

RenovoRx Highlights Recent Presentation of Clinical Data Abstract at the 2024 Society of Interventional Radiology Annual Scientific Meeting

Sub-study of the pivotal Phase III TIGeR-PaC clinical trial offers important data to potentially assist in optimization of TAMP therapy

LOS ALTOS, Calif.--(BUSINESS WIRE)-- 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, today highlights a presentation of a clinical data abstract at the recent 2024 Society of Interventional Radiology (SIR) Annual Scientific Meeting, held March 23-27, 2024 in Salt Lake City, Utah. Clinical data was presented by David Sperling, MD, Associate Professor of Radiology at Columbia University Irving Medical Center in New York.

Dr. Sperling, together with his co-authors, presented "Mesenteric Venous Thrombosis as a Predictor of Target Artery Thrombosis and Tran-Arterial Micro Perfusion Treatment Completion Among Patients with Locally Advanced Pancreatic Cancer (LAPC)," a substudy of RenovoRx's ongoing pivotal Phase III TIGeR-PaC clinical trial. In this sub-study, baseline abdominal CT imaging completed prior to randomization into the TIGeR-PaC study was reviewed for the presence or absence of Mesenteric Venous Thrombosis (MVT) by an independent core imaging radiologist. Outcomes examined 1) patient inability to complete the planned 8 treatments with RenovoRx's patented Trans-Arterial Micro-Perfusion (TAMP™) therapy platform, 2) target vessel thrombosis during or after TAMP, and 3) side effects of pain or discomfort associated with the use of TAMP.

Patients with pancreatic cancer are commonly at risk of both arterial and venous thromboembolism, obstructions of an artery or blood vessel by a blood clot, and MVT can also be an incidental finding when treating this important patient population. MVT is a blood clot impacting one or more of the major veins that drain blood from the intestine that may make certain treatments difficult.

The data presentation highlighted that of the 25 patients randomized to the TAMP therapy, 6 failed to complete all 8 planned procedures due to thrombosis of the targeted arterial artery. Among those 6 patients, the prevalence of MVT on the baseline abdominal CT imaging was 100%.

"Our sub-study presents important data to assist in optimization of TAMP with better risk stratification of patients while improving guidance of TAMP therapy for LAPC treatment," said Dr. Sperling. "After retrospectively evaluating 25 patients randomized to the TAMP therapy in the TIGeR-PaC study, we concluded that MVT on baseline CT imaging is a strong

predictor of target artery thrombosis which could be a limitation of TAMP for repeated procedures for these specific patients."

"Identification of the presence of MVT as a risk factor, if addressed clinically, can potentially increase frequency of patients undergoing successful TAMP procedures during treatment with proper management," said Ramtin Agah, MD, Chief Medical Officer and Founder of RenovoRx. "It is important to understand appropriate candidates for TAMP, and managing patients who could be at any risk is paramount to helping underserved patient populations, like those diagnosed with LAPC. This is especially important given the potential of the TAMP therapy platform. The first interim analysis in the Phase III TIGeR-PaC study 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 has a primary endpoint is a 6-month Overall Survival benefit with secondary endpoints including reduced side effects versus standard of care."

TIGeR-PaC (NCT03257033) 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 www.clinicaltrials.gov. RenovoRx's first product candidate, **RenovoGem™**, is a novel oncology drug-delivery combination utilizing TAMP administration technology, is currently under investigation for therapeutic delivery of the FDA-approved chemotherapy gemcitabine and has not been approved for commercial sale.

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.

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 RenovoGem

RenovoGem™ is the first drug-device combination product candidate that utilizes the **TAMP™** therapy platform via pressure-mediated delivery technology to deliver gemcitabine, an FDA-approved systemic chemotherapy, locally across the arterial wall to bathe tumor tissue in the chemotherapy. RenovoGem is currently being evaluated in the Phase III TIGeR-PaC clinical trial study in Locally Advanced Pancreatic Cancer (LAPC) patients.

The first interim analysis in the TIGeR-PaC study at the 26th event of the specified events (deaths), was completed in March 2023, with the Data Monitoring Committee recommending

a continuation of the study. The TIGeR-PaC study's primary endpoint is a 6-month OS benefit with secondary endpoints including reduced side effects versus standard of care. The data was first presented at the 2023 American Association for Cancer Research Annual Meeting in April 2023 and then as a Late Breaker Oral Presentation with additional secondary endpoint data at the 2023 European Society of Medical Oncology World Congress on Gastrointestinal Cancer in June 2023. The second interim analysis for this study will be triggered by the 52nd event, which is estimated to occur in late 2024.

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 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 <u>www.renovorx.com</u>. Follow RenovoRx on <u>Facebook</u>, <u>LinkedIn</u>, and <u>Twitter</u>.

Cautionary Note Regarding Forward-Looking Statements

This press release and statements of the Company's management and collaborators 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 forwardlooking 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 the sub-study data described herein will not provide 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.

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