

March 28, 2025



RenovoRx Highlights New Human Pharmacokinetic Data Abstract at SSO 2025 Annual Meeting

Data supports the novel Trans-Arterial Micro-Perfusion (TAMP™) therapy platform for targeted chemotherapy delivery for the potential to minimize a therapy's toxicities versus systemic intravenous therapies

Data shows localized, intra-arterial delivery of gemcitabine with FDA-cleared RenovoCath® device (known as IAG) resulted in lower systemic levels of drug compared to intravenous delivery of gemcitabine

MOUNTAIN VIEW, Calif.--(BUSINESS WIRE)-- [RenovoRx, Inc.](#) ("**RenovoRx**" or the "**Company**") (**Nasdaq: RNXT**), a life sciences company developing innovative targeted oncology therapies and commercializing **RenovoCath®**, a novel, FDA-cleared drug-delivery device, announced today that a new human pharmacokinetic (PK) data abstract was presented at the Society of Surgical Oncology (SSO) 2025 Annual Meeting on March 27 – 29, 2025 in Tampa, FL: ePoster P379.

The abstract provides new human PK data relevant to RenovoRx's proprietary **Trans-Arterial Micro-Perfusion (TAMP™)** therapy platform. TAMP is key to the Company's Phase III investigational drug-device combination oncology product candidate (intra-arterial gemcitabine, with RenovoCath, known as **IAG**) and is designed to ensure targeted 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 therapies. RenovoRx's novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy.

The abstract, titled "*Pharmacodynamics of Intra-arterial vs. Intravenous Gemcitabine in Locally Advanced Pancreatic Cancer: Results of a Phase III Randomized Clinical Trial*," was authored by Emmanuel E. Zervos, M.D. of East Carolina University, and co-authored by Ramtin Agah, M.D., founder and Chief Medical Officer of RenovoRx and others.

"The data presented in this abstract support the potential for the TAMP therapy platform to provide a meaningful advancement in the standard of care for oncology therapy in difficult-to-treat tumors," said Dr. Zervos. "This study shows additional support for TAMP as a potential treatment option in locally advanced pancreatic cancer (LAPC). Specifically, in this analysis, localized, dual-balloon catheter-mediated IAG resulted in lower systemic levels of gemcitabine compared to intravenous gemcitabine. IAG may prove beneficial in decreasing chemotherapy-related systemic side effects. We are awaiting final outcomes in the ongoing Phase III TIGeR-PaC clinical trial for IAG to validate this benefit."

PK analyses were performed on 19 patients with locally advanced pancreatic cancer

receiving IAG from six sites as part of the TIGeR-PaC trial. In this analysis, localized, dual-balloon catheter-mediated IAG resulted in lower systemic levels compared to intravenous delivery of gemcitabine. As such, the study found that IAG may be beneficial in decreasing chemotherapy-related systemic side effects. Correlative patient reported outcomes in patients receiving IAG supports this approach as an alternative for LAPC patients who are having difficulty tolerating more traditional systemic regimens.

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 LAPC. RenovoRx's first investigational drug-device combination product candidate using the TAMP therapy platform enabled with the Company's FDA-cleared **RenovoCath®** device for the intra-arterial administration of chemotherapy, gemcitabine (IAG).

About RenovoRx, Inc.

RenovoRx (**Nasdaq: RNXT**) is a life sciences company developing innovative targeted oncology therapies and commercializing **RenovoCath®**, a novel, U.S. Food and Drug Administration (FDA)-cleared local drug delivery device, targeting high unmet medical needs. RenovoRx's patented **Trans-Arterial Micro-Perfusion (TAMP™)** therapy platform is designed to ensure targeted 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.

In addition to the RenovoCath device, RenovoRx is also evaluating our novel Phase III drug-device combination oncology product candidate (intra-arterial gemcitabine, known as **IAG**). IAG is being evaluated under a U.S. investigational new drug application that is regulated by the FDA's 21 CFR 312 pathway. The investigational IAG 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 combination of intra-arterial infusion of chemotherapy, gemcitabine, and the RenovoCath device is currently being evaluated for the treatment of LAPC by the Center for Drug Evaluation and Research (the drug division of FDA).

The combination product candidate, which is enabled the RenovoCath device, 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 new drug application approval by the FDA.

RenovoRx is also engaged in implementing commercialization strategies utilizing its TAMP technology and FDA-cleared RenovoCath device as stand-alone device. In December 2024, RenovoRx announced the receipt of its first commercial purchase orders for RenovoCath devices. Additionally, certain of these customers have already initiated repeat orders as RenovoRx works to expand the number medical institutions that have initiated the process for RenovoCath purchase orders, including several esteemed, high volume National Cancer Institute-designated centers. 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 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 pre-clinical and clinical trials and studies, including the overall timing and timing for additional interim data readouts and full patient enrollment for our ongoing TIGeR-PaC Phase III clinical trial study in LAPC, (ii) the potential of RenovoCath® or TAMP™ as standalone commercial products, our anticipated timing for revenue generation from RenovoCath sales, and our commercialization plans in general, including our estimates of total addressable market (iii) the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases and (iv) 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, commercial 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 significant 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 or repeating 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/20250328315439/en/>

KCSA Strategic Communications

Valter Pinto or Jack Perkins

T: 212-896-1254

RenovoRX@KCSA.com

Source: RenovoRx, Inc.