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INVESTOR RELATIONS

RenovoRx Announces FDA Orphan Drug Designation Granted: Oxaliplatin for the Treatment of Pancreatic Cancer

Third FDA Orphan Drug Designation Continues to Advance RenovoRx's Therapeutic Oncology Pipeline and Provides Seven Years of Market Exclusivity

MOUNTAIN VIEW, Calif., May 28, 2026 (GLOBE NEWSWIRE) -- **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 the U.S. Food and Drug Administration (FDA) recently granted RenovoRx Orphan Drug Designation (ODD) of oxaliplatin for the treatment of pancreatic cancer.

The designation was issued by the FDA's Office of Orphan Products Development pursuant to Section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb). Oxaliplatin is an approved and commonly used chemotherapy.

As RenovoRx continues to advance its therapeutic pipeline, it is simultaneously expanding commercialization of RenovoCath as a stand-alone device, driving adoption at leading cancer centers and building strategic and clinical collaborations that can support future revenue growth and broader platform use. RenovoCath, a patented FDA-cleared device, employs a dual-balloon infusion catheter for targeted delivery of therapeutic agents directly near a tumor.

This is RenovoRx's second ODD in pancreatic cancer, and third designation in total, reflecting the Company's differentiated approach to targeted intra-arterial drug-delivery using RenovoCath. RenovoRx previously received ODD for intra-arterial gemcitabine delivered via RenovoCath (known as IAG) in locally advanced pancreatic cancer (LAPC) and bile duct cancer. This designation for oxaliplatin, a platinum-based chemotherapy widely used in pancreatic cancer treatment, further supports the versatility of RenovoRx's novel approach to delivering multiple therapeutic agents directly near the tumor site.

ODD carries meaningful regulatory and financial benefits, including:

- **Seven years of market exclusivity:** Upon FDA approval of the designated indication (in this case, intra-arterial oxaliplatin for pancreatic cancer via RenovoCath), RenovoRx would be entitled to seven years of exclusive marketing rights, during which the FDA cannot approve the same drug for the same orphan indication by another sponsor.
- **Federal tax credit:** A 25% tax credit on qualified clinical research expenses incurred in connection with the designated drug.

- **FDA application fee waiver:** A waiver of the FDA application filing fee, which currently exceeds several million dollars for applications requiring clinical data.
- **Eligibility for orphan product development grants:** Access to grant funding from the FDA's Orphan Products Development grants program to support clinical development.

"Receiving a third ODD from the FDA is an important milestone as it provides additional validation of our strategy to build a multi-agent, targeted, drug-delivery oncology pipeline enabled by our patented RenovoCath device," said Shaun Bagai, Chief Executive Officer of RenovoRx. "Our differentiated technology is designed to deliver therapeutic agents intra-arterially across the arterial wall directly near the tumor site, with potential applications across multiple therapeutic agents and multiple cancer types. The FDA's ODD of oxaliplatin not only expands our pipeline, but also provides valuable regulatory incentives, including seven years of potential market exclusivity and a waiver of FDA application fees that can total several million dollars. While we are laser focused on finishing our current Phase III clinical trial and advancing commercialization of RenovoCath as a standalone device, we remain committed to advancing our platform and exploring the full potential of targeted oxaliplatin delivery in patients diagnosed with difficult-to-treat cancers."

Pancreatic cancer remains one of the deadliest malignancies, with an estimated 67,530 new cases and more than 52,740 deaths expected in the United States in 2026, according to the American Cancer Society.[1] Despite advances in oncology, the disease is often diagnosed at a late stage in the majority of patients, and the five-year survival rate remains approximately 13%[1], underscoring the profound unmet, yet urgent, medical need for new therapeutic approaches.

Oxaliplatin is a key component of FOLFIRINOX, one of the most widely used chemotherapy regimens for patients with advanced pancreatic cancer. RenovoRx is advancing a differentiated approach by delivering oxaliplatin directly near the tumor site using its RenovoCath device.

"This designation for intra-arterial oxaliplatin highlights the breadth of what RenovoCath may offer to pancreatic cancer patients," said Leesa Gentry, Chief Clinical Officer of RenovoRx. "Intra-arterial oxaliplatin may broaden the range of pancreatic cancer targets beyond LAPC that could benefit from localized drug-delivery with RenovoCath."

This ODD for intra-arterial oxaliplatin is separate from and in addition to RenovoRx's existing ODD for IAG in LAPC and bile duct cancer, which also carries seven years of market exclusivity upon NDA approval by the FDA. RenovoRx's TIGeR-PaC Phase III clinical trial evaluating IAG in LAPC continues to advance, with the Company anticipating notification of enrollment closure in June 2026 and final data readout in mid to late 2027.

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.

[1]https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2026-cancer-facts-figures.html

About RenovoRx, Inc.

RenovoRx, Inc. (Nasdaq: RNXT) is a life sciences company developing innovative targeted oncology therapies and commercializing **RenovoCath®**, a patented, 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 actively commercializing its TAMP technology and FDA-cleared RenovoCath as a standalone device. For its first full year of commercial efforts in 2025, RenovoRx generated approximately $1.1 million in RenovoCath sales and a record $563,000 of sales in the first quarter of 2026. RenovoRx is actively working to expand the number of medical institutions initiating new RenovoCath orders, including esteemed, high-volume National Cancer Institute-designated centers.

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, which is FDA-cleared for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. RenovoRx anticipates full enrollment in the TIGeR-PaC trial in June 2026 and final data readout in mid to late 2027.

The IAG combination product candidate, enabled by the RenovoCath device, is currently under investigation and has not been approved for commercial sale. RenovoCath with gemcitabine received ODD for pancreatic cancer and bile duct cancer, and oxaliplatin has received ODD for pancreatic cancer, each of 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 (i) our clinical trials and studies, (ii) the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases, and (iii) our efforts to commercialize our RenovoCath and TAMP technology. Statements (including those regarding the anticipated benefits to the Company

of the ODD described herein) that are not purely historical are forward-looking statements. These and other 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 such 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,” "aim," "goal," “estimates,” “intends,” and “potential,” or derivatives of these terms or other comparable terminology regarding RenovoRx’s statements about the future, although not all forward-looking statements contain these words. Risks, uncertainties and assumptions that could cause actual events to differ materially from those projected or indicated by forward-looking statements, include, without limitation: (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 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, needs for additional financing, our ability to obtain additional capital and our ability to maintain the listing of our common stock on Nasdaq; (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 scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform, product candidates, and research programs; (xvii) our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; (xix) the pricing, coverage, and reimbursement of our product candidates, if approved; and (xx) 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, which can be accessed

at https://ir.renovorx.com/sec-filings.

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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