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RenovoRx Announces Key Phase III Milestone: TIGeR-PaC Trial Surpasses 100 Randomized Patients as Study Nears Completion of Enrollment

TIGeR-PaC Trial Enrollment Remains on Track for Completion in First Half of 2026, with Final Data Expected in 2027

Select TIGeR-PaC Cancer Centers Now Using RenovoCath® as a Stand-Alone Device for Drug-Delivery in Oncology Management

MOUNTAIN VIEW, Calif., March 26, 2026 (GLOBE NEWSWIRE) -- **RenovoRx, Inc.** ("**RenovoRx**" or "**the Company**") (Nasdaq: RNXT), a life-sciences company developing innovative targeted oncology therapies and commercializing RenovoCath®, a patented, FDA-cleared drug-delivery device, today announced the Company has achieved a key milestone in its ongoing Phase III TIGeR-PaC clinical trial by surpassing 100 randomized patients and remains on track for enrollment completion in the first half of 2026, with final data expected in 2027.

"Reaching over 100 randomized patients marks an important milestone in our Phase III trial as we maintain strong momentum toward enrollment completion. We remain committed to completing the TIGeR-PaC trial and delivering final data in 2027," said Leesa Gentry, Chief Clinical Officer of RenovoRx. "In parallel, select TIGeR-PaC cancer centers have begun using the TAMP™ therapy platform, enabled by the RenovoCath device, for targeted drug-delivery in the treatment of patients diagnosed with solid tumors."

RenovoRx's novel drug-device combination oncology product candidate (intra-arterial gemcitabine delivered via RenovoCath, known as **IAG**) is being evaluated in the TIGeR-PaC trial. IAG is being evaluated by the Center for Drug Evaluation and Research (the drug division of the FDA) under a U.S. investigational new drug application that is regulated by the FDA's 21 CFR 312 pathway. IAG utilizes RenovoCath, the Company's patented, FDA-cleared drug-delivery device, indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. TIGeR-PaC is evaluating IAG in locally advanced pancreatic cancer, and its potential to minimize a therapy's toxicities versus systemic intravenous therapy.

The current protocol and statistical analysis plan for the TIGeR-PaC trial requires 114 randomized patients, with 86 events (deaths) necessary to complete the final analysis. As of March 24, 2026, 104 patients have been randomized and 72 events have occurred. RenovoRx anticipates completion of enrollment by the end of the first half of 2026, ensuring a minimum of 114 patients will be randomized.

The first and second pre-planned interim analyses were conducted per protocol specifications and triggered upon the 26th event (2023) and the 52nd event (2025), respectively. In both the first and second interim analyses, the independent data monitoring committee (DMC) for the trial recommended that RenovoRx continue with the trial, based on its review of the data.

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 select 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 RenovoRx, Inc.

RenovoRx, Inc. (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 for 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.

RenovoRx is in the initial stages of actively commercializing its TAMP technology and FDA-cleared RenovoCath as a stand-alone device. In December 2024, RenovoRx announced the receipt of its first commercial purchase orders for RenovoCath devices, and for the first nine months of 2025, approximately \$900,000 of revenues were generated from RenovoCath sales. Several customers have already initiated repeat orders in parallel to RenovoRx expanding the number of medical institutions initiating new RenovoCath 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.

RenovoRx is also evaluating its novel drug-device combination oncology product candidate (intra-arterial gemcitabine delivered via RenovoCath, known as IAG) in the ongoing Phase III TIGeR-PaC trial. IAG is being evaluated by the Center for Drug Evaluation and Research (the drug division of the FDA) under a U.S. investigational new drug application that is regulated by the FDA’s 21 CFR 312 pathway. IAG utilizes RenovoCath, the Company’s patented, FDA-cleared drug-delivery device, indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion.

The IAG combination product candidate, which is enabled by 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 seven years of market exclusivity upon new drug application approval by the FDA.

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 the anticipated benefits to the Company of the trial enrollment milestone described herein as well as (i) our clinical trials and studies generally (including the timing for full enrollment and final data readout in the TIGeR-PaC trial), (ii) the potential for IAG to treat or provide clinically meaningful outcomes for certain medical conditions or diseases, and (iii) our efforts to commercialize our RenovoCath and 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, 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 our exploration of commercial opportunities for our TAMP technology may not lead to viable, 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 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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