ImmVirX

Receptor Targeted Oncolytic Viruses

Bell Potter Healthcare Conference

November 16, 2023

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Overview

AMBITION

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

APPROACH

- Highly inflame “cold” tumor types with current low responsiveness to immune checkpoint therapy
- Trigger both innate and adaptive immune responses
- Infiltrate tumors 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

Prof. Darren Shafren
CSO and Co-Founder

Robert Vickery
CFO

Dr. Leonard Post
Non-Executive Director

Robert Routley
Non-Executive Director

Dr Jeannie Joughin
Non-Executive Director

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
- 23 strong R&D team in facility at University of Newcastle Hunter Medical Research Institute
- Raised $19M in Series B financing led by OneVentures
- $29.6M cash end October 2023

Excellent Operational Team with Viralytics and Merck Experience with Strong Bench to Clinic capability

Dr. Min Quah

Director
Discovery & Pre-clinical Research

Bronwyn Davies

Director
CMC

Dr. Susanne Johansson

Director
Quality Management

Dr. Yvonne Wong

Director
Manufacturing Science

Dr. Jennifer Rosenthal

Director
Quality & Regulatory Affairs

Dr. Roberta Karpathy

Director
Clinical Science

Dr Naomi Croll

Consultant Project Manager
Clinical Operations

Proven Oncolytic Virus Development Team

- Preclinical development and translation of Viralytics' CAVATAK into clinic
- Established advanced preclinical models to assess immunotherapy combinations
- Manufacturing 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

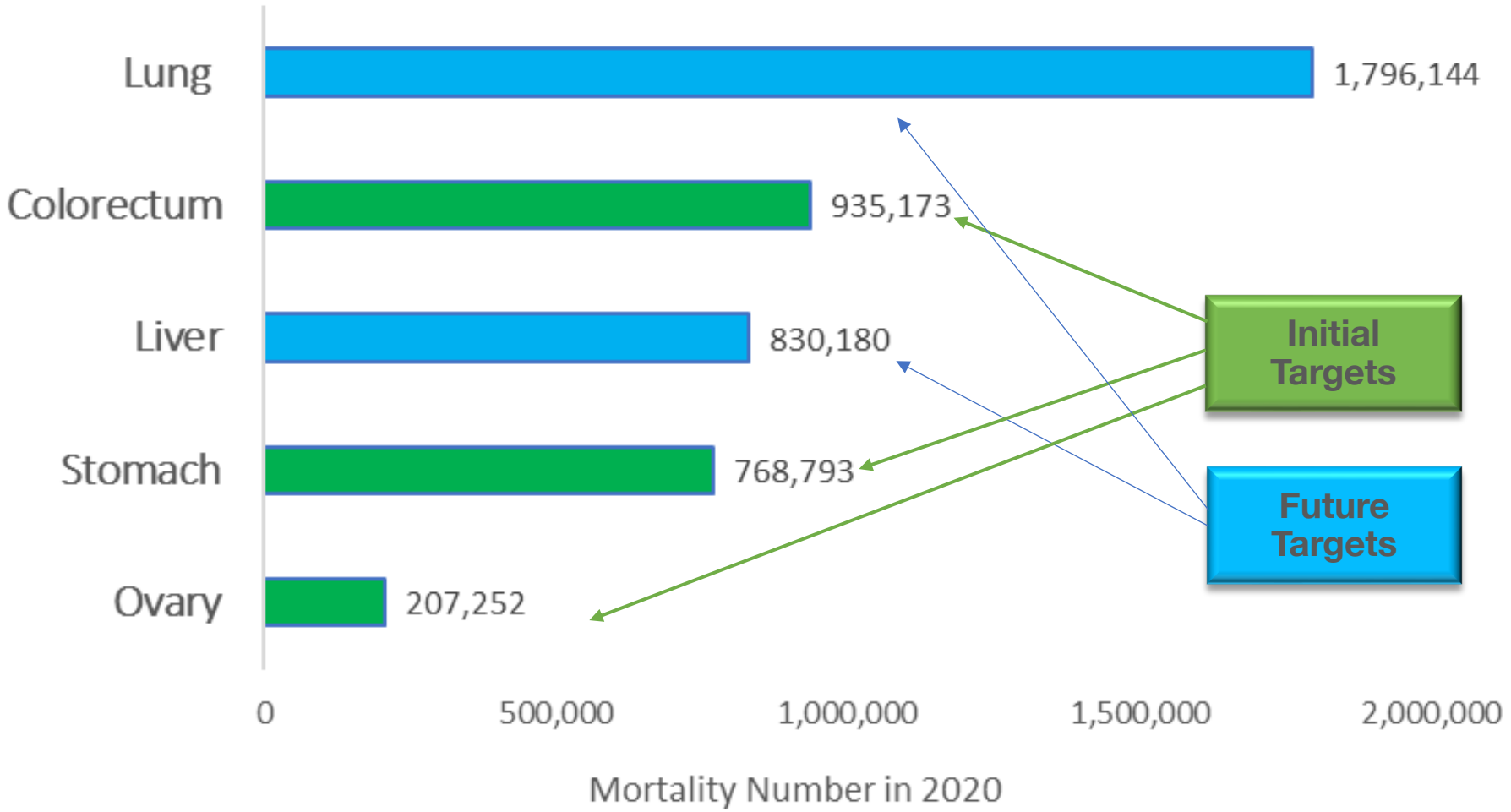
Market cap ~ USD$700M (November 9 2023)

ImmVirX

* Precedence Research Dec 2021

ImmVirX Targeting Substantial Markets

Estimated number of deaths worldwide, both sexes, all ages



ImmVirX

International Agency for Research on Cancer
World Health Organization

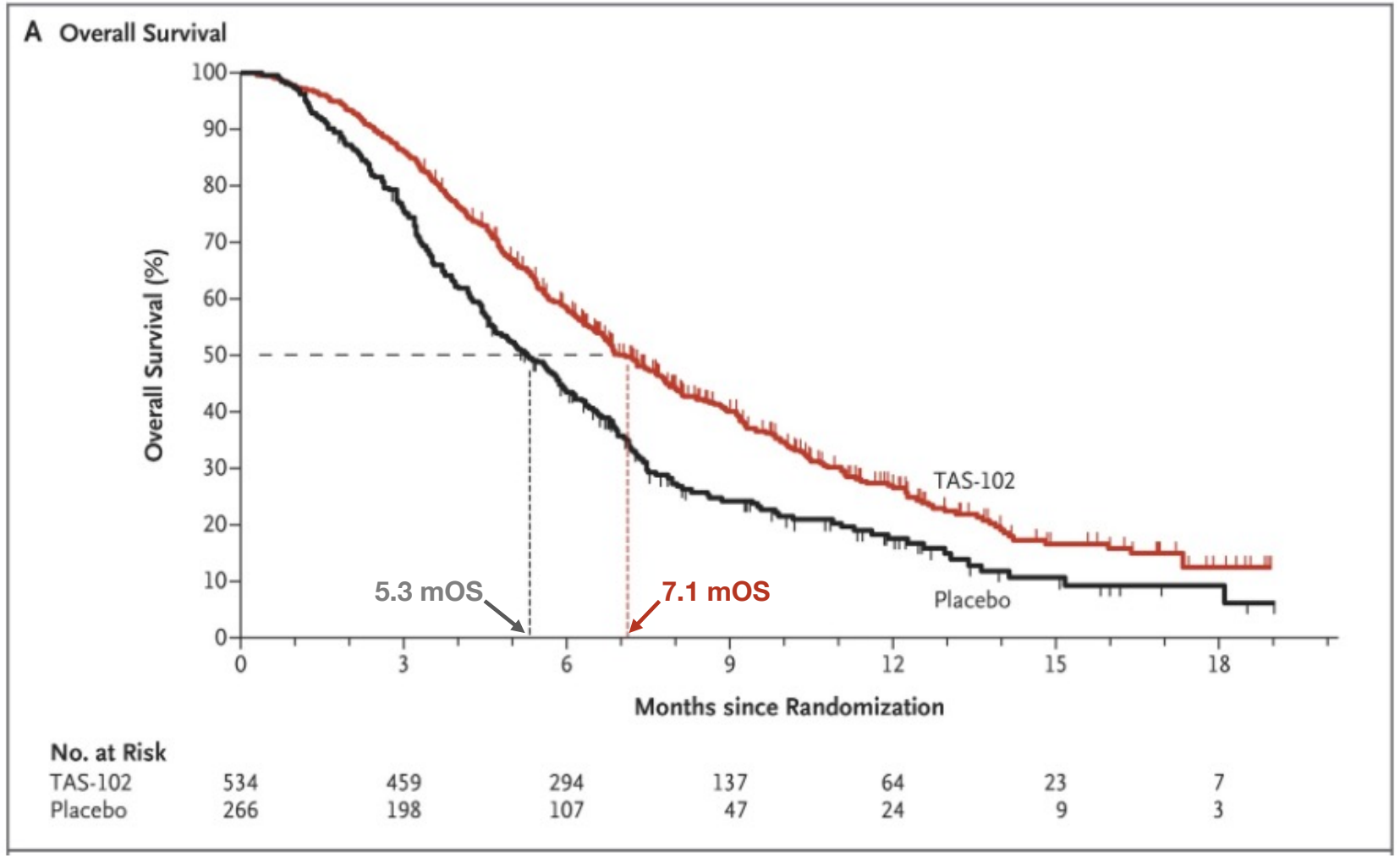
High Unmet Need with Current Treatments

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**
Hepatocellular	**32,332**	**412,216**	**16% KEYTRUDA**	**KEYNOTE-224 (cohort 2)**
Lung Cancer[4]	**144,913**	**766,898**	**18% KEYTRUDA**	**KEYNOTE-010**
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
[4] Non small cell lung cancer with tumor proportion score >1%

Limited Efficacy and Significant Toxicity of Therapies in 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 tumor types and using different receptor.

Clinical Strategy

- Virus specificity enables targeted approach in indications with high unmet needs including colorectal, gastric, ovarian and liver cancer
- Planned combination therapy with immune checkpoint inhibitors in indications with poor response rates
- Clinical program advancing – Recruitment in cohort 1 and 2 complete. Cohort 3 dosing ongoing.
- No dose limiting toxicities in first two cohorts. Several sites recruiting.

Pre-Clinical Data: IVX037

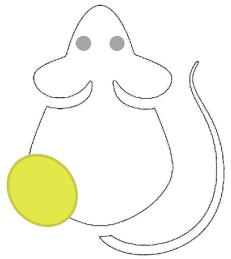
Lead Candidate
Receptor Targeted
RNA Oncolytic Virus

Measuring *In Vivo* Oncolytic Activity of IVX037

Human cancer xenograft model

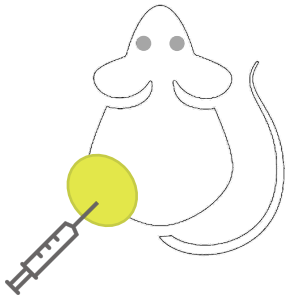
Day 0

Implant human cancer* cells into left flank



SCID Balb/C

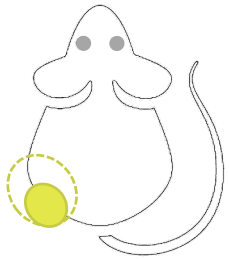
Single intratumoral treatment with IVX037 or control



IVX037
or control i.t

End of study

Monitor for tumor burden and treatment tolerance



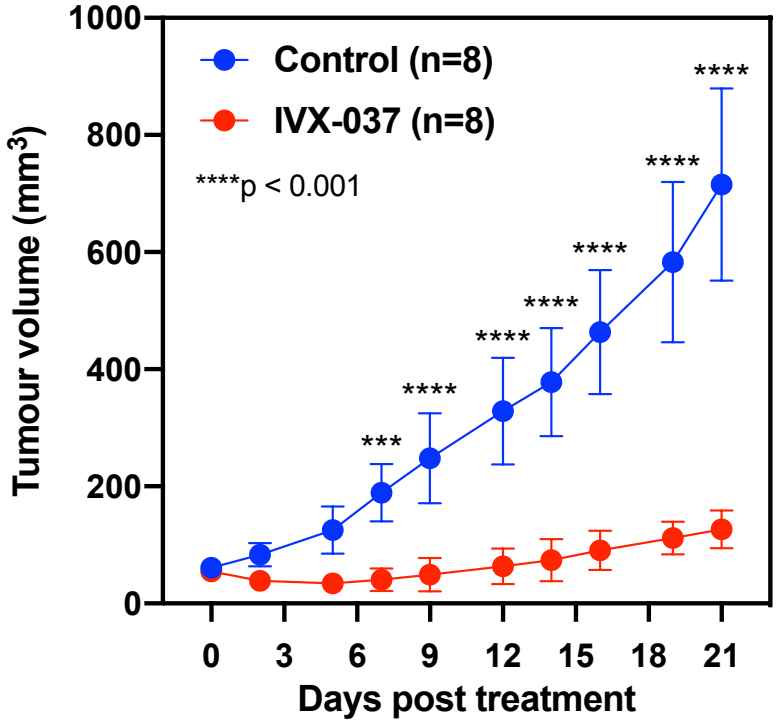
Monitor

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

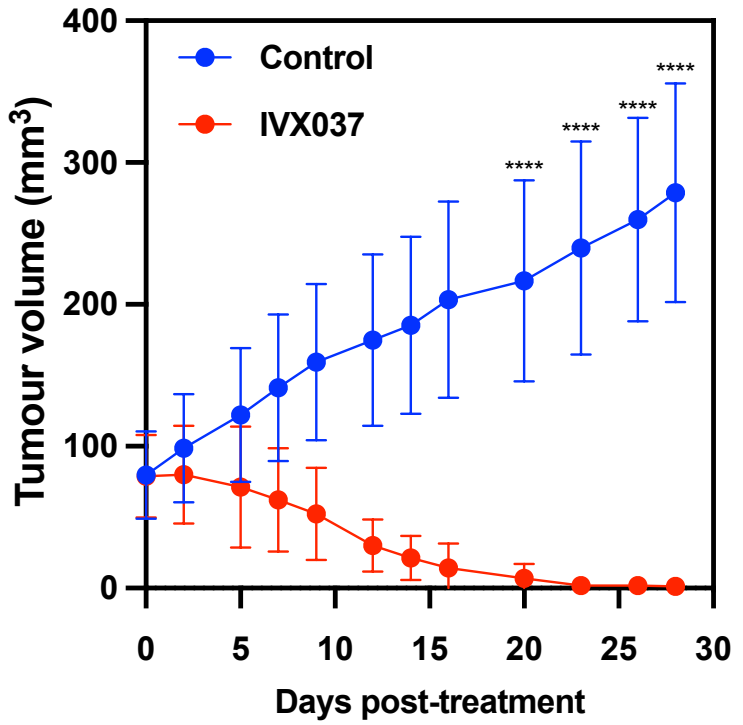
IVX037: *In Vivo* Oncolytic Activity in Colorectal Cancer

Two human MSS colorectal cancer cell lines assessed in xenograft models

Colorectal tumor model #1 – **WiDr**



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

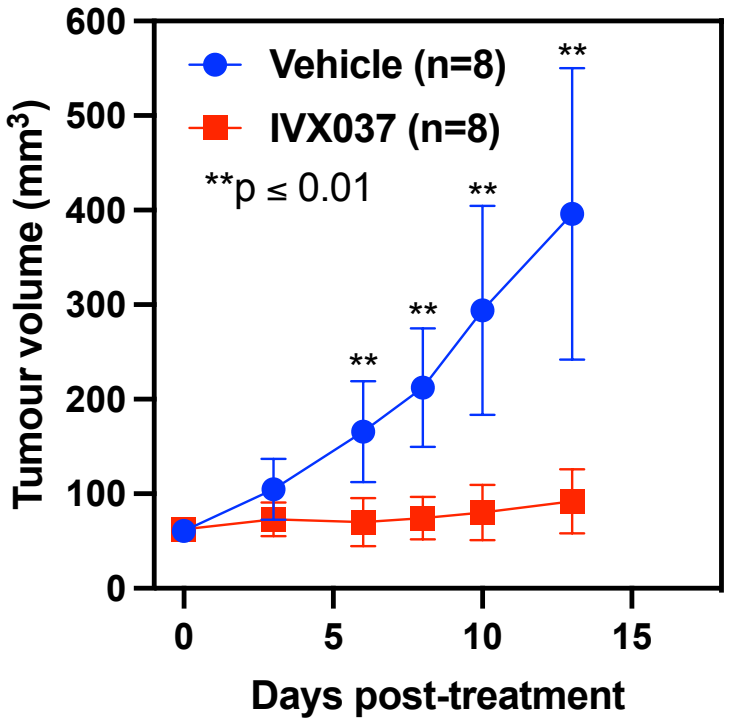


Striking impact in two colorectal cancer models in immune deficient mice provides clear signal of potency solely attributed to oncolytic activity of IVX037 with favorable tolerability

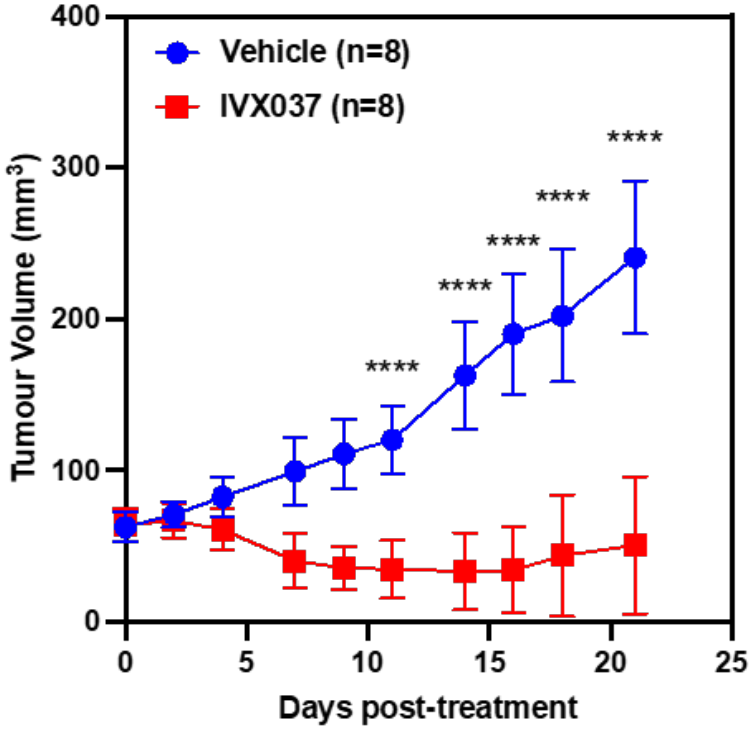
IVX037: *In Vivo* Oncolytic Activity in Ovarian Cancer

Two human ovarian cancer cell lines assessed in xenograft models

Ovarian tumor model #1 – **IGROV-1**



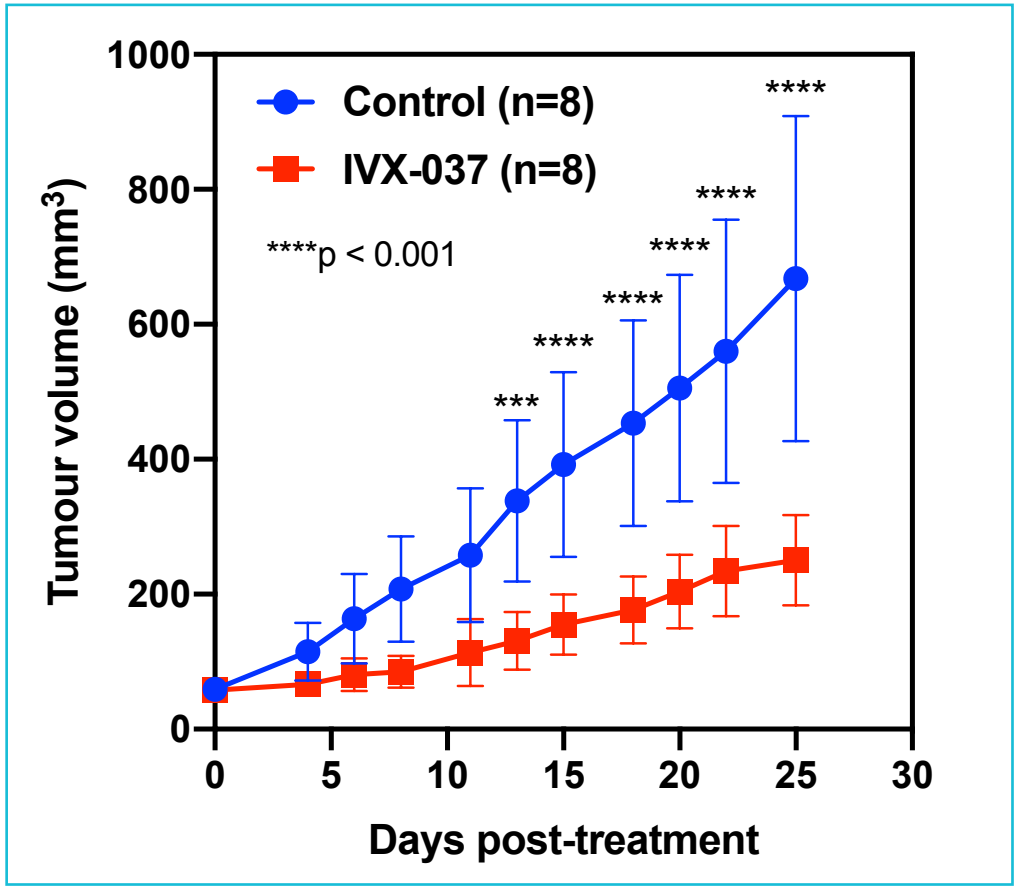
Ovarian tumor model #2 – **OVSAHO**



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

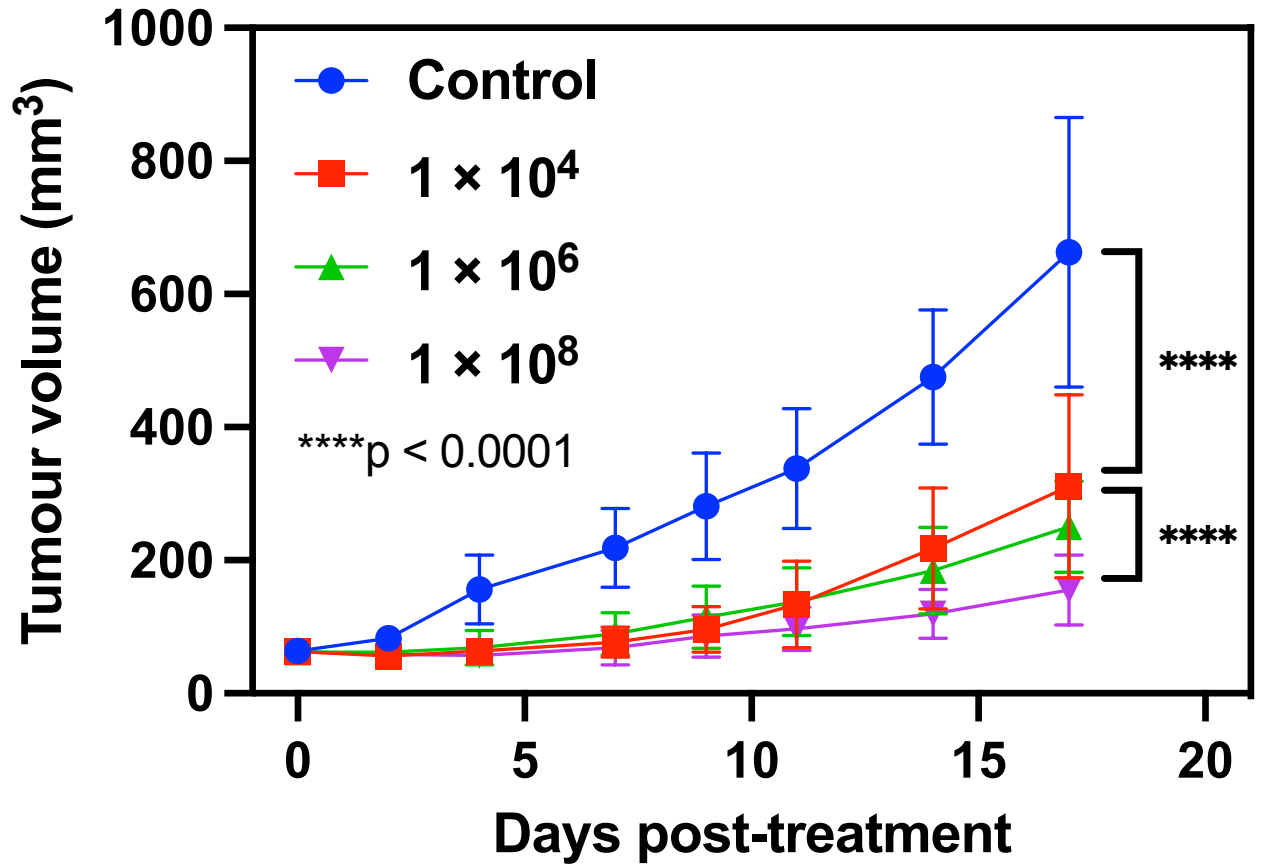
Human Gastric cancer (NCI-N87) xenograft model



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

Potency Observed Across Dose Levels

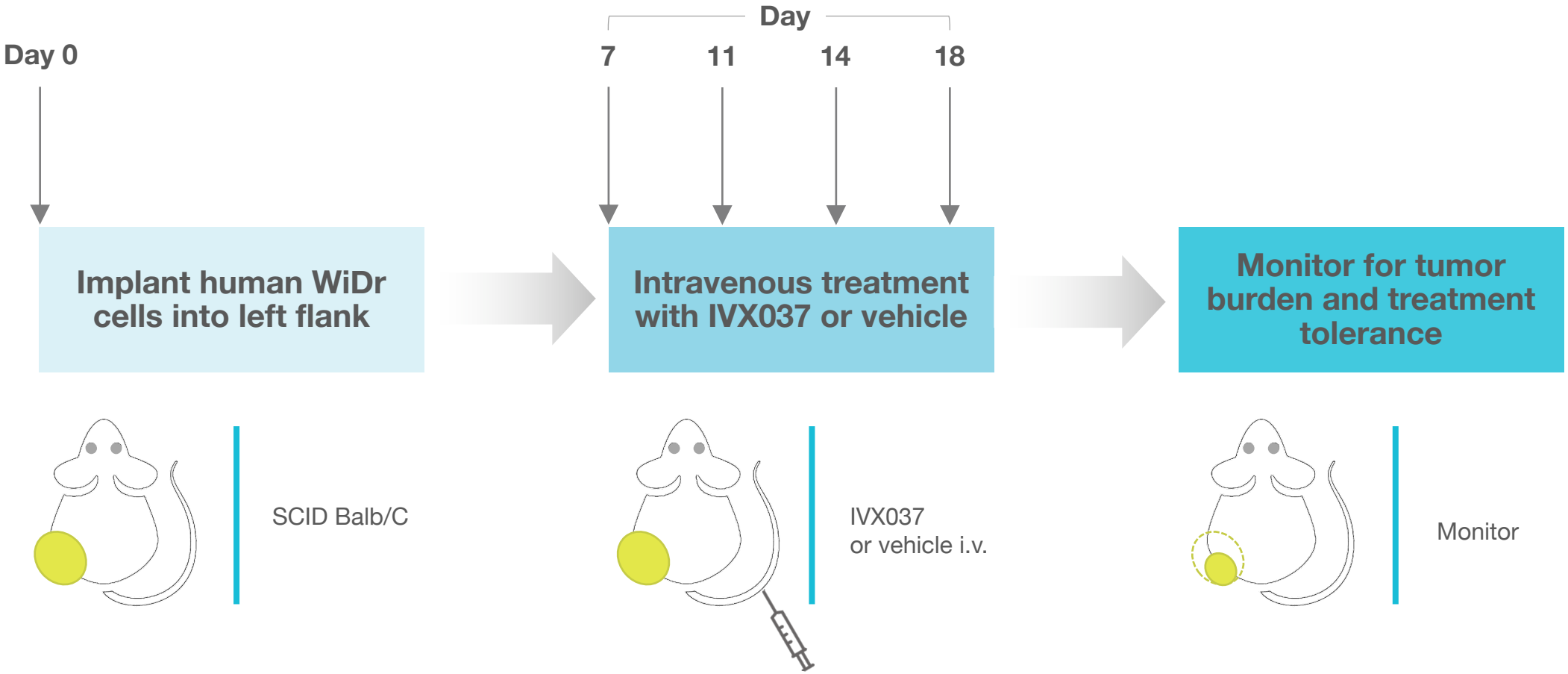
Dose escalation in human MSS colorectal cancer (WiDr) xenograft model



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

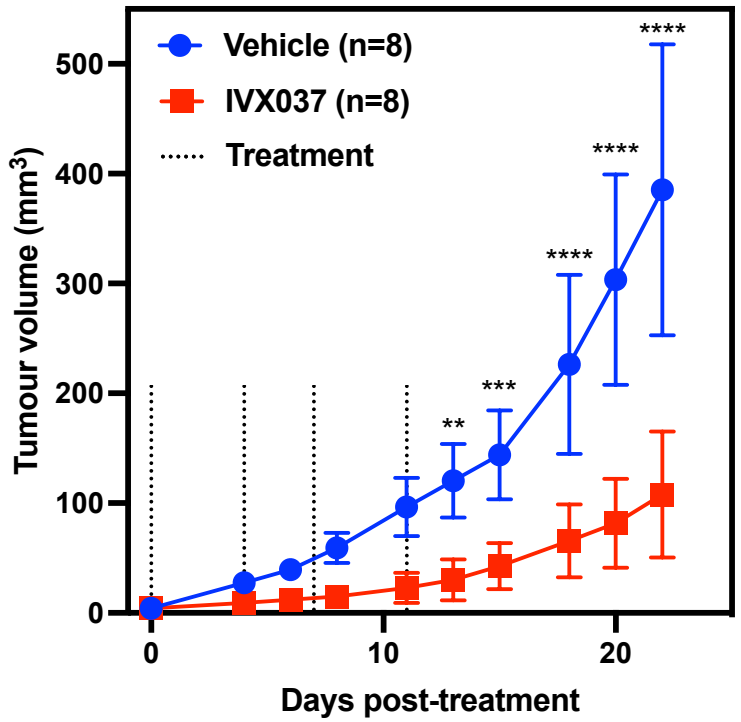
Measuring *In Vivo* Oncolytic Activity of IVX037 Intravenously

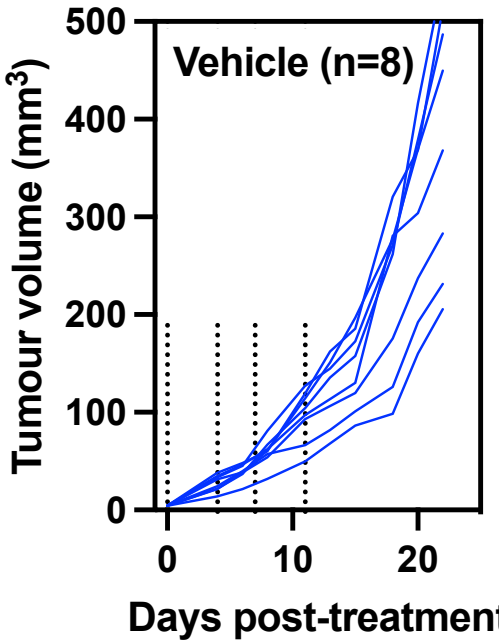
Human MSS colorectal cancer (WiDr) xenograft model – intravenous delivery

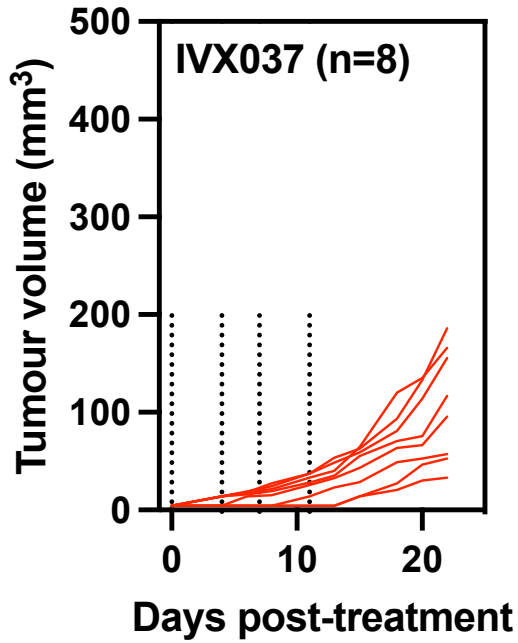


Intravenous Delivery of IVX037 Achievable in Colorectal Xenograft

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





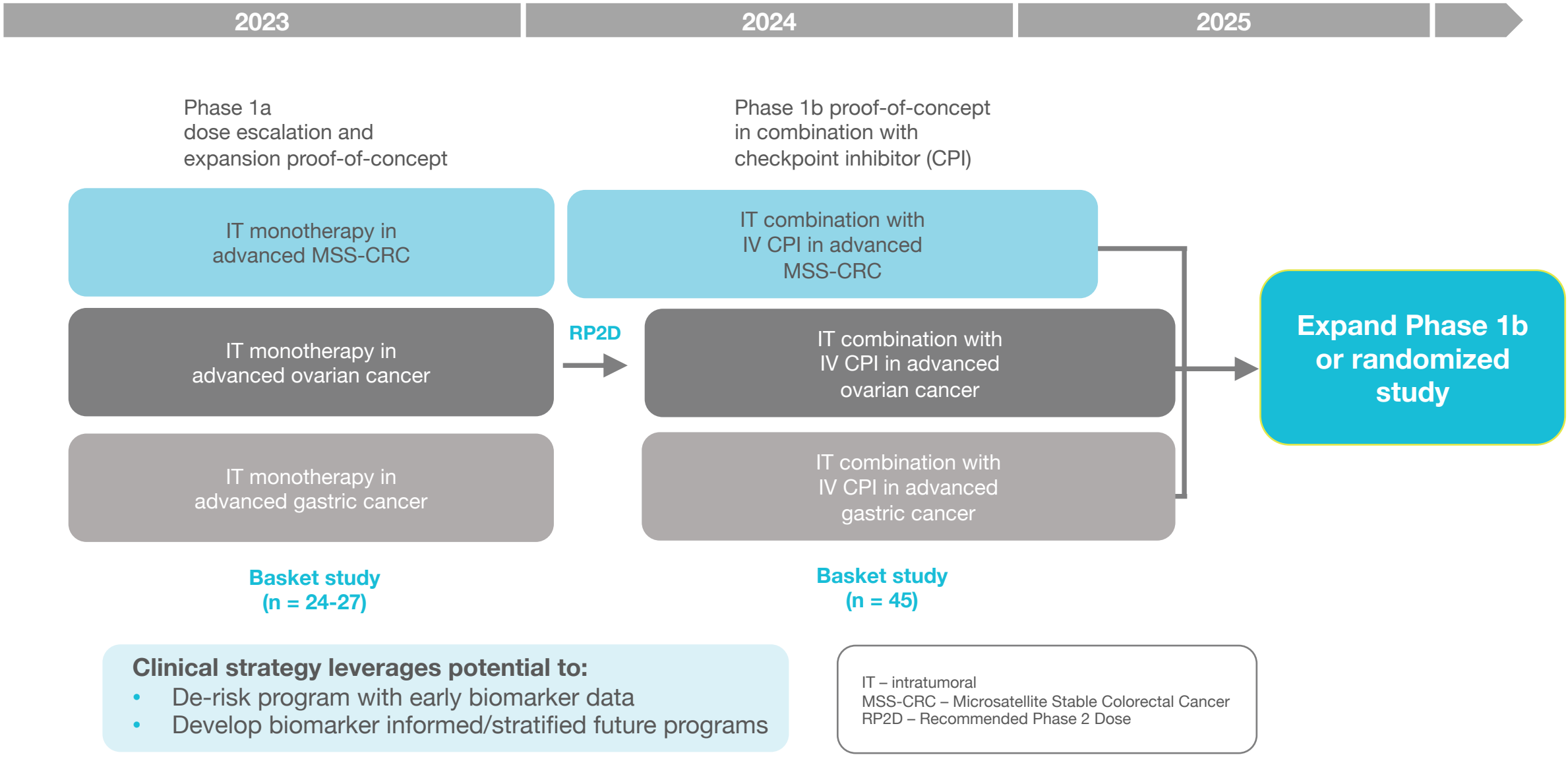


Evidence of impressive anti-tumor efficacy and no treatment related toxicity observed

In the Clinic

Lead Candidate IVX037
Receptor Targeted
RNA Oncolytic Virus

Clear Path Forward in the Clinic



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

Recent Milestones

Preclinical / IP / Corporate

- Successful completion of safety and biodistribution study of IVX037 administered intravenously
- Further liver cancer cell line studies underway
- Underway with bioselection of IVX055 to target lung cancer
- Successful $19M series B financing led by OneVentures
- Patents filed including Composition of Matter claim

CMC / Quality

- Successful completion of first GMP batch at US CDMO site
- IVX037 Drug Product stable for 20 weeks at 2-8°C with study ongoing

Clinical

- Four sites open for recruitment - strong clinician engagement
- Cohorts 1 and 2 are complete with Cohort 3 dosing ongoing
- IVX037 intralesional administration has been well tolerated with no dose-limiting toxicities observed
- IVX037 has been successfully administered to liver, lymph node and abdominal metastases
- Preliminary serum biomarker analysis has indicated early signs of IVX037 induction of potentially beneficial inflammatory cytokines/chemokines, such as CXCL10

Upcoming Milestones – through to Q2 2024

Preclinical / IP

- Ongoing preclinical studies including investigation of combination immunotherapies
- Complete preclinical assessment in liver cancer indication
- Preclinical assessment of activity of IVX055 in lung cancer
- Progressing patent filings

CMC / Quality

- Initiate second GMP batch at US CDMO
- Further stability data on improved formulation
- Progress on enhancement of production process in collaboration with US CDMO
- Initiate production of IVX055 for clinical studies

Clinical

- Phase 1a advancing through dose expansion
- Open new sites as commence Phase 1b and new indications
- Phase 1b for MSS CRC to be initiated with multidose IVX037 and immune checkpoint inhibitor
- US FDA IND filing

Summary

- **Clinical stage oncology company**
- Major opportunity in most important cancers with high unmet need
- Strong preclinical data set across multiple cancer types
- US CDMO site with product available in Q4 2023
- Clinical data readouts through Q4 2023/ 2024
- Options to partner / licence / sell / list as clinical data unfolds
- Initiated second asset IVX055 targeting NSCLC using our bioselection platform
- Strong cash position - $29.6M at October 31 2023 - runway to early 2026

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Receptor Targeted Oncolytic Viruses

Thank You

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