

July 31, 2024



RenovoRx Announces Publication of Positive Early-Stage Clinical Data in International Peer-Reviewed Journal, The Oncologist®

Published data shows that chemotherapy delivered via TAMP™ with prior chemoradiation in Locally Advanced Pancreatic Cancer (LAPC) observed an Overall Survival (OS) of 27-months

Targeted chemotherapy delivery via TAMP is currently being evaluated in an ongoing Phase III clinical trial in LAPC

LOS ALTOS, Calif., July 31, 2024 (GLOBE NEWSWIRE) -- [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 a publication of positive early-stage clinical data relating to RenovoRx’s Trans-Arterial Micro-Perfusion (TAMP) therapy platform in the international peer-reviewed journal, The Oncologist.

The scholarly article titled, “**Treatment of Locally Advanced Pancreatic Cancer (LAPC) Using Localized Trans-Arterial Micro Perfusion (TAMP) of Gemcitabine: Combined Analysis of RR1 and RR2,**” is a publication of early-stage clinical data, primarily procedure safety, overall survival (OS), and evaluation of factors associated with OS, in LAPC patients undergoing TAMP from the foundational studies conducted by the Company. The studies included the intra-arterial administration of gemcitabine utilizing the TAMP read in an early Phase I/II dose escalation safety study (RR1) and acquired data from a post-marketing post-treatment observational registry study (RR2). The lead author, Hassan Hatoum, MD, is an oncologist and hematologist at the University of Oklahoma Health Sciences Center (OUHSC).

“These important foundational studies highlight the potential for a meaningful advancement in the standard of care for cancer treatment, with less toxicity and improved outcomes,” said Hassan Hatoum, MD. “These clinical data support that TAMP has the potential to extend OS compared to systemic chemotherapy in difficult-to-treat solid tumors and provide a paradigm-shifting treatment option for patients diagnosed with LAPC.”

TAMP 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. TAMP is currently being evaluated in a Phase III clinical trial investigating intra-arterial delivery of chemotherapy via TAMP for the treatment of LAPC versus the standard of care, systemic intravenous delivery of chemotherapy. Access The Oncologist manuscript: [Treatment of locally advanced](#)

[pancreatic cancer using localized trans-arterial micro perfusion of gemcitabine: combined analysis of RR1 and RR2 | The Oncologist | Oxford Academic \(oup.com\).](#)

TAMP is designed to bypass traditional systemic delivery methods to provide precise drug-delivery through the artery near the tumor site to bathe the target tumor in chemotherapy. This approach creates the potential to minimize systemic toxicities. The RR1 and RR2 foundational studies investigated an unmet medical need for a more effective locoregional LAPC therapy to improve survival and increase resectability of the cancer.

In this study, data from RR1 and RR2 were pooled. The aims of the analysis were to assess TAMP procedure safety, OS, and evaluate factors associated with OS. The median OS for the 35 evaluable patients with LAPC disease was 12.6 months, TAMP-delivered chemotherapy in LAPC patients with prior radiation was associated with significantly longer OS (27.1 months) compared to prior systemic chemotherapy (14.6 months) or no prior treatment (7.0 months). The most common side effects were gastrointestinal-related (abdominal pain, emesis, and vomiting); the most common Grade 3 toxicity was sepsis. Study results concluded that treatment with TAMP-mediated drug-delivery in patients with LAPC is potentially safe, feasible, and provides several potential clinical benefits.

“All three current FDA approved treatments for pancreatic cancer (Abraxane[®], Lynparza[®] and Onivyde[®]) in the past ten years have shown less than a two-month median survival benefit with increased toxicity rates,” said Ramtin Agah, Chief Medical Officer and Founder of RenovoRx. “With more than one year survival benefit and less side effects compared to the current standard of care, this early-stage clinical data highlights the potential represented by our TAMP platform as a promising treatment option for pancreatic and other difficult to treat cancers.”

Dr. Agah added, “This article is a comprehensive publication of our RRI and RR2 studies. The initial results from those early-stage clinical studies were the basis for testing our novel approach in the ongoing pivotal Phase III trial, TIGeR-PaC. The TIGeR-PaC study aims to validate the benefit of administration of chemotherapy with TAMP to pancreatic tumors in head-to-head comparison with current standard of care, systemic chemotherapy.”

About The Oncologist

The Oncologist is an international peer-reviewed journal for practicing oncologists and hematologists. It is dedicated to translating the latest research developments into the best multidimensional care for cancer patients and is committed to helping physicians excel in this ever-expanding environment through the publication of timely reviews, original studies, and commentaries on important developments.

About the Phase III TIGeR-PaC Clinical Trial

TIGeR-PaC is RenovoRx's ongoing Phase III randomized multi-center study evaluating the proprietary TAMP therapy platform for the treatment of Locally Advanced Pancreatic Cancer (LAPC). RenovoRx's first product candidate using the TAMP technology, **RenovoGem[™]**, is a novel investigational oncology drug-delivery combination utilizing the Company's FDA-cleared **RenovoCath[®]** device for the intra-arterial administration of chemotherapy, gemcitabine. The study is comparing treatment with TAMP to the current standard of care of systemic intravenous chemotherapy.

The first interim analysis in the Phase III clinical trial was completed in March 2023, with the Data Monitoring Committee recommending a continuation of the study. The TIGeR-PaC study is investigating TAMP in LAPC. The study's primary endpoint is a 6-month Overall Survival benefit with secondary endpoints including reduced side effects versus standard of care. The second interim analysis for this study will be triggered by the 52nd event, which is estimated to occur in late 2024.

About Locally Advanced Pancreatic Cancer (LAPC)

According to the American Cancer Society's Cancer Facts & Figures 2024 and PanCAN, respectively, pancreatic cancer has a 5-year all stages combined relative survival rate of 13% (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 the 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 RenovoRx, Inc.

RenovoRx is a clinical-stage biopharmaceutical company developing novel precision oncology therapies based on a local drug delivery platform for high unmet medical need with a goal to improve therapeutic outcomes for cancer patients undergoing treatment. RenovoRx's patented **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 therapy. RenovoRx's novel and patented 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 U.S. investigational new drug application that is regulated by the FDA's 21 CFR 312 pathway. RenovoGem is currently being evaluated for the treatment of locally advanced pancreatic cancer (LPAC) by the Center for Drug Evaluation and Research (the drug division of FDA). RenovoGem 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.

RenovoRx is also actively exploring the use of TAMP to treat cancers beyond LAPC as well as other commercialization strategies for its technology.

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](#).

Cautionary Note Regarding Forward-Looking Statements

This press release and statements of the Company's management made in connection therewith 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 (i) 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, (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 expand our intellectual property. 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 the publication of data as described herein will not lead to any benefits for the Company; (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.

Contact:

KCSA Strategic Communications

Valter Pinto or Jack Perkins

T:212-896-1254

Renovorx@KCSA.com

RENOVO | RX

Source: RenovoRx, Inc.