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RENOVO | RX
INVESTOR RELATIONS

Johns Hopkins Medicine Initiates Patient Enrollment for RenovoRx's Ongoing Phase III TIGeR-PaC Clinical Trial

Johns Hopkins Medicine's Valerie Lee, MD joins Michael J. Pishvaian, MD in an Appointed Key Role for TIGeR-PaC Trial

By becoming an additional clinical site for TIGeR-PaC, Johns Hopkins Medicine joins several esteemed cancer centers to support RenovoRx's initiative to complete patient enrollment for the trial during 2025

MOUNTAIN VIEW, Calif.--(BUSINESS WIRE)-- RenovoRx, Inc. **("RenovoRx" or the "Company") (Nasdaq: RNXT)**, a life sciences company developing innovative targeted oncology therapies and commercializing **RenovoCath®**, a novel, FDA-cleared drug-delivery device, today announced that Johns Hopkins Medicine is now initiated to enroll patients with locally advanced pancreatic cancer (LAPC) in RenovoRx's ongoing Phase III TIGeR-PaC clinical trial. Johns Hopkins Medicine becomes the newest addition to a distinguished network of clinical cancer sites across the United States participating in this important trial.

The initiation of patient enrollment at Johns Hopkins Medicine will be at their Sibley Memorial Hospital campus and marks the most recent site to support RenovoRx's path to completing patient enrollment for the trial. RenovoRx is expecting to achieve full enrollment in the TIGeR-PaC trial during 2025.

In addition, RenovoRx announced that John Hopkins Medicine's Valerie Lee, MD, Medical Oncologist, has been appointed as TIGeR-PaC Principal Investigator (PI) at Johns Hopkins Medicine. Michael J. Pishvaian, MD, PhD, Director of Gastrointestinal, Developmental Therapeutics and Clinical Research Programs at John Hopkins Medicine, currently serves as Trial Chairman for the entire TIGeR-PaC trial.

The TIGeR-PaC trial is evaluating RenovoRx's lead drug-device combination product candidate, intra-arterial delivery of gemcitabine (IAG) via the FDA-cleared RenovoCath device, which uses RenovoRx's proprietary **Trans-Arterial Micro-Perfusion (TAMP™)** therapy platform for the treatment of LAPC. This drug-device combination product candidate is currently under FDA investigation and has not been approved for commercial sale. The trial is comparing treatment with IAG in LAPC to the current standard-of-care (systemic intravenous chemotherapy).

"We are pleased that Johns Hopkins Medicine has been initiated to begin enrollment in our ongoing Phase III TIGeR-PaC clinical trial," said Leesa Gentry, Chief Clinical Officer of RenovoRx. "The addition of this prestigious cancer center further strengthens our trial. The philosophy of Johns Hopkins Medicine's leading researchers and clinicians aligns strongly with our vision of providing specialized medicine that translates into personalized care for

improved patient outcomes. Dr. Michael Pishvaian, who has served as our TIGeR-PaC Trial Chair since the trial's inception, will continue to provide deep understanding of the pancreatic cancer landscape. With the addition of Johns Hopkins Medicine as a clinical trial site, Dr. Valerie Lee will join the trial serving as Principal Investigator. This new clinical site will help drive enrollment of the TIGeR-PaC trial to completion as they treat a large number of patients diagnosed with pancreatic cancer. We are proud to partner with Johns Hopkins Medicine as well as our other TIGeR-PaC clinical sites as they strive to provide the best in care for patients diagnosed with difficult-to-treat tumors like pancreatic cancer."

At Johns Hopkins Medicine, Dr. Lee's expertise includes management of gastrointestinal malignancies, including gastric, colon, and pancreatobiliary cancers. She also oversees multiple early-phase clinical trials, with her research being published in numerous peer-reviewed journals.

Johns Hopkins Medicine's Sibley Memorial Hospital campus ranks among the top hospitals in the Washington, D.C., metropolitan area, delivering comprehensive healthcare services to local communities. The hospital provides an extensive array of care, including medical, surgical, intensive care, obstetric, oncology, and orthopedic services, alongside numerous inpatient and outpatient offerings.

The current protocol and statistical analysis plan for the TIGeR-PaC trial requires 114 randomized patients, with 86 events (i.e., patient deaths) necessary to complete the final analysis. As of March 28, 2025, 90 patients have been randomized with 50 events having occurred. A second interim analysis will be triggered by the 52nd event. The timing required to analyze the data after the 52nd event is expected to take several months and includes a full review with recommendations by the TIGeR-PaC Data Monitoring Committee. RenovoRx currently anticipates the 52nd event to occur during the second quarter of 2025. The key recommendation from the Data Monitoring Committee on whether or not to continue the study based on the data reviewed is expected to be announced in the second half of 2025.

About RenovoCath

Based on its FDA clearance, RenovoCath® is intended for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. RenovoCath is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. For further information regarding our RenovoCath Instructions for Use ("IFU"), please see: IFU-10004-Rev.-G-Universal-IFU.pdf.

About the TIGeR-PaC Clinical Trial

TIGeR-PaC is an ongoing Phase III randomized multi-center trial evaluating the proprietary **TAMP™** (Trans-Arterial Micro-Perfusion) therapy platform for the treatment of LAPC. RenovoRx's first investigational drug-device combination product candidate using the TAMP therapy platform enabled with the Company's FDA-cleared **RenovoCath®** device for the intra-arterial administration of chemotherapy, gemcitabine (IAG).

About RenovoRx, Inc.

RenovoRx **(Nasdaq: RNXT)** is a life sciences company developing innovative targeted

oncology therapies and commercializing **RenovoCath®**, a novel, U.S. Food and Drug Administration (FDA)-cleared local drug delivery device, targeting high unmet medical needs. RenovoRx's patented **Trans-Arterial Micro-Perfusion (TAMP™)** therapy platform is designed to ensure targeted therapeutic delivery across the arterial wall near the tumor site to bathe the target tumor, while potentially minimizing a therapy's toxicities versus systemic intravenous therapy. RenovoRx's novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy, and its mission is to transform the lives of cancer patients by providing innovative solutions to enable targeted delivery of diagnostic and therapeutic agents.

In addition to the RenovoCath device, RenovoRx is also evaluating our novel Phase III drug-device combination oncology product candidate (intra-arterial gemcitabine, known as **IAG**). IAG is being evaluated under a U.S. investigational new drug application that is regulated by the FDA's 21 CFR 312 pathway. The investigational IAG utilizes RenovoCath**,** the Company's FDA-cleared drug-delivery device, indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. The combination of intra-arterial infusion of chemotherapy, gemcitabine, and the RenovoCath device is currently being evaluated for the treatment of LAPC by the Center for Drug Evaluation and Research (the drug division of FDA).

The combination product candidate, which is enabled the RenovoCath device, is currently under investigation and has not been approved for commercial sale. RenovoCath with gemcitabine received Orphan Drug Designation for pancreatic cancer and bile duct cancer, which provides 7 years of market exclusivity upon new drug application approval by the FDA.

RenovoRx is also engaged in implementing commercialization strategies utilizing its TAMP technology and FDA-cleared RenovoCath device as stand-alone device. In December 2024, RenovoRx announced the receipt of its first commercial purchase orders for RenovoCath devices. Additionally, certain of these customers have already initiated repeat orders as RenovoRx works to expand the number medical institutions that have initiated the process for RenovoCath purchase orders, including several esteemed, high volume National Cancer Institute-designated centers. To meet and satisfy the anticipated demand, RenovoRx will continue to actively explore further revenue-generating activity either on its own or in tandem with a medical device commercial partner.

For more information, visit www.renovorx.com. Follow RenovoRx on Facebook, LinkedIn, and X.

Cautionary Note Regarding Forward-Looking Statements

This press release and statements of the Company's management made in connection therewith contain 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 pre-clinical and clinical trials and studies, including the overall timing and timing for additional interim data readouts and full patient enrollment for our ongoing TIGeR-PaC Phase III clinical trial study in LAPC, (ii) the potential of RenovoCath® or TAMP™ as standalone commercial products, our anticipated timing for and levels of revenue generation from RenovoCath sales, and our commercialization plans

in general, (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 commercialization strategies utilizing our TAMP 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, commercial 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 significant 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 our execution of our commercial strategy for RenovoCath or our TAMP technology may not lead to viable or repeating revenue generating operations; (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 TIGeR-PaC and any other 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, including our Annual Report on Form 10-K for the period ended December 31, 2024, which was filed with the Securities and Exchange Commission on April 1, 2025.

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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