

# ImmVirX

Receptor Targeted Oncolytic Viruses

## Corporate Presentation

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February 2024

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# ImmVirX - Clinical Stage Oncology Company

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## AMBITION

To provide durable responses and 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 picornaviruses

## APPROACH

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

## PROGRESS

- Operations initiated in April 2020 following seed financing
- First patient dosed with lead asset, IVX037, in April 2023 – net cashburn of \$A11m to that time
- Second asset, IVX055, bioselected and advancing to the clinic
- Partnered with Innovent Biologics for Phase 1b combination study

# Experienced Team Driving ImmVirX into the Clinic



Dr. Malcolm McColl  
CEO and Co-Founder



Prof. Darren Shafren  
CSO and Co-Founder



Dr Jeannie Joughin  
Non-Executive Director



Dr. Leonard Post  
Non-Executive Director



Robert Routley  
Non-Executive Director



Robert Vickery  
Co. Sec & CFO



## Cohesive Team with record of Success

- Leadership and scientific team comprised of ex-Viralitics 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
- 27 strong R&D team in facility at University of Newcastle Hunter Medical Research Institute
- Strong balance sheet - \$31.6M cash on February 9 2024
- Partnered with **Innovent Biologics** for assessment of TYVYT® (sintilimab) and IVX037 in Phase 1b study

# Excellent Operations Team (ex Viralytics, Merck)

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



# 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\*

## 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



### CG Oncology IPO

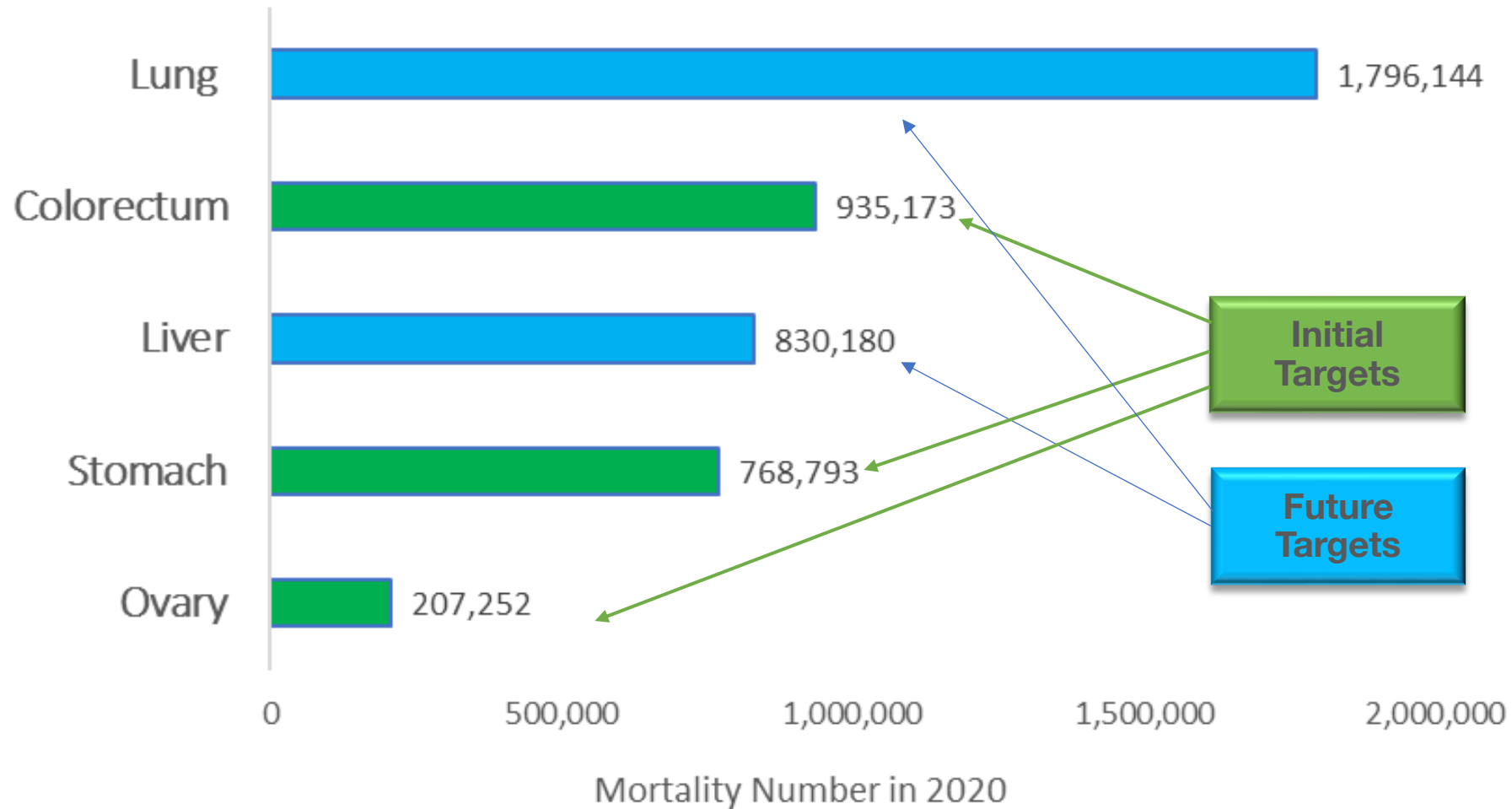
Market cap ~ USD\$3Bn (Feb 16 2024) following \$380m IPO



**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

# ImmVirX Targeting Substantial Markets

Estimated number of deaths worldwide, both sexes, all ages



# High Unmet Need with Current Treatments

Indication	Forecast Deaths per Annum 2022		Clinical Response	
	USA <sup>1</sup>	China <sup>1</sup>	ICI ORR <sup>3</sup>	Study Identifier
Colorectal <sup>2</sup>	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 <sup>4</sup>	144,913	766,898	18% KEYTRUDA	KEYNOTE-010
Melanoma (CAVATAK™ lead target indication)	7,530	4,369	33% KEYTRUDA	KEYNOTE-006

<sup>1</sup> Chinese Medical Journal 2022; 135(5)

<sup>2</sup> 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).

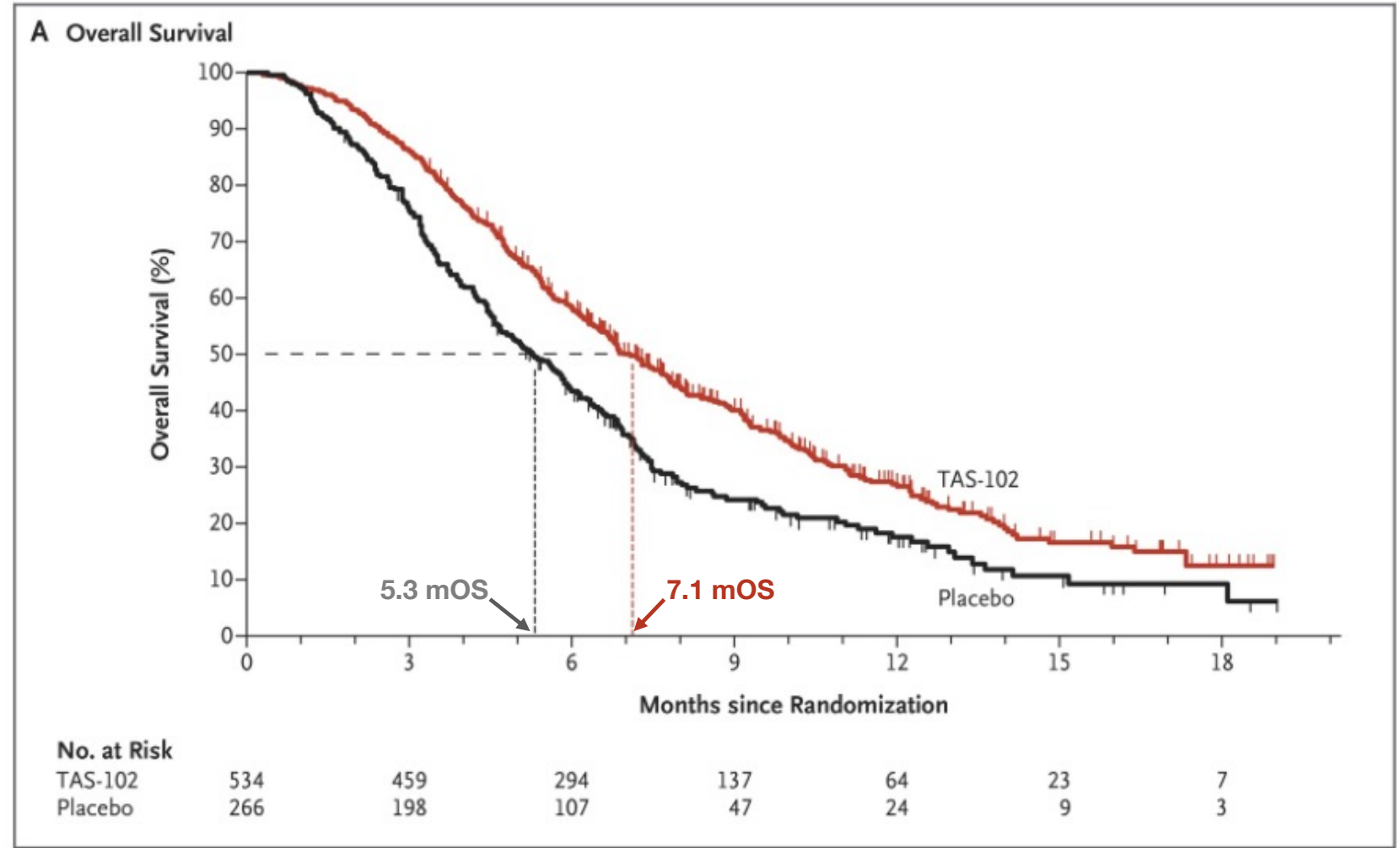
<sup>3</sup> ICI ORR = Immune Checkpoint Inhibitor Overall Response Rate

<sup>4</sup> 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
  - IVX037 in phase 1
  - IVX055 in preclinical development
- 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 of IVX037 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 near completion
- No dose limiting toxicities in first two cohorts. Several sites recruiting.



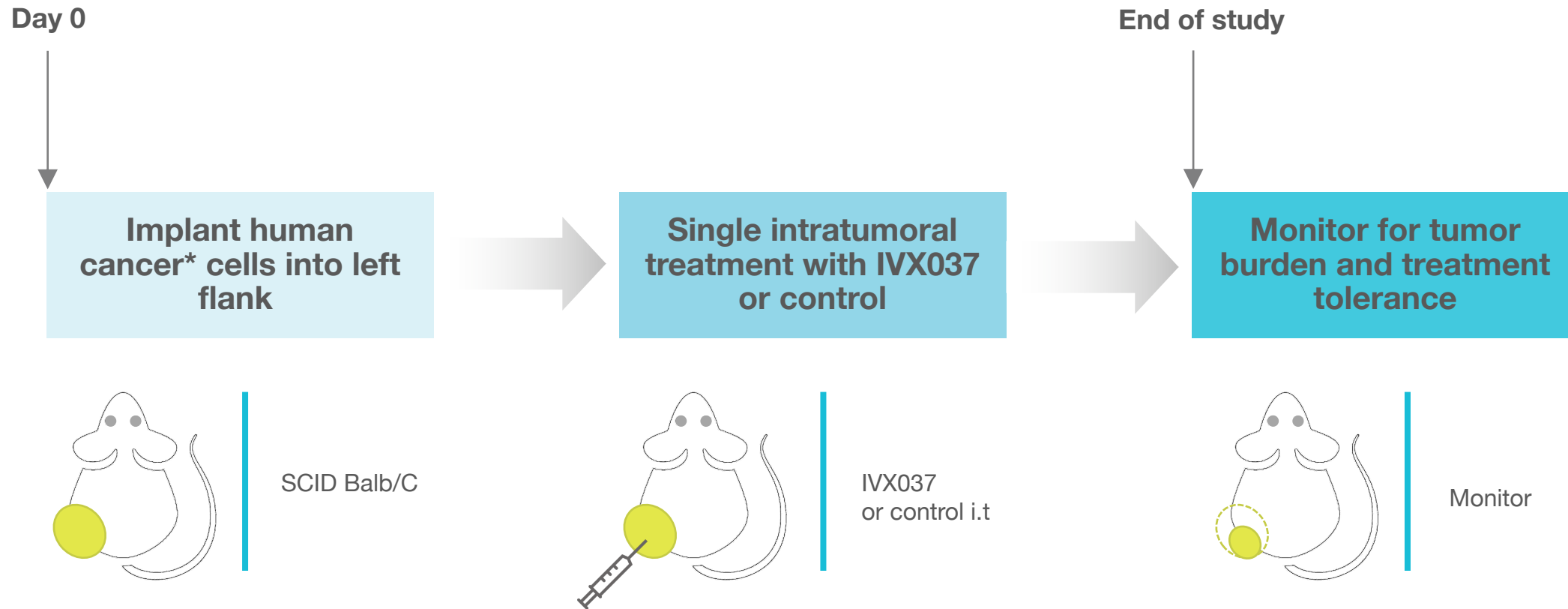
## Pre-Clinical Data: IVX037



Lead Candidate  
Receptor Targeted  
RNA Oncolytic Virus

# Measuring *In Vivo* Oncolytic Activity of IVX037

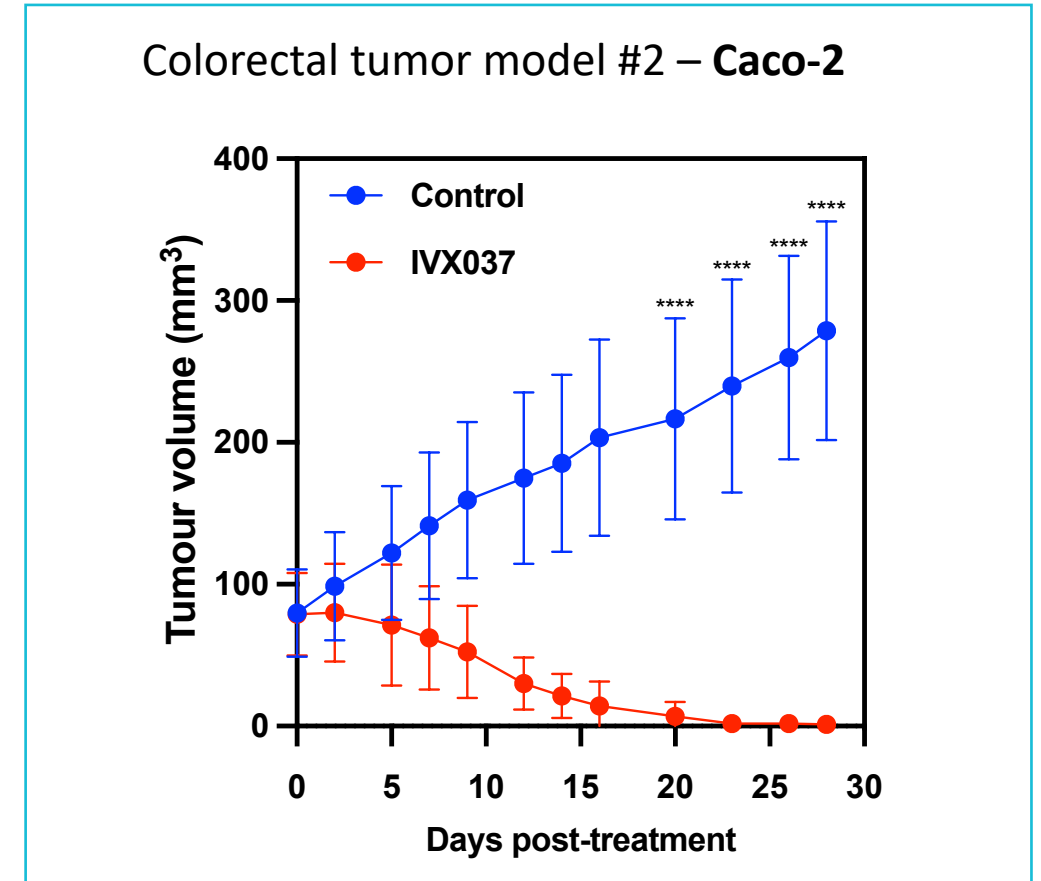
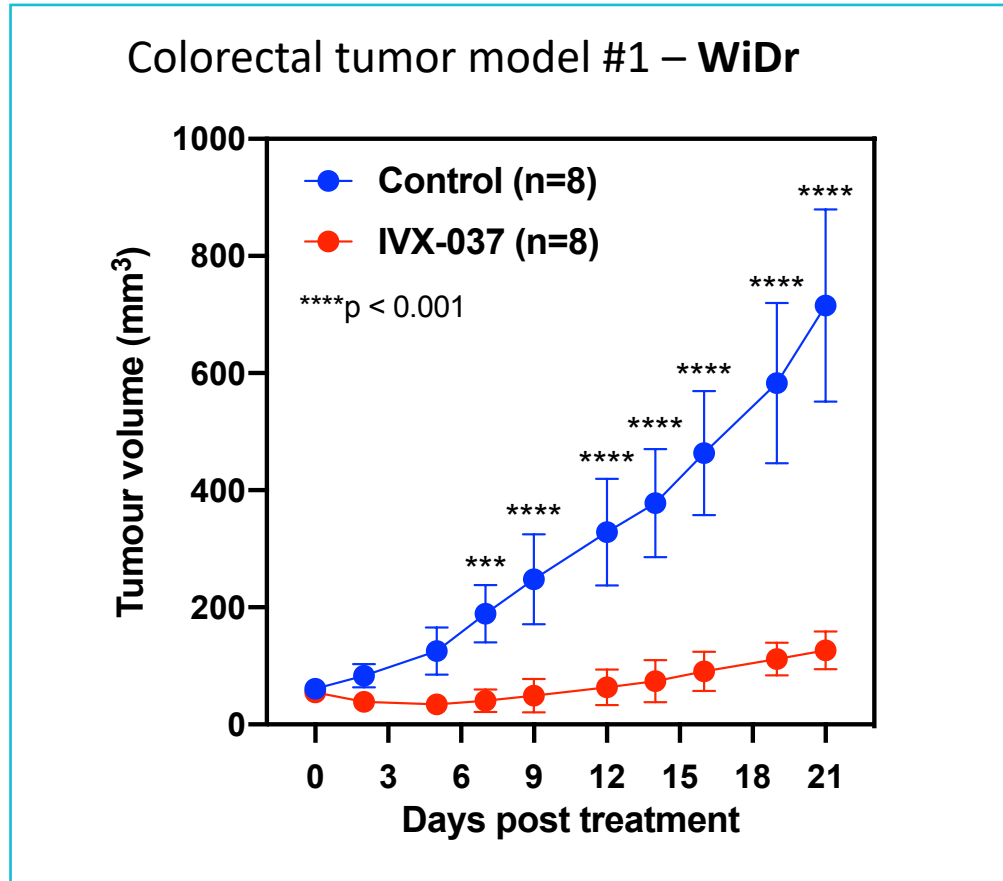
## Human cancer xenograft model



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

# IVX037: *In Vivo* Oncolytic Activity in Colorectal Cancer

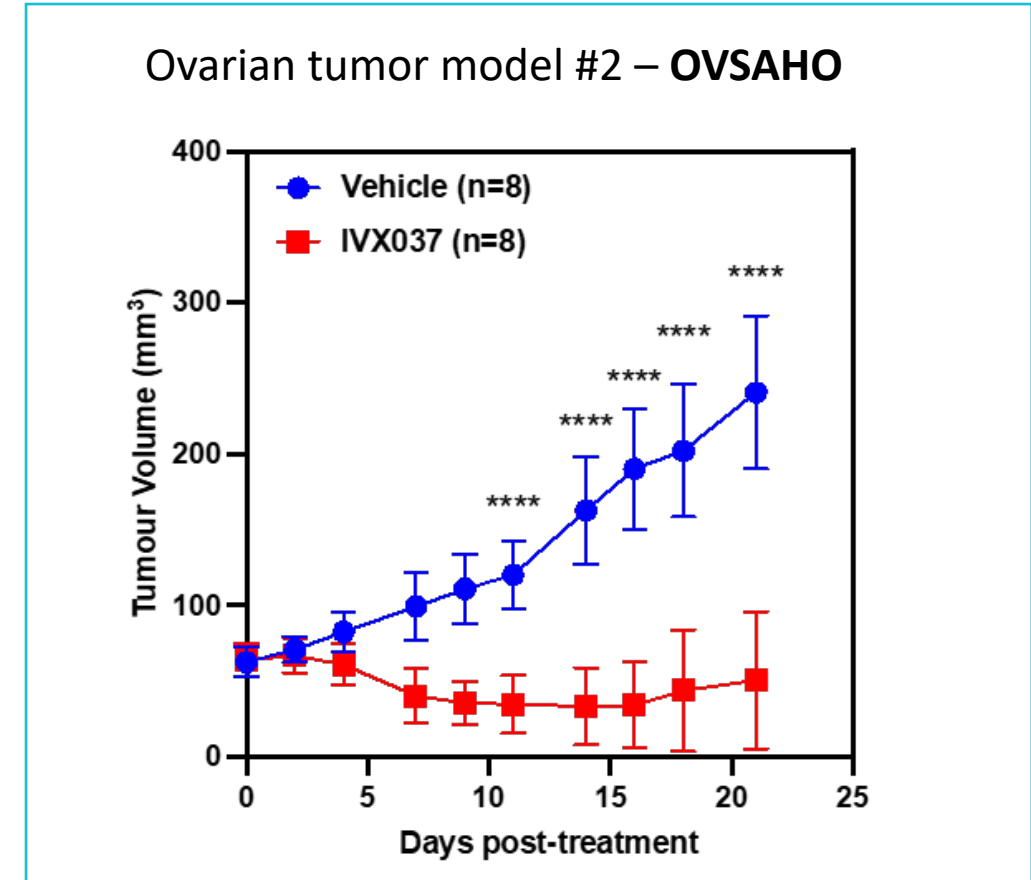
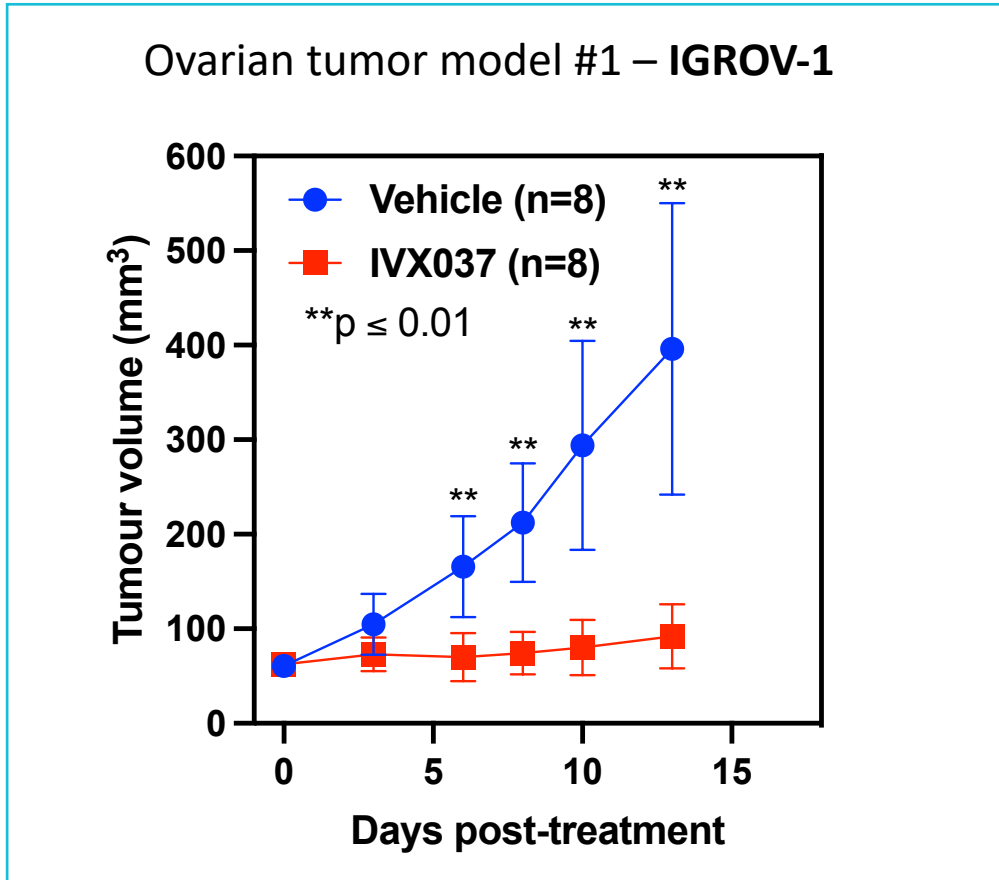
Two human MSS colorectal cancer cell lines assessed in xenograft models



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

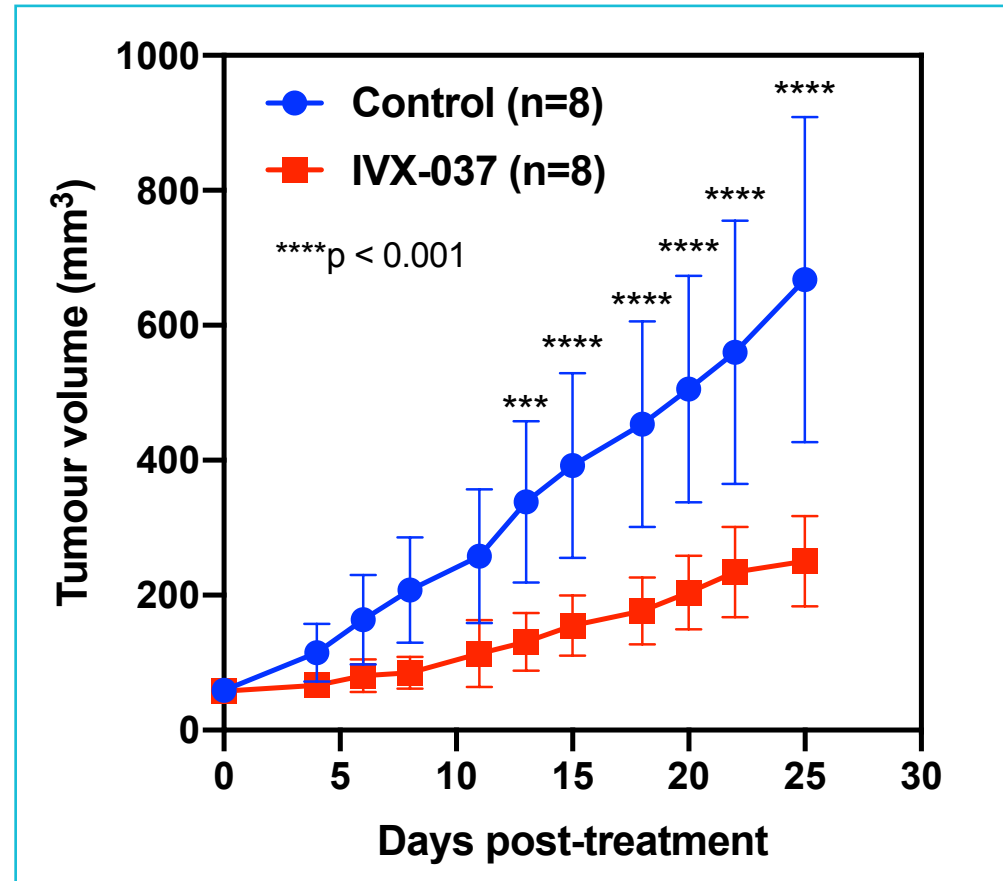
## Two human ovarian cancer cell lines assessed in xenograft models



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

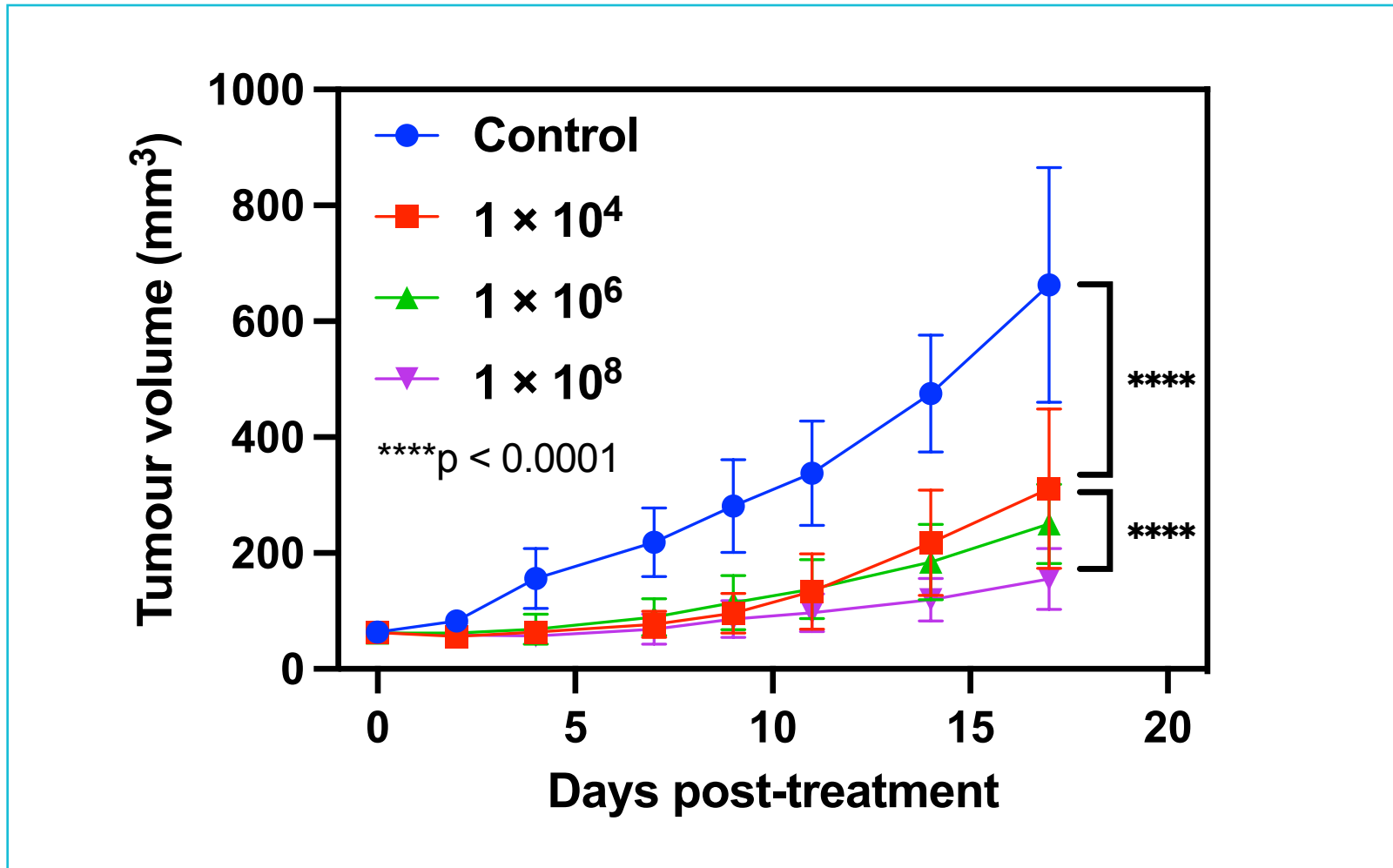
## Human Gastric cancer (NCI-N87) xenograft model



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

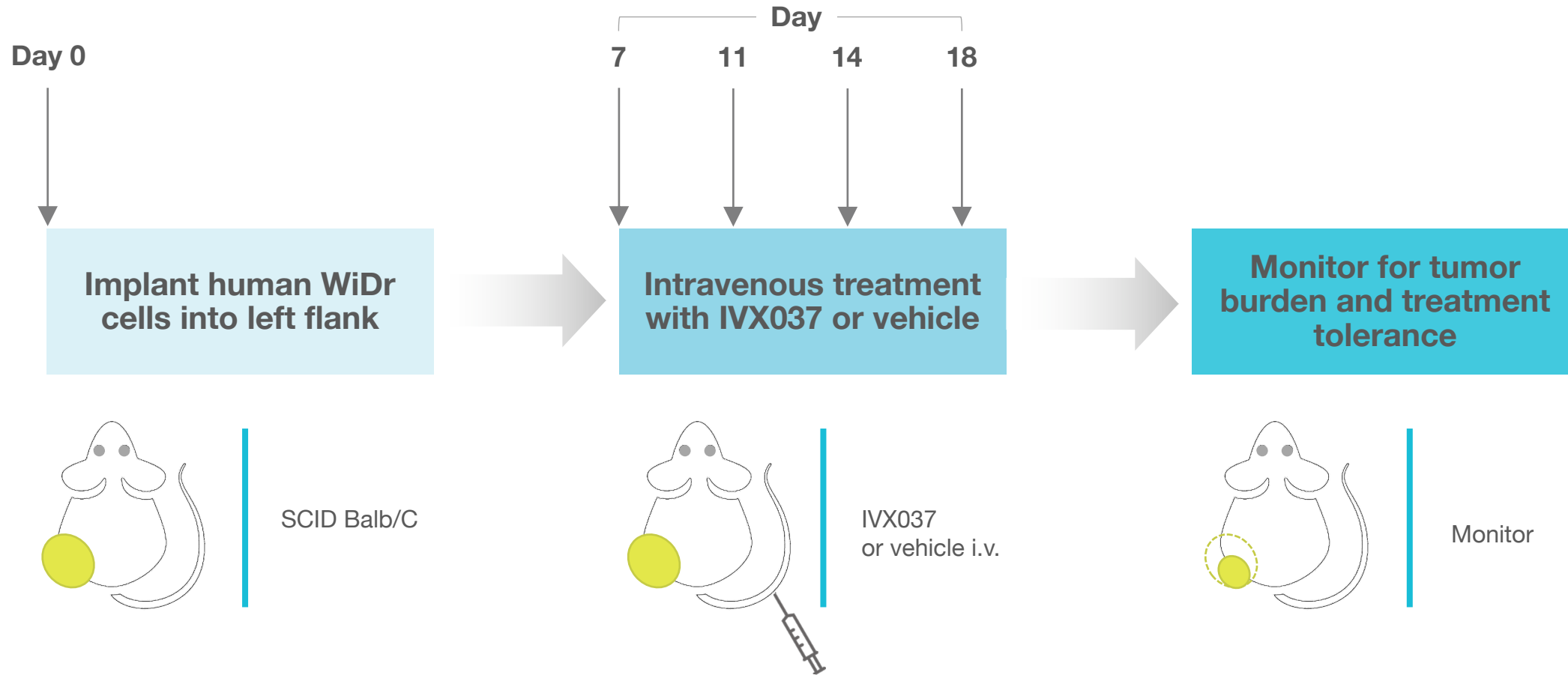


IVX037 potency enables robust antitumor activity at a 10,000-fold lower dose



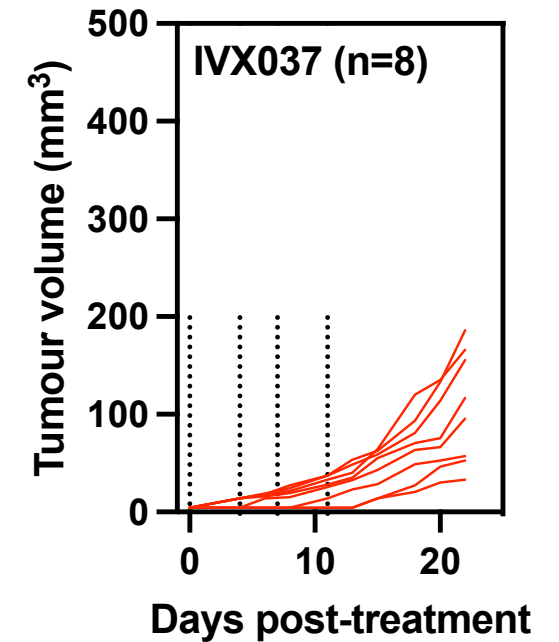
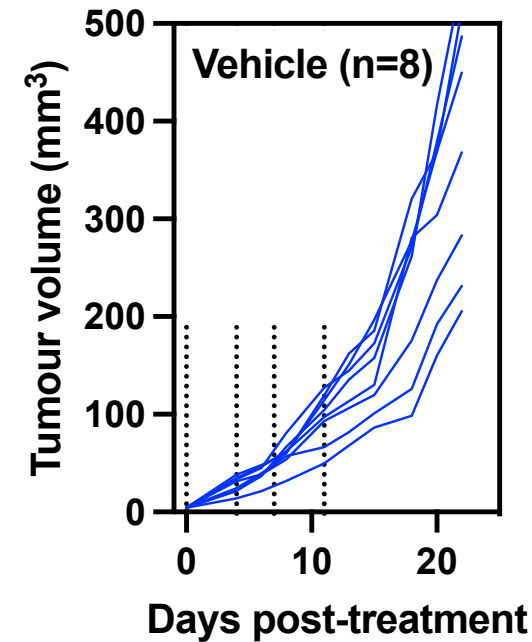
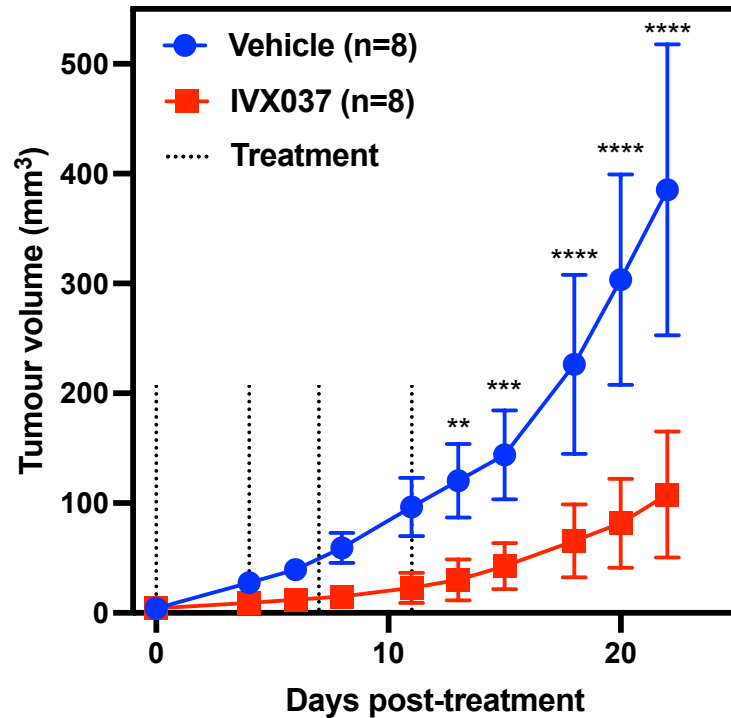
# Measuring *In Vivo* Oncolytic Activity of IVX037 Intravenously

## 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

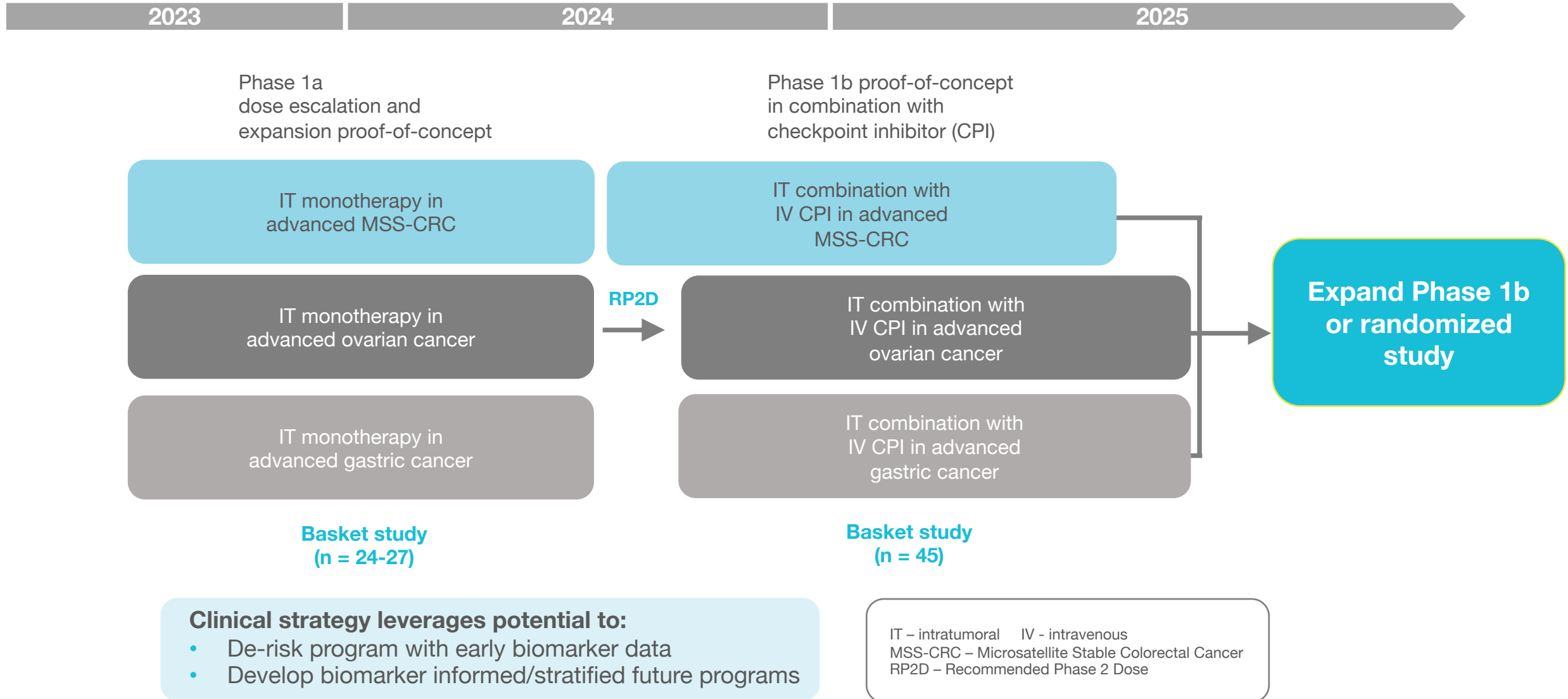


## In the Clinic

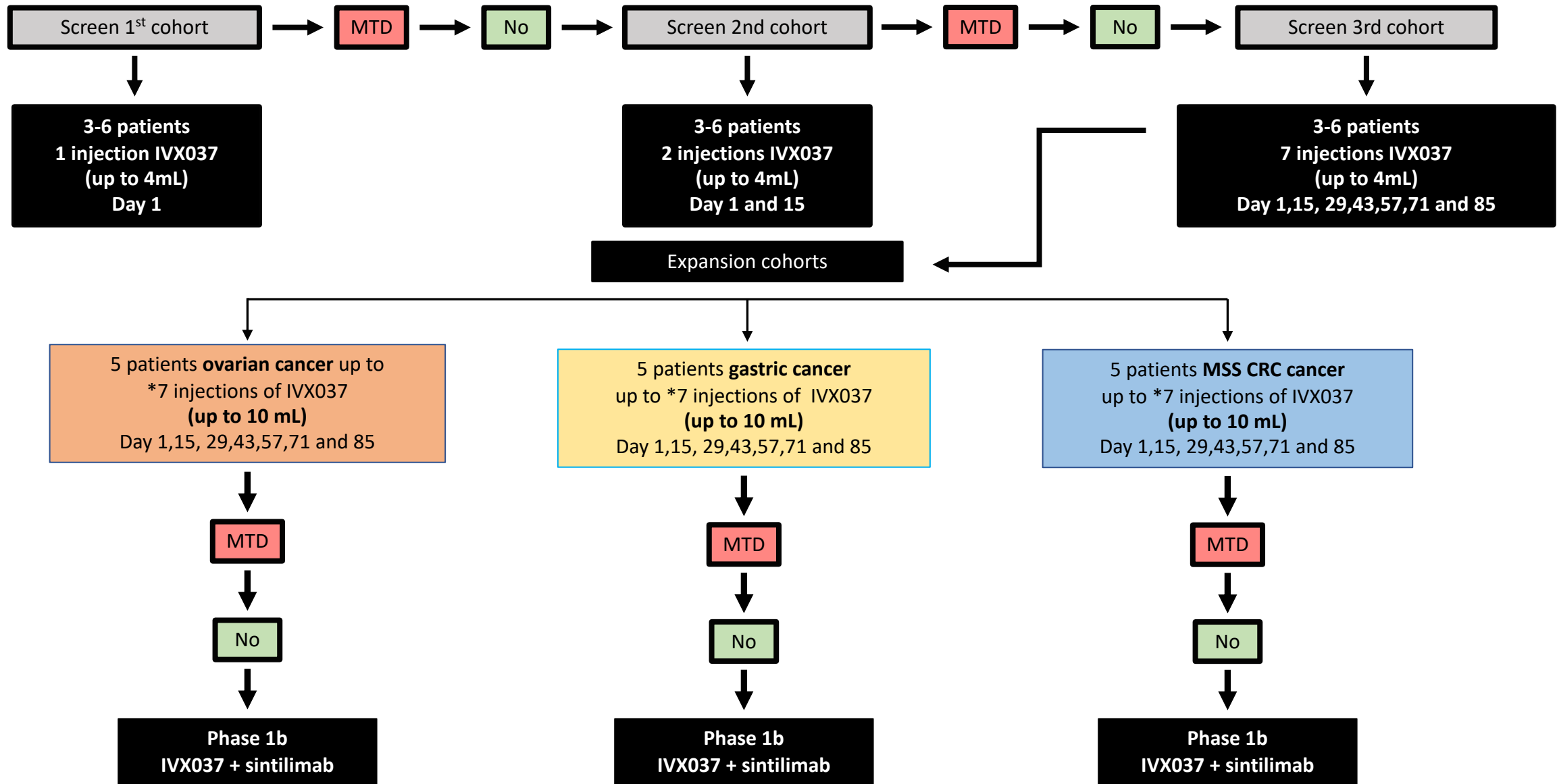


Lead Candidate IVX037  
Receptor Targeted  
RNA Oncolytic Virus

# Clear Path Forward in the Clinic



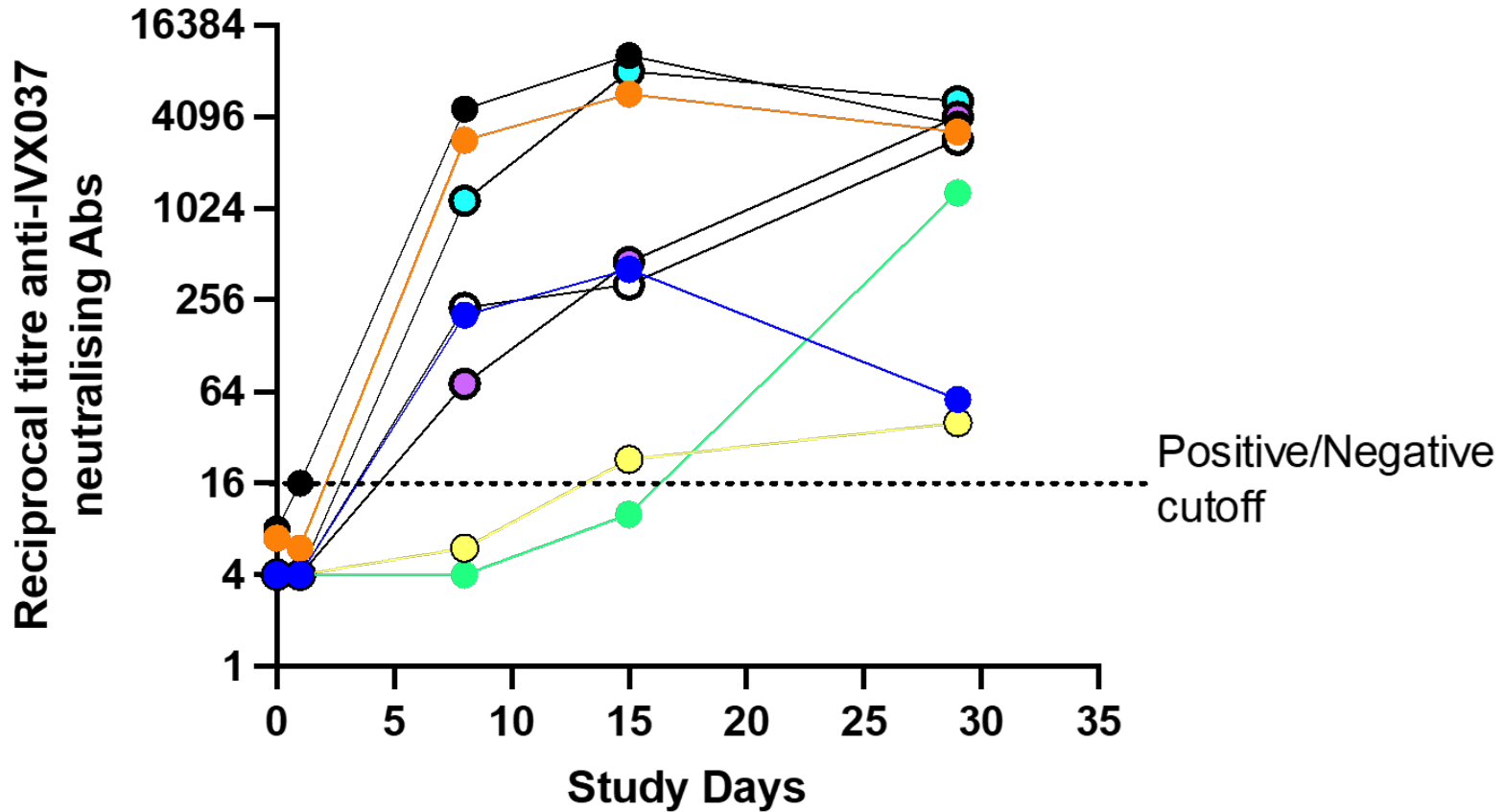
# Escalating viral dose and volume during cohort advancement in Phase 1a



*\*, Up to 7 doses permitted at Investigator discretion in absence of DLTs'*

# IVX037 well tolerated and immunogenic in seronegative patients

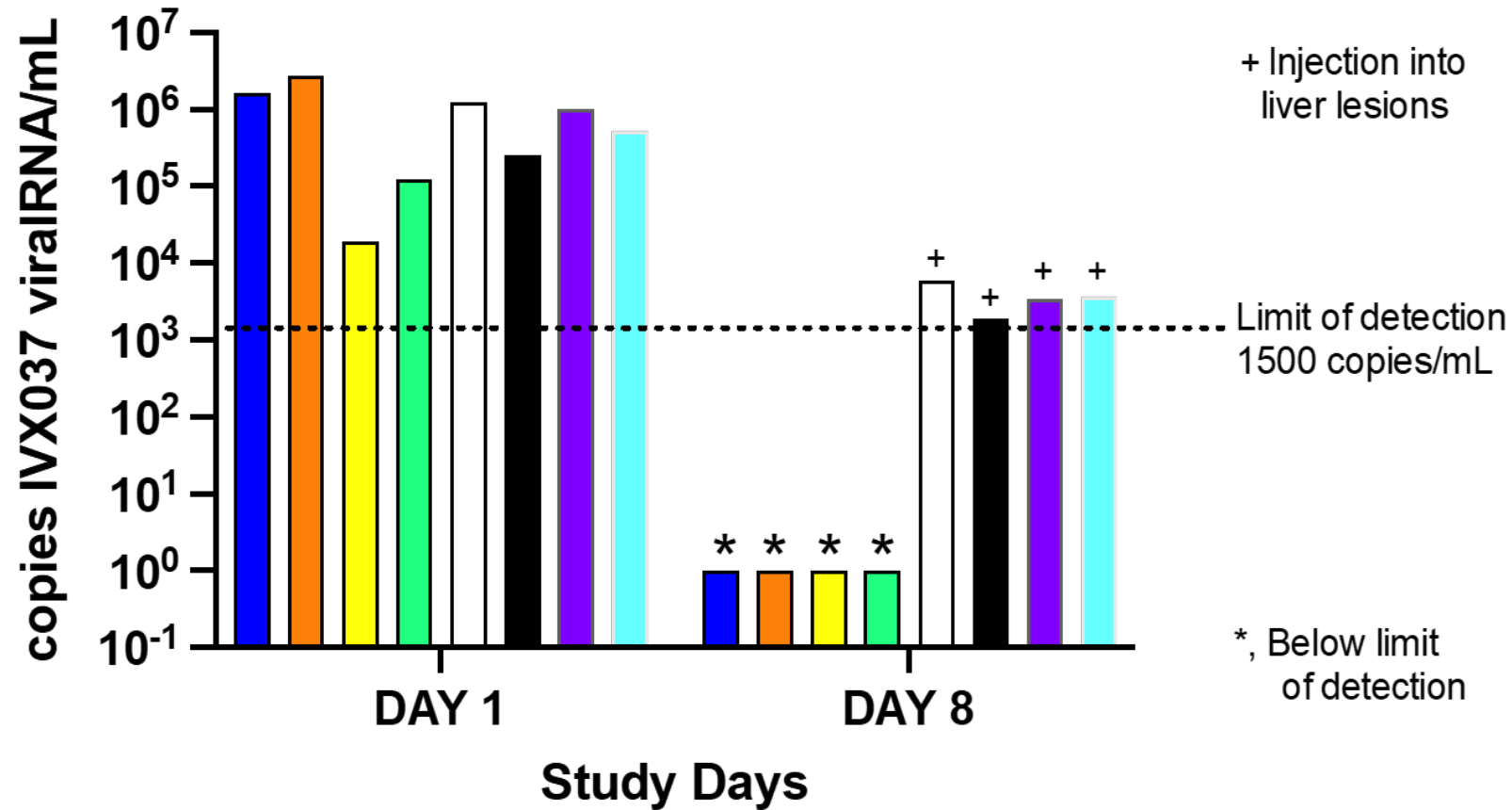
Level of anti-IVX037 serum neutralizing antibodies (nAbs)



# Evidence of secondary viral replication

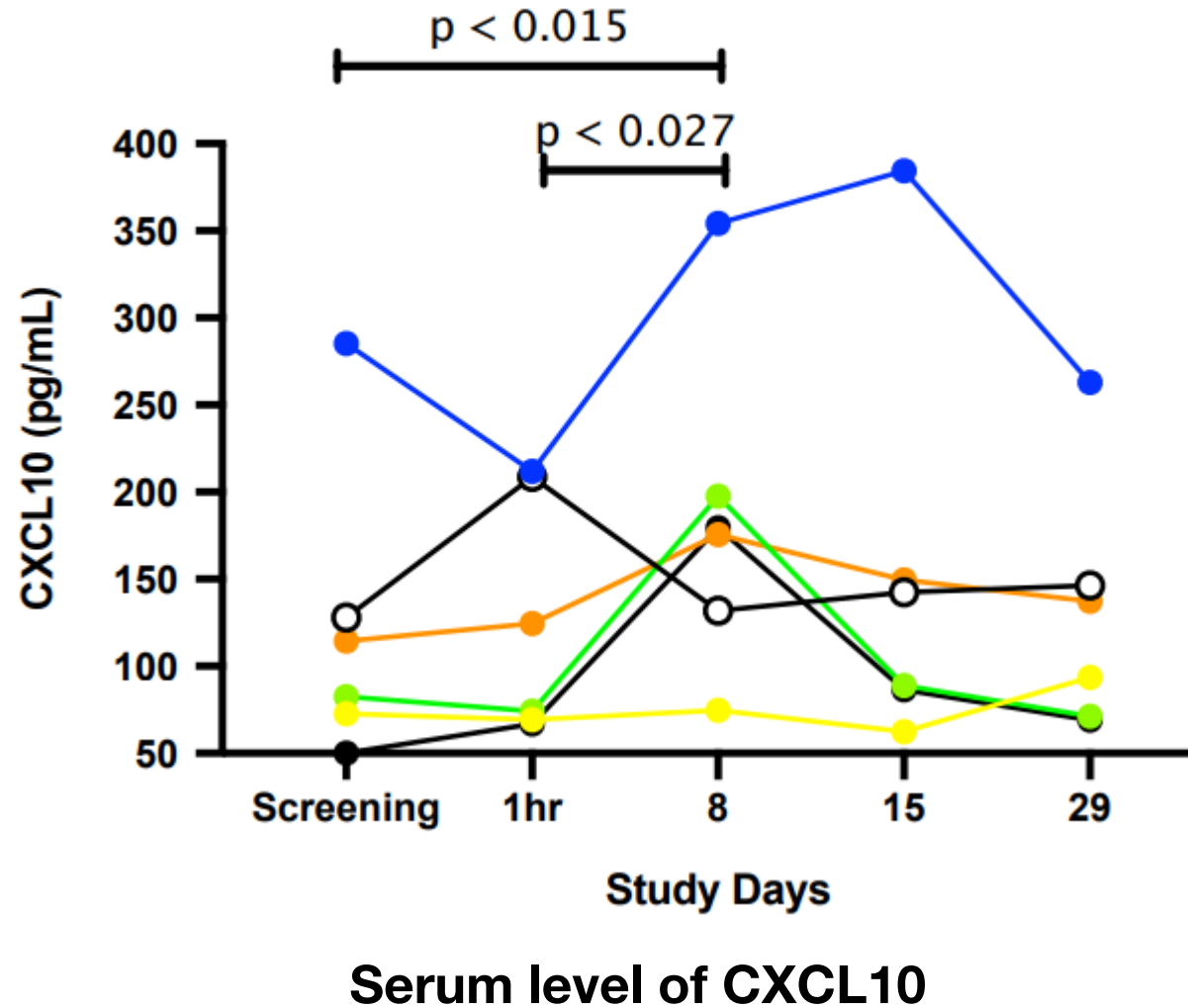
- with persistence of virus in patient serum

## Serum level of IVX037 viral RNA



# Significant elevation of CXCL10 following administration of IVX037

- favorable biomarker activation for success in combination with CPI\*



\*Silk AW et al. Cancer Immunol Immunother. 2023 Jun;72(6):1405-1415



# Early Positive Signals in the Clinic

- commencing greater dose number / volume

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- IVX037 dosing in Cohorts 1 and 2 is complete, with near completion of Cohort 3
- To date IVX037 intralesional administration has been well tolerated, with all patients exhibiting some level of systemic exposure immediately following injection with no dose-limiting toxicities observed
- Mild flu-like reactions after injection (fatigue, chills, rigors) and injection site discomfort 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 beneficial inflammatory cytokines/chemokines, such as CXCL10
- Recruitment is ongoing and Phase 1b in combination with CPI, sintilimab to commence in mid-2024

# Recent Milestones

## Preclinical / IP / Corporate

- In-vitro liver cancer cell line studies complete with demonstrated activity in this setting
- Bioselection complete of second asset, IVX055, to target lung cancer
- Executed Clinical Trial Collaboration and Supply Agreement with Innovent as partner in Phase 1b study assessing IVX037 and TYVYT® (sintilimab)
- Patent filed including Composition of Matter claim
- RDTI - \$3.8M payment to ImmVirX

## CMC / Quality

- Successful completion of first GMP batch at US CDMO site
- Second GMP batch underway at US CDMO site
- Enhanced formulation of 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 near completion
- 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 beneficial inflammatory cytokines/chemokines, such as CXCL10

# Upcoming Milestones – through to mid 2024

## Preclinical / IP

- Complete in vivo preclinical assessment of IVX037 in liver cancer indication
- Preclinical assessment of activity of IVX055 in lung cancer
- File provisional patent for IVX055

## CMC / Quality

- Complete 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 colorectal cancer to be initiated with multidose IVX037 and TYVYT® (sintilimab)
- US FDA IND filing

# Summary

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- **Clinical stage oncology company with platform technology**
- Early positive signals with IVX037 in the clinic and well tolerated by patients
- Clinical trial collaboration with Innovent Biologics for Phase 1b study (with supply of sintilimab)
- Major opportunity in most important cancers with high unmet need
- Strong preclinical data set across multiple cancer types
- Successful manufacture of IVX037 at US CDMO site
- Ability to further partner / licence / sell / list as clinical data unfolds
- Bioselected second asset, IVX055, targeting NSCLC using our proprietary platform
- Strong cash position - \$31.6M (9 Feb 2024) runway to early 2026

# ImmVirX

Receptor Targeted Oncolytic Viruses

**Thank You**

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