# RENOVO | RX



# Investor Presentation

Delivering therapy where it matters®

September 2025

# **Cautionary Note Regarding Forward-Looking Statements**

This presentation and statements of the Company's management made in connection therewith contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934, including but not limited to statements regarding (i) the potential of RenovoCath® or TAMP™ as standalone commercial products, the estimated maximum total annual sales and addressable market for RenovoCath® and our commercialization plans in general, (ii) the prospects of our marketing and sales strategies, (iii) our clinical trials and studies, including the overall timing and timing for additional interim data readouts and patient enrollment for our ongoing TIGeR-PaC Phase III clinical trial study in LAPC, (iv) the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases and (v) our commercialization strategies utilizing our TAMP technology. Statements that are not purely historical are forward-looking statements. These statements may be identified using words such as "may," "expects," "plans," "aims," "anticipates," "believes," "forecasts," "estimates," "intends," and "potential," or the negative of these terms or other comparable terminology. Forward-looking statements are based upon our current expectations and beliefs regarding future events, many of which, by their nature, are inherently uncertain, outside of our control and involve assumptions that may never materialize or may prove to be incorrect. These may include estimates, projections and statements which are based on current expectations and assumptions that are subject to known and unknown risks and uncertainties that may cause actual results to differ materially and adversely from those expressed or implied by these forward-looking statements. These risks include, among others: (i) the risk that our exploration of commercial opportunities for our TAMP technology may not lead to viable, revenue generating or profitable operations; (ii) circumstances which would adversely impact our ability to efficiently utilize our cash resources on hand or raise additional funding; (iii) the timing of the initiation, progress and potential results (including the results of interim analyses and the timing for patient enrollment) for TIGeR-PaC and any other preclinical studies, clinical trials and our research programs; (iv) the possibility that interim results may not be predictive of the outcome of our clinical trials, which may not demonstrate sufficient safety and efficacy to support regulatory approval of our product candidate; (v) that the applicable regulatory authorities may disagree with our interpretation of the data and cause delays in research and clinical development plans and timelines, and the regulatory process for our product candidates; (vii) future potential regulatory milestones for our product candidates, including those related to current and planned clinical studies; (vii) our ability to use and expand our therapy platform to build a pipeline of product candidates; (viii) our ability to advance product candidates into, and successfully complete, clinical trials; (ix) the timing or likelihood of regulatory filings and approvals; (x) our estimates of the number of patients who suffer from the diseases we are targeting and the number of patients that may enroll in our clinical trials; (xi) the commercialization potential of our other product candidates, if approved; (xii) our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; (xiii) future strategic arrangements and/or collaborations and the potential benefits of such arrangements; (xiv) our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; (xv) the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements; (xvi) our ability to retain the continued service of our key personnel and to identify, and hire and retain additional qualified personnel; (xvii) the implementation of our strategic plans for our business and product candidates; (xviii) the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform, product candidates and research programs; (xix) the pricing, coverage and reimbursement of our product candidates, if approved; and (xx) developments relating to our competitors and our industry, including competing product candidates and therapies. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in documents that we file from time to time with the Securities and Exchange Commission. Forward-looking statements included herein are made as of the date hereof, and RenovoRx does not undertake any obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as required by law.

# **RenovoRx Investment Highlights**



Developing combination therapies based on proprietary Trans-Arterial Micro-Perfusion (TAMP<sup>TM</sup>) platform

FDA Orphan Drug Designation granted to lead device/drug combination product candidate (RenovoCath plus Gemcitabine) in pancreatic and bile duct cancers.



Initiated commercialization of FDA-cleared RenovoCath® 2025; 1H '25 revenues exceeded expectations

Established customer demand and reimbursement dynamics driving organic growth. Thirteen cancer centers from other medical institutions have been approved to purchase the device, with four of these centers currently using the device with patients as of 8/14. Over 20 additional potential customers in discussions.



Advancing pivotal Phase III TIGeR-PaC study for the treatment of locally advanced pancreatic cancer (LAPC)

Observed increased OS and PFS, with 65% reduction in adverse effects in 1st interim analysis. The 52nd event occurred in Q2 2025, triggering 2nd interim analysis. The independent Data Monitoring Committee recommended continuation of the study. Enrollment completion expected late 2025 or early 2026.



Pursuing initial ~\$400M¹ potential peak annual U.S. revenue opportunity for RenovoCath as a stand-alone device

Opportunity over time to expand potential RenovoCath use applications and estimated TAM of several billion dollars, with patent protection until 2038.



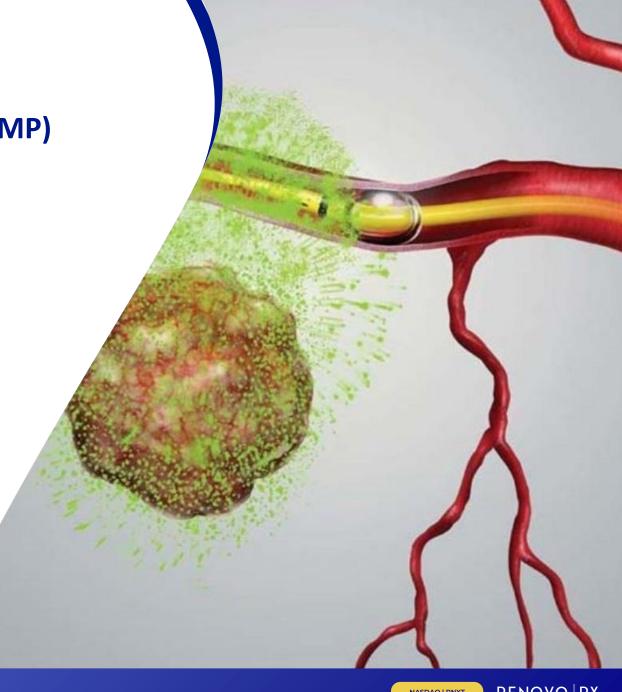
Led by experienced Leadership Team and Board of Directors

Expertise in clinical development and commercial execution at scale in pharma, medical device, and combination therapy companies.

<sup>&</sup>lt;sup>1</sup> Based on Internal RenovoRx Estimates

**Proprietary Trans-Arterial Micro-Perfusion (TAMP) Therapy Platform** 

Enabled by RenovoCath



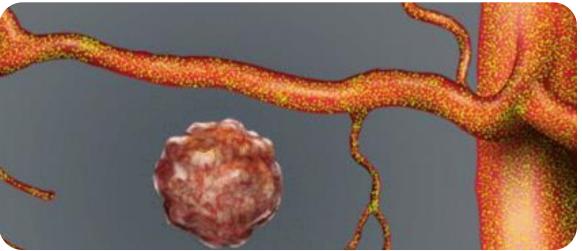
# **Addressing a Significant Problem in Cancer Treatment**





#### For example, liver tumors are highly vascularized

- Large tumor feeders excellent targets for systemic therapy
- Can be accessed and treated with current local therapy techniques
- Despite the abundance of blood vessels, systemic therapy may not always be effective due to drug delivery challenges
- Techniques like trans-arterial chemoembolization (TACE) and radioembolization are commonly used

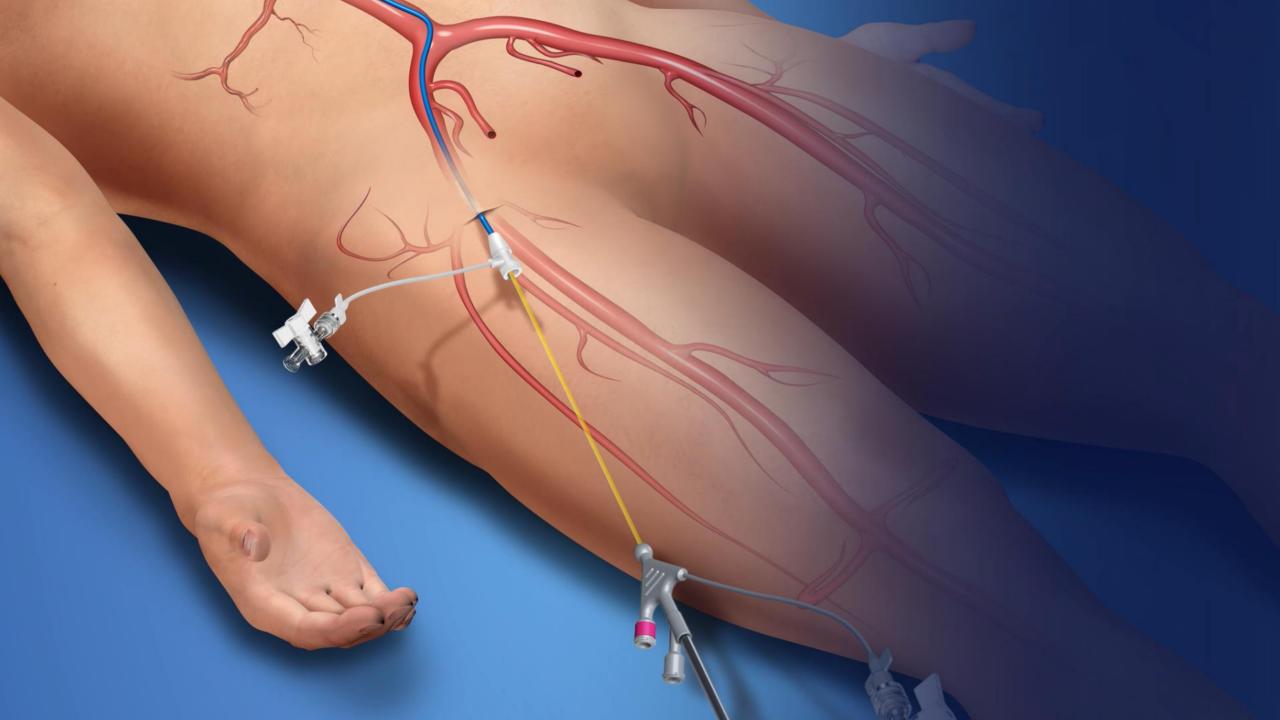


#### Hypovascular tumors = major barrier to chemotherapy treatment success

#### Many tumors, like pancreatic tumors have poor blood supply

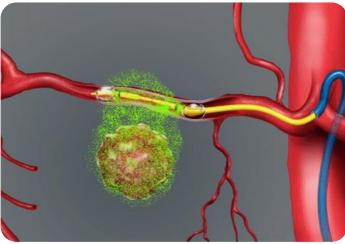
- No visible tumor feeder vessels
- Systemic therapy does not reach tumor tissue
- Inability to identify or engage tumor feeder vessels: local therapy is ineffective
- Poor perfusion impacts drug delivery, leading to lower treatment efficacy

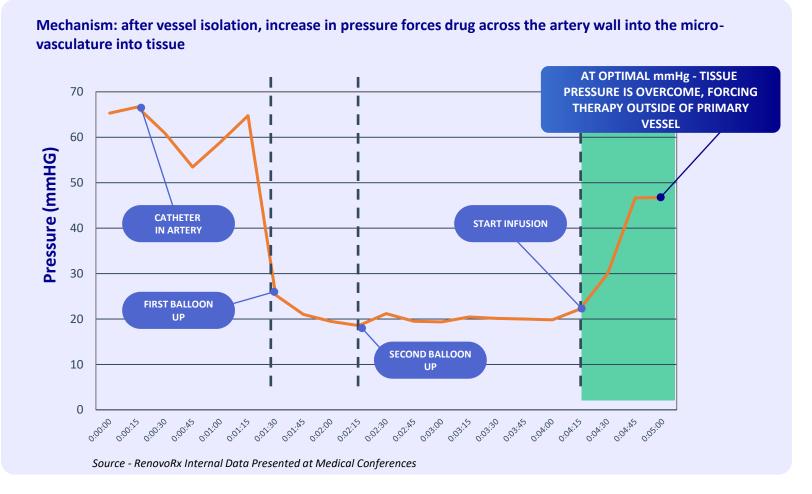
RenovoRx Addresses this Unmet Medical Need



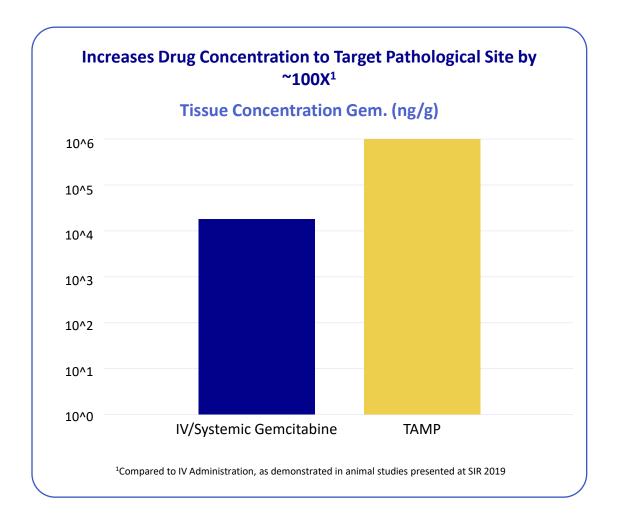
# **Mechanism: Trans-Arterial Micro-Perfusion (TAMP)**

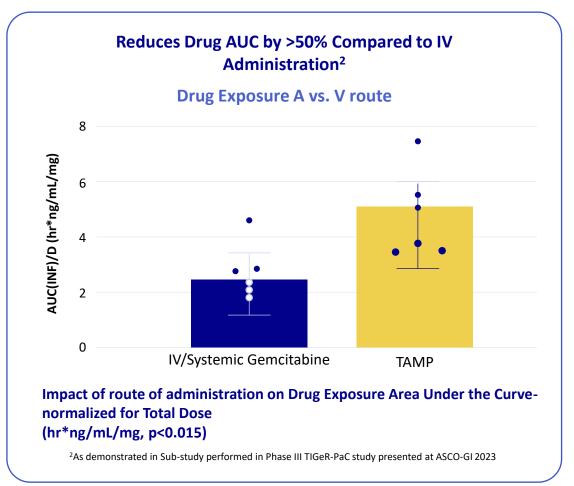






# **TAMP Improves a Drug's Therapeutic Index**





# **Patient and Clinical Experience**

#### RenovoCath

#### **RenovoCath Patient Experience**

- 8 treatments over 4-months (2x/month hospital visits) with disposable device (no implant)
- 20-minute infusion; ~90-minute <u>outpatient procedure</u> (shorter for subsequent procedures)
- Patients not put under general anesthesia (only conscious sedation for comfort)

#### RenovoCath Physician Experience

- Easy to learn and quick procedure for interventional radiologists / oncologists
- Transferrable techniques utilized in liver directed therapies resulting in fast learning curve for physicians
- Physicians demonstrate expertise after 2-3 proctored procedures and are able to train their colleagues

#### **Other Treatment Options**

#### **Other Patient Experience**

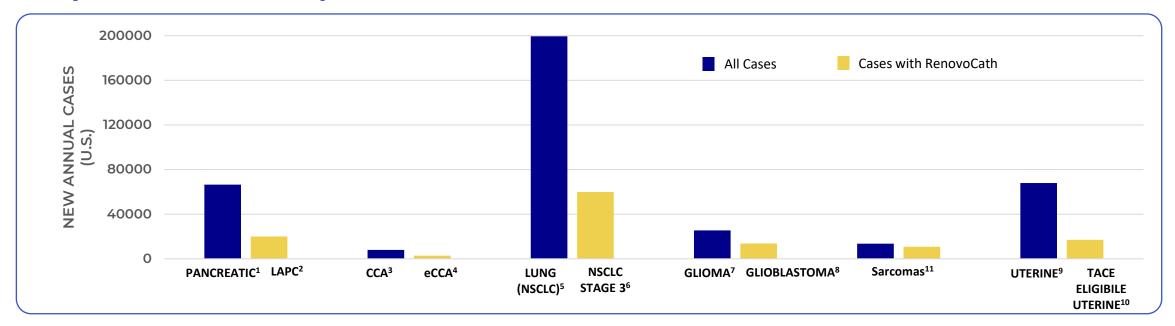
- Traditional systemic gem/Abraxane: 12 hospital/clinic visits over
   4-month period
- Other technologies require overnight stay
- Other technologies require general anesthesia
- Systemic chemo associated with days of lasting side effects

#### **Other Physician Experience**

 Majority of novel technologies require large sales/physician proctor effort with training courses and/or on-site support for every procedure



# Physicians Have Expressed Interest in RenovoCath Across Broad Market



#### **US Annual Incidence of Initial RenovoCath Estimated Usage**

- o RenovoCath is broadly applicable to solid tumors
- RenovoCath may be used with additional agents in multiple solid tumor indications
- Multibillion dollar opportunity in the United States with meaningful global potential for expansion

- <sup>1</sup> https://seer.cancer.gov/statfacts/html/pancreas.html
- <sup>2</sup> https://pmc.ncbi.nlm.nih.gov/articles/PMC4746088/
- <sup>3</sup> https://journals.lww.com/cmj/Fulltext/2022/03050/Cancer\_statistics\_in\_China\_and\_United\_States,.11.aspx
- 4 https://journals.lww.com/cmj/Fulltext/2022/03050/Cancer\_statistics\_in\_China\_and\_United\_States,.11.aspx
- <sup>5</sup> https://seer.cancer.gov/statfacts/html/lungb.html
- <sup>6</sup> https://pmc.ncbi.nlm.nih.gov/articles/PMC10047909/
- <sup>7</sup> https://seer.cancer.gov/statfacts/html/brain.html

https://www.ncbi.nlm.nih.gov/books/NBK470003/#: ``:text=Glioblastoma%20(GBM)%20 is %20 the %20 most%20 aggressive %20 diffuse %20 lioma%20 of %20 astrocytic, primary %20 brain %20 tumors %20(2).

- <sup>9</sup> https://seer.cancer.gov/statfacts/html/corp.html
- <sup>10</sup> https://journals.lww.com/cmj/Fulltext/2022/03050/Cancer\_statistics\_in\_China\_and\_United\_States,.11.aspx
- <sup>11</sup> https://www.cancer.org/cancer/types/soft-tissue-sarcoma/about/key-statistics.html

Disclaimer - This data is based upon independent interviews conducted by Fletcher Spaght, Inc. in 2019. Intra-arterial delivery of gemcitabine via the RenovoCath® is currently in an ongoing Phase III randomized multi-center study evaluating its use for the treatment of locally advanced pancreatic cancer, this drug/device combination has not been approved by the FDA or any regulatory authority and is limited to investigational use only. The mechanism of action for this combination is theoretical only, based on currently available scientific evidence and product design, and may not be reflective of what happens in the human body. RenovoCath® is cleared for the delivery of agents (diagnostic or therapeutic) to the peripheral vascular system and for chemotherapeutic drug infusion with agents based on their manufacturer's label. RenovoCath's full indication for use is available here: https://renovorx.com/for-clinicia ns/. The efficacy and safety using RenovoCath® with specific agents and in specific clinical settings has not yet been established and RenovoRx makes no claims to such uses.



# Potential High Margin, Large Market Opportunity for RenovoCath Device Alone

# **RenovoCath Market Opportunity**

Analogous pressure-mediated delivery catheter ASPs	\$6k-\$8.5k/unit <sup>1</sup>
Annual average procedures	5-8+ per patient <sup>2</sup>
Initial peak U.S. addressable market	\$400M³

<sup>&</sup>lt;sup>1</sup> - https://trisaluslifesci.com/wp-content/uploads/2025/01/TLSI-corporate-deck-011425-Final-2.pdf

• Most-recently filed cases expire after 2043
• TAMP-specific cases (covering pressure mediated trans-arterial delivery) expire 2038
• RenovoRx kit claims expires 2032
• Dual-occlusion device patent expires 2031
• First RenovoRx patent expires December 2030

Areas of Expressed Interest by Physicians in the U.S.

- ~67k Patients
- ~7k Patients where
   RenovoCath has clinical data

RenovoRx now holds a robust IP portfolio of 19 issued patents (9 U.S.) and 12 pending patents

Most recent patent expires 2043

**Disclaimer** - We have based our estimates of total addressable market size, peak annual sales projections and similar matters above and elsewhere in this presentation on our market research, third party reports and publicly available information which we consider reliable. However, readers are cautioned our projected sales and similar metrics are merely our current, preliminary estimates and are subject to many risk factors, many of which are or may be beyond our control. As such, no assurances are given that such estimates will prove to be accurate.

<sup>&</sup>lt;sup>2</sup> - Rosemurgy et al 2017 and TIGeR-PaC design (101 cycles over 20 pts; 8 catheterizations)

<sup>&</sup>lt;sup>3</sup> - Based on Internal RenovoRx Estimates

# RenovoCath Commercialization Strategy

#### **Go-To-Market Strategy**



Deepen relationships with high volume users



#### **Expand relationships with KOLs**

(surgical oncologists, medical oncologists, and interventional radiologists)

- Customer pipeline expands including high volume NCI designated centers as of August 2025
- Build on 1H 2025 RenovoCath revenues of ~ \$600,000
- 13 cancer centers approved to purchase the device, an increase from five centers in Q1 2025. Four of these centers have used the device in patients, and all have made repeat purchase orders subsequently.
- 18 cancer centers that have used RenovoCath as part of TIGeR-PaC likely to convert to commercial after enrollment completion
- Initiated the hiring of 3–5 sales representatives to target this focused market. This lean, high-impact team is designed to drive meaningful penetration while maintaining efficiency and capital discipline.

# RenovoCath potential high-volume centers<sup>1</sup>



Fewer than 200 hospitals treat majority of estimated patients where RenovoCath is seeing interest in utilization

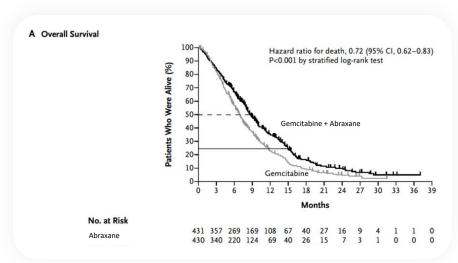
Average number of patients per hospital in areas of expressed interest with RenovoCath: 6-12+ per year<sup>2</sup>

**Pivotal Phase III TIGeR-PaC** Clinical Trial (NCT03257033) in **Locally Advanced Pancreatic** Cancer (LAPC)



# **Significant Unmet Need**

Three FDA approvals in last 10 years experienced less than two months median overall survival and increased toxicity<sup>1</sup>

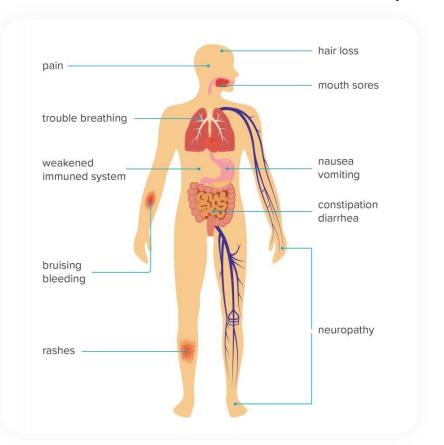


Abraxane obtained FDA approval in 2013 on a **7**week Median Overall Survival benefit<sup>2</sup>



38% Grade 3 or Higher Neutropenia and 17% Neuropathy<sup>4</sup>

Olaparib received full FDA approval in 4Q 2019 with no Median OS Difference (<4-mo PFS benefit); Onivyde received FDA approval on a 1.9-mo Median OS benefit in 2015<sup>3</sup>.



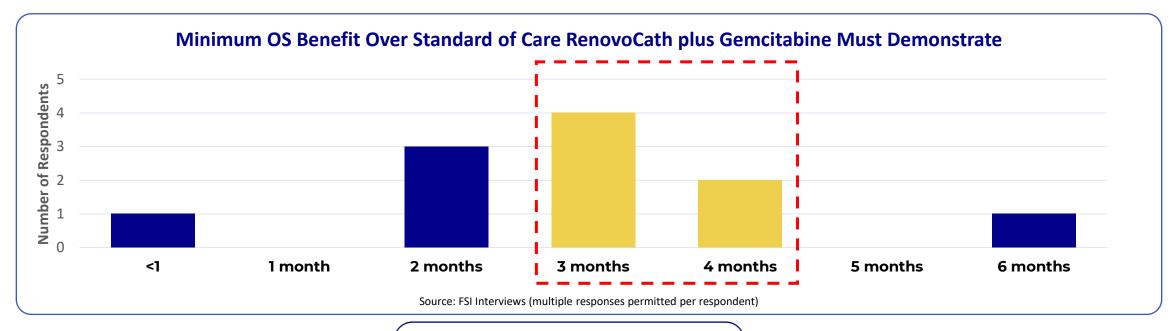
<sup>&</sup>lt;sup>1</sup> https://www.cancer.gov/news-events/cancer-currents-blog/2015/irinotecan-liposome-pancreatic

<sup>&</sup>lt;sup>2</sup> https://www.accessdata.fda.gov/drugsatfda\_docs/nda/2013/021660Orig1s037.pdf

³ https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-olaparib-gbrcam-metastatic-pancreatic-adenocarcinoma

<sup>&</sup>lt;sup>4</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7479547/

# Potential Market Penetration Based on Modest Efficacy from TIGeR-PaC



#### **Testimonials**

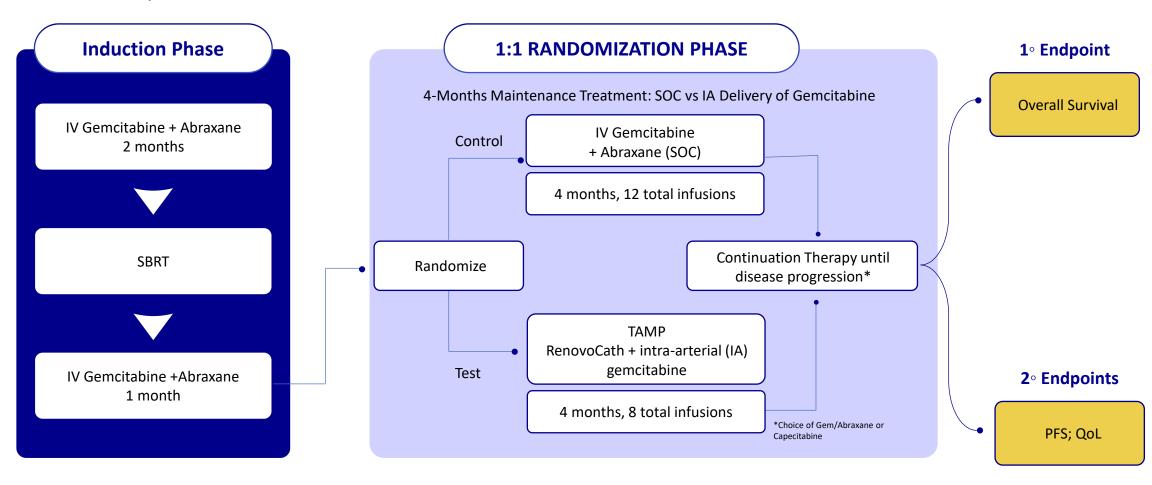
"Any amount of time, if it is from a phase III. We started using erlotinib about 15 years ago based on a <u>14-day</u> <u>benefit.</u>" -Abushahin, MedOnc, The Ohio State University "The idea of an infusional therapy, avoiding systemic toxicity is appealing." -Iyer, MedOnc, Roswell "This targets local vessel involvement and you can up the delivery of concentration." -Astsaturov, 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

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# **RR3 TIGeR-PaC: Randomized Combo Product Clinical Trial**

TAMP Delivery of IA Gemcitabine via FDA Cleared RenovoCath



First Pre-Planned Interim Analysis presented at AACR and ESMO GI 2023

# **Statistics and Trial Status**

Interim Analysis	Percent of Final Analysis Events	Total Number of Observed Events (Deaths) to Trigger Analysis	Incremental Significance Level at time of Interim Analysis
First	30%	26	0.0001
Second	60%	52	0.008
Final	100%	86	0.048

# **Statistical Design**

- Sample Size = 114 randomized patients
- Primary Endpoint: Overall Survival from the time of randomization
- $\circ$  Study designed to have a 80% power to detect a hazard ratio of 0.6 using the stratified Wilcoxin test at 2-sided α = 0.048

#### **Enrollment Status**

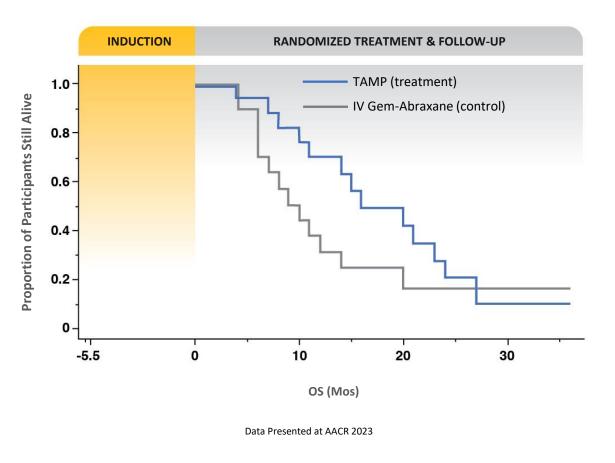
- As of August 12, 2025, 95 patients have been randomized, and 61 events have occurred
- Enrollment completion expected late 2025 or early 2026.

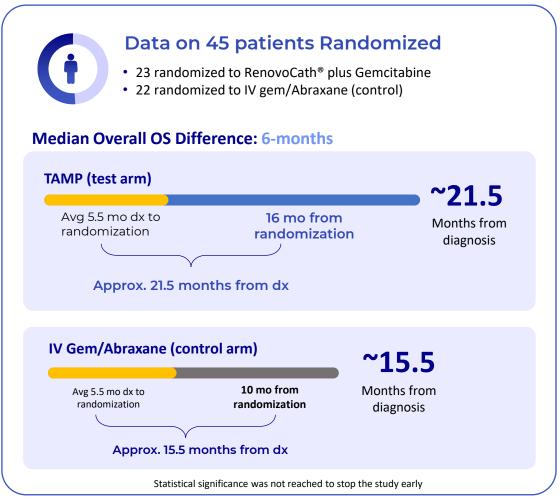
# **Preplanned Endpoint Status**

- First interim analysis COMPLETED 2023 Presented 6-month survival improvement and 65% reduction in side effects
- Second interim analysis COMPLETED Aug 2025 -Data Monitoring Committee recommended continuation of the study

# TAMP 6-month Median OS Benefit vs. IV (systemic) Gem-Abraxane (control)

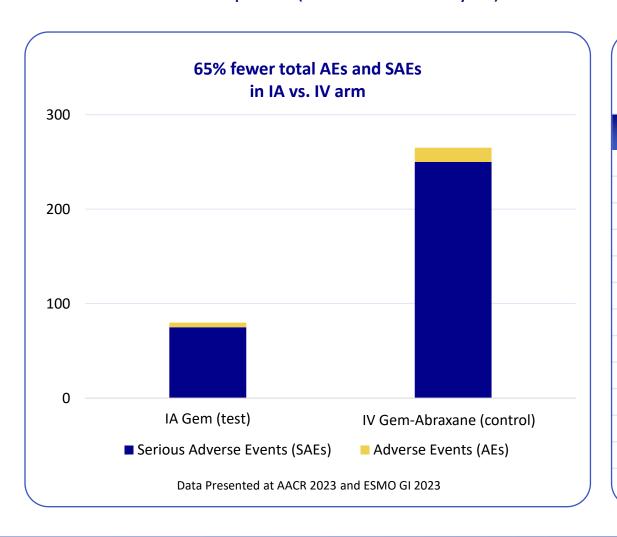
TIGeR-PaC Phase III Update (1st Interim Analysis)





# TAMP (IA Gem) Observes Fewer AEs and SAEs vs. IV (systemic) Gem-Abraxane (control)

### TIGeR-PaC Phase III Update (1st Interim Analysis)



# Fewer AEs in 11/13 categories with greater than 10% frequency in each arm (All Grades)

Adverse Events	IV Gem + Pac	IA Gem
Neutropenia	81%	21%
Anemia	48%	8%
Thrombocytopenia	38%	4%
Elevated AST	33%	4%
Elevated ALT	29%	13%
Fatigue	19%	8%
Neuropathy	19%	0%
Dehydration	19%	8%
Hypertension	14%	4%
Hypokalemia	14%	4%
Hypoalbunemia	14%	4%
<b>Abdominal Pain</b>	0%	21%
Nausea	10%	17%

# **Experienced Management Team**

#### **Executive Team**



Shaun R. Bagai

Chief Executive Officer & Board Member

- HeartFlow (>\$2B IPO) Ardian (acq for > \$900M)
- Medtronic Vascular
- TransVascular (Acquired by Medtronic)



Ramtin Agah, MD

Chief Medical Officer, Founder & Chairman of the Board

- Interventional Cardiology, El Camino Hospital
- Consultant, Abbott Vascular



**Leesa Gentry** 

**Chief Clinical Officer** 

- Evotec
- Otsuka America Pharmaceuticals
- Omnicare Clinical Research



**Richard Stark** 

**Commercial Advisor Consultant** 

- Innoblative Designs
- AngioDynamics



Ronald B. Kocak, CPA

Vice President, Controller & Principal Financial Officer

- Sensei Biotherapeutics, Inc.
- Member of the American Institute of Certified Public Accountants
- Member of Chartered Global Management Accountant



**Robert Strasser** 

Vice President, Operations and R&D

- SentreHeart/AtriCure
- Boston Scientific
- o Cordis/Johnson & Johnson



**Ryan Witt** 

Senior Vice President, Head of Corporate Strategy and Partnerships

- Spinogenix
- o Immix Biopharma
- StartX

# **Board of Directors and Scientific Advisory Board**

#### **Board of Directors**



Una S. Ryan, PhD, OBE

**Board Member** 

o Board: Cortexyme, Elemental Machines



Laurence J. Marton, MD

**Board Member** 

o 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
- o CMO, Schering-Plough (\$41.1B merger with Merck)

#### **Scientific Advisory Board**



#### Mike Pishvaian, MD, PhD

- Associate Professor, Department of Oncology Director of the Gastrointestinal, Developmental Therapeutics, and Clinical Research Programs at the NCR Kimmel Cancer Center at Sibley Memorial Hospital
- Johns Hopkins University School of Medicine



### Karyn A. Goodman, MD, MS

- Associate Professor, Department of Oncology Director of the Gastrointestinal, Developmental Therapeutics, and Clinical Research Programs at the NCR Kimmel Cancer Center at Sibley Memorial Hospital
- Johns Hopkins University School of Medicine



# Margaret A. Tempero, M.D

- o Professor of Medicine and Director of the UCSF Pancreas Center
- Editor-in-Chief of JNCCN
- Former ASCO President



# Michel Ducreux, M.D., Ph.D.

- Head of the Gastrointestinal Oncology Unit and Gastrointestinal Oncology Tumor Board at Gustave Roussy
- o Professor of Oncology at Paris-Saclay University in France
- Vice-Chair of ESMO GI

# **Financial Highlights**

Revenue (Q2 2025): Over \$400,000

# Cash: \$12.3 Million<sup>1</sup>

Anticipated that growing revenues from RenovoCath will reduce cash burn rate and eventually fully fund both RenovoCath commercialization scale-up and continued progress towards the completion of the TIGeR-PaC trial

# **Institutional Ownership**

- 30% or ~11M shares<sup>3</sup>
- Held by multiple fundamental healthcare institutional investors

#### Initial TAM for RenovoCath

- Estimated \$400 million<sup>3</sup> annual RenovoCath U.S. sales opportunity as standalone device
- Multi-billion-dollar market opportunity as new applications are pursued
- Beyond historical RenovoCath usage, RenovoRx commercial efforts are already indicating the adoption of RenovoCath technology for the treatment of other solid tumors.

#### RNXT (USD) Q2 2025 Daily Performance



High:	\$1.45
Low:	\$0.75
Avg Daily Volume:	166,000 shares
Market Cap:	\$48M <sup>1</sup>
Shares Outstanding:	36.6M <sup>2</sup>

# RENOVO | RX



# **Thank You**

#### **Investor Relations Contact:**

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