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RenovoRx Highlights Peer-Reviewed Publication of Pharmacokinetic and Pharmacodynamic (PK/PD) Data Supporting TAMP™ Platform's Targeted Drug-Delivery in Locally Advanced Pancreatic Cancer

PK/PD Data is from a Sub-Study in the Phase III TIGeR-PaC Clinical Trial

The Study Shows Approximately 51% Tumor-Site Drug Extraction, Decreased Systemic Exposure, and Significant Correlation Between Drug Metabolite Levels and Tumor Marker Reduction

MOUNTAIN VIEW, Calif., Aug. 25, 2026 (GLOBE NEWSWIRE) -- [RenovoRx, Inc.](#) ("**RenovoRx**" or "**the Company**") (Nasdaq: **RNXT**), a life sciences company developing innovative targeted oncology therapies and commercializing **RenovoCath**®, a patented, FDA-cleared drug-delivery device, today announced the publication of pharmacokinetic and pharmacodynamic (PK/PD) data from a sub-study of its ongoing Phase III TIGeR-PaC clinical trial (NCT03257033) in the journal *Cancer Chemotherapy and Pharmacology*.

The data shows that TAMP (Trans-Arterial Micro-Perfusion)-mediated delivery concentrated chemotherapy at the tumor site, extracting roughly 51% of the drug locally before it entered the bloodstream, meaningfully lowering systemic exposure in a way that could reduce systemic side effects. In addition, a statistically significant correlation between the drug's local metabolism and a drop in the CA 19-9 tumor marker provided an early indication of improved drug penetration into the tumor area and potential tumor response with intra-arterial delivery.

RenovoRx also recently announced the closing of enrollment of the TIGeR-PaC trial, with trial completion expected in the first half of 2027 and expected initial top line data availability in the second half of 2027.

"The findings from this PK/PD study provide additional meaningful mechanistic support for our TAMP platform's targeted drug-delivery approach," said Ramtin Agah, M.D., Executive Chairman, Chief Medical Officer, and Founder of RenovoRx. "The results provide direct pharmacokinetic evidence supporting TAMP's potential to deliver chemotherapy more selectively to the tumor while limiting systemic exposure. These findings strengthen TAMP, enabled by our RenovoCath device, as a differentiated approach to improving the therapeutic index of chemotherapy in patients with LAPC."

The PK/PD study, titled “*Pharmacokinetic and Pharmacodynamic Sub-study of Trans-arterial vs Intravenous Gemcitabine in the TIGeR-PaC Phase 3 Clinical Trial*,” compared the systemic drug levels of intra-arterial gemcitabine (IAG) delivered via TAMP using RenovoCath against standard intravenous gemcitabine (IVG) delivered systemically in 16 patients with LAPC across six clinical sites (11 patients received IAG; 5 received IVG). Funding for this study was provided by RenovoRx.

Key Findings:

- **Reduced systemic exposure:** IAG resulted in significantly lower total systemic gemcitabine exposure compared to IVG, despite being administered at a 50% higher infusion concentration rate, supporting the potential of TAMP to concentrate therapy at the intended treatment site while limiting systemic exposure.
- **Substantial local drug extraction:** A targeted extraction ratio of 0.511 was observed (derived from a bioavailability estimate of 0.489), indicating approximately 51% of the intra-arterially delivered gemcitabine was extracted at the site of intra-arterial delivery before entering systemic circulation. This finding provides direct pharmacokinetic evidence supporting the targeted drug-delivery mechanism underlying the TAMP platform.
- **Tumor marker response:** A statistically significant correlation was observed between higher systemic levels of dFdU and greater reductions in CA 19-9 tumor marker levels following IAG treatment (Pearson’s $r = -0.75$; $P = 0.034$; based on eight evaluable patients, with three excluded for normal baseline CA 19-9). dFdU is gemcitabine’s inactive metabolite, and higher dFdU levels are consistent with rapid local uptake and metabolism of gemcitabine at the treatment site, providing an initial pharmacodynamic signal linking drug exposure with a biomarker of tumor response.
- **Consistent delivery across arterial sites:** No statistically significant differences in gemcitabine or dFdU pharmacokinetic parameters were observed based on IAG delivery site, whether administered via the superior mesenteric artery or the celiac artery.

The Company believes this data provides evidence that IAG delivery via the TAMP therapy platform achieves meaningful local drug extraction while reducing systemic gemcitabine exposure, supporting RenovoRx’s differentiated approach to targeted intra-arterial chemotherapy in patients with LAPC.

Publication Details

Title: *Pharmacokinetic and Pharmacodynamic Sub-study of Trans-arterial vs Intravenous Gemcitabine in the TIGeR-PaC Phase 3 Clinical Trial*

Journal: Cancer Chemotherapy and Pharmacology

DOI: [10.1007/s00280-026-04939-0](https://doi.org/10.1007/s00280-026-04939-0)

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: <https://renovorx.com/wp-content/uploads/2026/06/IFU-10004-Rev.-H-Universal-IFU.pdf>.

About the TIGeR-PaC Clinical Trial

TIGeR-PaC is an ongoing Phase III randomized multi-center trial evaluating the proprietary TAMP™ (Trans-Arterial Micro-Perfusion) therapy platform for the treatment of locally advanced pancreatic cancer (LAPC). RenovoRx's first investigational drug-device combination product candidate, using the TAMP therapy platform enabled with the Company's FDA-cleared RenovoCath® device, is designed for the intra-arterial administration of chemotherapy, gemcitabine (IAG).

About RenovoRx, Inc.

RenovoRx, Inc. (Nasdaq: RNXT) is a life sciences company developing innovative targeted oncology therapies and commercializing **RenovoCath®**, a patented, 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 for 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.

RenovoRx is actively commercializing its TAMP technology and FDA-cleared RenovoCath as a standalone device. For its first full year of commercial efforts in 2025, RenovoRx generated approximately \$1.1 million in RenovoCath sales, followed by record quarterly revenue of \$909,000 in the second quarter of 2026. RenovoRx is actively working to expand the number of medical institutions initiating new RenovoCath orders, including esteemed, high-volume National Cancer Institute-designated centers.

RenovoRx is also evaluating its novel drug-device combination oncology product candidate intra-arterial gemcitabine delivered via RenovoCath (known as IAG) in the ongoing Phase III TIGeR-PaC trial. IAG is being evaluated by the Center for Drug Evaluation and Research (the drug division of the FDA) under a U.S. investigational new drug application that is regulated by the FDA's 21 CFR 312 pathway. IAG utilizes RenovoCath, which is FDA-cleared for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. RenovoRx achieved full enrollment in the TIGeR-PaC trial in August 2026, with completion of the trial expected in the first half of 2027 and topline data readout expected in the second half of 2027.

The IAG combination product candidate, enabled by the RenovoCath device, is currently under investigation and has not been approved for commercial sale. RenovoCath with gemcitabine received Orphan Drug Designation (ODD) for pancreatic cancer and bile duct cancer, and oxaliplatin has received ODD for pancreatic cancer, each of which provides seven years of market exclusivity upon new drug application approval by the FDA.

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 and third parties 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) our clinical trials and studies (including the anticipated benefits to the Company of the published sub-study described herein and potential positive implications for the TAMP therapy platform and RenovoCath), (ii) the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases, and (iii) our efforts to commercialize our RenovoCath and TAMP technology. Statements that are not purely historical are forward-looking statements. These and other 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 and other plans and strategies, intellectual property development, clinical trials, our therapy platform, financing plans, objectives, and expected operating results, which are based on such 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," "aim," "goal," "estimates," "intends," and "potential," or derivatives of these terms or other comparable terminology regarding RenovoRx's statements about the future, although not all forward-looking statements contain these words. Risks, uncertainties and assumptions that could cause actual events to differ materially from those projected or indicated by forward-looking statements, include, without limitation: (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 of our preclinical studies, clinical trials, and our research programs (notably with respect to our lead TIGeR-PaC trial); (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 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 (notably IAG); (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, needs for additional financing, our ability to obtain additional capital and our ability to maintain the listing of our common stock on Nasdaq; (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 scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform, product candidates, and research programs; (xviii) our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; (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, which can be accessed at <https://ir.renovorx.com/sec-filings>.

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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