December 21, 2023

RENOVO | RX
INVESTOR RELATIONS

RenovoRx Engages Oklahoma University (OU) Health as First Clinical Site in Preparation for the Pivotal Phase III CouGar Clinical Trial in Bile Duct Cancer

This study will be the Second Clinical Trial Evaluating RenovoGem™, a Combination Drug-Device Product, in a Difficult-to-Access Solid Tumor Cancer

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 announced the expansion of their clinical development pipeline in preparation for the commencement of a second Phase III trial. The CouGar Trial will evaluate RenovoGem in bile duct cancer, specifically unresectable locally advanced extrahepatic cholangiocarcinoma (eCCA).

"We are pleased to engage our first clinical site for our second pivotal clinical trial. The CouGar Trial marks an important milestone for RenovoRx as we expand our clinical pipeline for RenovoGem into bile duct cancer, a difficult-to-treat solid tumor cancer," said Leesa Gentry, Senior Vice President of Clinical Operations at RenovoRx. "I'm extremely proud of our team and our collaborators for their tremendous work reinforcing our mission to improve patient lives by delivering innovative therapies that can potentially change the current paradigm of cancer care."

The pivotal Phase III CouGar study is a randomized study designed to evaluate the safety and efficacy of unresectable, locally advanced eCCA using intravenous cisplatin, gemcitabine, and durvalumab (all forms of chemotherapy) versus Trans-Arterial Micro-Perfusion via RenovoGem (delivery system and gemcitabine) with intravenous durvalumab. Oklahoma University (OU) Health is the first clinical site for the CouGar study.

"Unfortunately, bile duct cancer today has a poor prognosis for patients. Despite early diagnosis, the five-year survival rate is approximately 24%," said Paula Novelli, MD FSIR, CouGar National Principal Investigator, and Associate Professor of Radiology and Director of Interventional Radiology Research at the University of Pittsburgh Medical Center. "There are currently limited treatment options for patients diagnosed with this aggressive cancer, which only prolongs life by a few months. The CouGar study brings hope for a new treatment option. RenovoGem has the potential to meet the urgent clinical need for a safe and effective therapy in this important patient population."

Dr. David Geller, Director, UPMC Liver Cancer Center, Richard L. Simmons Professor of Surgery, University of Pittsburgh School of Medicine is the CouGar study's Co-Investigator.

"The current standard of care for bile duct cancer is systemic (intravenous) chemotherapy,

which has poor uptake and delivery since there are few blood vessels feeding this type of tumor," said Dr. Hassan Hatoum, Principal Investigator, Associate Professor and Hematologist and Oncologist at Oklahoma University Health Stephenson Cancer Center – Gastrointestinal Cancer Clinic. "RenovoRx's clinical trial is evaluating targeted, trans-arterial delivery of chemotherapy that is locally directed to the tumor site. Our team looks forward to participating in the CouGar study to bring this novel therapy to patients."

RenovoGem received FDA Orphan Drug Designation for pancreatic cancer and bile duct cancer which provides 7 years of market exclusivity upon NDA approval.

About RenovoRx, Inc.

RenovoRx is a clinical-stage biopharmaceutical company developing proprietary targeted combination therapies for high unmet medical need with a goal to improve therapeutic outcomes for cancer patients undergoing treatment. The Company's proprietary 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 (IV) therapy). RenovoRx's unique 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 US IND that is regulated by FDA 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.)

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.

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 RenovoCath®, RenovoGem™ or TAMP™ 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 possibility that 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; our ability to comply with the continued listing standards of Nasdaq Stock Market LLC (“Nasdaq”) or the continued listing of our securities on Nasdaq; 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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Source: RenovoRx, Inc.