

Bell Potter Healthcare Conference

November 11 2021

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Successful Track Record in Oncolytic Immunotherapy



Dr. Malcolm McColl
CEO and Co-Founder









Prof. Darren Shafren CSO and Co-Founder







Robert Vickery





Dr. Leonard Post
Non-Executive Director







Robert Routley
Non-Executive Director





Dr. Jennifer Rosenthal
Director Quality & Regulatory Affairs



Cohesive Team Leveraging Viralytics Experience

- 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
- R&D team in ex-Viralytics facility at TUNRA/University of Newcastle Hunter Medical Research Institute
- Recently completed Series A-1 financing raising \$25M to provide runway to mid 2023



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\$125B by 2024*

Oncolytic virus immunotherapies are an emerging class of combination therapy agents with 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





Oncorus Valuation

Early clinical stage, IPO October 2020, current market cap ~ USD\$300M





ImmVirX Targeting Substantial Markets with High Unmet Need

Indication	Incidence		Clinical Response	
	USA ¹	China ³	ICI ORR ⁴	Study Identifier
Ovarian	21,750	52,971	9% KEYTRUDA	KEYNOTE-100
Colorectal ²	147,950	521,490	4% KEYTRUDA	KEYNOTE-028
Gastric	27,600	392,868	17% KEYTRUDA	KEYNOTE-224
Pancreatic	57,600	116,291		

ImmVirX 😘

¹ Cancer Facts and Figures 2020, American Cancer Society, 2019

² Includes all types of colorectal cancer (CRC). ImmVirX focus in on MMRp (Mismatch Repair Proficient) accounting for ~94% of all CRC (Dung et al., Science, 2017; 357 (6349):409-413).

³ WHI Globocan 2018 - China Factsheet

⁴ ICI ORR = Immune Checkpoint Inhibitor Overall Response Rate

ImmVirX: Receptor Targeted Oncolytic Virus Entering the Clinic mid-2022

Platform

- Proprietary bioselection 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, replicating CAVATAK's oncolytic activity and molecular mechanism

Clinical Strategy

- Virus specificity enables targeted approach in indications with high unmet needs including ovarian, CRC, gastric and pancreatic 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 mid-2022



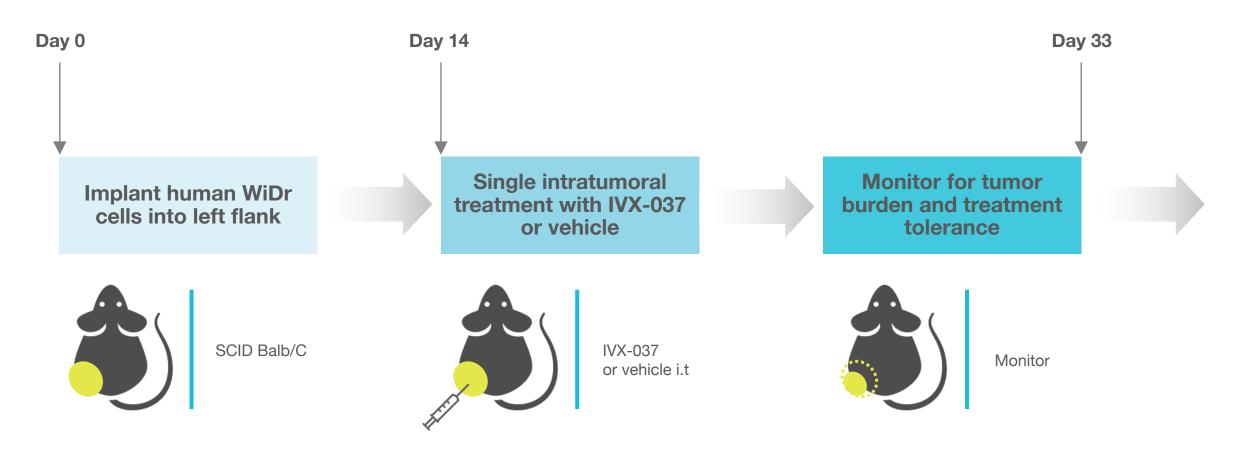


IVX-037

Lead Candidate
Receptor Targeted
RNA Oncolytic Virus

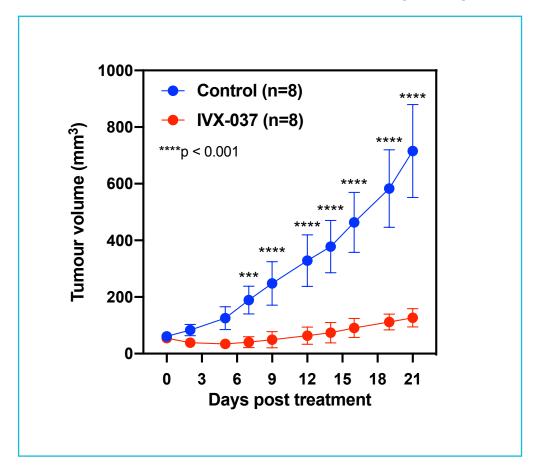
Measuring In Vivo Oncolytic Activity of IVX-037

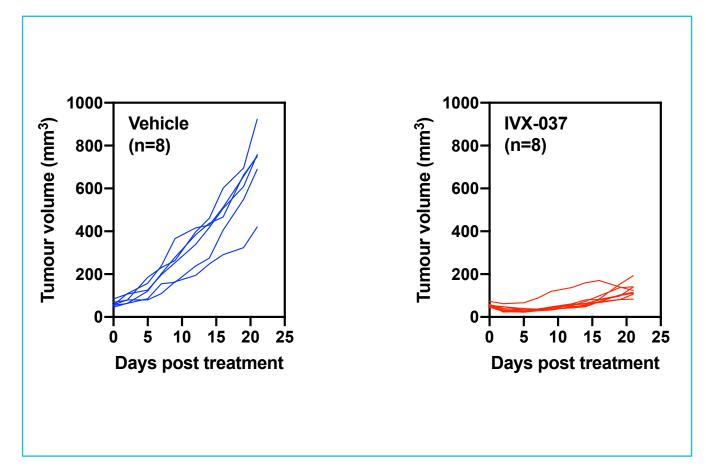
Human MSS colorectal cancer (WiDr) xenograft model





Human MSS colorectal cancer (WiDr) xenograft model



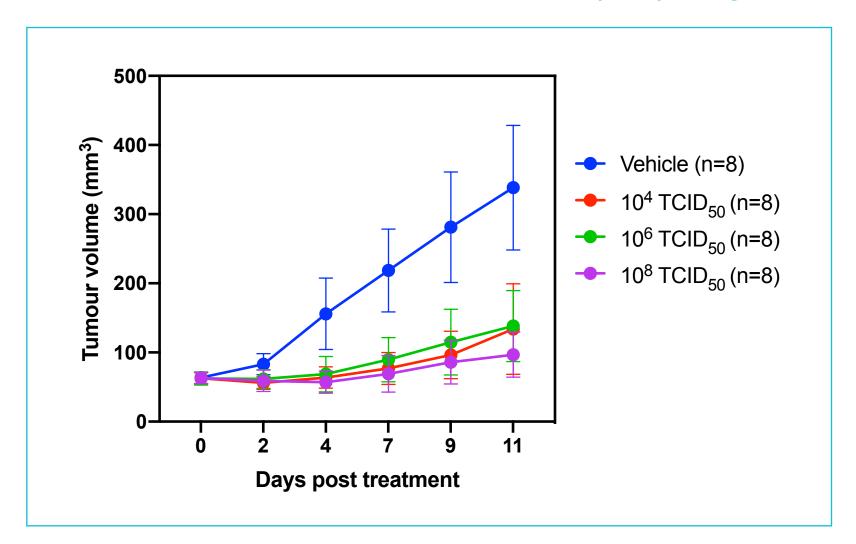


Striking reduction in tumor volume achieved in immune deficient mice provides clear signal of potency solely attributed to oncolytic activity of IVX-037 with favorable tolerability



Potency Observed Across Dose Levels

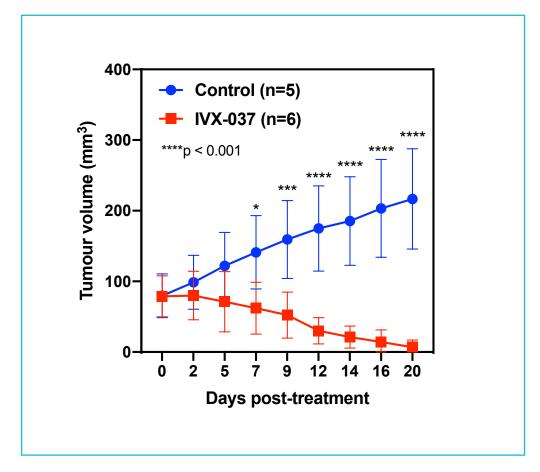
Dose escalation in human MSS colorectal cancer (WiDr) xenograft model

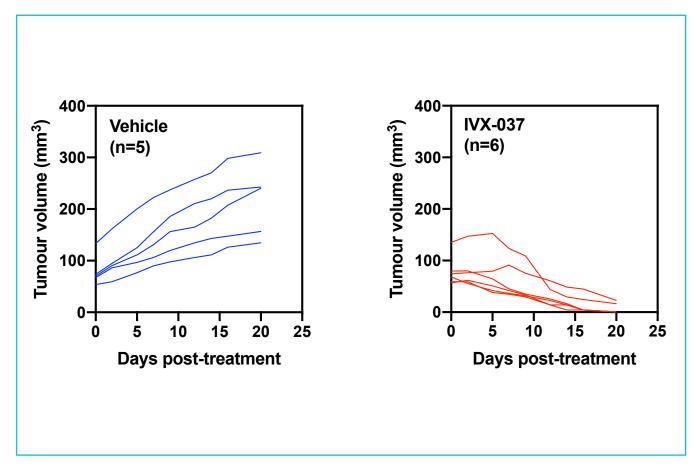


IVX-037 potency
enables robust
antitumor activity at a
10,000-fold lower dose



Human MSS colorectal cancer (Caco-2) xenograft model

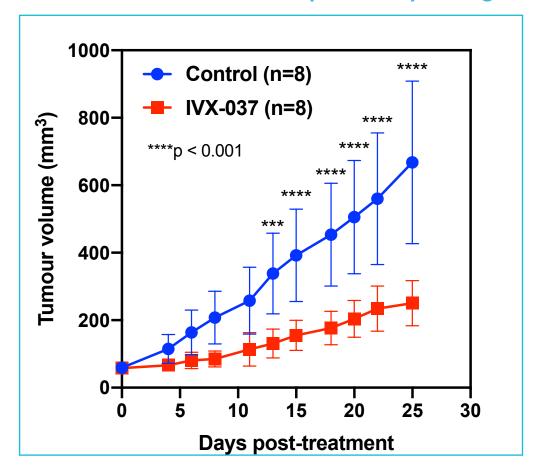


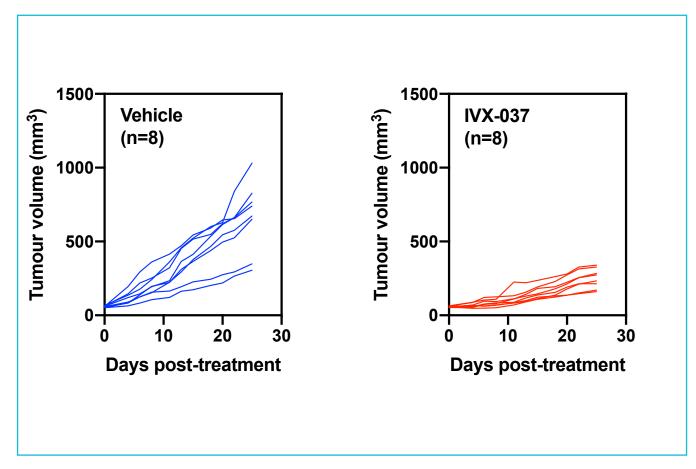


Activity of single dose of IVX-037 confirmed in a second model of colorectal cancer



Human Gastric cancer (NCI-N87) xenograft model

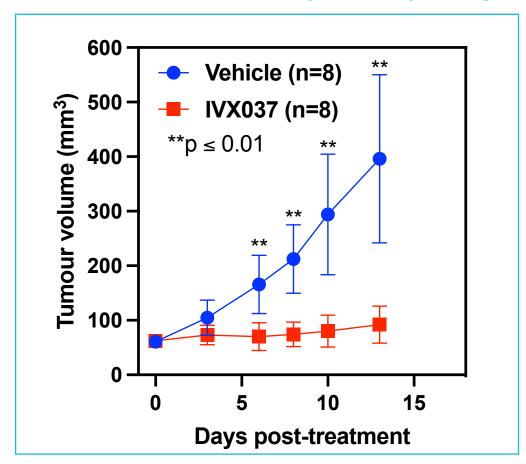


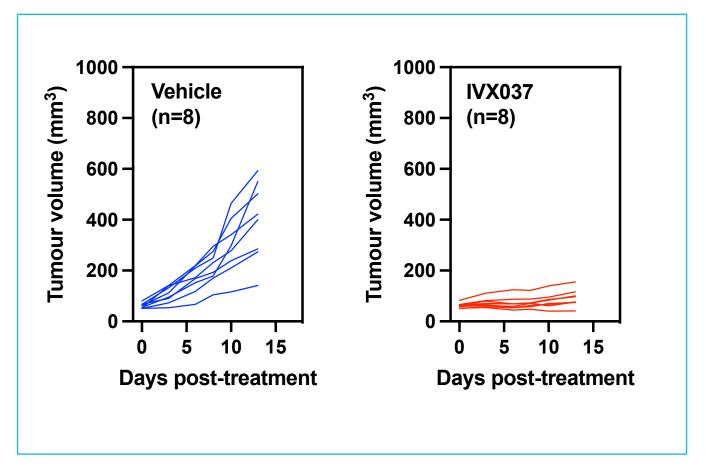


Activity of single dose of IVX-037 also demonstrated in gastric cancer with favorable tolerability



Human ovarian cancer (IGROV-1) xenograft model

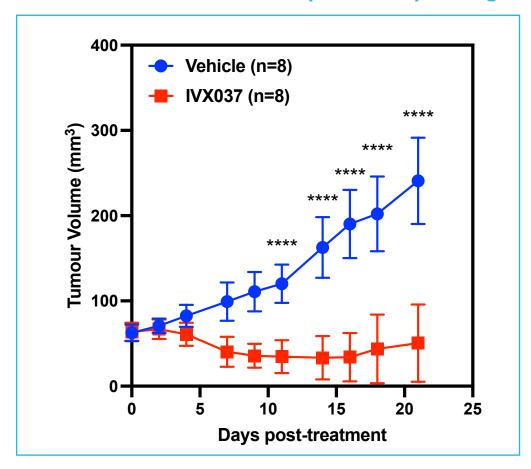


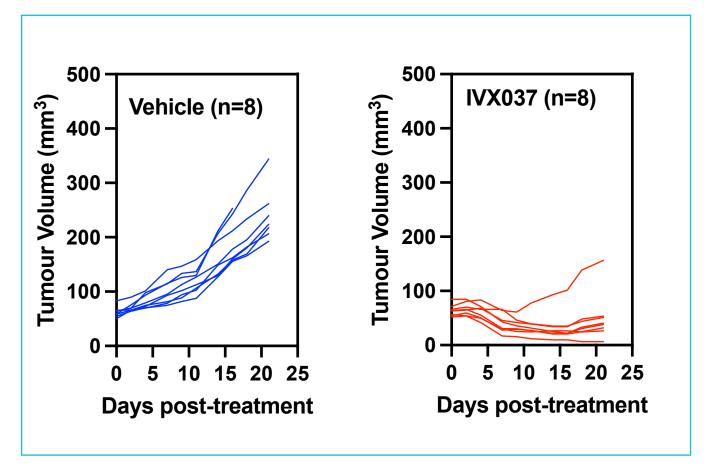


Striking reduction in tumor volume provides clear signal of potency solely attributed to oncolytic activity of single dose of IVX-037 with favorable tolerability



Human ovarian cancer (OVSAHO) xenograft model



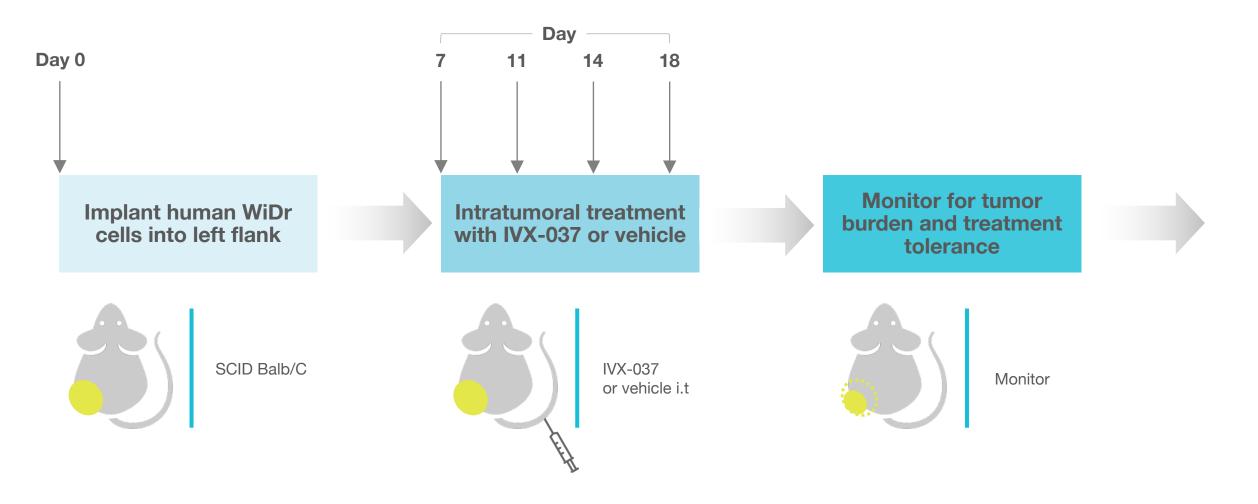


Oncolytic activity of single dose of IVX-037 confirmed in a second model of ovarian cancer



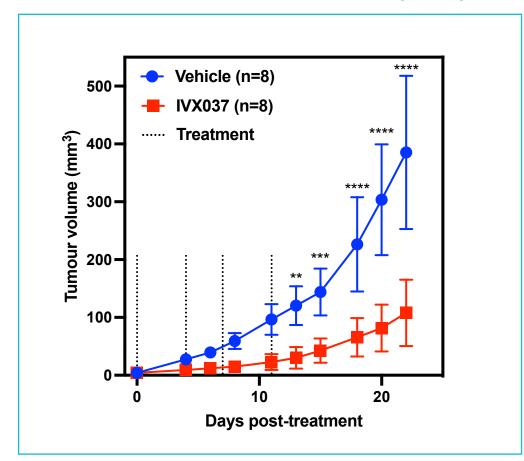
Measuring In Vivo Oncolytic Activity of IVX-037

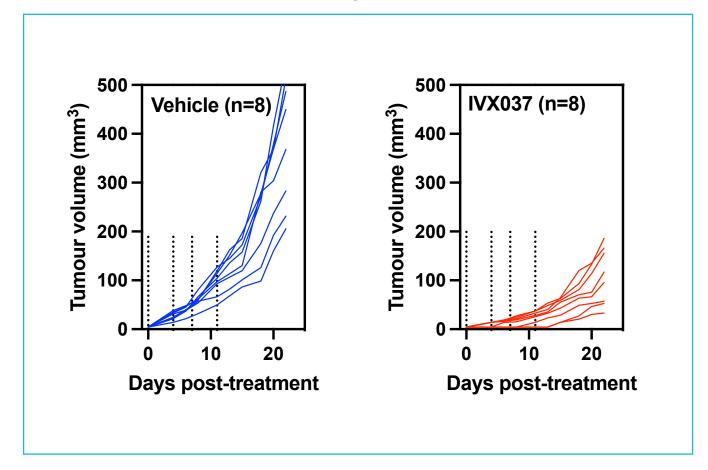
Human MSS colorectal cancer (WiDr) xenograft model – intravenous delivery





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





Intravenous delivery of IVX037 achievable in colorectal xenograft. Evidence of impressive antitumour efficacy and no treatment related toxicity observed



ImmVirX: Impressive Progress since May 2021 Financing

Preclinical / IP

- Further xenografts completed with excellent results across CRC, gastric and ovarian cancer
- Targeted small animal model supply from the US to Australia for preclinical toxicology studies
- Different routes of administration including IV delivery in CRC and ovarian cancer underway
- Further findings regarding IVX037 receptor usage strengthens support for patent filings

CMC / Quality

- Master virus seed prepared at FDA approved GMP facility
- Logistics and documentation in readiness for IVX037 production including fill / finish for FIP study
- Contract completed with US GMP facility for production of clinical batches of drug product for US and Australian trials
- Viral formulation with potential for improved cold chain shipping and storage

Clinical

- Clinical Trial Protocol in development for phase 1a and 1b basket study
- Australian KOLs identified to lead and participate in the phase 1 study
- Short list of CROs identified with review and selection underway

Strengthened ImmVirX with 5 new hires across preclinical, CMC and clinical teams



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Upcoming Milestones – through to Q3 2022

Preclinical / IP

- IV preclinical studies complete
- Preclinical toxicology complete
- Preclinical assessment in further indications
- Preclinical studies assessing IVX037 in combination with immune checkpoint inhibitors and CAR T-cell therapy

CMC / Quality

- Complete production at Australian sites for FIP studies
- Tech transfer to USA and engineering run and first GMP batch

Clinical

- Appoint CRO
- Ethics application for Australian Clinical Trial Sites
- Establish Australian Clinical Trial Sites
- Ethics and TGA approvals to commence phase 1 study
- First patient on trial
- Planning for US FDA IND filing



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Advancing the Next Generation of Oncolytic Viruses

First patient dosed in Phase 1b Research Services **ImmVirX** First patient dosed Viralytics \$A502M checkpoint Agreement with bioselection Preclinical Expansion of in Phase 1 combination acquisition by TUNRA - University platform proof-of-concept preclinical Preclinical monotherapy of Newcastle established xenograft models toxicology study study Merck achieved June 2018 2020 2022 2021 2019 2023 Seed round: Candidate Series A Manufacture for Monotherapy trial Small scale Production **ImmVirX** of MCB nominated manufacturing Phase 1 clinical data founded by exand MVSS developed supply Viralytics team





Thank You

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