

January 8, 2025



RenovoRx Announces Acceptance of Abstract for Presentation at ASCO Gastrointestinal Cancers Symposium 2025

Two additional abstracts have been accepted to be presented at upcoming prestigious industry conferences, SIO 2025 and SSO 2025

The accepted abstracts support RenovoRx's novel Trans-Arterial Micro-Perfusion (TAMP™) therapy platform via additional human pharmacokinetic (PK) data and pre-clinical data

MOUNTAIN VIEW, Calif.--(BUSINESS WIRE)-- [RenovoRx, Inc.](#) ("RenovoRx" or the "Company") (Nasdaq: RNXT), a life sciences company developing novel targeted oncology therapies and commercializing **RenovoCath**®, a novel, FDA-cleared delivery platform, today announced three abstracts were accepted to be presented at several upcoming industry conferences including ASCO Gastrointestinal Cancers Symposium (ASCO GI) 2025, Society of Interventional Oncology (SIO) 2025 and Society of Surgical Oncology (SSO) 2025.

The abstracts support RenovoRx's novel and patented **TAMP** therapy platform via additional human PK data and pre-clinical data. TAMP is designed to ensure precise therapeutic delivery across the arterial wall near the tumor site to bathe the target tumor, while potentially minimizing a therapy's toxicities versus systemic intravenous therapy. RenovoRx's novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy.

RenovoRx's pivotal ongoing Phase III *TIGeR-PaC clinical trial is evaluating the Company's* first product candidate, a novel investigational oncology drug-device combination utilizing the Company's FDA-cleared **RenovoCath** device via TAMP for the intra-arterial administration of chemotherapy, gemcitabine. RenovoRx currently anticipates completion of both patient enrollment and the second interim analysis for TIGeR-PaC by the end of the first half of 2025.

Abstract Details:

ASCO GI 2025

- **Title:** Intra-arterial Gemcitabine Versus Intravenous Gemcitabine: Pharmacokinetic Sub-study of the TIGeR-PaC Phase 3 Clinical Trial
- **Authors:** Paula Novelli MD, Amer Zureikat MD, Michael Pishvaian MD, Kenneth Meredith MD, Hassan Hatoum MD, Emmanuel Zervos MD, Reza Nazemzadeh MD, Sandeep Loria MD, Ramtin Agah MD
- **Location:** Moscone West, San Francisco CA
- **Date/Time:** January 24, 2025 at 11:30 a.m. PT

SIO 2025

- **Title:** Micro-CT imaging following intra-arterial delivery of a radiopaque silicone polymer using a double-balloon occlusion catheter in pigs: a model to analyze tissue penetration via the trans-arterial micro perfusion (TAMP) technique
- **Authors:** Paula Novelli MD, Christopher Laing MD, Alope Finn MD, Frank Kolodgie PhD, Robert Strasser BSc, Ramtin Agah MD
- **Location:** Horseshoe Las Vegas, Las Vegas NV
- **Date/Time:** February 2, 2025 at 12:30 p.m. PT

SSO 2025

- **Title:** Pharmacodynamics of Intra-arterial vs. Intravenous Gemcitabine in Locally Advanced Pancreatic Cancer: Results of a Phase III Randomized Clinical Trial
- **Authors:** Emmanuel Zervos MD, Paula Novelli MD, Amer Zureikat MD, Michael Pishvaian MD, Kenneth Meredith MD, Hassan Hatoum MD, Reza Nazemzadeh MD, Sandeep Loria MD, Ramtin Agah MD
- **Location:** Tampa Convention Center, Tampa FL
- **Dates:** March 27 – 29, 2025

The abstracts accepted at ASCO GI 2025 and SSO 2025 are sub-studies of the ongoing Phase III TIGeR-PaC clinical trial.

“These abstracts support the potential for our TAMP therapy platform to provide a meaningful advancement in the standard of care for cancer treatment,” said Ramtin Agah, MD, Chief Medical Officer and Founder of RenovoRx. “TAMP focuses on drug concentration optimization in tumors by delivering therapies with our RenovoCath delivery system. This targeted approach to cancer treatment is designed to enable physicians to isolate segments of the vascular anatomy closest to tumors and ensure precise therapeutic delivery, while potentially minimizing a therapy’s toxicities versus the standard of care. Specifically, our approach enables physicians to utilize RenovoCath to use pressure to force chemotherapy across the arterial wall near the tumor site to bathe the target tumor.”

Dr. Agah added, “We also look forward to the completion of patient enrollment and our second interim analysis in our pivotal Phase III TIGeR-PaC clinical trial in LAPC by the end of the first half of 2025.”

About RenovoCath

Based on its FDA clearance, **RenovoCath®** is intended for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. RenovoCath is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. For further information regarding our RenovoCath Instructions for Use (“IFU”), please see: [IFU-10004-Rev.-F-Universal-IFU.pdf](#).

About the TIGeR-PaC Clinical Trial

TIGeR-PaC is an ongoing Phase III randomized multi-center study evaluating the proprietary **TAMP™** (Trans-Arterial Micro-Perfusion) therapy platform for the treatment of Locally

Advanced Pancreatic Cancer (LAPC.) RenovoRx's first product candidate using the TAMP technology, is a novel investigational oncology drug-device combination utilizing the Company's FDA-cleared **RenovoCath**[®] device for the intra-arterial administration of chemotherapy, gemcitabine.

The first interim analysis in the Phase III clinical trial was completed in March 2023, with the Data Monitoring Committee recommending a continuation of the study. The study's primary endpoint is an Overall Survival benefit with secondary endpoints including reduced side effects versus standard of care. The second interim analysis for this study will be triggered by the 52nd event (i.e., patient death), which is estimated to occur in late 2024 or early 2025. The second interim data readout would follow thereafter, with the timing for such readout depending on customary factors such as time needed for analysis. RenovoRx is also aiming to complete patient enrollment in the TIGeR-PaC study in the first half of 2025.

About RenovoRx, Inc.

RenovoRx is a life sciences company developing novel targeted oncology therapies and commercializing **RenovoCath**[®], a novel, U.S. Food and Drug Administration (FDA)-cleared local drug-delivery platform, targeting high unmet medical needs. RenovoRx's patented **Trans-Arterial Micro-Perfusion (TAMP**[™]) therapy platform is designed to ensure precise therapeutic delivery across the arterial wall near the tumor site to bathe the target tumor, while potentially minimizing a therapy's toxicities versus systemic intravenous therapy. RenovoRx's novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy, and its mission is to transform the lives of cancer patients by providing innovative solutions to enable targeted delivery of diagnostic and therapeutic agents.

The Company's Phase III lead product candidate is a novel oncology drug-device combination product. It is being investigated under a U.S. investigational new drug application that is regulated by the FDA's 21 CFR 312 pathway. The investigational drug-device combination candidate utilizes **RenovoCath**[®], the Company's FDA-cleared drug-delivery device, indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. The intra-arterial infusion of chemotherapy, gemcitabine, utilizing the RenovoCath catheter is currently being evaluated for the treatment of locally advanced pancreatic cancer (LAPC) by the Center for Drug Evaluation and Research (the drug division of FDA).

The intra-arterial infusion of gemcitabine by the RenovoCath catheter is currently under investigation and has not been approved for commercial sale. RenovoCath with gemcitabine received Orphan Drug Designation for pancreatic cancer and bile duct cancer, which provides 7 years of market exclusivity upon NDA approval by the FDA.

RenovoRx is also actively exploring other commercialization strategies utilizing its TAMP technology and FDA-cleared RenovoCath delivery system as a stand-alone device.

For more information, visit www.renovorx.com. Follow RenovoRx on [Facebook](#), [LinkedIn](#), and [X](#).

Cautionary Note Regarding Forward-Looking Statements

This press release and statements of the Company's management made in connection therewith and at the investor conference described herein 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) our clinical trials and studies, including the overall timing and timing for additional interim data readouts for our ongoing TIGeR-PaC Phase III clinical trial study in LAPC, (ii) the potential of RenovoCath® or TAMP™ as standalone commercial products and our commercialization plans in general, (iii) the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases and (iii) our efforts to explore commercialization strategies utilizing our TAMP technology. Statements that are not purely historical are forward-looking statements. The forward-looking statements contained herein 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 relating to our research and development plans, intellectual property development, clinical trials, our therapy platform, business plans, financing plans, objectives and expected operating results, 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 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 regarding RenovoRx's expectations strategy, plans or intentions, although not all forward-looking statements contain these words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, that could cause actual events to differ materially from those projected or indicated by such statements, including, among other things: (i) the risk that our exploration of commercial opportunities for our TAMP technology may not lead to viable, revenue generating 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) of 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; research and clinical development plans and timelines, and the regulatory process for our product candidates; (vi) 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 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) our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; (xx) the pricing, coverage and reimbursement of our product candidates, if approved; and (xxi) 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.

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