this setting to extend survival without significant toxicity



Mayer RJ et al. *N Engl J Med* 2015; 372:1909-1919

ImmVirX: Receptor Targeted Oncolytic Virus

Platform

- Proprietary bio-selection platform for receptor targeted oncolytic RNA viruses
- Selection for extracellular receptor targeting drives exquisite selectivity and potency in specific tumor types
- Oncolytic potency enables development of non-genetically modified virus with potential for future “armed” virus to express key immune stimulatory molecules

Proven Mechanism

- RNA virus drives tumor inflammation and immune cell infiltration via RIG-I pathway activation
- De-risked through preclinical in vitro and in vivo proof-of-concept. Comparable to oncolytic activity and molecular mechanism of CAVATAK but now in other tumour types and using different receptor.

Clinical Strategy

- Virus specificity enables targeted approach in indications with high unmet needs including colorectal, gastric, ovarian, liver, and breast cancer
- Planned combination therapy with immune checkpoint inhibitors in indications with poor response rates to readily detect signals of activity
- Clear clinical development pathway with trial initiation expected Q4 2022

IVX037

Lead Candidate
Receptor Targeted
RNA Oncolytic Virus

Measuring *In Vivo* Oncolytic Activity of IVX037

Human cancer xenograft model

Day 0

Implant human cancer* cells into left flank

SCID Balb/C

Single intratumoral treatment with IVX037 or control

IVX037
or control i.t

End of study

Monitor for tumor burden and treatment tolerance

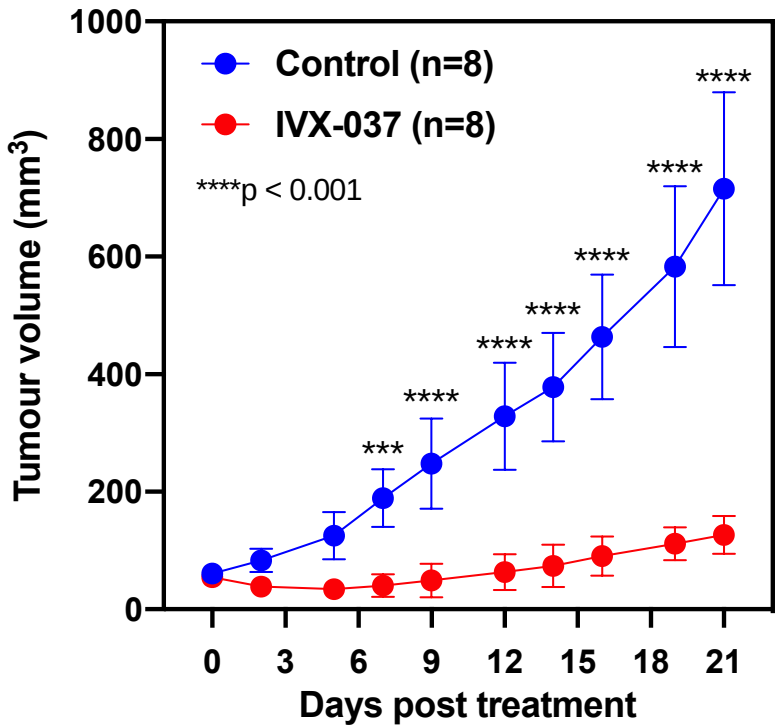
Monitor

* Assessing human colorectal (X2), gastric (X1) and ovarian (X2) cancer cell lines in initial studies

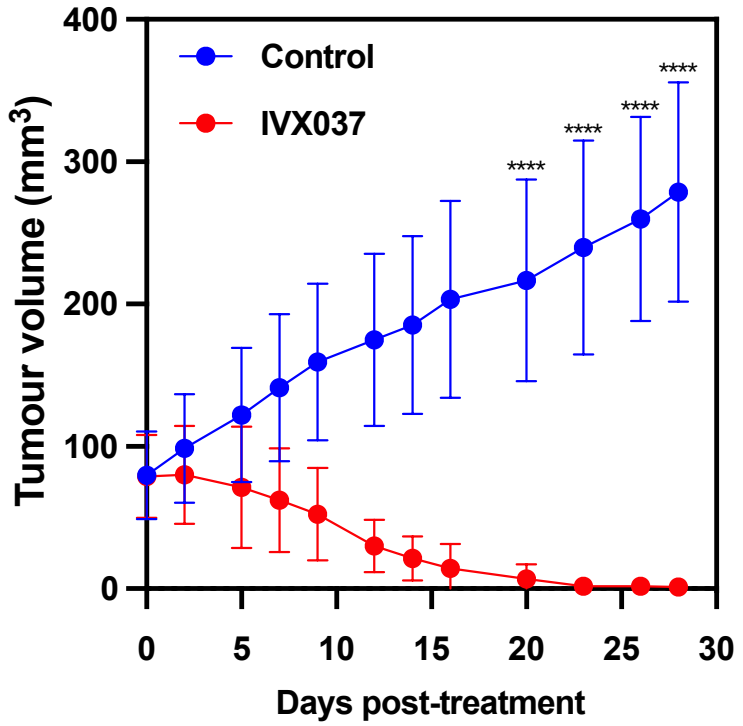
IVX037: *In Vivo* Oncolytic Activity in Colorectal Cancer

Two human MSS colorectal cancer cell lines assessed in xenograft models

Colorectal tumour model #1 – **WiDr**



Colorectal tumour model #2 – **Caco-2**

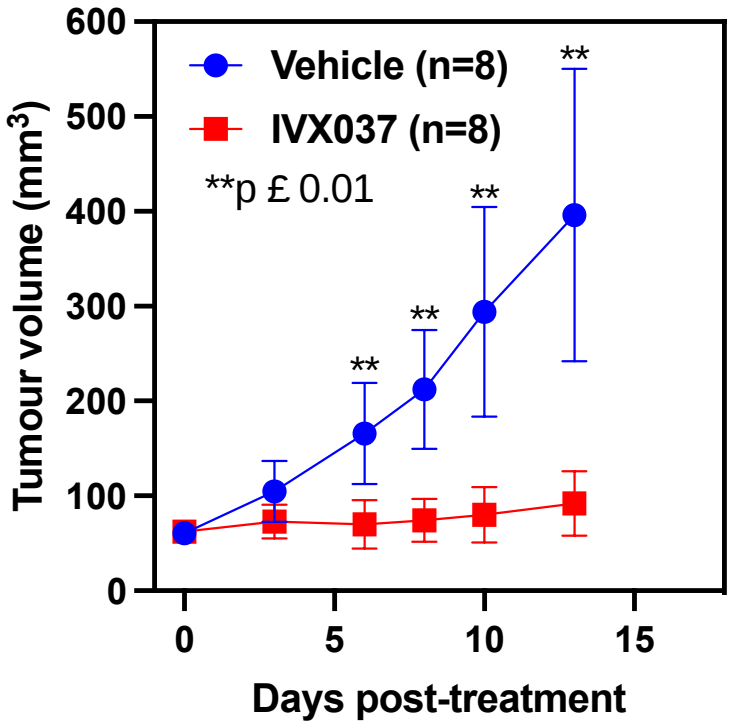


Striking impact in two colorectal cancer models in immune deficient mice provides clear signal of potency solely attributed to oncolytic activity of IVX037 with favorable tolerability

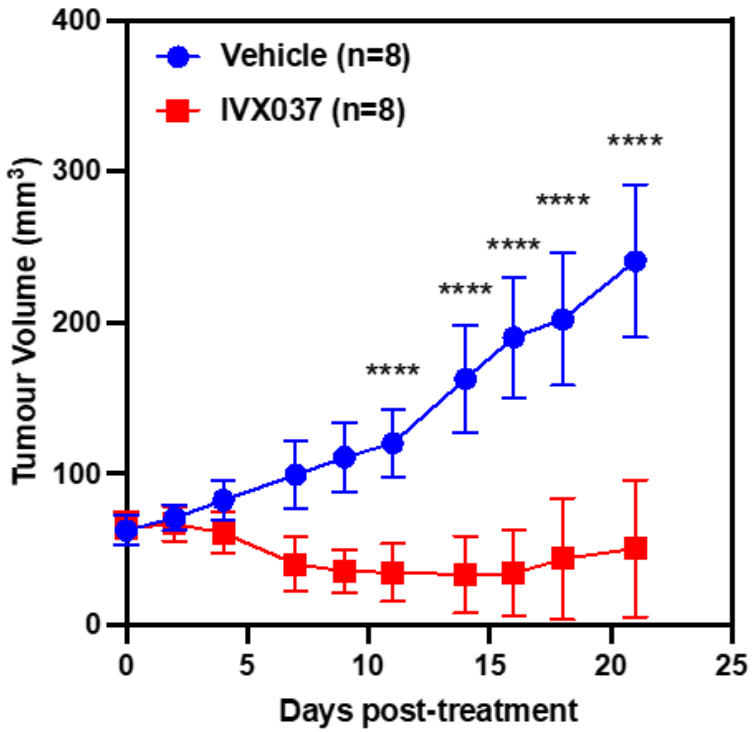
IVX037: *In Vivo* Oncolytic Activity in Ovarian Cancer

Two human ovarian cancer cell lines assessed in xenograft models

Ovarian tumour model #1 – **IGROV-1**



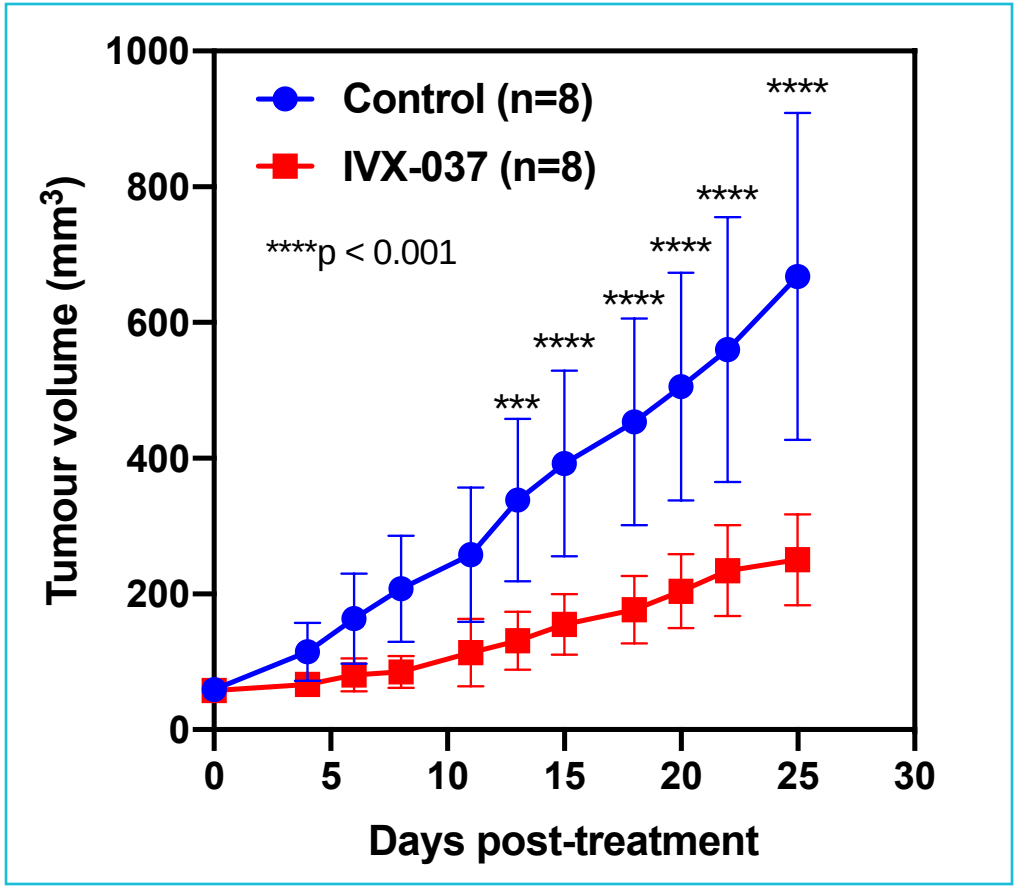
Ovarian tumour model #2 – **OVSAHO**



Striking reduction in tumor volume provides clear signal of potency solely attributed to oncolytic activity of single dose of IVX037 with favorable tolerability

IVX037: Demonstrated *In Vivo* Oncolytic Activity in Gastric Cancer

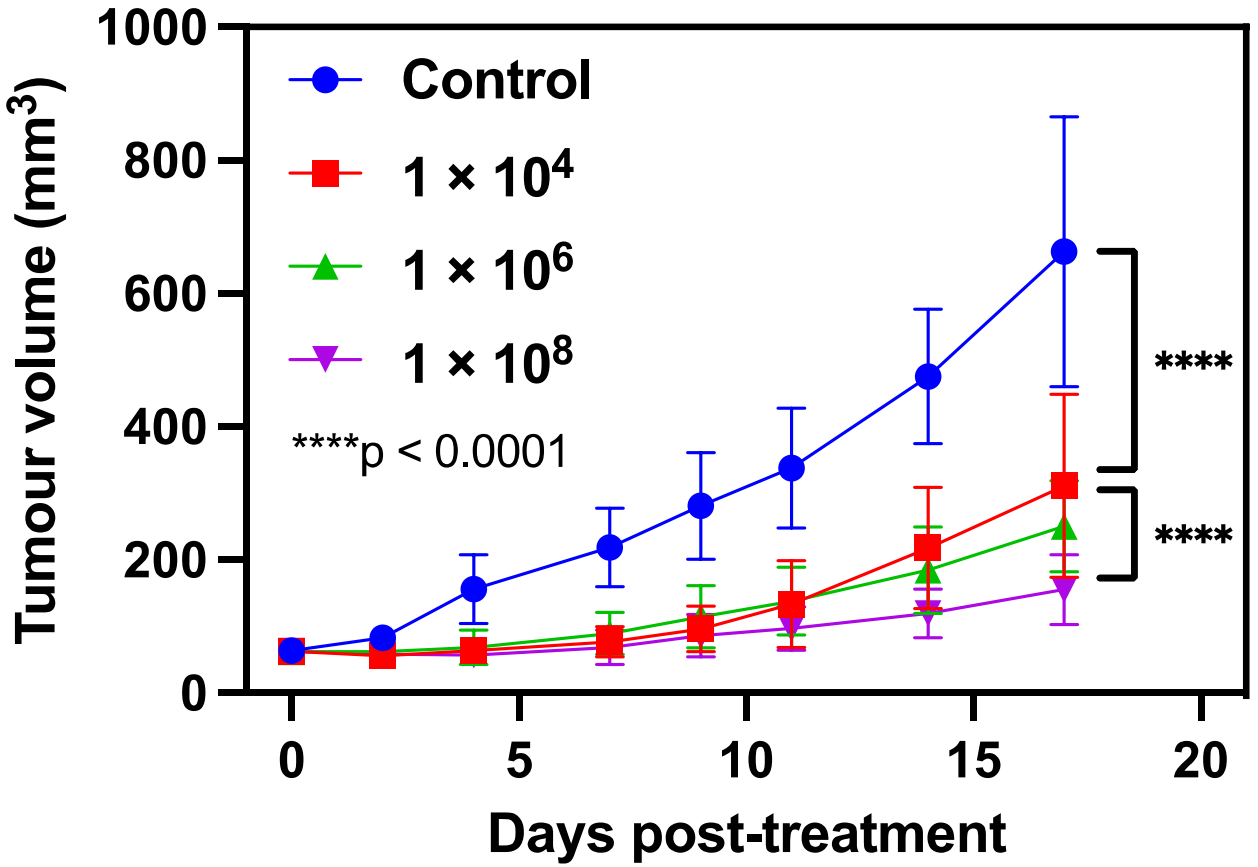
Human Gastric cancer (NCI-N87) xenograft model



Activity of single dose of IVX037 demonstrated in gastric cancer with favorable tolerability

Potency Observed Across Dose Levels

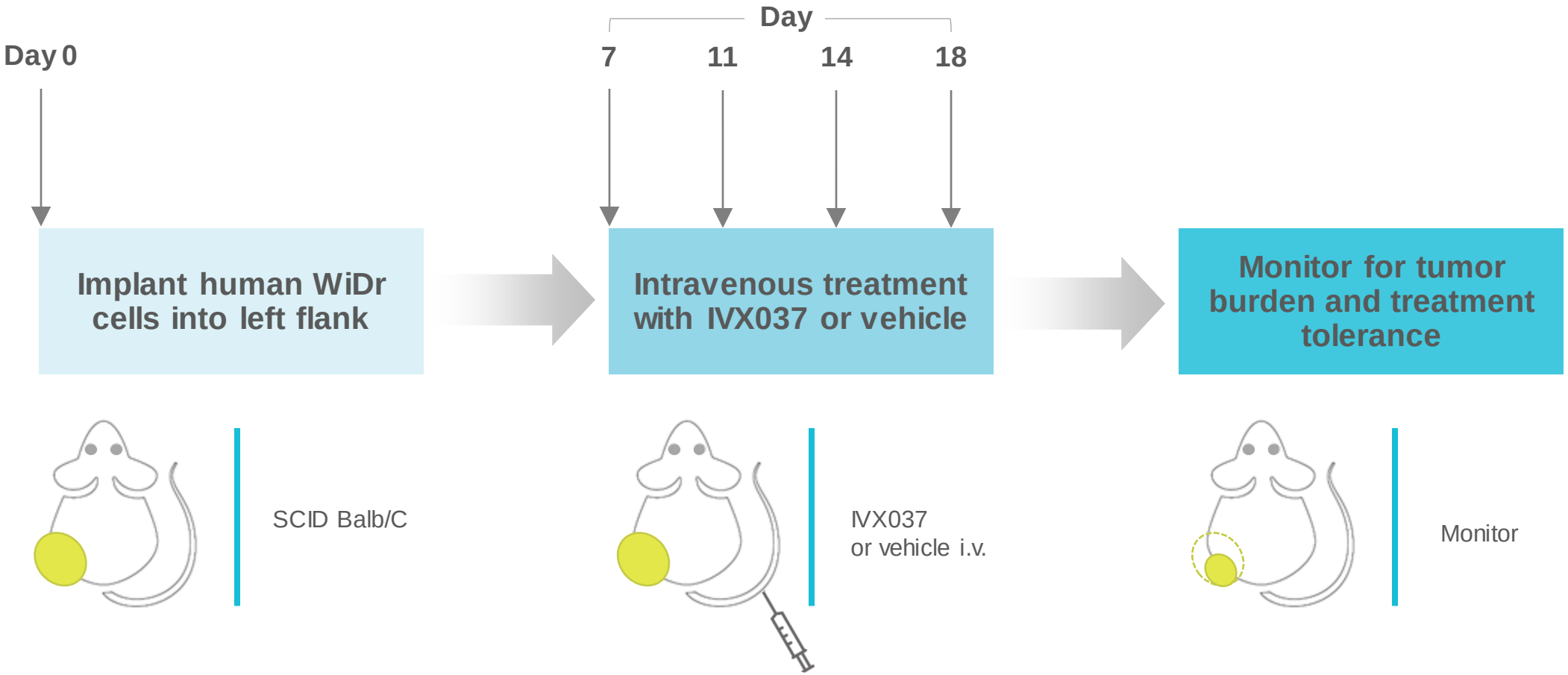
Dose escalation in human MSS colorectal cancer (WiDr) xenograft model



IVX037 potency enables robust antitumor activity at a 10,000-fold lower dose

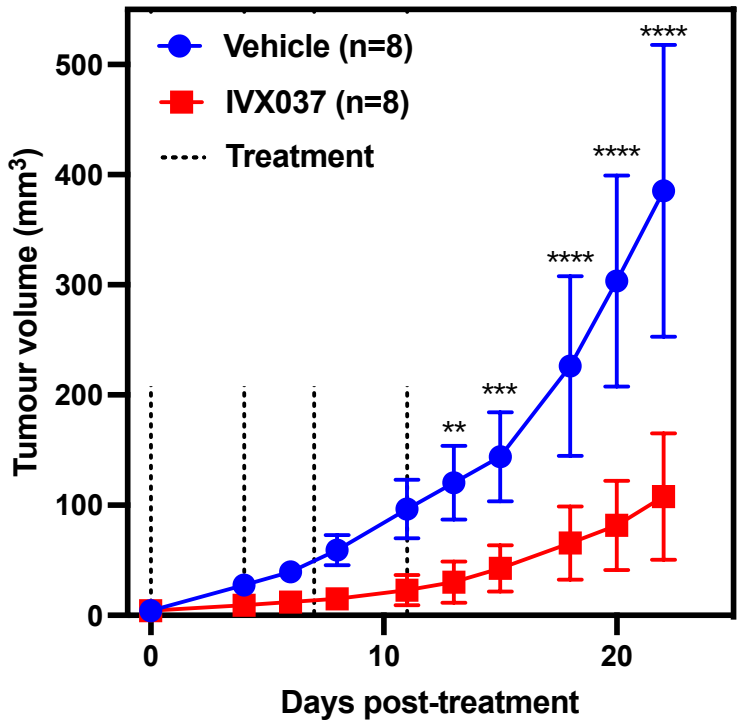
Measuring *In Vivo* Oncolytic Activity of IVX037 Intravenously

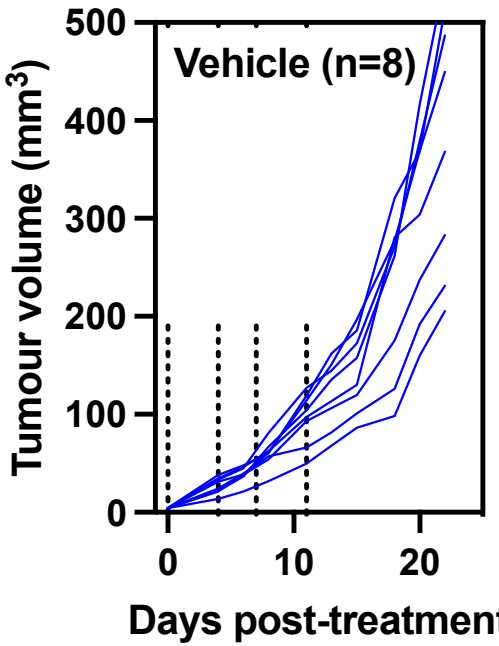
Human MSS colorectal cancer (WiDr) xenograft model – intravenous delivery

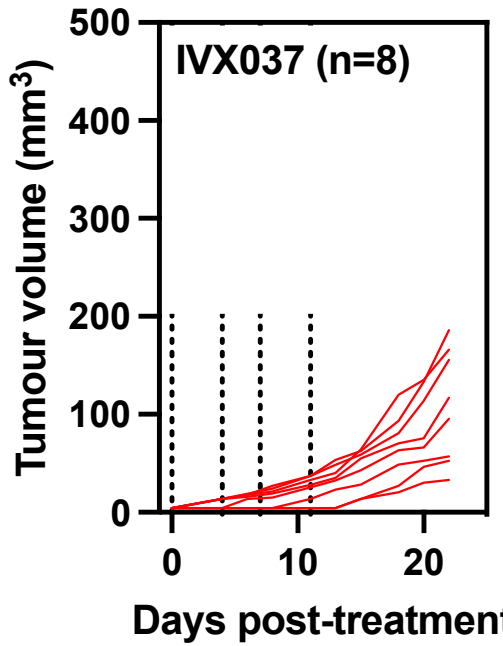


Intravenous Delivery of IVX037 Achievable in Colorectal Xenograft

Human MSS colorectal cancer (WiDr) xenograft model – intravenous delivery







Evidence of impressive anti-tumour efficacy and no treatment related toxicity observed

Preclinical Toxicology Summary: IVX037 was Safe and Well Tolerated

Gross pathology

- Observations during necropsy of vehicle and IVX037 treated mice, unremarkable
- Weight gains and organ weights comparable between vehicle and IVX037 treated mice

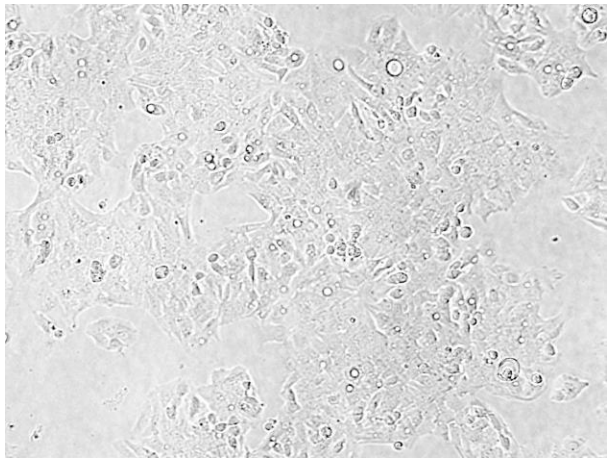
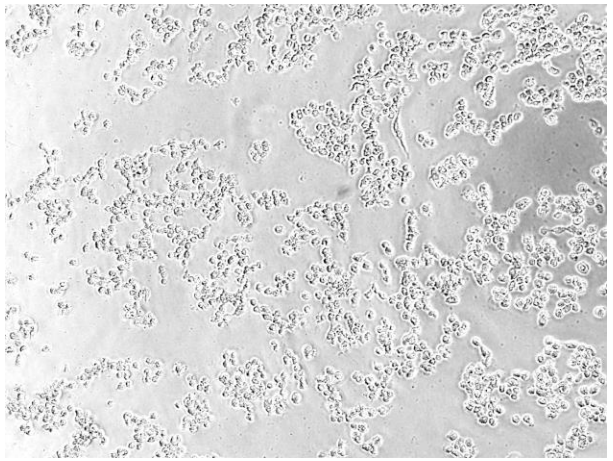
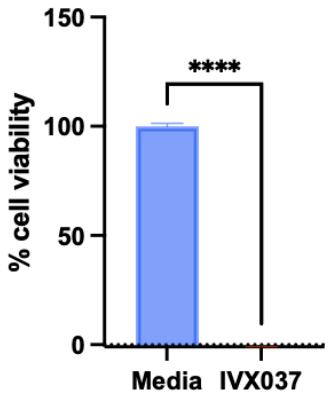
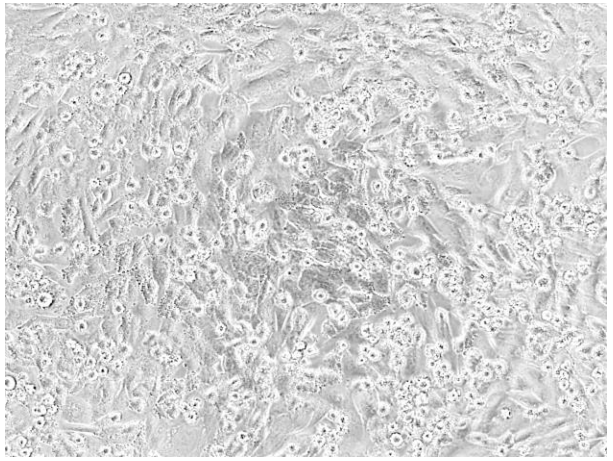
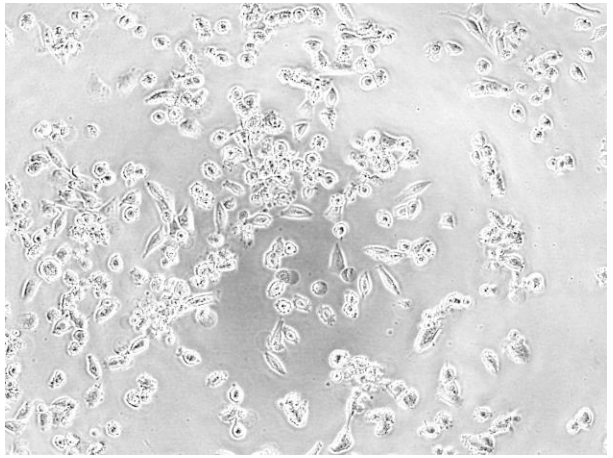
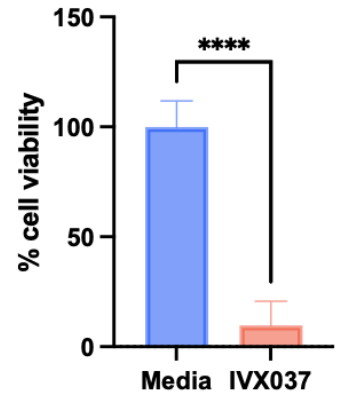
Biochemistry/Haematology

- IVX037 undetected in serum by qPCR at 21 days post-intrahepatic injection (x3)
- Biochemistry and Haematology analysis, vehicle and IVX037 treated mice, unremarkable.

Histopathology

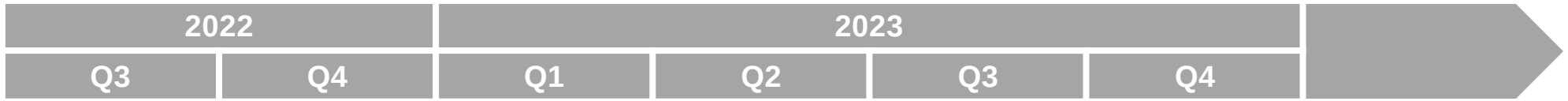
- Histopathological findings of the liver were either incidental or artefactual and not attributable to the administration of IVX037
- No significant histological changes in the spleen
- Remaining organs had no significant findings

Confirmed Cell death in Liver Cancer Cells

	Media	IVX037	Cell viability assay
Hep G2 C3A			
SK-Hep-1			

Cytopathic effects in hepatocellular carcinoma cells resulting from IVX037 infection. Cells have lost their original structure and are unable to reproduce

Clear Path Forward in the Clinic



Phase 1
dose escalation
proof-of-concept

IT monotherapy in advanced MSS-CRC

IT monotherapy in advanced ovarian cancer

IT monotherapy in advanced gastric cancer

Basket study (n = 24-27)

RP2D

Phase 1b proof-of-concept in combination with checkpoint inhibitor

IT combination with IV CPI in advanced MSS-CRC

IT combination with IV CPI in advanced ovarian cancer

IT combination with IV CPI in advanced gastric cancer

Basket study (n = 45)

Phase 2 - Registration Studies

Clinical strategy leverages potential to:

- De-risk program with early biomarker data
- Develop biomarker informed/stratified future programs

IT – intratumoral
MSS-CRC – Microsatellite Stable Colorectal Cancer
RP2D – Recommended Phase 2 Dose

Update: Significant progress since June 2022

Preclinical / IP / Corporate

- Successful completion of the preclinical toxicology studies
- Underway with assessment in liver and breast cancer cell line studies
- Applied for further credit of $2.81M from the Federal Government RDTI program
- Extended agreement with HMRI through to November 2024

CMC / Quality

- Excellent yields from production batch for first in patient studies
- Drug Product fill completed with final testing underway
- Completion of engineering run batch at US site
- Qualification of analytical assays for product testing
- IVX037 Drug Product stable for 6 months at -80ºC and -25ºC, studies at 2-8ºC ongoing

Clinical

- Site selection visits complete at 3 Australian sites
- Ethics and TGA approval for first Australian site
- Ongoing strong clinician interest in trial participation

Strengthened team as we approach first in patient studies with 20 staff at the Newcastle facility

Upcoming Milestones – through to Q1 2023

Preclinical / IP

- Preclinical studies to be conducted including investigation of combination immunotherapies
- Complete preclinical assessment in liver and breast cancer indications
- Strengthen patent position with further filings

CMC / Quality

- Second production batch for Australian sites
- Initiate first GMP batch at US site
- Further stability data on improved formulation

Clinical

- First site initiation and first patient on trial
- Achieve approval for other Australian Clinical Trial Sites
- Planning for US FDA IND filing

Summary

- Major opportunity in most important cancers with high unmet need
- Strong pre-clinical data set across multiple cancer types
- Drug Product for clinic near complete. Adding US CMO site with product in mid 2023
- Clinical stage oncology company by Q4 2022
- Clinical data readouts through 2023
- Options to partner / licence / sell / list as clinical data unfolds
- Other opportunities in early pipeline
- Strong cash position with runway to mid 2024

ImmVirX

Receptor Targeted Oncolytic Viruses

Thank You

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