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INVESTOR RELATIONS

RenovoRx Announces Positive New Data from Phase III Clinical Trial Interim Analysis: 60% Survival Benefit and Fewer Side Effects than Systemic Chemotherapy

RenovoGem™ Patients had Greater than 65% Reduction in Side Effects, which can Include Nausea, Fatigue, and Reduced White Blood Cells During Pancreatic Cancer Treatment

These Data and Additional Secondary Endpoint Analyses to be Presented at American Association for Cancer Research (AACR) Annual Meeting on April 17, 2023

LOS ALTOS, Calif.--(BUSINESS WIRE)-- RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a biopharmaceutical company focused on the localized treatment of solid tumors, announced that it will present detailed, open label, planned Phase III interim data analysis of its innovative RenovoGem therapy for pancreatic cancer patients at the American Association for Cancer Research (AACR) Annual Meeting on April 17, 2023 in Orlando, Florida.

The interim analysis shows a 6-month median overall survival benefit for patients. That is nearly a 60% improvement versus the study control arm and current standard of care: intravenous (IV) administration of gemcitabine and nab-paclitaxel for locally advanced pancreatic cancer ("LAPC"). RenovoGem patients also had greater than 65% reduction in adverse events. These can include nausea, fatigue, and a decline in white blood cells.

TIGeR-PaC study Principal Investigator, Michael J. Pishvaian, M.D., Ph.D. at Johns Hopkins Medicine, said, "Results from the interim analysis echo the Phase I/II data and observational studies. The TIGeR-PaC clinical trial is ongoing, but it appears RenovoGem enhances patient survival and has fewer side effects than the standard of care treatment that impacts the entire body of a patient rather than the targeted treatment area. This is important because treatment of LAPC is often limited to systemic, high dose, IV chemotherapy. It often has debilitating side effects."

Dr. Pishvaian added, "These positive results offer hope for a compelling new treatment option that could greatly benefit this important patient population and perhaps many others as the research advances."

Ramtin Agah, MD, Chief Medical Officer and Founder of RenovoRx, said, "This planned, early interim data analysis is a critical look into our Phase III randomized study. When you compare the results with other approved and widely adopted drugs used for treatment of pancreatic cancer, our six-month median survival benefit is dramatically better than other options currently available. It is worth noting that ten years ago, Celgene announced positive, Phase III trial results for pancreatic cancer patients. Its Abraxane® drug, plus

gemcitabine, provided an overall survival benefit of seven weeks."

"As a result, we will be advancing discussions with the FDA about expediting forward progress, while continuing our current trial enrollment," said Dr. Agah.

RenovoRx CEO, Shaun Bagai, commented, "We are more than a third way through our Phase III TIGeR-PaC study and are encouraged by these data. Every extra day these patients enjoy is invaluable. With decreased adverse events, the six-month survival benefit we are reporting is even more profound."

Mr. Bagai added, "We believe the current standard of care needs a disruptive therapy like RenovoGem. There is a growing consensus our platform has the potential to impact other cancers and more advanced cancer stages. Consequently, we are evaluating RenovoGem for additional indications and having ongoing discussions with possible strategic partner oncology companies."

About TIGeR-PaC Interim Analysis Data

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, RenovoTAMP®, to provide targeted intra-arterial delivery of FDA-approved chemotherapy, gemcitabine, to treat LAPC following SBRT. The study is comparing treatment with RenovoGem versus standard of care treatment.

In this interim analysis, the control and treatment arms demonstrated divergence in median overall survival for patients. The study is designed to randomize 114 patients (57 in each arm) with all patients receiving upfront induction chemotherapy and SBRT. The TIGeR-PaC Data Monitoring Committee ("DMC") met and determined the interim data is promising and warrants continuation of this pivotal trial. As of the date of the analysis, 45 patients from U.S. sites had been randomized in this trial and the survival status of all subjects was used for the analysis.

- Twenty-three patients were randomized to intra-arterial gemcitabine (RenovoGem investigational treatment) arm and 22 to continuation of IV gemcitabine and nab-paclitaxel (standard of care control) arm.
- The median overall survival in the IV gemcitabine and nab-paclitaxel control arm was 10 months, versus 16 months in the intra-arterial RenovoGem arm from time of randomization. (NOTE: Both arms' median overall survival calculations do not include 4 to 5-months of life from diagnosis to randomization during the induction chemotherapy and radiation phase of the trial).
- Observed a positive trend in median overall survival by 24-weeks (6 months); in this interim analysis, the statistical significance was not reached to stop the study early ($p=0.051$).
- Observed that patients had greater than 65% reduction in adverse events compared to the control arm: In the IV gemcitabine and nab-paclitaxel control arm there were 11 reported Serious Adverse Events (out of 22 patients) vs. 4 reported Serious Adverse Events (out of 23) intra-arterial RenovoGem patients.

The second interim analysis of this Phase III trial is expected in mid-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 12% (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 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 RenovoTAMP® 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 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 with a vision to disrupt the current paradigm of cancer treatment. Our mission is to lead a revolution in oncology therapy by delivering its innovative and targeted intra-arterial (IA) delivery of chemotherapy directly to solid tumors. The proprietary RenovoRx Trans-Arterial Micro-Perfusion (RenovoTAMP®) therapy platform aims to avoid the harsh side effects typical of the current standard of care, or systemic delivery methods, thus improving patient well-being and, potentially extension of life, so more time may be enjoyed with loved ones. RenovoTAMP utilizes approved chemotherapeutics with validated mechanisms of action and well-established safety and clinical use, with the goal of improving their safety, tolerance, and widening their therapeutic window by providing more targeted delivery at the location of the tumor tissue. RenovoRx's lead product candidate, RenovoGem™, is a combination of gemcitabine and its patented delivery system, RenovoCath®, and is regulated by the FDA as a novel oncology drug product to treat unresectable locally advanced pancreatic cancer (LAPC). RenovoGem is currently being studied in the Phase III TIGeR-PaC clinical trial for the treatment of LAPC.

RenovoRx's patent portfolio for its therapy platform and product candidates includes eight issued U.S. patents, one issued European patent, and several additional patents pending in the US, EU and Asia. RenovoRx has been granted Orphan Drug Designation for intra-arterial delivery of gemcitabine for the treatment of both pancreatic cancer and bile duct cancer (cholangiocarcinoma).

Learn more by visiting the RenovoRx website or following RenovoRx on Facebook, LinkedIn and Twitter.

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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