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RenovoRx Initiates Patient Enrollment at University of Texas Southwestern Medical Center for Pivotal Phase III TIGeR-PaC Clinical Trial

Study is Investigating RenovoGem™ as Potential New Option for Pancreatic Cancer Treatment

Recent Positive Interim Data Analysis from Study Revealed 60% Survival Benefit and 65% Side Effect Reduction Versus Systemic Chemotherapy

LOS ALTOS, Calif. & DALLAS--(BUSINESS WIRE)-- [RenovoRx, Inc.](#) ("RenovoRx" or the "Company") (Nasdaq: RNXT), a clinical-stage biopharmaceutical company developing targeted combination therapies, today announced that the University of Texas (UT) Southwestern Medical Center is now enrolling pancreatic cancer patients in the open label, randomized Phase III TIGeR-PaC clinical trial. The study is investigating RenovoGem which utilizes RenovoRx's proprietary therapy platform, TAMP™, to provide improved and targeted intra-arterial delivery of FDA-approved gemcitabine chemotherapy to treat Locally Advanced Pancreatic Cancer (LAPC).

The study is comparing RenovoGem with standard of care treatment (intravenous gemcitabine and nab-paclitaxel). RenovoRx recently announced interim analysis data that suggested a 6-month improvement in median overall survival and a 65% reduction in side effects versus standard of care.

"Pancreatic cancer is expected to be the second largest cause of cancer-related deaths before 2030*," said Principal Investigator, Salwan Al Mutar, MD, MSc, Assistant Professor at UT Southwestern Medical Center. "Systemic, intra-venous chemotherapy uses blood vessels to deliver treatment. However, pancreatic cancer tumors have poor blood supply so systemic chemotherapy may not reach the tumor. This clinical trial is evaluating targeted, intra-arterial chemotherapy that is singularly focused on the tumor."

Ramtin Agah, M.D., RenovoRx's Founder and Chief Medical Officer, commented, "UT Southwestern Medical Center is one of the world's premier academic medical organizations, integrating research with exceptional clinical care. We are excited Dr. Al Mutar and his team are enrolling patients in this important and transformative study. Our shared vision is providing cancer patients with novel therapies to enhance survival and quality of life."

UT Southwestern is the most recent clinical trial site to join the Phase III TIGeR-PaC study which continues enrolling patients at U.S. sites. UT Southwestern's staff of more than 2,800 providers is responsible for groundbreaking medical advances and is committed to translating science-driven research quickly to new clinical treatments. Physicians there

provide medical care in about 80 specialties to more than 105,000 hospitalized patients, nearly 370,000 emergency room cases and oversee approximately three million outpatient visits annually.

About the TIGeR-PaC Study

TIGeR-PaC is a randomized multi-center Phase III open label clinical trial designed to investigate the Company's first product candidate, RenovoGem™, which utilizes RenovoRx's proprietary therapy platform, TAMP™, to provide targeted intra-arterial delivery of FDA-approved chemotherapy, gemcitabine, to treat locally advanced pancreatic cancer (LAPC) following stereotactic body radiation therapy (SBRT). The study is comparing treatment with TAMP versus standard of care systemic intravenous (IV) administration of gemcitabine and nab-paclitaxel. The study is designed to randomize 114 patients (57 in each arm) with all patients receiving upfront induction chemotherapy and SBRT. Final analysis will be conducted after 86 protocol-specified events have occurred in the SBRT population with two planned interim analyses: the first analysis when 30% of the specified events has been reported and the second analysis when 60% of the events have been reported (expected in mid-2024).

TIGeR-PaC 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://renovorx.com/clinical-trial/>.

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 chemotherapy, locally across the arterial wall to bathe tumor tissue in the chemotherapy. RenovoGem is currently being evaluated in the open label, randomized Phase III TIGeR-PaC clinical trial study in Locally Advanced Pancreatic Cancer (LAPC) patients. The Company plans to investigate RenovoGem in extrahepatic Cholangiocarcinoma (eCCA) in a clinical trial, which is anticipated to begin in the first half of 2023. RenovoGem is currently under investigation for the intra-arterial delivery of gemcitabine and has not been approved for commercial sale.

About RenovoRx, Inc.

RenovoRx is a clinical-stage biopharmaceutical company developing targeted combination therapies for high unmet medical needs. The Company's proprietary Trans-Arterial Micro-Perfusion (TAMP™) therapy platform is designed to bypass traditional systemic delivery methods and ensure precise therapeutic delivery to a target tissue, while minimizing a therapy's systemic toxicities. RenovoRx's unique approach to drug-delivery offers the potential for increased treatment safety, tolerance, and wider therapeutic windows. The Company's lead product candidate, RenovoGem™, combines gemcitabine with the company's patented delivery system and is regulated by FDA under its 505(b)2 pathway. RenovoGem is currently in a Phase III clinical trial (TIGeR-PaC) for the treatment of LAPC. RenovoRx is committed to transforming the lives of patients by delivering innovative solutions to change the current paradigm of cancer care. For more information, visit www.renovorx.com. Follow RenovoRx on [Facebook](#), [LinkedIn](#) and [Twitter](#).

* According to a recent report from the American Cancer Society.

Forward-Looking Statements

This press release 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 our clinical trials and studies, including anticipated timing, statements regarding the potential of RenovoTAMP®, RenovoCath® or RenovoGem™ or regarding our ongoing TIGeR-PaC Phase III clinical trial study in LAPC, statements regarding the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases, and our preliminary financial results, cash position and related ability to continue as a going concern. 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, clinical trials, therapy platform, business 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 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: the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our research programs; the interim results may not be predictive of the outcome of our clinical trial, which may not demonstrate sufficient safety and efficacy to support regulatory approval of our product candidate, or the regulatory authority may disagree with our interpretation of the data; research and clinical development plans and timelines, and the regulatory process for our product candidates; future potential regulatory milestones for our product candidates, including those related to current and planned clinical studies; our ability to use and expand our therapy platform to build a pipeline of product candidates; our ability to advance product candidates into, and successfully complete, clinical trials; the timing or likelihood of regulatory filings and approvals; 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; the commercialization potential of our product candidates, if approved; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; future strategic arrangements and/or collaborations and the potential benefits of such arrangements; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements; our ability to retain the continued service of our key personnel and to identify, hire and retain additional qualified personnel; the implementation of our strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform,

product candidates and research programs; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the pricing, coverage and reimbursement of our product candidates, if approved; developments relating to our competitors and our industry, including competing product candidates and therapies; negative impacts of the ongoing COVID-19 pandemic on our operations; and other risks. 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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