

January 27, 2025



RenovoRx Highlights Promising Pharmacokinetic Data Abstract Presented at ASCO GI 2025

Abstract was presented by TIGeR-PaC Phase III clinical trial Investigator, Paula Novelli, MD, from the University of Pittsburgh Medical Center

Sub-study of the pivotal Phase III TIGeR-PaC clinical trial offers insight that supports the potential effectiveness of RenovoRx's TAMP therapy platform in locally advanced pancreatic cancer

PK data shows intra-arterial delivery of gemcitabine via TAMP is a targeted treatment option to potentially improve local drug potency and treatment effectiveness

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 an abstract presentation highlighting promising pharmacokinetic (known as PK) data from the use of RenovoRx's patented **Trans-Arterial Micro-Perfusion (TAMP**[™]) therapy platform in treating locally advanced pancreatic cancer (LAPC).

The abstract was presented at the ASCO Gastrointestinal Cancers Symposium (ASCO GI) 2025, by Paula Novelli, MD, University of Pittsburgh Medical Center, which is currently underway in San Francisco, CA.

Dr. Novelli, together with her co-authors, presented "*Intra-arterial Gemcitabine Versus Intravenous Gemcitabine: Pharmacokinetic Sub-study of the TIGeR-PaC Phase 3 Clinical Trial*," a sub-study of RenovoRx's ongoing pivotal Phase III TIGeR-PaC clinical trial in LAPC. In this sub-study, PK analyses were performed on a sample of participants across TIGeR-PaC study clinical sites. These analyses compared treatment with intra-arterial gemcitabine (IAG), using the RenovoCath delivery system via TAMP, versus systemic intravenous gemcitabine, which is the current standard of care for patients with LAPC.

Results of the sub-study showed RenovoRx's IAG approach to drug delivery via TAMP decreased systemic levels of gemcitabine versus standard of care. In addition to providing increased local drug potency, the IAG approach may also be beneficial to decreasing gemcitabine-related systemic side effects. 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.

"Pancreatic cancer remains one of the most challenging cancers to treat, and this new data further highlights the potential of RenovoRx's TAMP therapy platform as a transformative therapeutic option," said Paula Novelli MD, TIGeR-PaC Principal Investigator at University of

Pittsburgh Medical Center. “TAMP is intended to direct a drug and more effectively target the tumor while minimizing systemic impact, and this sub-study shows that despite delivering more gemcitabine in a shorter time, the total systemic drug exposure was significantly lower compared to intravenous treatment. This data further demonstrates that TAMP has the potential to deliver gemcitabine to the tumor more efficiently, enhancing local treatment effectiveness while reducing the broader impact on the body, ultimately minimizing the systemic side effects of chemotherapy.”

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 RenovoRx’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 early 2025. The second interim data readout is anticipated to occur by the end of the first half of 2025, with the timing for such readout, however, being dependent 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 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 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.

RenovoRx'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 engaged in implementing commercialization strategies utilizing its TAMP technology and FDA-cleared RenovoCath delivery system as a stand-alone device. In December 2024, RenovoRx announced the receipt of its first commercial purchase orders for RenovoCath devices. Additionally, over ten medical institutions have initiated the process for RenovoCath purchase orders. To meet and satisfy the anticipated demand, RenovoRx will continue to actively explore further revenue-generating activity either on its own or in tandem with a medical device commercial partner.

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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20250127937369/en/>

KCSA Strategic Communications
Valter Pinto or Jack Perkins

T:212-896-1254

RenovoRX@KCSA.com

Source: RenovoRx, Inc.