

Delivering  
therapy where  
it matters<sup>®</sup>

NASDAQ | RNXT



## A Late-Clinical Stage Biotechnology Company

with lead program in a Phase III registrational clinical trial in pancreatic cancer

LD Micro June 2023



What does cancer look like to you?

It doesn't look like life.

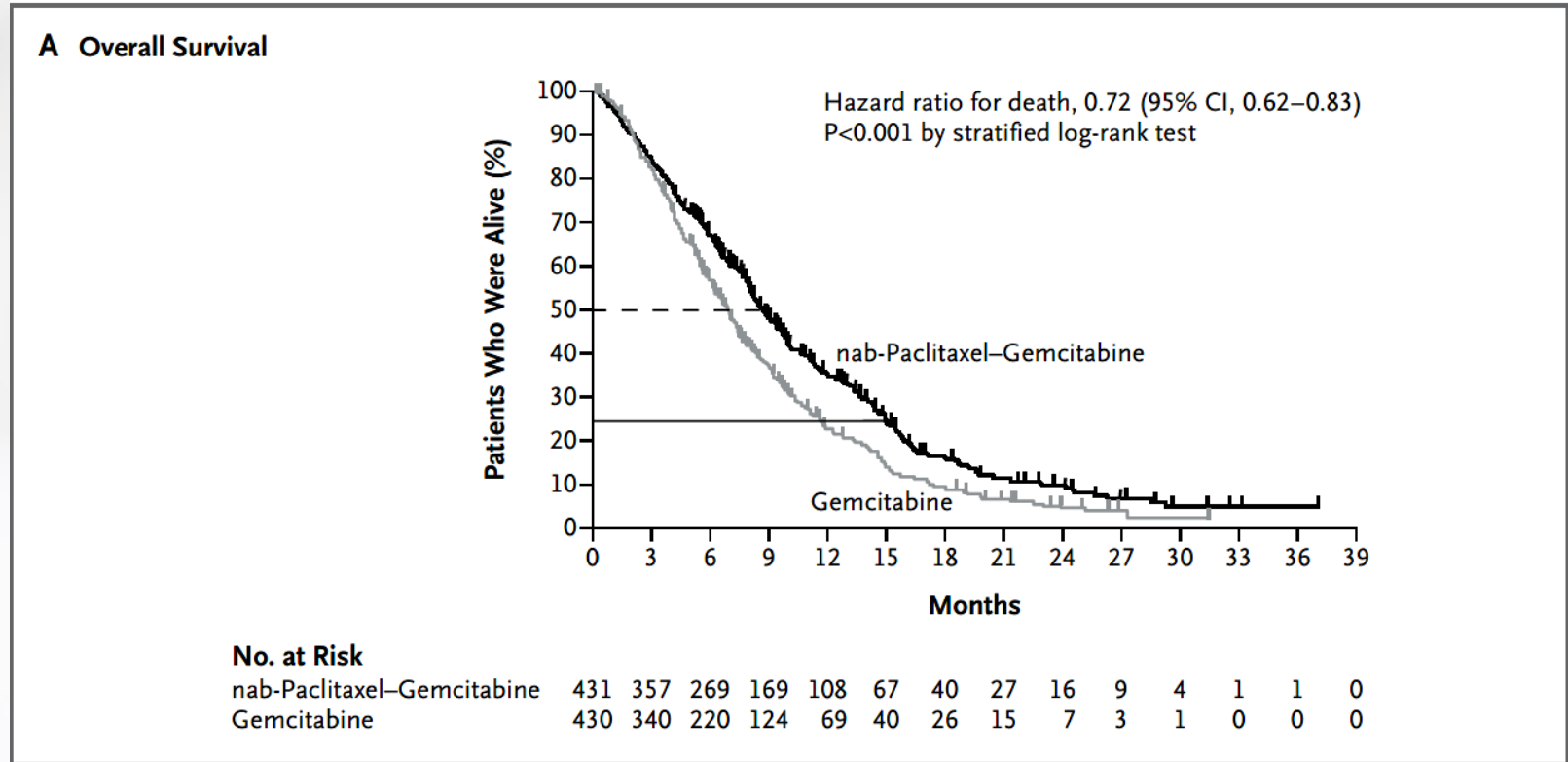
And yet, success is measured by Survival Benefit.

What is “Survival Benefit”?

# What does a billion-dollar drug look like in pancreatic cancer?

## Nab-paclitaxel (Abraxane)

8.5 vs 6.7 months of survival  
= **7-week Survival "Benefit"**

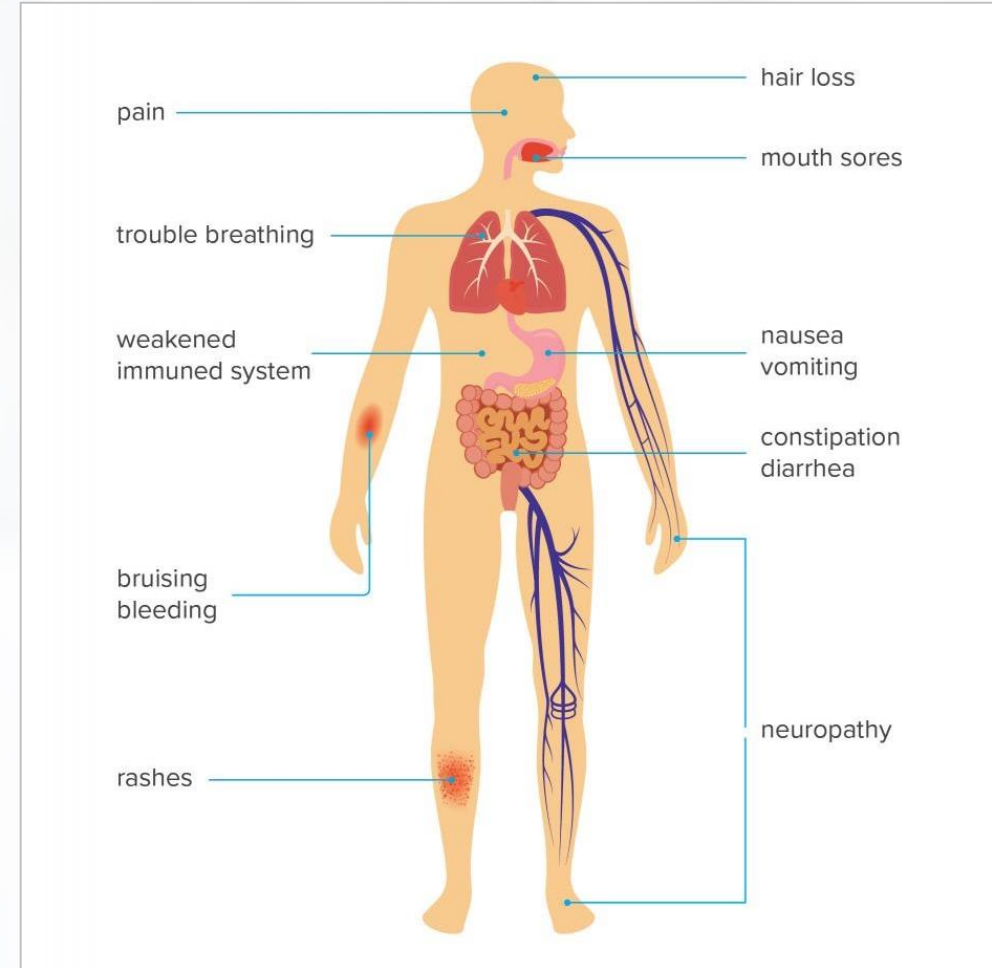


Von Hoff, et. al., Increased Survival in Pancreatic Cancer with nab-Paclitaxel plus Gemcitabine. N ENGL J MED 369;18; 2013

# What does a billion-dollar drug look like in pancreatic cancer?

## *At what cost?*

**Chemotherapy Side Effects:**  
*Are you aware of them?*



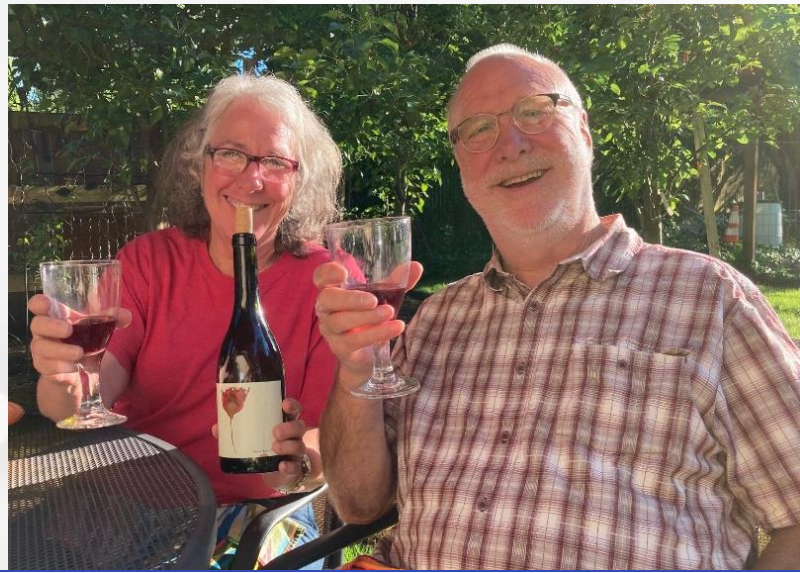
What does cancer look like to you?

It doesn't look like life.

And yet, success is measured by Survival Benefit.

What is “Survival Benefit”?

Does it have to be this way?



Imagine



# Company Overview



Founded in 2009 by a physician with first external funding 2012. Last private financing led by Boston Scientific, 2018. IPO, Q 3 2021. HQ: Los Altos, CA



Developing proprietary drug-delivery Trans-Arterial Micro-Perfusion (TAMP™) platform with goal of improving a treatment's therapeutic index across drug class



Registrational, **Phase III TIGeR-PaC** study with positive interim analysis announced at AACR 2023, **secondary endpoint data planned to be presented at ESMO World GI June 29, 2023**, & potential study stoppage for significance at 2<sup>nd</sup> interim analysis



FDA Orphan Drug Designation granted to RenovoGem™ in pancreatic and bile duct cancers



Market opportunity estimated >\$1B per year in first marketed indication



# Pipeline Highlights: Two Registration Opportunities

|            | Locally Advanced Pancreatic Cancer (LAPC)                                                                                                                             | Bile Duct Cancer                                                   |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Status     | Positive interim data reported from registrational, randomized Phase III trial (TIGeR-PaC)                                                                            | Phase II/III randomized, controlled study launch estimated 2H 2023 |
| Key Data   | First interim analysis presented at AACR 2023:<br>6-month improvement in median Overall Survival vs. Standard of Care (Control)<br><br>>65% reduction in side effects |                                                                    |
| Next Steps | Second interim analysis estimated YE 2024*                                                                                                                            |                                                                    |

**U.S. FDA Orphan Drug Designation for 7 Year Market Exclusivity**

\*Potential for early approval with positive second interim results

# Locally-Advanced Pancreatic Cancer (LAPC)

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# RenovoGem Lead Indication: LOCALLY ADVANCED PANCREATIC CANCER

Pancreatic Cancer Worldwide Incidence:  
495,000 new cases/year with 30% locally advanced at presentation



 62,000 / 48,000

 134,000 / 131,203



Current Standard of Care:

## 12 to 18.8-month median Overall Survival

using chemo-radiation regimens with  
gemcitabine+nab-paclitaxel OR mFOLFIRINOX as base  
treatment

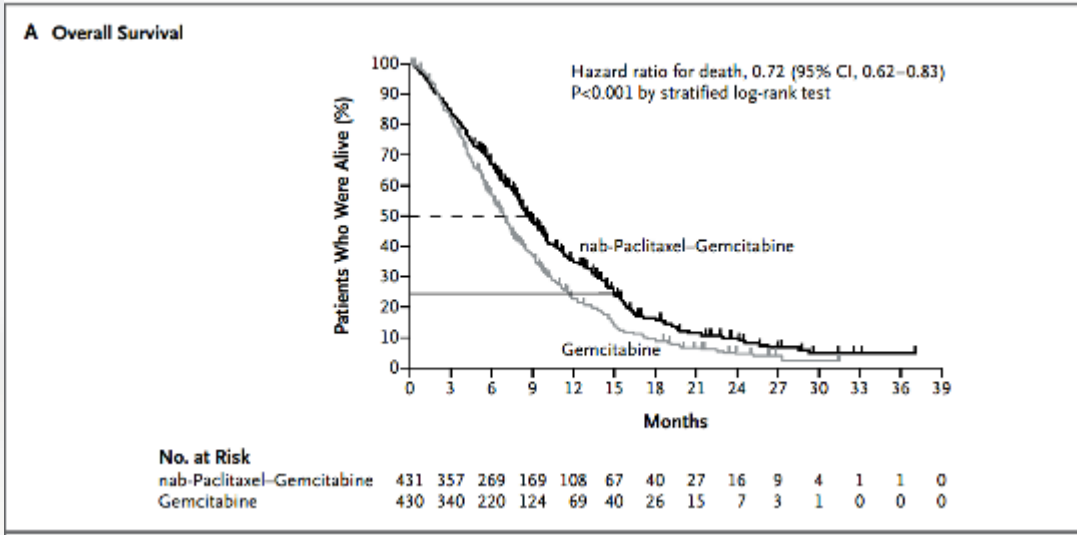
### Soon to be second leading cause of cancer-related death in US

*Three Drugs Approved by FDA to Treat PDAC within Past 10 Years*

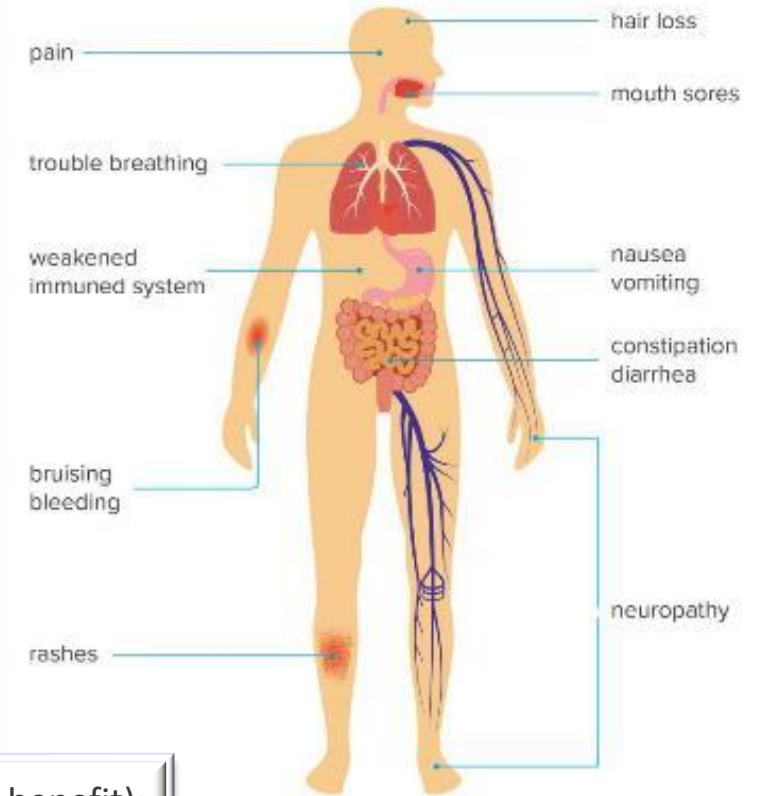
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# All Three FDA Approvals (Abraxane, Olaparib, Onivyde) in past 10-years observed <2mo Median Overall Survival Benefits and Increases in Toxicity Rates

## Highlighting FDA continued concordance of Pancreatic Cancer as High Unmet Need



**38% Grade 3 or Higher Neutropenia and 17% Neuropathy**



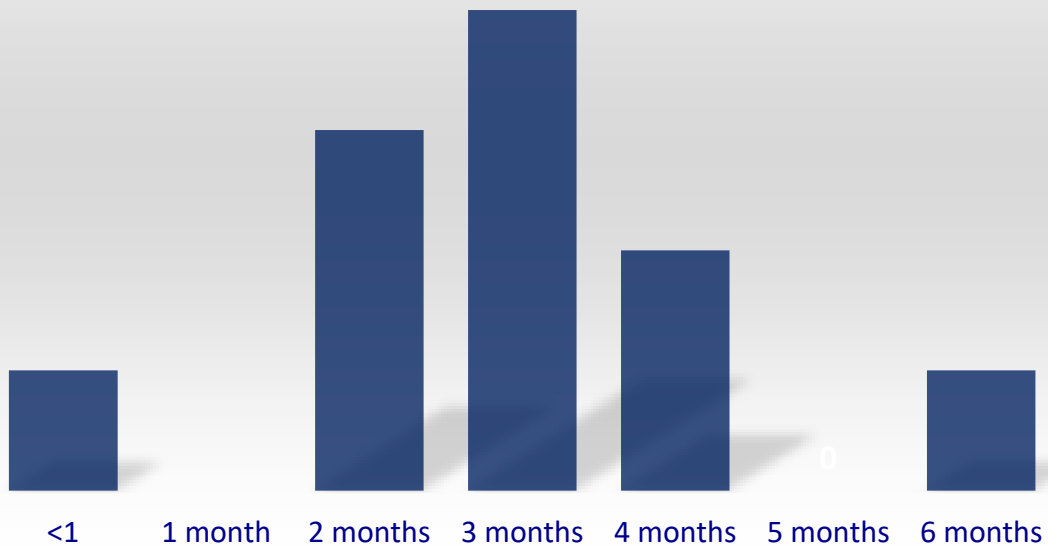
Nab-paclitaxel (Abraxane) obtained FDA approval in 2013 on a 7-week Median Overall Survival benefit

Olaparib received full FDA approval in 4Q 2019 with no Median Overall Survival Difference (a <4-mo PFS benefit);

Onivyde received FDA approval on a 1.9-mo Median OS benefit in 2015

# Independent Interviews suggest Community & Academic Medical Oncologists *Likely* to Adopt RenovoGem™ if ~4-month Overall Survival Benefit and Toxicity Improvement

Minimum OS Benefit Over Standard of Care  
RenovoGem Must Demonstrate



“Any amount of time, if it is from a phase III. **We started using erlotinib about 15 years ago based on a 14-day benefit.**” Abushahin, MedOnc, Ohio State

The idea of an infusional therapy, **avoiding systemic toxicity is appealing.**” Iyer, MedOnc, Roswell

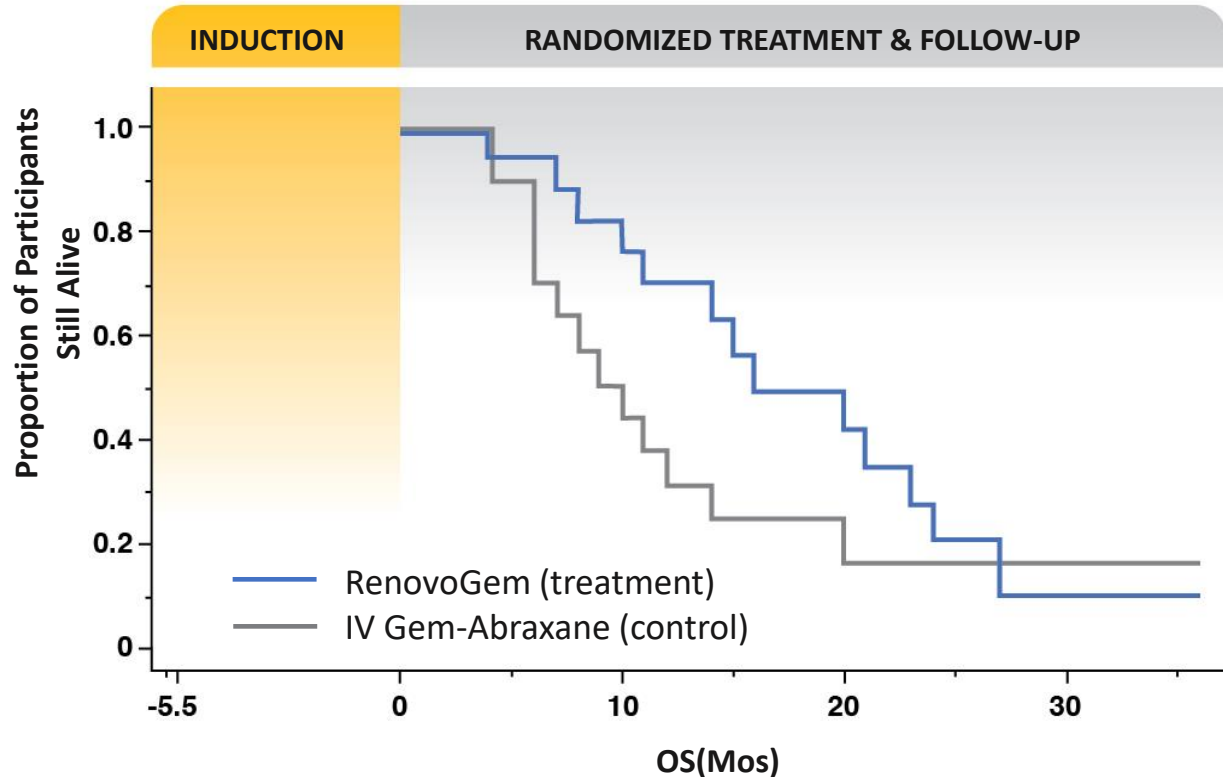
This targets local vessel involvement and **you can up the delivery of concentration.**” Astsaturon, HemOnc, Fox Chase

“What do we do with the [unresectable] patients that don’t develop metastatic disease for a while? We’ve essentially talked only about two lines of treatment. But eventually **toxicity builds up** and they can’t tolerate treatment. For that subset of patients...it would be **highly attractive to offer them something like this.**” Mettu, MedOnc, Duke

Source: FSI Interviews (multiple responses permitted per respondent)

# RR3 TIGeR-PaC Phase III Data Update (1<sup>st</sup> Interim Analysis):

RenovoGem Arm observes 6-month Median Overall Survival benefit over IV Gem-Abraxane (control)



Data Presented at AACR 2023



## Data on 45 patients Randomized

- 23 randomized to RenovoGem
- 22 randomized to IV gem/Abraxane (control)

## Median Overall Survival (OS) Difference: 6-months

IV Gem Abraxane (control arm)



RenovoGem (test arm)

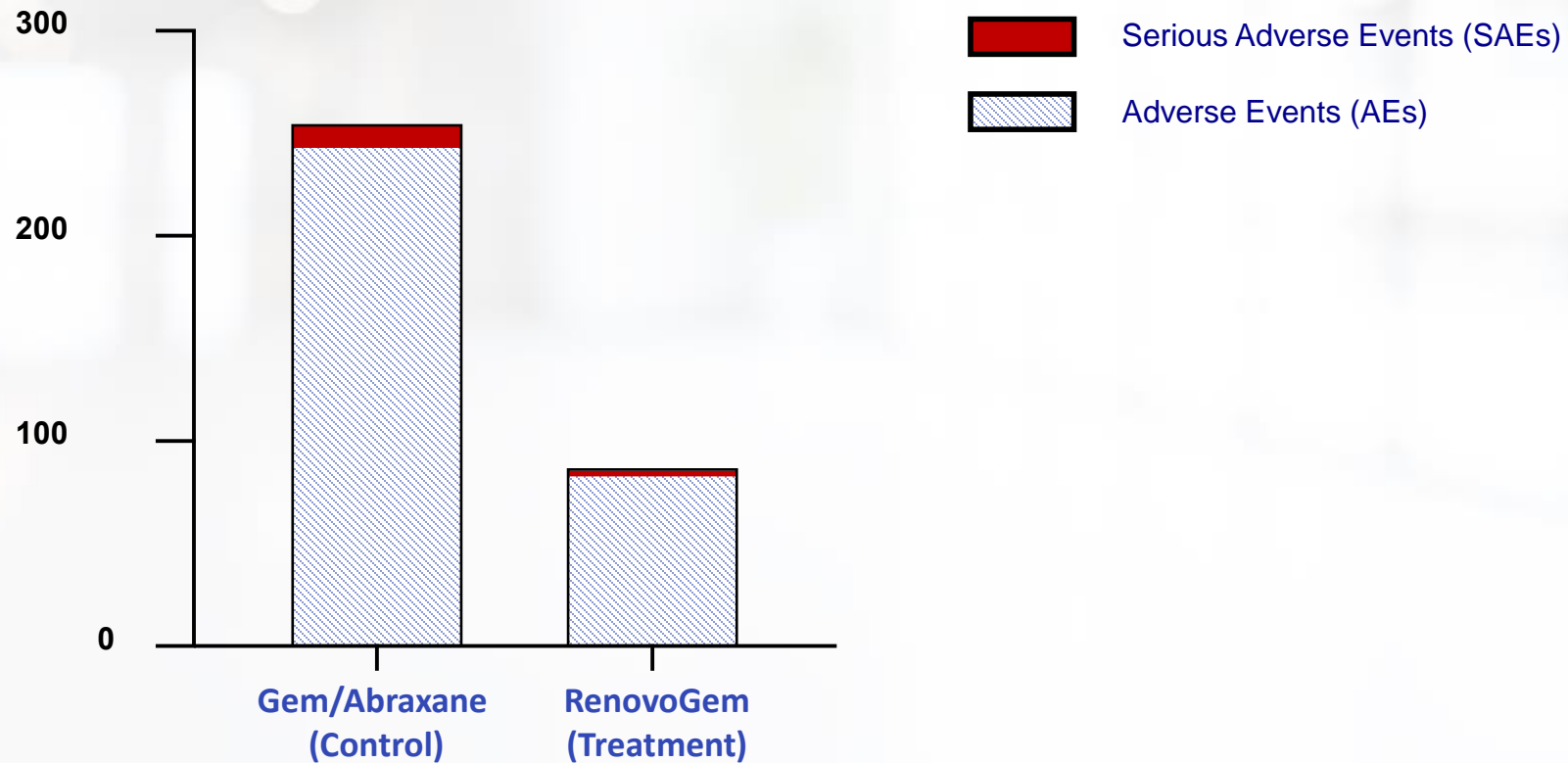


Statistical significance was not reached to stop the study early

# RR3 TIGeR-PaC Phase III Data Update (1<sup>st</sup> Interim Analysis)

RenovoGem (treatment) arm observes >65% Fewer AEs and SAEs compared to standard of care systemic/IV Gem/Abraxane (control), Despite Novel Procedure

## Total AEs and SAEs



# Locally Advanced Pancreatic Cancer Market Opportunity\*

**\$1B**

MARKET  
OPPORTUNITY\*

US: \$500M  
REST OF WORLD: \$500M

## New Orphan Drug Product Regulatory and Reimbursement:

- **Orphan Drug Protection** (2 indications)
- Will submit New Drug Application (NDA) approval for RenovoGem
- **National Drug Code (J-Code) reimbursement** upon FDA NDA approval

## New Oncology Drug Market

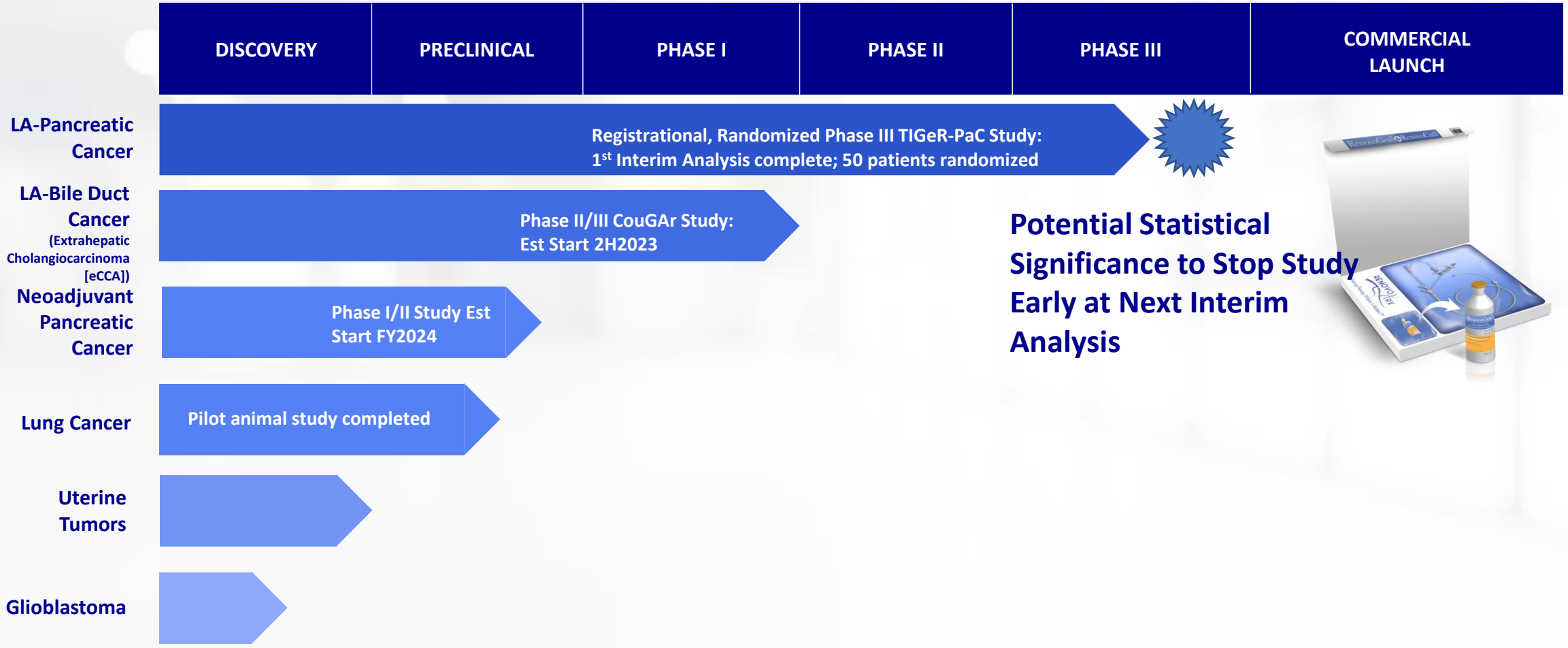
Average new oncology drug pricing: \$150,000/year\*

*Prospective/formal pricing analysis to be conducted with Phase III data prior to commercial launch of RenovoGem*

\*Fletcher Spaght, 2019



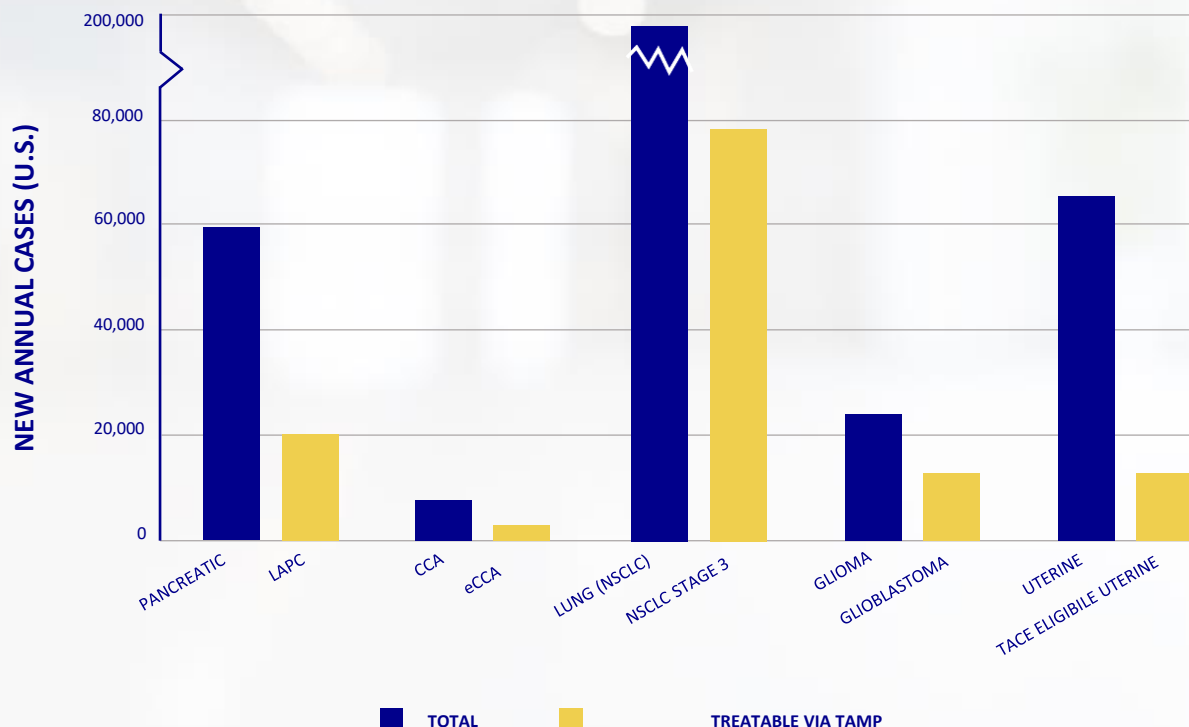
# RenovoGem Product Development Plan



**Potential Statistical Significance to Stop Study Early at Next Interim Analysis**



# RenovoGem Broad Market Opportunity in Target Cancers



## US Annual Incidence of Initial RenovoGem Target Tumor Types

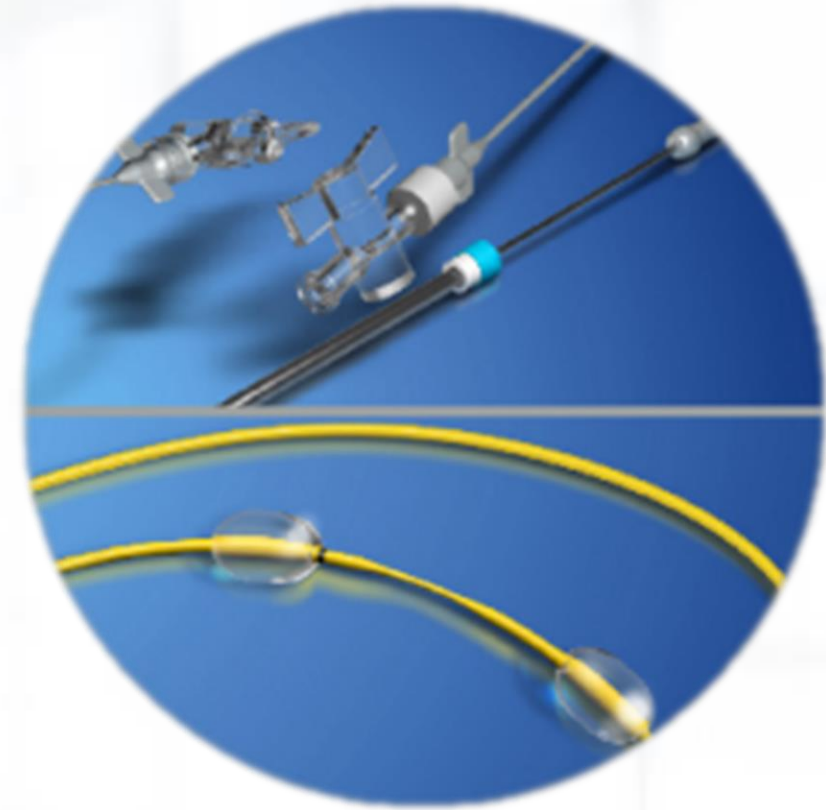
- 350,000 total patients diagnosed/year
- ~125,000 all locally advanced (stage 3) potentially addressable via RenovoGem

**TAMP is broadly applicable to locally advanced tumors:**

Platform may be used with multiple small molecule chemotherapeutic agents in multiple solid tumor indications

# Trans-Arterial Micro-Perfusion (TAMP) Proprietary Drug Delivery Platform

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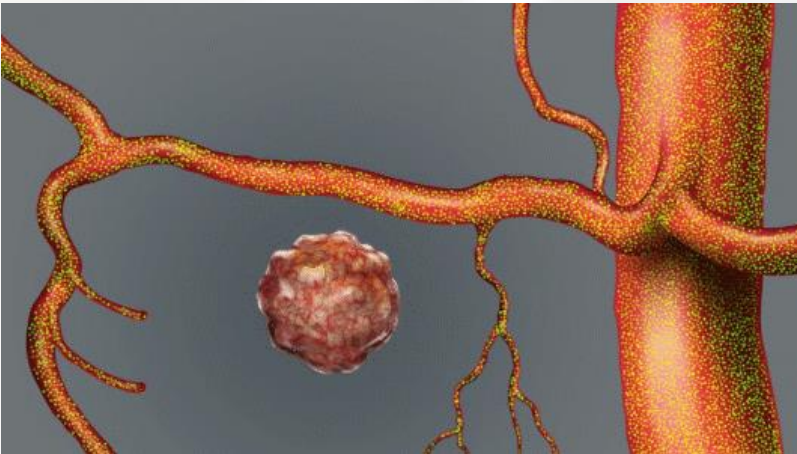
# A New Way: We Are Addressing a Significant Problem in Cancer Treatment



## Hypervascular tumors are adequately treated with current therapies

Liver tumors are highly vascularized

- Large tumor feeders – excellent targets for systemic therapy
- Can be accessed and treated with current local therapy techniques



## Hypovascular tumors = major barrier to chemotherapy treatment success

Pancreatic tumors have poor blood supply

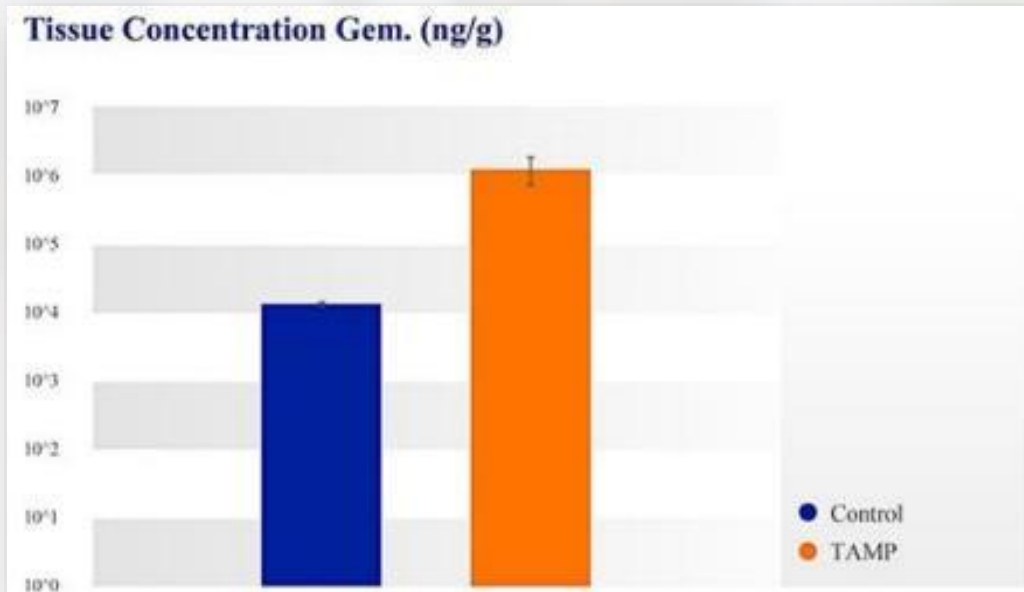
- No visible tumor feeder vessels
- Systemic chemotherapy does not reach tumor tissue
- Inability to identify or engage tumor feeder vessels: local therapy is ineffective

# TAMP Improves a Drug's Therapeutic Index

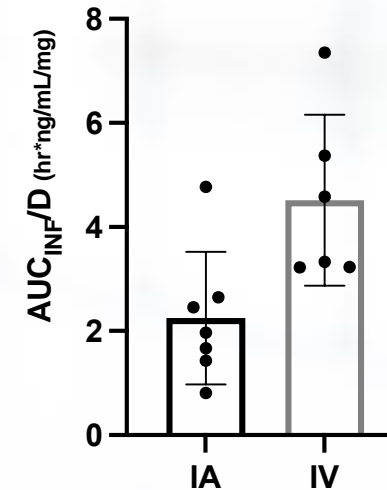
Higher Amounts of Drug to Pathological Site (↑ Efficacy) & Less Systemic Exposure (↑ Safety)

Increases Drug Concentration to Target Pathological Site by ~100X\* Compared to IV Administration\*

Reduces Drug AUC by >50% Compared to IV Administration<sup>+</sup>



Drug Exposure IA vs. IV route



Impact of route of administration on Drug Exposure Area Under the Curve-Normalized for Total Dose (hr\*ng/mL/mg, p<0.015)

\*As demonstrated in animal studies

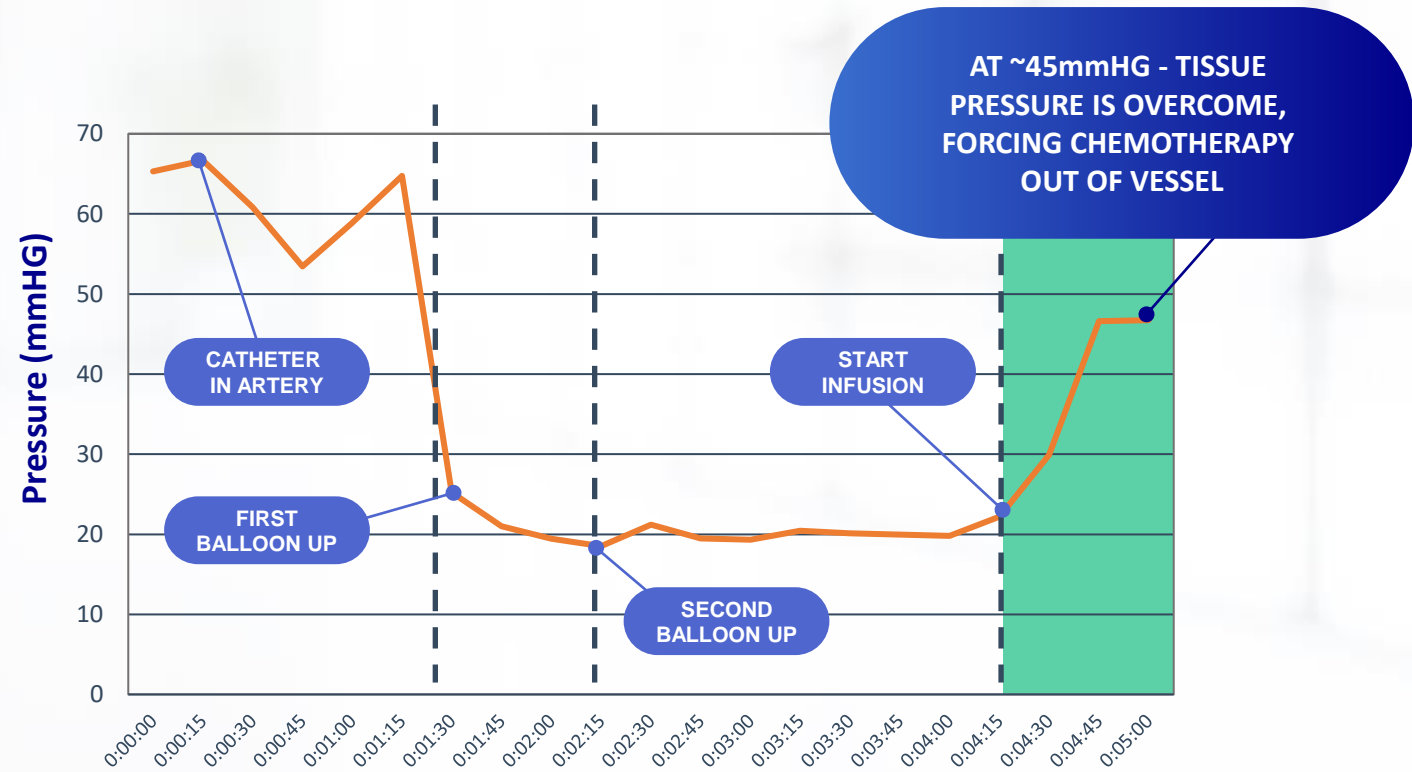
<sup>+</sup> Sub-study performed in Phase 3 TIGeR-PaC study =- presented at ASCO-GI 1023

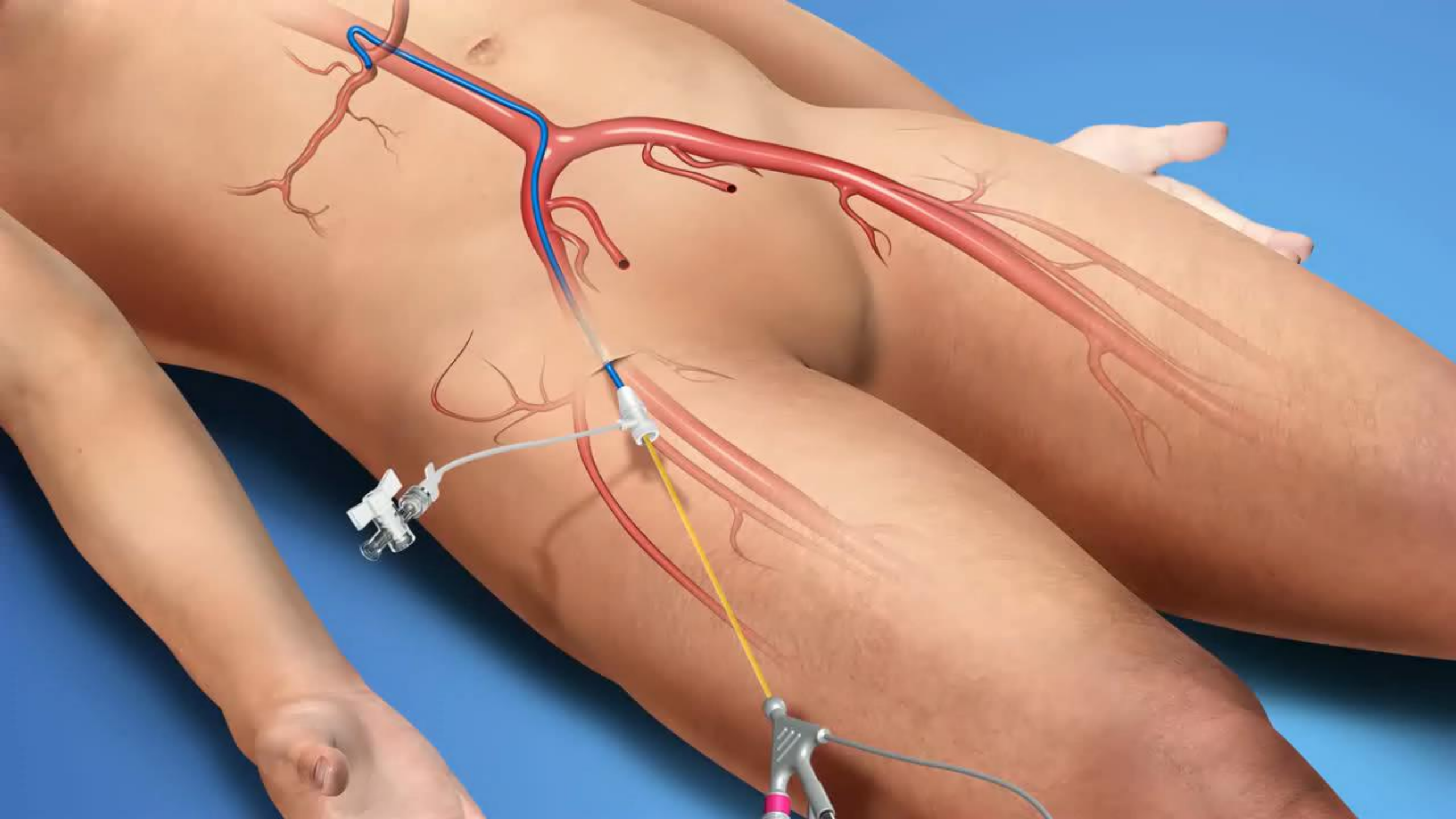
# Our Solution: Trans-Arterial Micro-Perfusion (TAMP) Delivery System

## An Enabling Technology For Therapeutic Delivery in Solid Tumors



Mechanism: after vessel isolation, increase in pressure forces drug across the artery wall into the micro-vasculature into tumor tissue





# RenovoGem Patient & Physician Experience

Fewer hospital/clinic visits for patients

Easy to learn, quick procedure for interventional radiologists/oncologists

## Patient Experience

20-minute infusion; ~90-minute outpatient procedure (shorter for subsequent procedures)

8 treatments over 4-months (2x/month hospital visits)

33% less hospital/clinic visits compared to IV Administration (*more time at home with family*)

## Clinician Experience

Similar techniques used in liver directed therapies

Shallow learning curve

Physicians demonstrate expertise after 2-3 proctored procedures



## Targeted Approach: Designed to Decrease Side Effects and Increase Tumor Penetration

- Reduced systemic drug exposure (compared to systemic chemotherapy)
- Higher local drug concentration

## Phase III Lead Drug Product Candidate: RenovoGem

- Drug/Device Combination:
  - Intra-arterial gemcitabine (chemotherapy) delivered through FDA cleared RenovoCath delivery system
- Randomized open label registrational Phase III TIGeR-PaC positive interim analysis data released at AACR 2023:
  - 6-month survival benefit
  - 65% reduction in side effects
- Additional Phase III data to be presented at ESMO World GI June 29, 2023

## Can be Applied to Locally Advanced Solid Tumors

- Initial indications: pancreatic cancer (\$1B addressable market) and cholangiocarcinoma
- Potential future indications include non-small cell lung cancer, uterine tumors, glioblastoma, sarcoma
- With AI-imaging techniques and liquid biopsies detecting cancer earlier, a rapidly growing patient population

## Novel Therapy Platform: TAMP

- Trans-Arterial Micro-Perfusion compatible with multiple potential targets
- Platform expanding pre-clinical studies underway

## TAMP Platform: Layers of Market Exclusivity (Regulatory and IP)

- 8 US patents issued on TAMP, delivery system, and drug/device combination
- Orphan Drug Designation for Pancreatic Cancer and Cholangiocarcinoma provides 7 years of market exclusivity for RenovoGem upon NDA approval

# Experienced Management Team Supported by World Class Board of Directors



**Shaun R. Bagai**  
Chief Executive Officer & Board Member  
  
HeartFlow (\$1B+ raised)  
Ardian (acq for > \$900M)  
Medtronic Vascular  
TransVascular



**Ramtin Agah, MD**  
Chief Medical Officer,  
Founder & Chairman of the Board  
  
Interventional Cardiology,  
Sutter Health; Consultant  
Abbott Vascular



**Angela Gill Nelms**  
Chief Operating Officer  
Florence Healthcare  
Emory University School  
of Medicine  
Medtronic



**Leesa Gentry**  
Senior Vice President of  
Clinical Operations  
  
Evotec  
Otsuka America  
Pharmaceuticals  
Omnicare Clinical Research



**James Ahlers**  
Chief Financial Officer  
  
Intactria Therapeutics;  
Titan Pharma; Ansan  
Pharma

## Led or Contributed to the Development of



**David Diamond**  
Board Member  
  
Fmrly Board Oncotelic  
Therapeutics



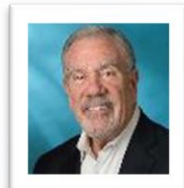
**Una S. Ryan,  
PhD, OBE**  
Board Member  
  
Board: Cortextyme,  
Elemental Machines



**Laurence J.  
Marton, MD**  
Board Member  
  
Board: Cellsonics, TOMA  
Biosciences, xCures



**Angela Macfarlane**  
Board Member  
  
CEO, Perceive  
Biotherapeutics (\$78M  
raised led by JJDC)  
CEO Foresight Labs



**Robert J. Spiegel, MD**  
Board Member  
  
CMO, PTC Therapeutics  
CMO, Schering-Plough (\$41.1B  
merger with Merck)

>200 years of combined development / commercial experience

Contributed to 30+ successful New Drug Application filings with the Food and Drug Administration

Launched multiple blockbuster drugs

Served as executives or board members in companies acquired by Medtronic, Roche, Merck, and Allergan

# Upcoming Milestones

**Phase III pancreatic cancer interim analysis/secondary endpoint Oral Abstract presentation at ESMO – World GI**

Publication of Final Pre-Phase III Data for pancreatic cancer

Identification of third Indication: Clinical trial design and study launch

**Phase II/III CouGAR eCCA Study launch (second indication)**

**2nd Interim Analysis: TIGeR-PaC Phase III pancreatic cancer study**

Enrollment and randomization completion: TIGeR-PaC Phase III pancreatic cancer study

Final Data Readout: TIGeR-PaC Phase III pancreatic cancer study



# Financial Highlights

**\$3.7M**

CASH & INVESTMENTS\*  
(AS OF 3/31/23)

**\$5M**

ADDITIONAL GROSS PROCEEDS FROM  
REGISTERED DIRECT OFFERING  
(CLOSED 4/23)

**9%**

OFFICER & DIRECTOR  
OWNERSHIP  
(AS OF 5/1/23)

**\$2.08**

RNXT/SHARE  
(AS OF 6/02/23)

**\$21M**

MARKET CAPITALIZATION  
(AS OF 6/02/23)

**10.7M**

SHARES OUTSTANDING  
(AS OF 4/4/23)

# Investment Opportunity

- De-risked drug development and validated TAMP approach
- Large first indication market (\$1B) and platform broadly applicable to growing market segment
- Experienced clinical and commercial Leadership Team and Board
- **First RenovoGem Phase III interim analysis completed Q1 '23 – presented positive results at AACR 2023:**
  - **6-month survival benefit**
  - **>65% reduction in side effects**
- **2<sup>nd</sup> Phase III interim analysis data presentation at ESMO World GI 6/29/23**

# Delivering therapy where it matters<sup>®</sup>

NASDAQ | RNXT



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