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RenovoRx Initiates Patient Enrollment at SCRI Oncology Partners for Ongoing Pivotal Phase III TIGeR-PaC Clinical Trial in Locally Advanced Pancreatic Cancer

TIGeR-PaC is Evaluating the TAMP™ (Trans-Arterial Micro-Perfusion) Therapy Platform for the Treatment of Locally Advanced Pancreatic Cancer

Dr. Meredith Pelster, Associate Director for GI Research Across Sarah Cannon Research Institute (SCRI), Appointed Principal Investigator for TIGeR-PaC Study

LOS ALTOS, Calif., Dec. 11, 2024 (GLOBE NEWSWIRE) -- [RenovoRx, Inc.](#) ("**RenovoRx**" or the "**Company**") (**Nasdaq: RNXT**), a life sciences company developing novel targeted oncology therapies and commercializing **RenovoCath®**, a novel, FDA-cleared local drug-delivery platform, announced today that SCRI Oncology Partners in Nashville, TN, is now enrolling patients with locally advanced pancreatic cancer (LAPC) in the Company's ongoing pivotal Phase III TIGeR-PaC clinical trial. SCRI Oncology Partners joins esteemed clinical sites throughout United States participating in the study.

The TIGeR-PaC study is using RenovoRx's **TAMP™** (Trans-Arterial Micro-Perfusion) therapy platform to evaluate the Company's first investigational drug-device combination product candidate (intra-arterial infusion of gemcitabine via RenovoCath delivery system). TAMP utilizes pressure-mediated delivery of gemcitabine to the target tumor. The study is comparing treatment with TAMP in LAPC to the current standard-of-care (systemic intravenous chemotherapy).

"I am honored to lead the TIGeR-PaC clinical trial at SCRI Oncology Partners. My goal as a clinician is to provide the most personalized and advanced care to patients, as each cancer journey is unique, requiring an individualized care plan," said Meredith S. Pelster, M.D., MSCI, Medical Oncologist and principal investigator for the TIGeR-PaC study at SCRI Oncology Partners as well as Associate Director of Gastrointestinal Research for SCRI. "Pancreatic cancer remains one of the most challenging cancers to treat. This important study potentially may offer patients new hope for improved survival and reduced systemic side effects."

"On an annual basis, SCRI and its affiliated sites reach one in five patients with cancer and is responsible for enrolling thousands of patients on clinical trials," said Leesa Gentry, Chief Clinical Officer of RenovoRx. "We believe this collaboration will assist the Company in both accelerating patient enrollment in our pivotal Phase III TIGeR-PaC clinical trial and driving the study towards its expected enrollment completion in the first half of 2025. Dr. Pelster's significant expertise and inspiring leadership, coupled with the world-class capabilities at SCRI, will be instrumental in driving TIGeR-PaC's completion forward."

SCRI Oncology Partners is the most recent clinical trial sites to join the Phase III TIGeR-PaC study. As part of SCRI, one of the world's leading oncology research organizations conducting community-based clinical trials, their mission is to advance therapies and expand access to clinical trials to patients closer to home. Today, the SCRI research network includes more than 250 locations across 24 states in the U.S.

About Sarah Cannon Research Institute

Sarah Cannon Research Institute (SCRI) is one of the world's leading oncology research organizations conducting community-based clinical trials. Focused on advancing therapies for patients over the last three decades, SCRI is a leader in drug development. It has conducted more than 800 first-in-human clinical trials since its inception and contributed to pivotal research that has led to the majority of new cancer therapies approved by the FDA today. SCRI's research network brings together more than 1,300 physicians who are actively enrolling patients into clinical trials at more than 250 locations in 24 states across the U.S. [Learn more about our research offerings.](#)

About Locally Advanced Pancreatic Cancer (LAPC)

According to the American Cancer Society's Cancer Facts & Figures 2024 and PanCAN, respectively, pancreatic cancer has a 5-year all stages combined relative survival rate of 13% (Stages I-IV) and is on track to be the second leading cause of cancer-related deaths before 2030. LAPC is diagnosed when the disease has not spread far beyond the pancreas, however, has advanced to the point where it cannot be surgically removed. LAPC is typically associated with patients in Stage 3 of the disease as determined by the TNM (tumor, nodes and metastasis) grading system.

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 [Twitter](#).

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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