August 14, 2024

RENOVO | RX
INVESTOR RELATIONS

RenovoRx Announces First Patient Enrolled at University of Nebraska Medical Center for the Ongoing Pivotal Phase III TIGeR-PaC Clinical Trial

Phase III clinical trial is evaluating RenovoGem™ for the treatment of Locally Advanced Pancreatic Cancer

UNMC opened enrollment of TIGeR-PaC in June 2024 and joins esteemed clinical sites throughout United States participating in the study

LOS ALTOS, Calif., Aug. 14, 2024 (GLOBE NEWSWIRE) -- **RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT)**, a clinical-stage biopharmaceutical company developing novel precision oncology therapies based on a local drug-delivery platform, announced today that the first patient has been enrolled at the University of Nebraska Medical Center ("UNMC") in RenovoRx's ongoing pivotal Phase III TIGeR-PaC clinical trial for Locally Advanced Pancreatic Cancer (LAPC).

The TIGeR-PaC study is using RenovoRx's TAMP™ (Trans-Arterial Micro-Perfusion) therapy platform, to evaluate the Company's first product candidate, RenovoGem, which is a drug-device combination that utilizes pressure-mediated delivery of gemcitabine (chemotherapy) across the arterial wall near the tumor site to bathe the target tumor. The study is comparing treatment with TAMP in LAPC to the current standard-of-care (systemic intravenous chemotherapy).

"Pancreatic cancer is aggressive, and difficult to detect and treat," said Associate Professor at UNMC, Kelsey Klute, MD, Division of Oncology & Hematology Gastrointestinal Cancer, Pancreatic Cancer. "Chemotherapy given intravenously is the current standard treatment for most patients with pancreatic cancer. One of the biggest challenges in treating pancreatic cancer is that the tumor cells build a thick layer of scar tissue around the tumor, and this scar tissue makes it difficult for drugs to penetrate the tumor itself. I think this is one of the reasons that many investigational drugs tested in pancreatic cancer fail – they simply aren't reaching the tumor at high enough concentration to have an effect. The ongoing TIGeR-PaC study is evaluating RenovoRx's innovative targeted (intra-arterial) approach to chemotherapy delivery, which aims to deliver medicine theoretically through the layer of scar tissue directly to the tumor in the pancreas. We are hopeful that this approach will lead to better outcomes for our patients: both improved survival as well as decreased side effects. With this initial enrollment since launching our participation in the study at UNMC just a little over a month ago, I am encouraged by the interest in this important study at UNMC."

"We are excited that UNMC has begun enrollment with their first patient in our ongoing Phase III TIGeR-PaC clinical trial," said Leesa Gentry, Chief Clinical Officer of RenovoRx.

“UNMC is the most recent clinical site to join our pivotal TIGeR-PaC clinical study. We believe UNMC will help drive enrollment of the TIGeR-PaC trial to completion next year because they treat a larger number of patients diagnosed with pancreatic cancer. We are proud to collaborate with them as they strive to provide best-in-class care and share our deep commitment to improving outcomes for patients diagnosed with difficult-to-treat tumors, like pancreatic cancer."

UNMC is the most recent clinical trial site to join the Phase III TIGeR-PaC study. The mission of the College of Medicine at the University of Nebraska Medical Center is to lead the world in transforming lives to create a healthy future for all individuals and communities through premier educational programs, innovative research, and extraordinary patient care.

The TIGeR-PaC clinical trial is currently enrolling unresectable LAPC patients at several sites across the US. To learn more about the study and the participating clinical trial sites, visit https://clinicaltrials.gov/ (NCT03257033).

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, **RenovoGem™**, is a novel investigational oncology drug-delivery 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 TIGeR-PaC study is investigating TAMP in LAPC. The study's primary endpoint is a 6-month 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, which is estimated to occur in late 2024.

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 RenovoRx, Inc.
RenovoRx is a clinical-stage biopharmaceutical company developing novel precision oncology therapies based on a local drug delivery platform for high unmet medical need with a goal to improve therapeutic outcomes for cancer patients undergoing treatment. RenovoRx’s patented **Trans-Arterial Micro-Perfusion (TAMP™)** therapy platform is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy’s toxicities versus systemic intravenous therapy. RenovoRx’s novel and patented approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy. Our Phase III lead product candidate, **RenovoGem™**, a novel oncology drug-device combination product, is being investigated under a U.S.

investigational new drug application that is regulated by the FDA's 21 CFR 312 pathway. RenovoGem 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). RenovoGem 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.

RenovoRx is also actively exploring the use of TAMP to treat cancers beyond LAPC as well as other commercialization strategies for its technology.

RenovoRx is committed to transforming the lives of patients by delivering innovative solutions to change the current paradigm of cancer care. RenovoGem is currently under investigation for TAMP therapeutic delivery of gemcitabine and has not been approved for commercial sale.

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 contains 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 anticipated timing, statements regarding the potential of RenovoCath®, RenovoGem™ or TAMP™ or regarding our ongoing TIGeR-PaC Phase III clinical trial study in LAPC, (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 expand our intellectual property. 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 the publication of data as described herein will not lead to any benefits for the Company; (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 our 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.

Contact:
KCSA Strategic Communications
Valter Pinto or Jack Perkins
T:212-896-1254
RenovoRX@KCSA.com

RENOVO | RX

Source: RenovoRx, Inc.