

June 26, 2024

University of Nebraska Medical Center Launches Patient Enrollment for RenovoRx's Pivotal Phase III TIGeR-PaC Clinical Trial

Ongoing Study is Investigating RenovoGem™ to treat Locally Advanced Pancreatic Cancer

LOS ALTOS, Calif., June 26, 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 University of Nebraska Medical Center (UNMC) is now enrolling patients with Locally Advanced Pancreatic Cancer (LAPC) in the Company's ongoing pivotal Phase III TIGeR-PaC clinical trial.

The TIGeR-PaC study is using RenovoRx's patented TAMP (Trans-Arterial Micro-Perfusion) therapy platform to evaluate its RenovoGem investigational drug-device combination product. RenovoGem utilizes pressure-mediated delivery of chemotherapy across the arterial wall to bathe tumor tissue. The study is comparing treatment with TAMP to the current standard-of-care (systemic intravenous chemotherapy).

“This year alone, more than 66,000 Americans are expected to be diagnosed with pancreatic cancer,” 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 very 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.”

“We are proud to partner with Dr. Klute and her team in our Phase III TIGeR-PaC trial,” said Leesa Gentry, Chief Clinical Officer of RenovoRx. “UNMC is renowned for its premier educational programs, innovative research, and extraordinary patient care. We appreciate UNMC's commitment to improving patient outcomes in pancreatic cancer through early detection and prevention education, multidisciplinary care, and the development of novel therapeutic approaches like TAMP in collaboration with the Sponsors.”

Shaun Bagai, CEO of RenovoRx stated, “We are at an exciting juncture at RenovoRx, and, importantly, in our pivotal TIGeR-PaC trial. With the addition of top cancer centers, like UNMC, we accelerate towards our goal of completing patient enrollment next year. Moreover, the data we are collecting from the TIGeR-PaC study is invaluable to us as we continue to explore using TAMP in other cancer tumors, as well as other clinical and commercial business development opportunities for our novel drug-delivery technology.”

About the Phase III 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, **RenovoGem™**, is a novel oncology drug-delivery combination utilizing TAMP administration technology combined with the FDA-approved chemotherapy, gemcitabine. The study is comparing treatment with TAMP to the current standard of care of systemic intravenous chemotherapy.

The TIGeR-PaC clinical trial is currently enrolling unresectable LAPC patients at esteemed cancer center sites across the United States. To learn more about the study and the participating clinical trial sites, visit <https://clinicaltrials.gov/> (NCT03257033).

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 American Cancer Society’s Cancer Facts & Figures 2023, pancreatic cancer has a 5-year combined overall 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 (LPAC) by the Center for Drug Evaluation and Research (the drug division of FDA).

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 and any interim analyses of such trials and studies, (ii) the potential of RenovoCath[®], RenovoGem[™] or TAMP[™], (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 clinical and commercial opportunities for our 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 UNMC's participation in the TIGeR-PaC study 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.