Focal Medical

Energy assisted drug transport for targeting inoperable and resistant tumors

Our Mission

Local, energy-based drug delivery

Effectively target **resistant** tumors

Decrease **toxicity**

Improve patient **outcomes**

Our Status

Now: IND-cleared first-in-human pancreatic cancer clinical trial

Soon: oral cavity cancer and melanoma products to IND stage

Our Ask

$10MM investment

Cancer Treatment Failures

"In the coming year, we're expecting to hit a bleak milestone — for the first time new cases of cancer in the US are expected to cross the 2-million mark, with over 611,000 deaths"[1]

"Multidrug resistance (MDR) is responsible for over 90% of deaths in cancer patients receiving traditional chemotherapeutics or novel targeted drugs."[2]

"Cancer drugs…fail for two reasons. They are too toxic for patients to safely take, or patients can safely take them, but they don't actually shrink a patient's tumor"[3]

Resistant cancers are the leading cause of cancer death

Focal Medical delivers existing and new drugs using more directed, more effective, and less toxic methods

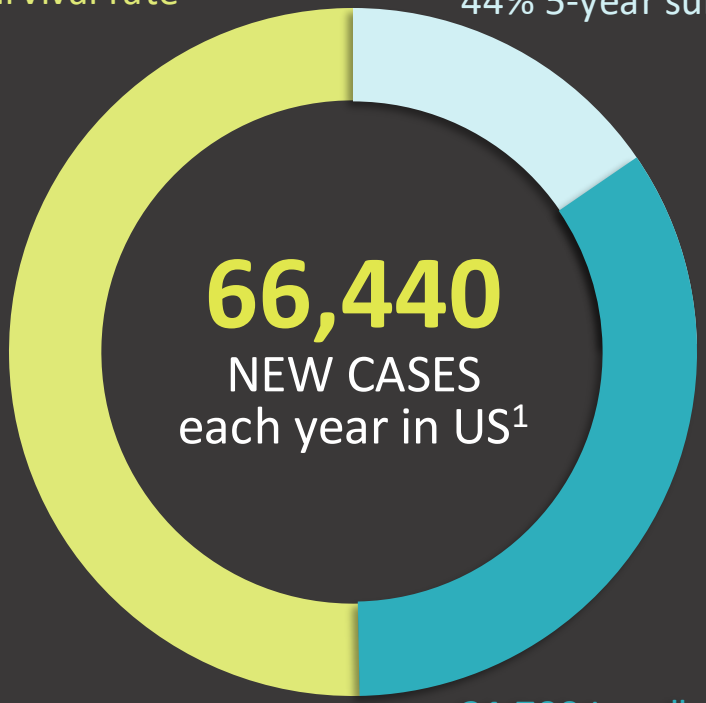
1. "2024—First Year the US Expects More than 2M New Cases of Cancer", Sonya Collins, American Cancer Society, January 17, 2024.
2. Bukowski K, Kciuk M, Kontek R. Mechanisms of Multidrug Resistance in Cancer Chemotherapy. Int J Mol Sci. 2020 May 2;21(9):3233.
3. "Yale-led Research Explains Why Many Cancer Drugs Fail During Clinical Trial Testing", Jason Sheltzer, PhD – Yale Cancer Center, October 20, 2023.

Pancreatic Cancer

Current survival by stage[1]

31,000 metastatic cases
3% 5-year survival rate

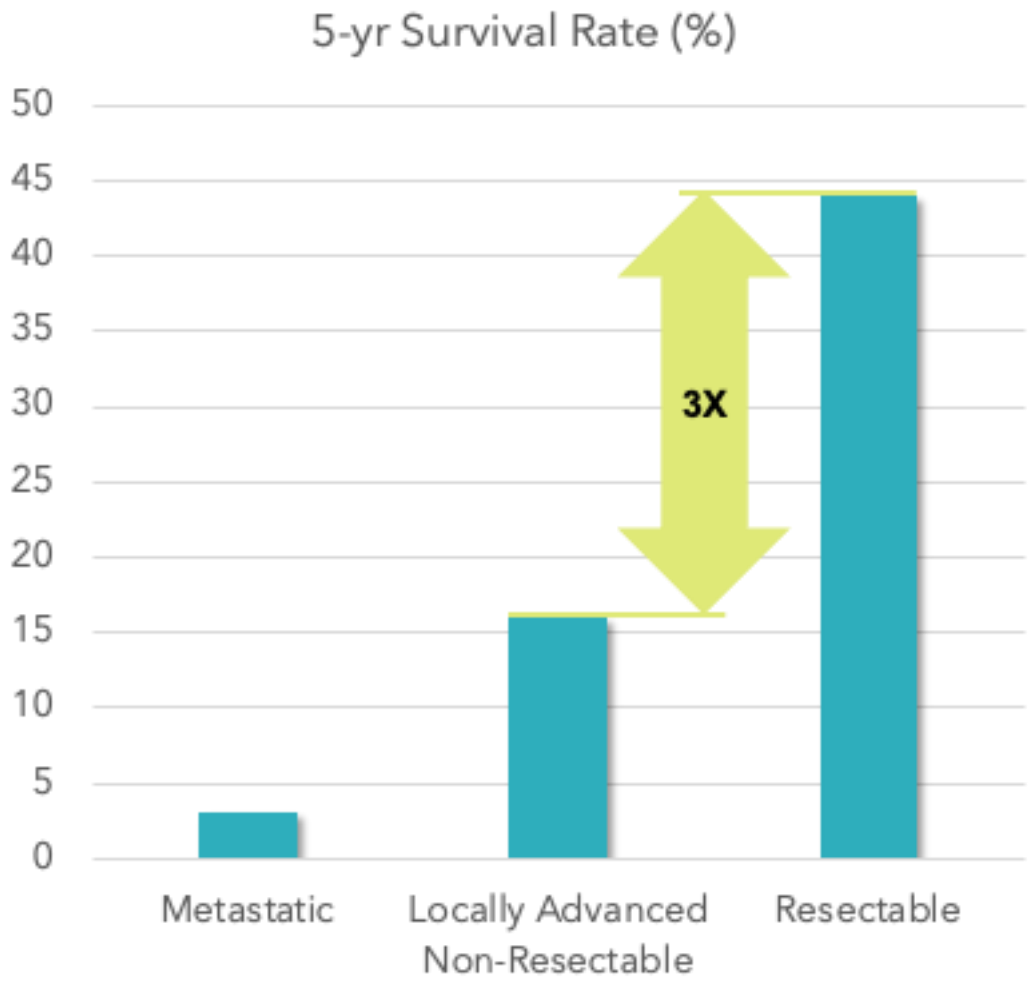
9,300 resectable cases
44% 5-year survival rate



21,700 Locally advanced non-resectable cases
16% 5-year survival rate
(**Target Market**)

1. American Cancer Society. Cancer Facts & Figures 2024. Atlanta: American Cancer Society; 2024

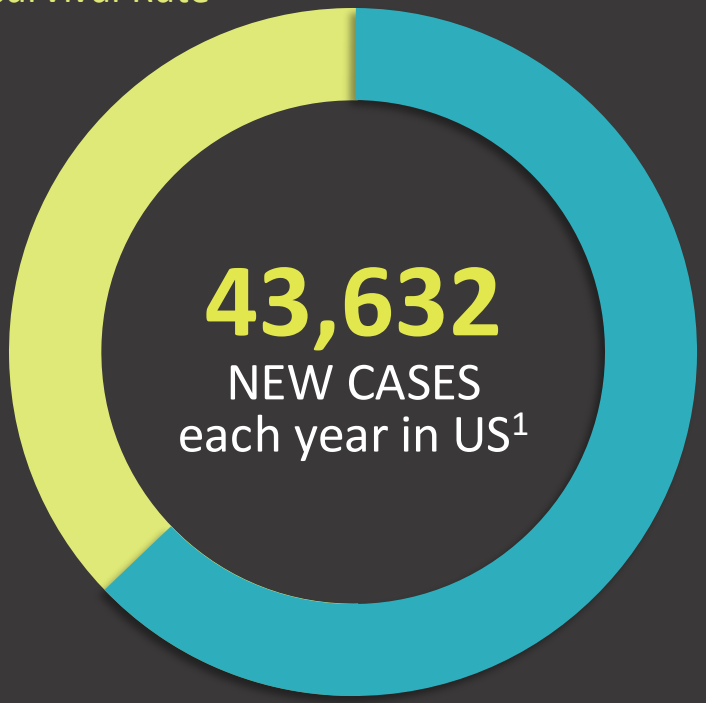
Getting People to Surgery
Game Changer



Oral Cavity Cancer

Current survival by stage[2]

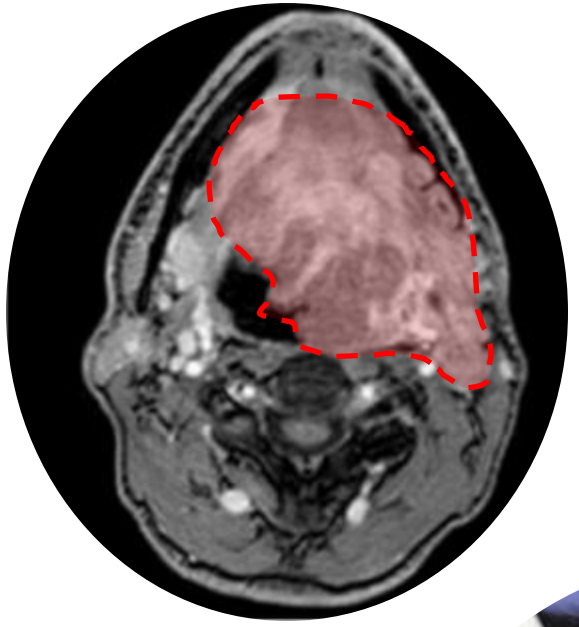
17,452 Resectable cases[1]
61% 5-year survival Rate



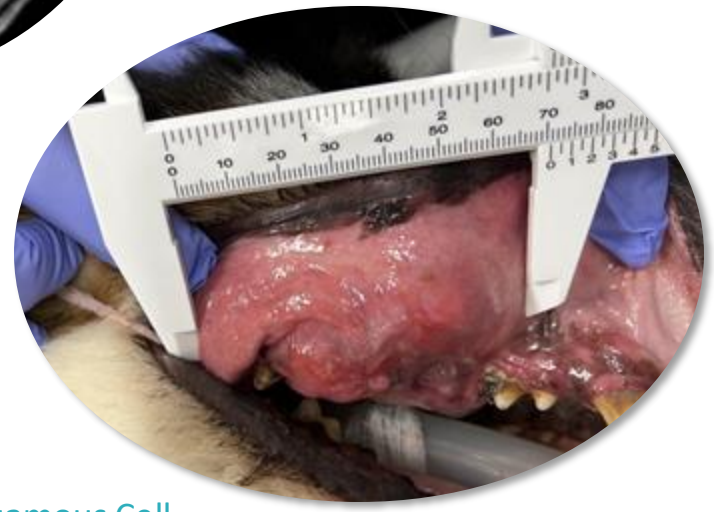
23,998 Locally recurrent cases[1]
15% 5-year survival rate
(**Target Market**)

1. SEER Incidence Data, November 2023 Submission (1975-2021)
2. Management of Locally Advanced Oral Cancers. Oral Oncology, Volume 105, June 2020
3. Therapeutic Intensification and Induction Chemotherapy for High-Risk Locally Advanced Squamous Cell Carcinoma. Curr. Treat. Options in Oncol. (2019) 20: 2

Canine Oral Cavity Cancer
Translatable Preclinical Model



High-Risk, Locally Advanced **Human** Squamous Cell Carcinoma[3]

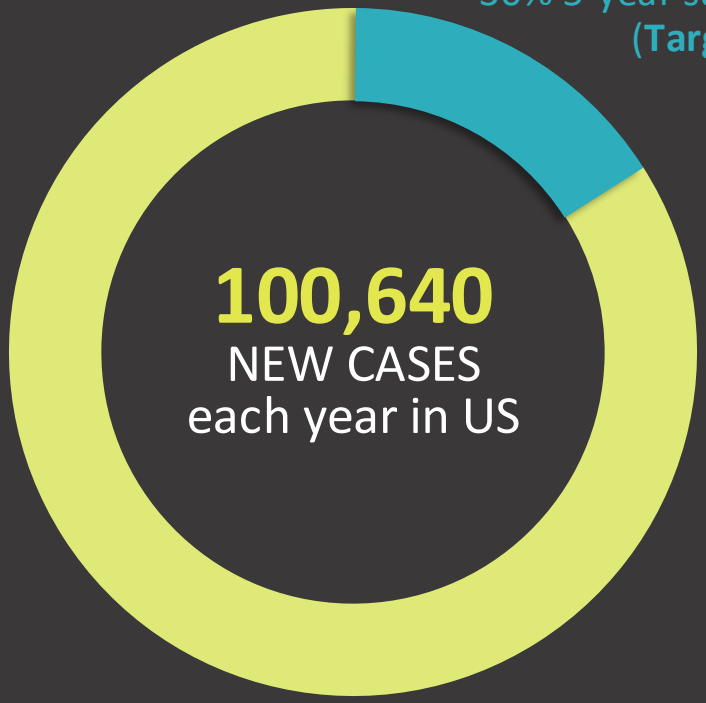


Locally Advanced Squamous Cell Carcinoma in a **Canine** Model

Melanoma

Current survival by stage

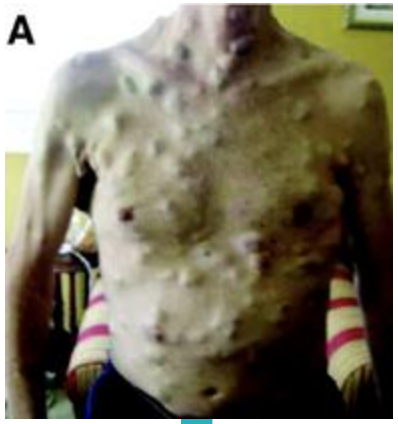
10,668 recurrent cases[1]
30% 5-year survival rate[2]
(**Target Market**)



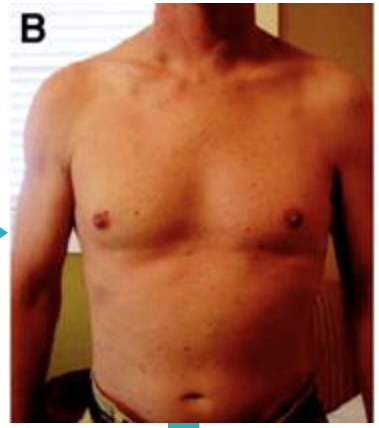
89,972 Non-recurrent treatable cases[1]
94% 5-year survival Rate[2]

1. Stage-Specific Risk of Recurrence and Death From Melanoma in Denmark, 2008-2021. JAMA Dermatol. 2023;159(11):1213-1222.
2. Cancer Stat Facts: Melanoma of the Skin.
3. Dissecting Therapeutic Resistance to RAF Inhibition in Melanoma by Tumor Genomic Profiling. Journal of Clinical Oncology, Volume 29, Number 22, August 2011.

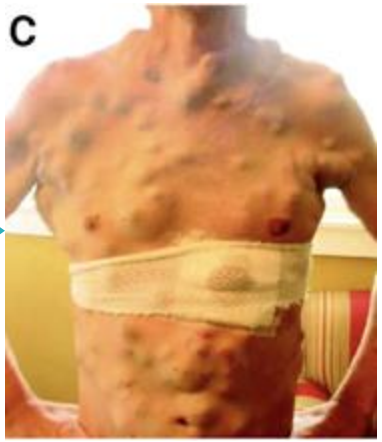
Attacking Drug-Resistant Cells Essential for Addressing Recurrence



Treatment with vemurafenib over 15 weeks[3]



Drug-resistant recurrence in 8 weeks[3]

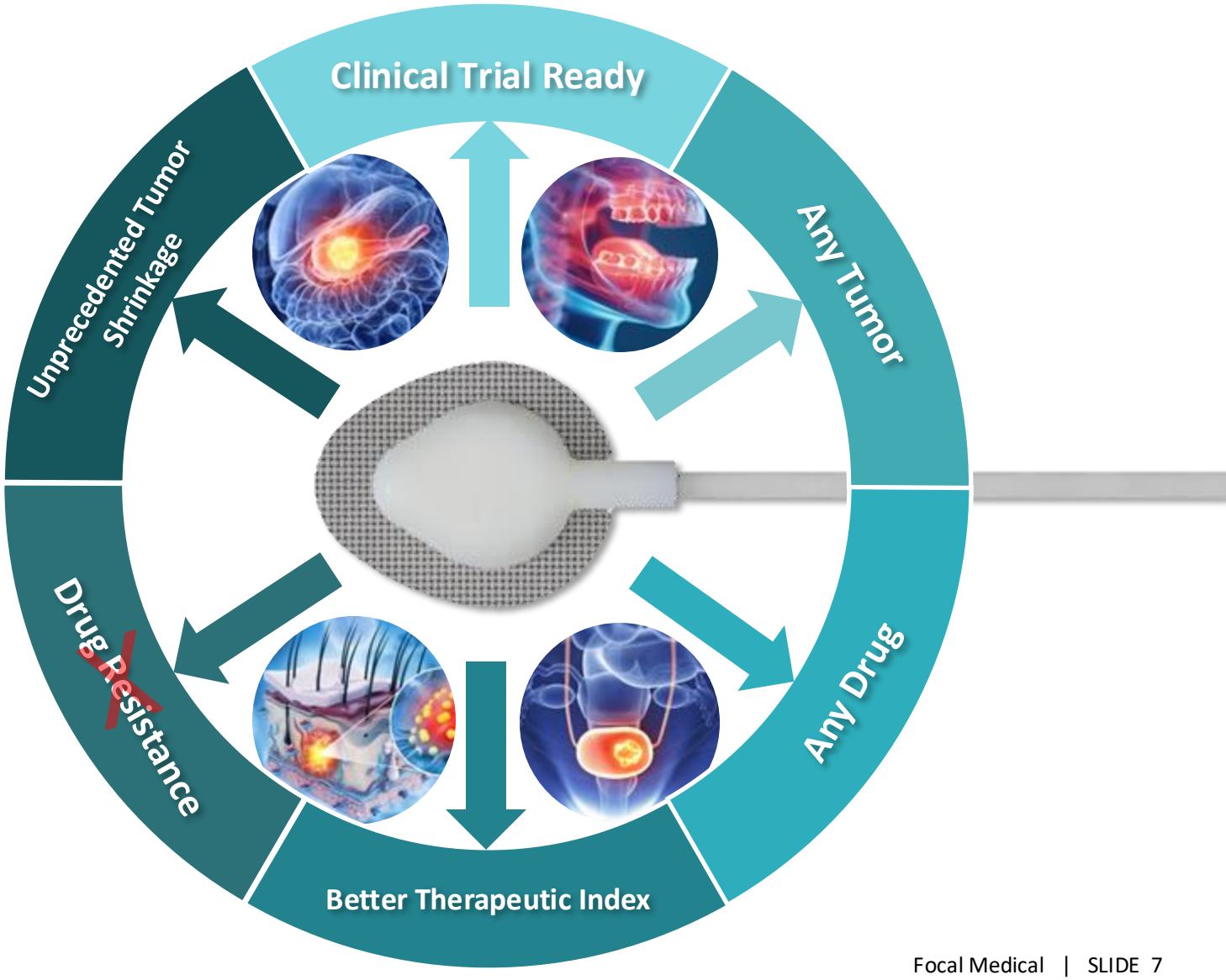


A True Technology Platform: one device – many targets

FDA-cleared IND

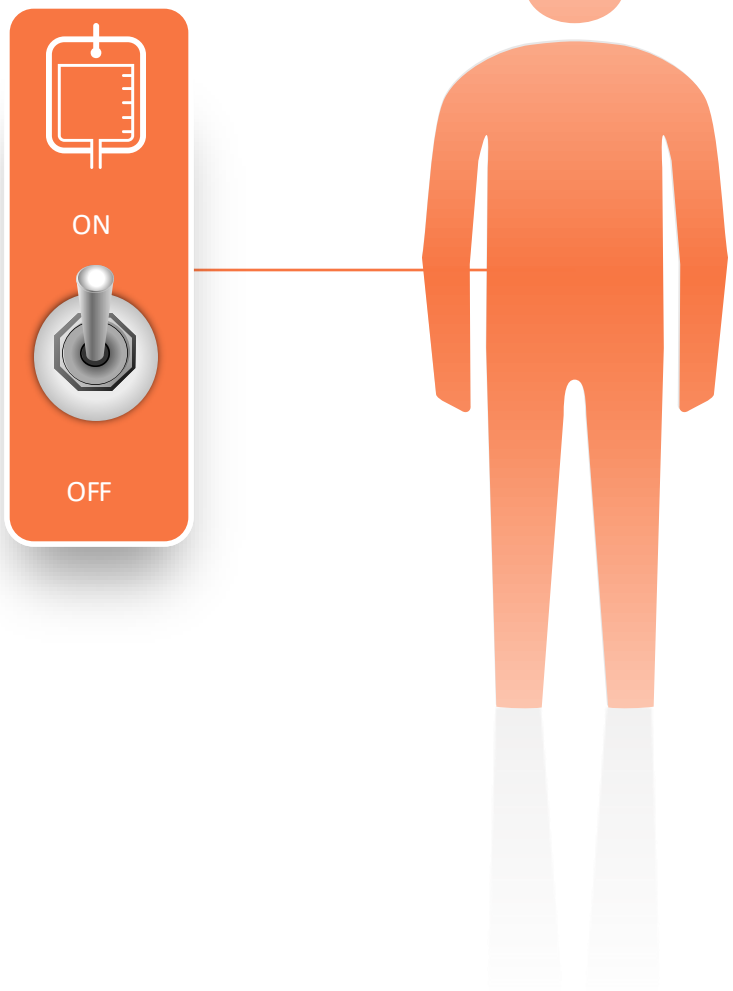
Compatible with approved drugs

Small and large animal model studies

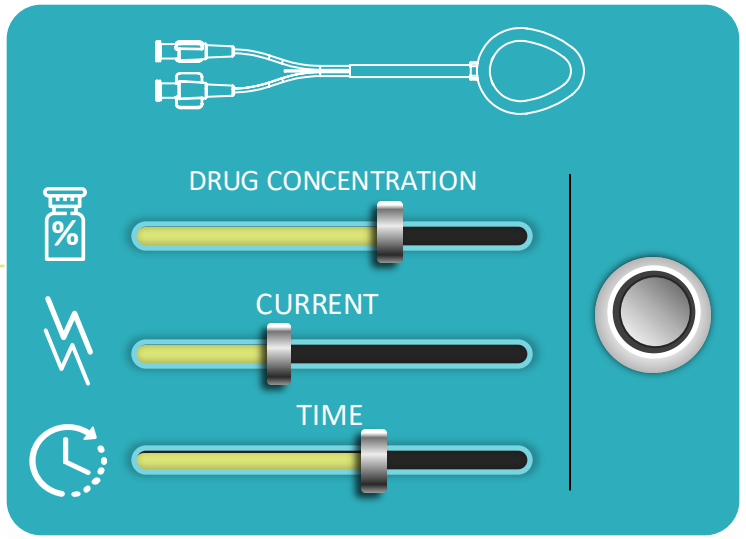


IOP Precision Delivery Targets the Tumor

SYSTEMIC DELIVERY

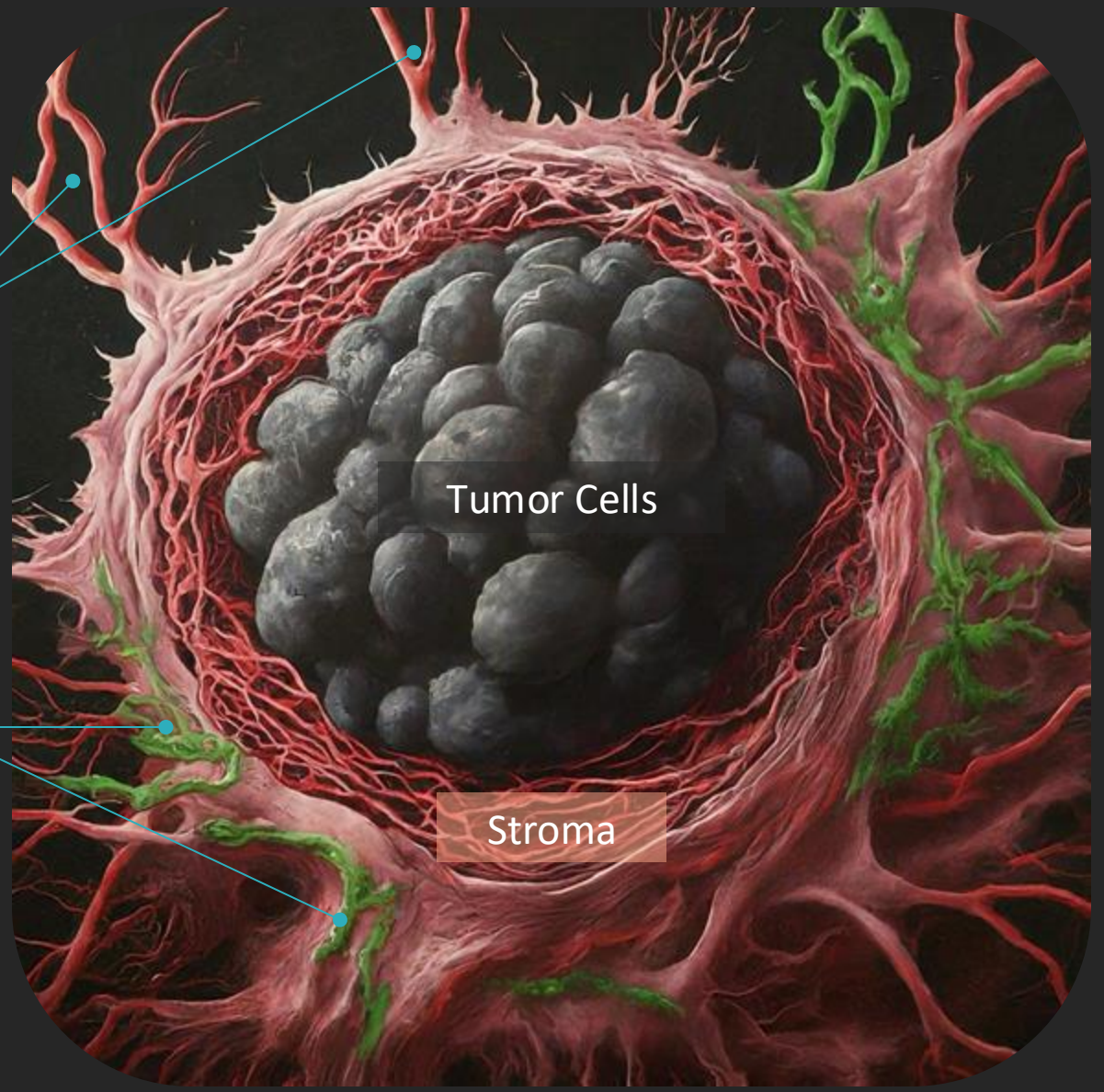


IONTOPHORESIS



- ✓ More effective
- ✓ Fewer side effects
- ✓ Customized Dosing and Delivery

Iontophoresis Overcomes Extrinsic Chemotherapy Resistance

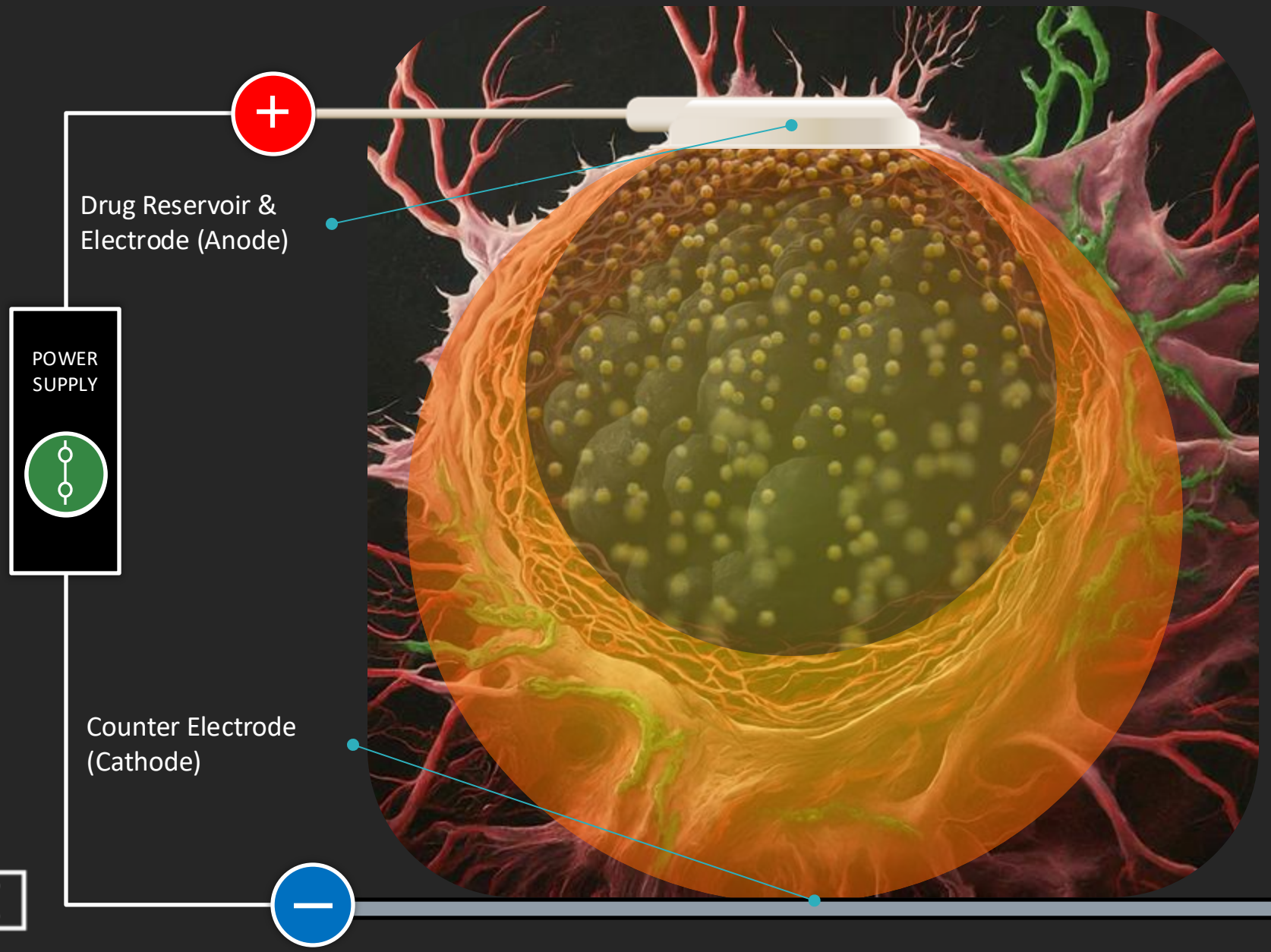


Fortress of surrounding cells prevent drug delivery

Increased intra-tumoral pressure

Decreased drug delivery

IOP System Reaches Deep to Shrink Tumors

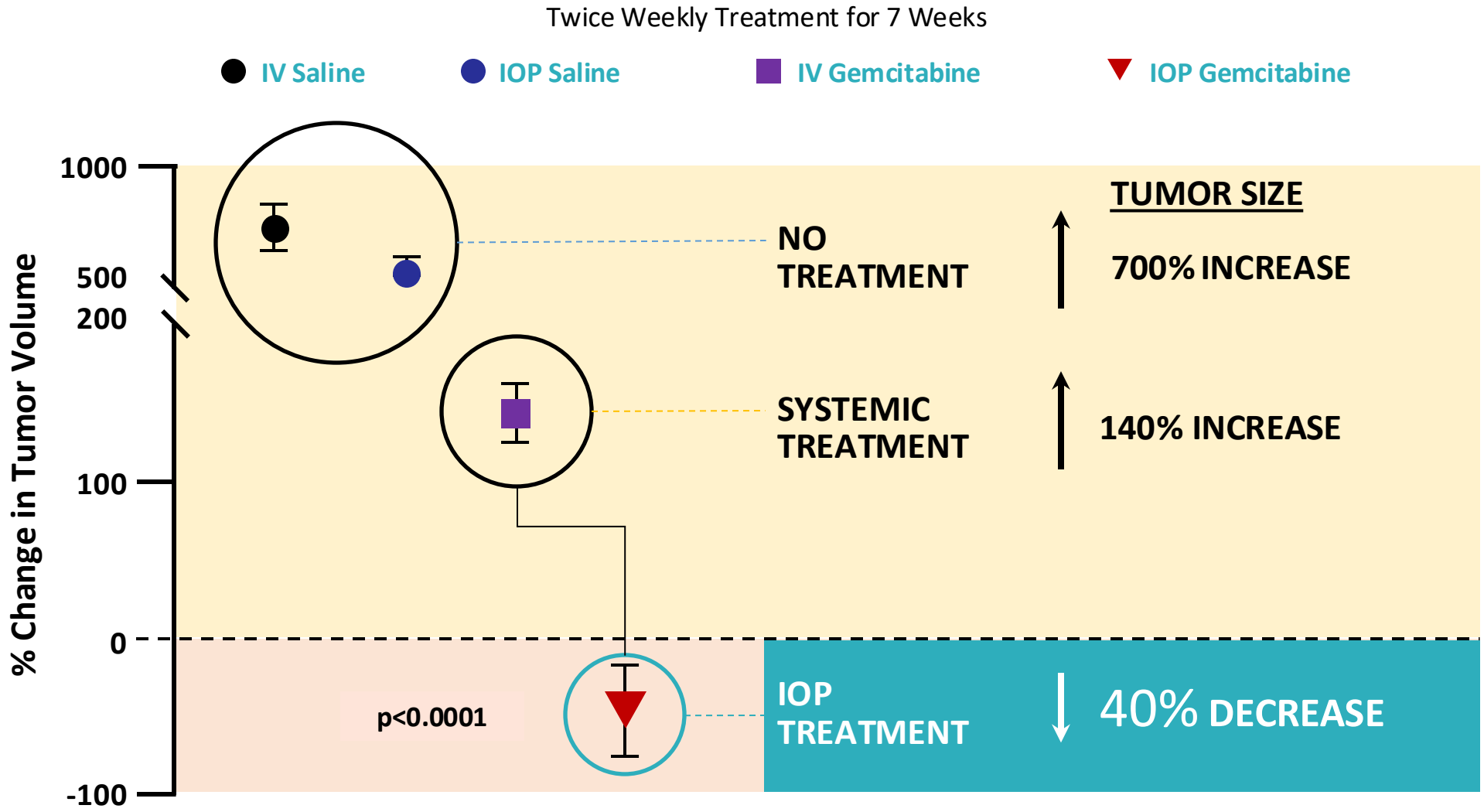


IOP overwhelms that fortress, delivering chemotherapy where it's most effective

X Overcomes intra-tumoral pressure

^ Increases drug delivery

Dramatic Tumor Reduction in Orthotopic PDX[1] Murine Model[2]



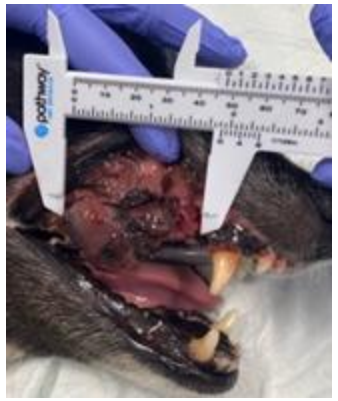
1. PDX = patient-derived xenograft
2. Local iontophoretic administration of cytotoxic therapies to solid tumors, Byrne JD et al. Sci Transl Med. 2015 Feb 4;7(273)

Dramatic Tumor Reduction after Single IOP Carboplatin Treatment

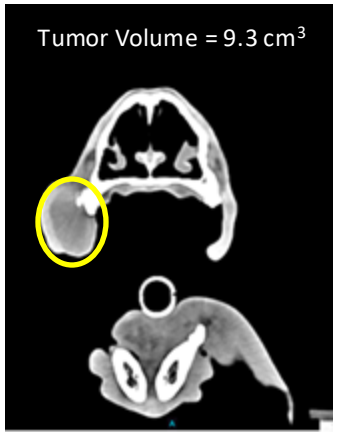
Advanced Oral Melanoma and Oral Squamous Cell Carcinoma

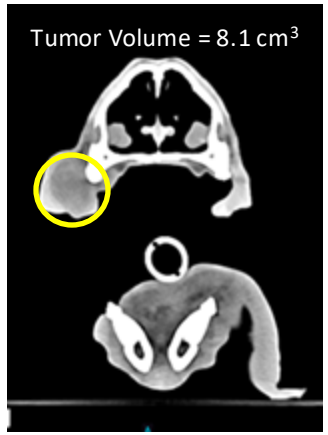
Single IOP Delivery Canine OM1

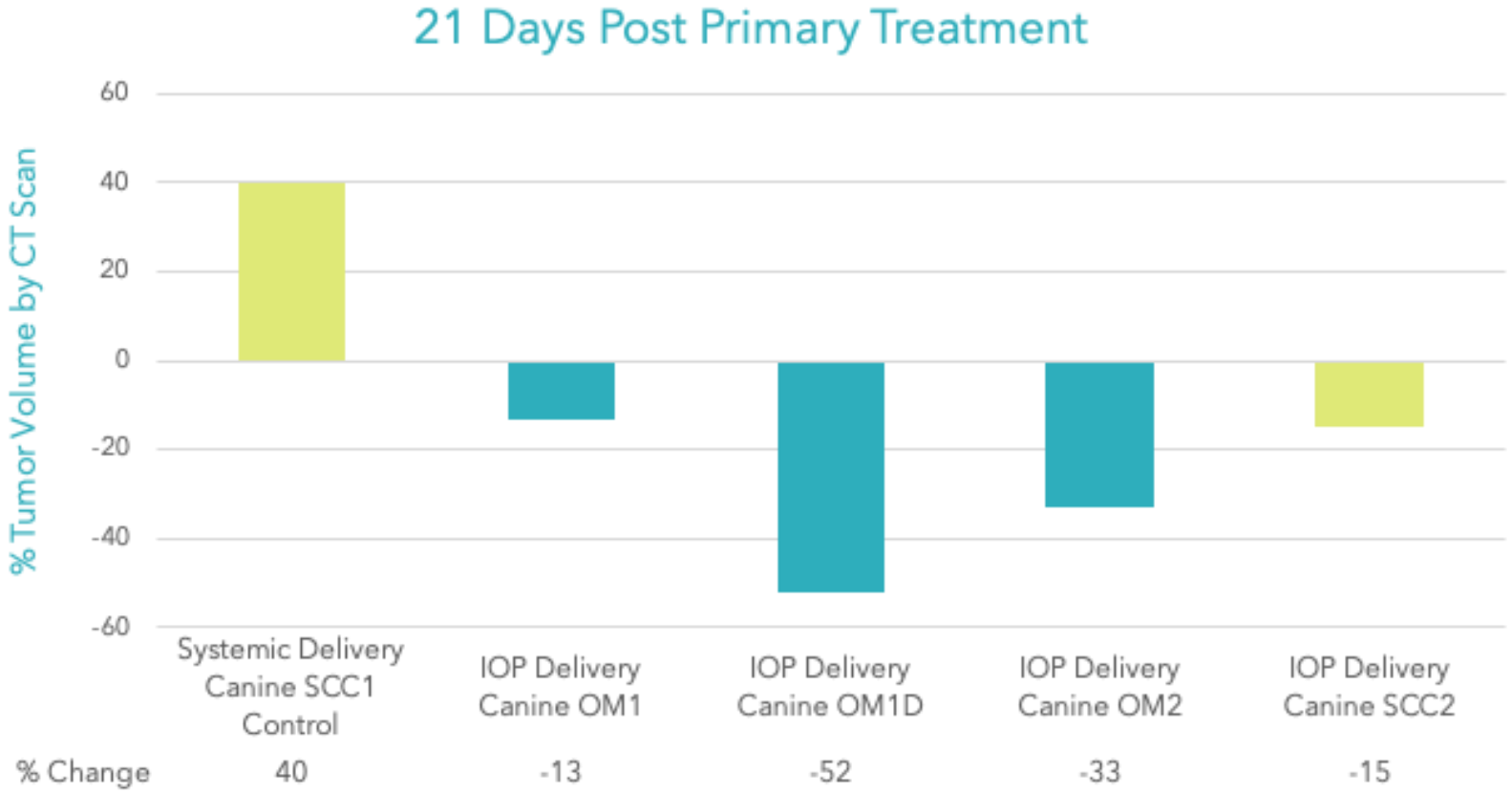
Pre-Treatment



3 Weeks Post-IOP







OM = Oral Melanoma ; **SCC = Squamous Cell Carcinoma**

Canine OM1D is a secondary tumor that was not directly treated and indicates an abscopal effect

Pipeline & Target Market Overview

Indication	5 Year Survival[1]	TAM	Discovery	Preclinical	Phase I	Phase II	Phase III	Launch
Locally advanced, unresectable pancreatic cancer	< 5%	$650MM	**IND Cleared. Initiating Phase 1b Study** Tumor volume reduction in PDX pancreatic tumor model, safety and tolerability in 2 large animal models					
Resistant squamous cell carcinoma and oral melanoma	32%	$720MM	**Pilot animal study complete** Safety, tolerability, tumor volume reduction in large animal spontaneous oral tumor model					
Resistant skin melanoma	35%	$320MM	**Pilot animal study complete** Safety, tolerability, tumor volume reduction in large animal spontaneous oral tumor model					

1. Surveillance, Epidemiology, and End Results (SEER) Program Populations (1969-2022) National Cancer Institute, DCCPS, Surveillance Research Program, released March 2024.

$10MM Investment Deliverables

Indication	5 Year Survival[1]	Invest	Discovery	Preclinical	Phase I	Phase II	Phase III	Launch
Locally advanced, unresectable pancreatic cancer	< 5%	$6MM	**IND Cleared. Initiating Phase 1b Study** Tumor volume reduction in PDX pancreatic tumor model, safety and tolerability in 2 large animal models		**Phase 1B Study Data Obtained**			
Resistant squamous cell carcinoma and oral melanoma	32%	$2MM[2]	**Pilot animal study complete** Safety, tolerability, tumor volume reduction in large animal spontaneous oral tumor model	**IND Filed for Clinical Study**				
Resistant skin melanoma	35%	$2MM[2]	**Pilot animal study complete** Safety, tolerability, tumor volume reduction in large animal spontaneous oral tumor model	**IND Filed for Clinical Study**				

1. Surveillance, Epidemiology, and End Results (SEER) Program Populations (1969-2022) National Cancer Institute, DCCPS, Surveillance Research Program, released March 2024.
2. Additional funds will be pursued through grant applications for these indications

Ready To Go: Phase 1B Pancreatic Cancer Clinical Trial

Phase 1B Trial ($6MM)

- **10 patients with locally advanced non-resectable disease**
- 2 cohorts under dose escalation design
- **Primary Endpoints**: safety and tolerability
- **Secondary Endpoints**: tumor regression and resectability

Timing:

- PI and primary clinical site on board and ready for IRB submission
- Top line report available in 2 years

Key Assessment Criteria:

- Adverse Events, Serious Adverse Events
  - a) drug-related;
  - b) device related
- Safety Data
  - a) electrocardiogram
  - b) blood chemistry / hematology
  - c) plasma PK Blood biomarkers (exploratory)
- CT Imaging
- % of patients that become eligible for surgical removal of tumor
- Local Progression Free Survival

Fast to Follow: Phase 2/3 Clinical Trial

Phase 1B Trial ($6MM)

Phase 2/3 Trial ($35-$50MM)

- **50 to 75 patients** with locally advanced non- resectable disease
- **Primary Endpoints**: Overall survival (1 year)
- **Secondary Endpoints**: Safety, tolerability, resectability

Experienced Board and Executive Team

Joe DeSimone, PhD
Founder & Board member

Sanjiv Sam Gambhir Professor of Translational Medicine and Chemical Engineering, Stanford University

Founder, Carbon Inc.
Valued over $2.4 billion

Recipient, Presidential National Medal of Technology & Innovation

Jen Jen Yeh, MD
Founder & Board member

Professor and Vice-Chair
Surgical Research, Lineberger Cancer Center, UNC Chapel Hill

Principal Investigator, NCI Specialized Programs in Research Excellence

Developer, single sample classifier licensed to GeneCentric Therapeutics

Developer, CTC marker, licensed to Biofluidica

Nessan Bermingham, PhD
Board member

Operating Partner at Khosla Ventures

Founder, President, and CEO at Intellia Therapeutics

Founder & Board Member, Liberate Bio

Founder & Executive Chair, Korro Bio

Tony Voiers
CEO

Developer of 13 products
(8X PMA and 5X 510k devices)

CEO, Novocor Medical

Director of R&D, Closure Medical
sold to J&J - $410 million

25 years medical device management

William Daunch, PhD
CTO

Sr. Director of R&D, Allergan:
development of soft tissue reconstruction and combination therapeutic delivery systems

Critical product launches supporting a $400 million technology portfolio at Ethicon

22 years medical and combination device development; 13 Regulatory submissions

Nancy Sacco, PhD
VP, Clinical Development

Chief Development Officer, Hexima

Executive Director; Astellas Pharma (Xtandi)

AveXis (ZolgenSMA)

25 years pharmaceutical & gene therapy development experience

Proposed Financing

- $10MM in Series A-2 securities of Focal Medical in a private placement with Accredited Investors
  - Operations for 27 months (end of 2026)
  - Complete Phase Ib clinical trial of IOP gem for pancreatic cancer
  - Complete IND submission resistant oral cavity cancer
  - Complete IND submission in resistant skin melanoma

Deliverables to mid 2026

Pancreatic Cancer

Phase 1b clinical trial of IOP gemcitabine in pancreatic cancer

- Safety and tolerability
- Evidence of activity in target patient population
- 1-2 centers: ~10 patients
- Dose escalation:1/week to 2/week Tx
- Pathway to phase 2/3

Resistant Oral Cavity Cancer

IND preparation

- Complete oral delivery device design
- Additional KOL interviews
- Pre-IND FDA meeting
- Non-clinical safety & tolerability studies
- Additional efficacy Studies
- Clinical study design

Resistant Skin Melanoma

IND preparation

- Complete skin delivery device design
- Additional KOL interviews
- Pre-IND FDA meeting
- Non-clinical safety & tolerability studies
- Additional efficacy Studies
- Clinical study design

Shareholdings (Fully Diluted)

Stockholders (post Series A)	# of shares	%
Common stock holders	420,000	14%
Khosla Ventures	1,175,998	40%
Spectrum Financial	323,076	11%
Piedmont Capital Partners	400,000	14%
Other preferred	144,086	5%
Stock options (fully diluted)	470,372	16%
Total	**2,933,532**	**100%**

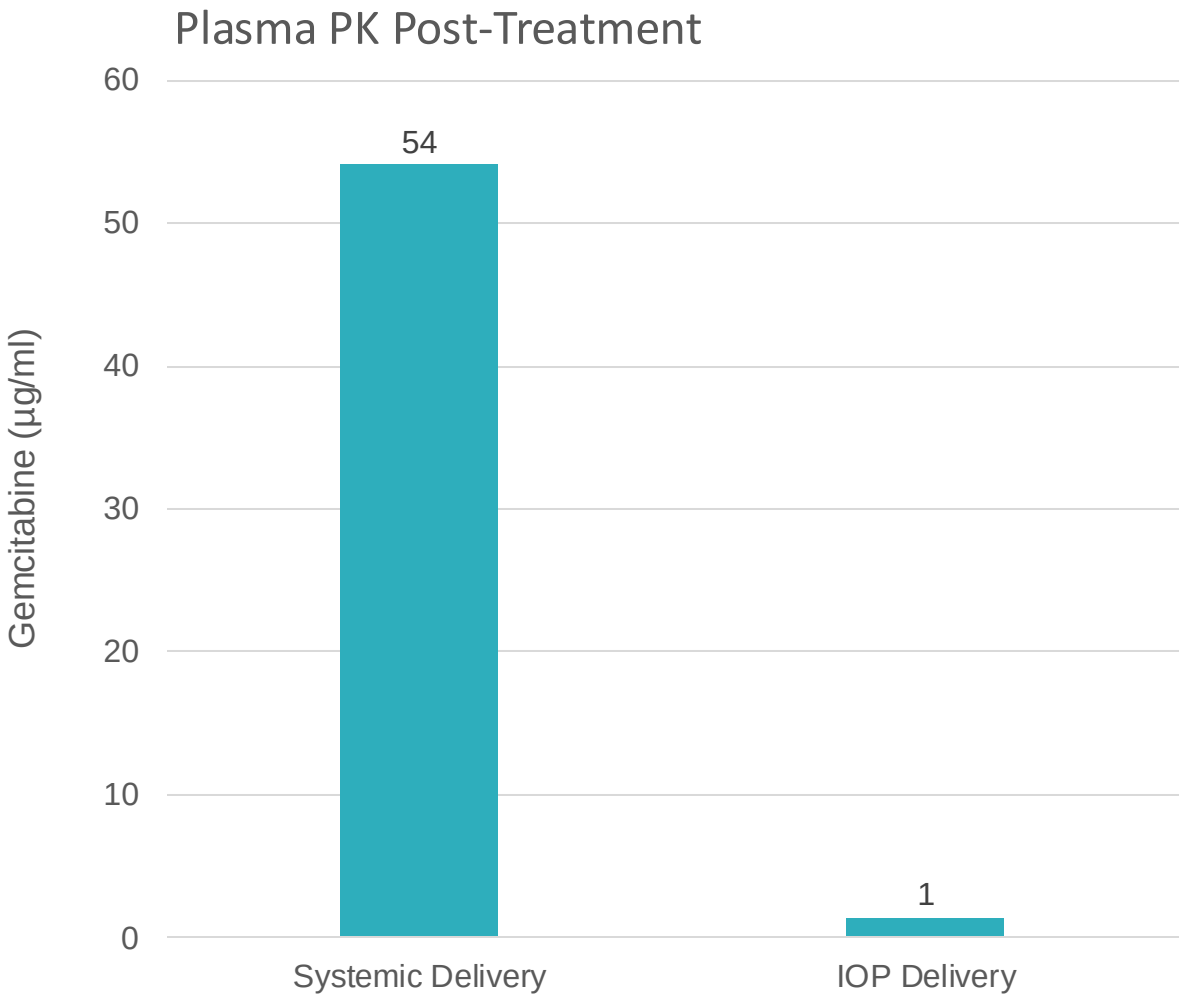
Share class	Authorized shares	Outstanding	Ownership	Fully diluted	Ownership	Amount raised
Common	3,420,000	420,000	17.16%	420,000	14.32%	$420
Series Seed Preferred	380,000	380,000	15.53%	380,000	12.95%	$273,011
Series Seed 1 Preferred	164,086	148,606	6.07%	148,606	5.07%	$599,997
Series A Preferred	1,822,151	1,499,074	61.25%	1,499,074	51.10%	$11,599,985
W Warrants				15,480	0.53%	$0
Shares outstanding under 2016 Stock Incentive Plan	470,372			432,053	14.73%	
Shares available under 2016 Stock Incentive Plan				38,319	1.31%	
Total		**2,447,680**	**100.00%**	**2,933,532**	**100.00%**	**$12,473,413**

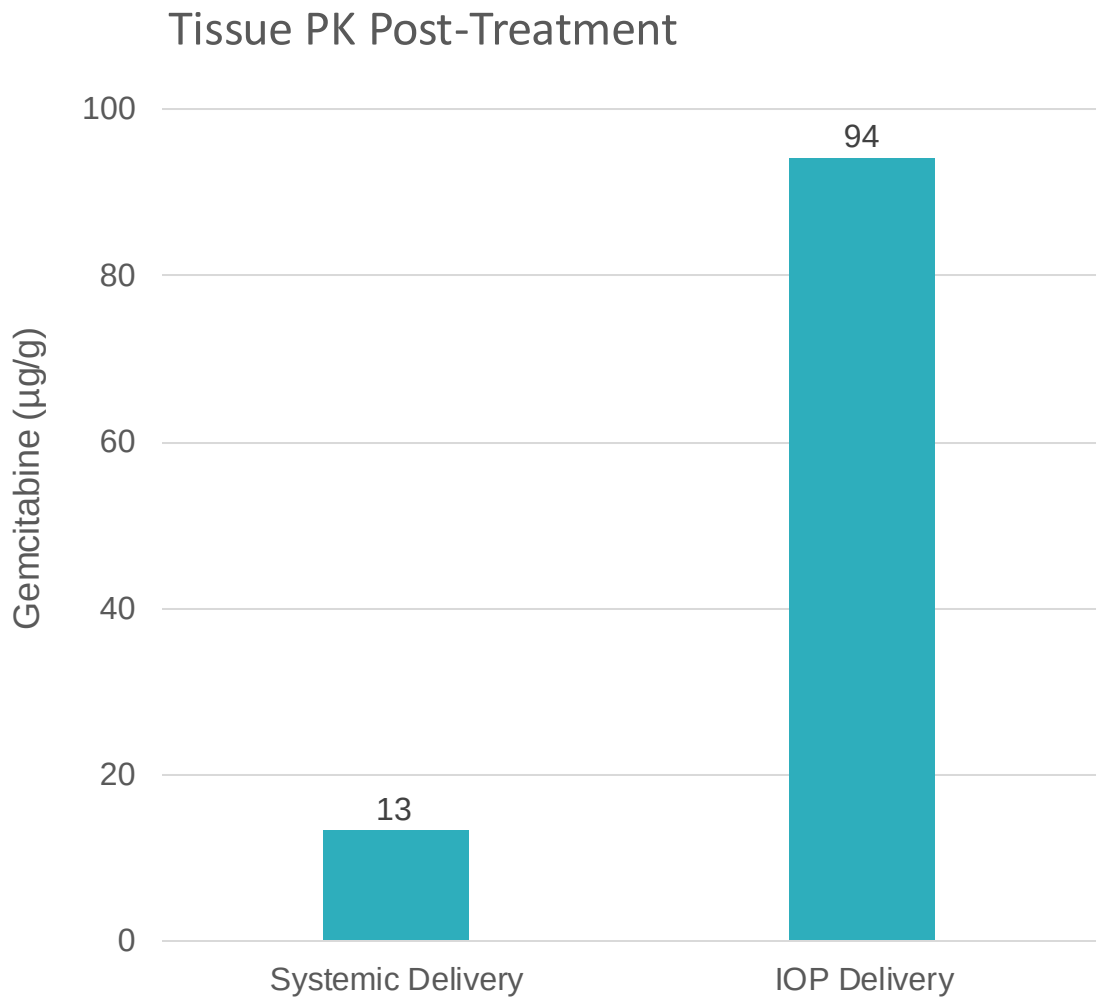
Reasons to Invest

1	Numerous hard-to-treat tumors leave **patients with no treatment options and no hope for recovery**	LAST HOPE
2	**New oncology treatments** take 10+ years to bring to market and face substantial risk along the way resulting in a **90% attrition rate**.	LOWER RISK
3	Focal Medical's IOP drug delivery system is **clinically ready system for treating cancer right now!**	CLINICALLY READY
4	**We are nimble!** Focal Medical's IOP platform is highly adaptable meaning **rapid advancement of INDs for two new indications**	NIMBLE
5	**We are experienced** with a world-class team of oncologists, researchers, and medical product development experts.	EXPERIENCED

Supplementary Slides

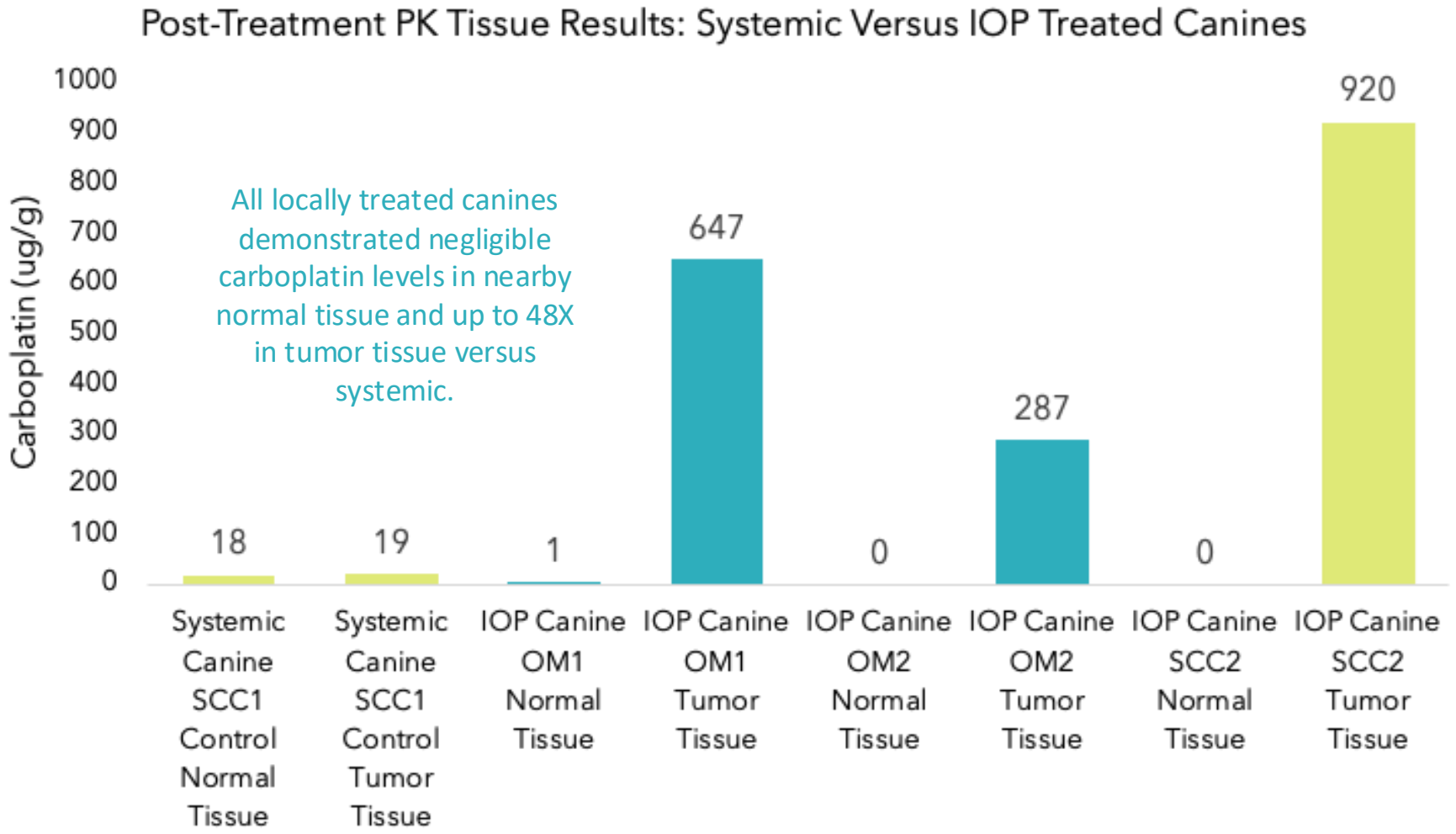
Canine Model: Target 7X Higher Gemcitabine Negligible Systemic Spillover[1]





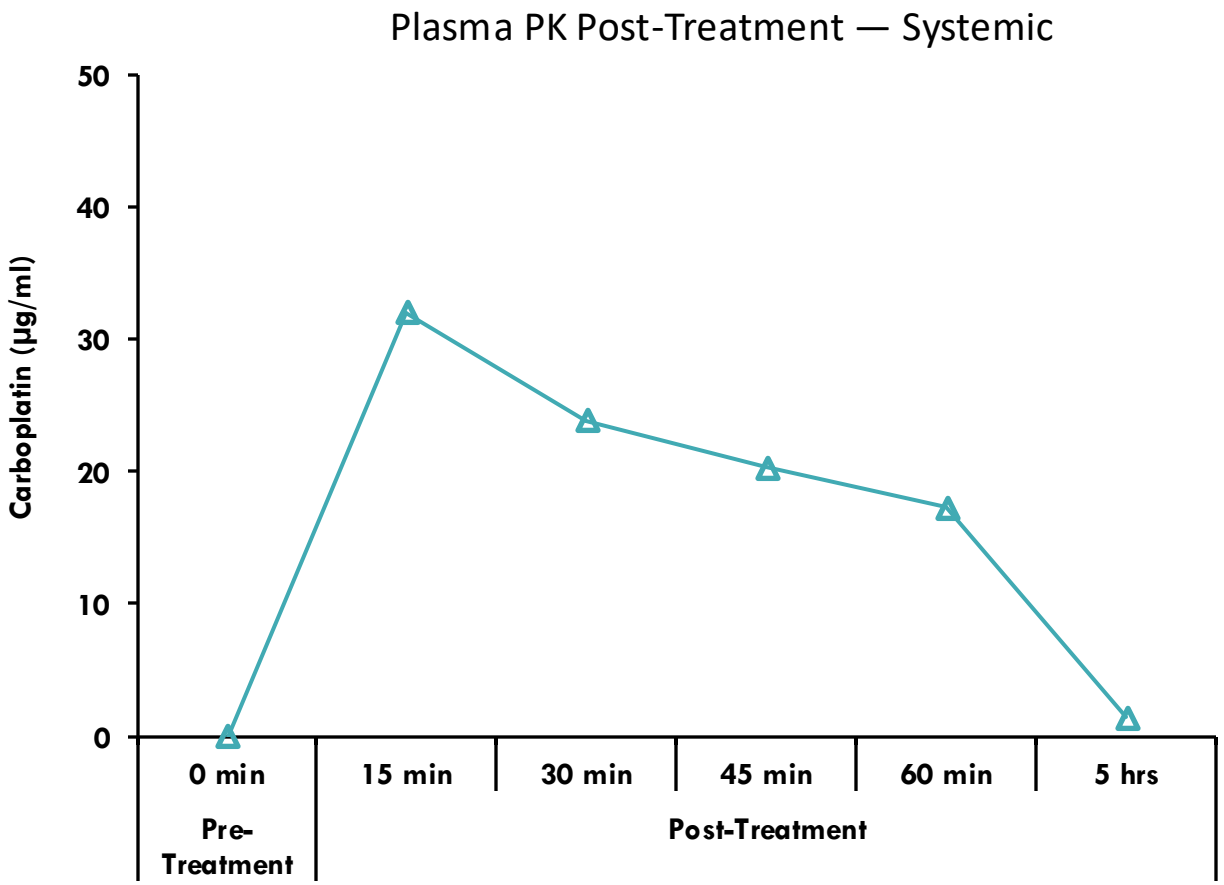
1. Local iontophoretic administration of cytotoxic therapies to solid tumors, Byrne JD et al. Sci Transl Med. 2015 Feb 4;7(273)

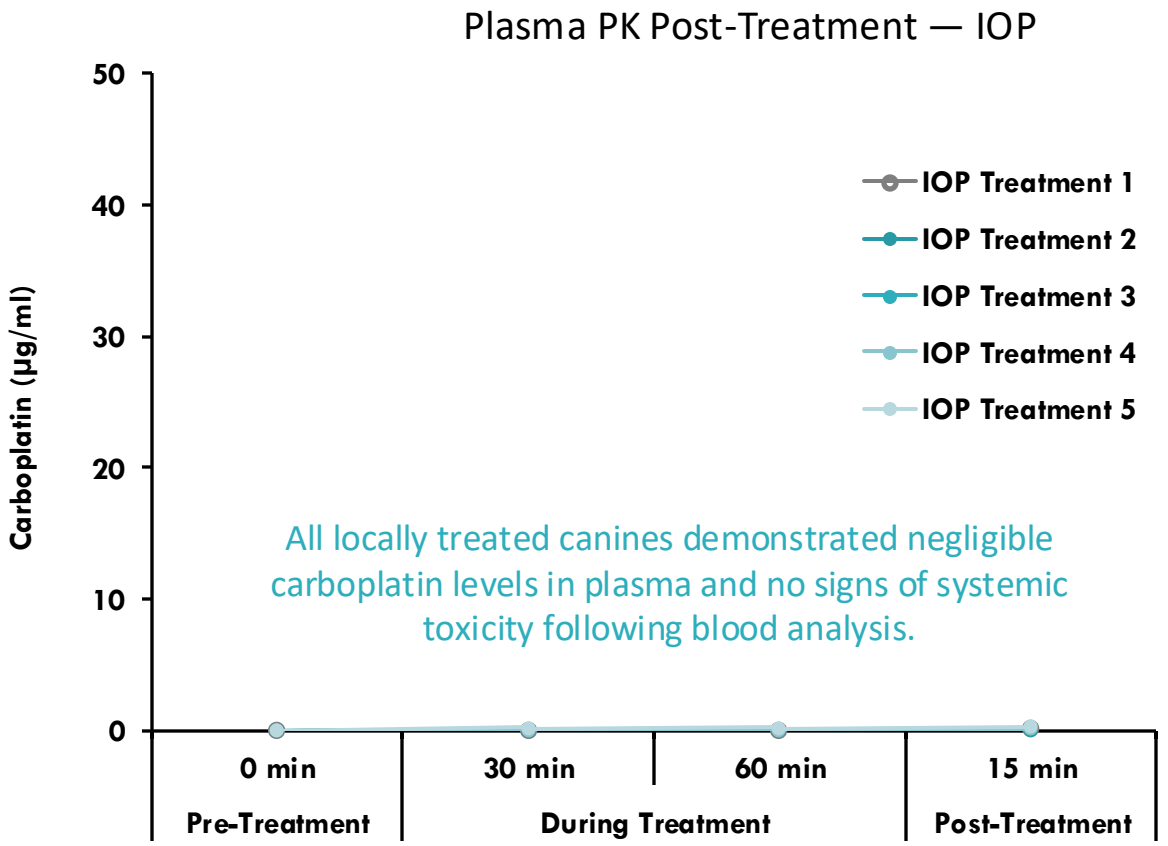
Canine Oral Tumor Tissue
16-48X Higher Carboplatin



OM = Oral Melanoma ; **SCC = Squamous Cell Carcinoma**

Negligible Plasma Levels of IOP Carboplatin vs Systemic Treatment





Active IOP Delivery is Superior to Passive

Active IOP:

Energy driven transport that does not rely on the circulatory system

Crosses the protective barriers of the tumor

Therapy precisely where it is needed and nowhere else

Gets more active drug directly to the tumor

	IOP	Drug-Eluting	Intra-Arterial	IT Injection
Reduces systemic toxicity	✓	✓	✓	✓
Enhances penetration	✓	✗	✗	✗
Crosses barriers	✓	✗	✗	✗
Overcomes drug resistance	✓	✗	✗	✗
Demonstrated tumor volume reduction	✓	✗	✗	✗
	Energy Driven Transport	Passive Diffusion		

Exciting Value Proposition Across Multiple Indications

Indication	Addressable Market (cases)	Potential ASP[1]	Market opportunity
Locally advanced unresectable pancreatic cancer	21,700	$30,000	$ 651,000,000
Recurrent oral cavity cancer	23,998	$30,000	$ 719,940,000
Recurrent melanoma	10,668	$30,000	$ 320,040,000
Total opportunity			$1,690,980,000

1. ASP modeled here is at the low end of the expected range

Phase 1b Clinical Trial Details

Population:
- Patients with non-metastatic, unresectable pancreatic adenocarcinoma

Open Label:
Gemcitabine via ACT-IOP-003 Device

Key Objectives:
- Safety and Tolerability post-implantation
- PK (plasma Gem, dFdU, V-GEM)
- Pharmacogenomic data (per ICF)
- Biomarkers (exploratory)

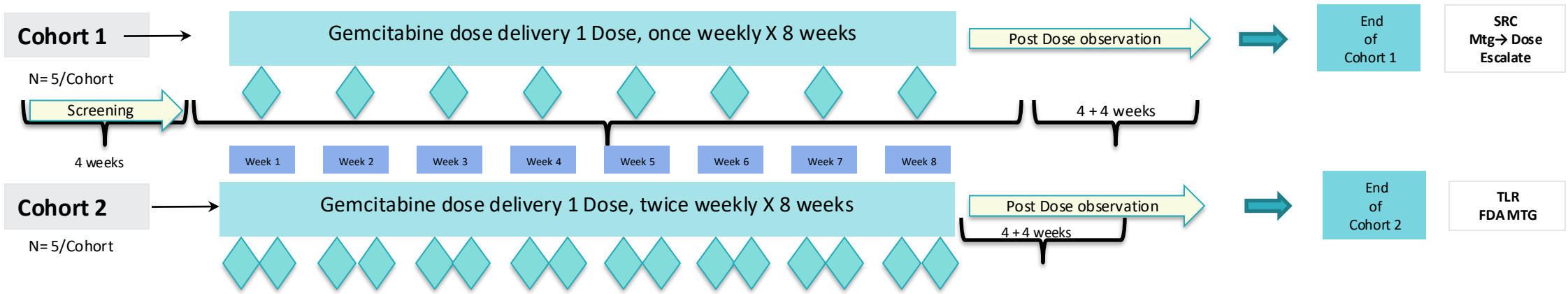
Key Assessments:
- AEs, SAEs
  a) drug-related;
  b) device related
- Safety data—ECG, Blood chemistry / hematology, plasma PK
- Blood biomarkers (exploratory)
- CT Imaging
- Overall Survival

Two Cohorts
Cohort 1:
- (5 pts), 1 Tx / week, 8 weeks

Cohort 2:
- (5 pts), 2 Tx / week, 8 weeks

Key Milestones:
1st patient in:
- 6 months from funding

Top line report:
- 18 months from 1st patient in



Intellectual Property: Strong and Getting Stronger

Broad granted international patents. An ongoing program of filings, supplemented by Orphan Drug, know-how and other market exclusivity mechanisms

Patents on internal drug delivery using iontophoresis

Patents on internal drug delivery using iontophoresis in combination with radiation

Continuations and new filings on patents in prosecution covering enhancements and improvements