

May 25, 2023



# RenovoRx Announces Late-Breaking Oral Presentation at 2023 ESMO World Congress on Gastrointestinal Cancer

*Company to Present Interim Analysis Secondary Endpoint Data Including Progression-free Survival from Phase III TIGeR-PaC Study, a Multi-center Open-label Study Evaluating RenovoGem™ to Treat Locally Advanced Pancreatic Cancer (LAPC)*

LOS ALTOS, Calif.--(BUSINESS WIRE)-- [RenovoRx, Inc.](#) ("RenovoRx" or the "Company") (Nasdaq: RNXT), a clinical-stage biopharmaceutical company developing targeted combination therapies, today announced the acceptance of a late-breaking oral presentation for its lead product candidate RenovoGem, in the treatment of locally advanced pancreatic cancer (LAPC), at the upcoming ESMO World Congress on Gastrointestinal Cancer (ESMO GI). The conference will be held June 28 – July 1, 2023, in Barcelona, Spain, with the presentation scheduled for Thursday, June 29, 2023, at 8:50 AM CEST.

The presentation will feature new secondary endpoint data from the first interim analysis triggered in the Phase III TIGeR-PaC study – a multi-center, open-label clinical trial. The study is evaluating RenovoGem to treat LAPC through RenovoRx's proprietary trans-arterial micro-perfusion (TAMP™) drug-delivery platform of FDA-approved gemcitabine.

The Phase III study has a primary endpoint of overall survival and several secondary endpoints, including progression-free survival (PFS) and quality of life. The study is designed to randomize 114 patients. Final analysis will be conducted after 86 events (deaths) from the stereotactic body radiation therapy (SBRT) population. The study includes two planned interim analyses, the first upon 30% (26 of 86) of total events and the second upon 60% (52 of 86) of total events.

Data from the planned first interim analysis of the Phase III TIGeR-PaC study, [presented at recent American Association of Clinical Research \(AACR\) 2023](#), demonstrated a 6-month median overall survival difference between the test arm (RenovoGem) and control arm (standard of care gemcitabine and Abraxane) along with a 65% reduction in adverse events.

"We are thrilled to announce that Dr. Michael J. Pishvaian, Principal Investigator, will present new secondary endpoint data from the interim analysis in our pivotal study at the upcoming ESMO GI," said Shaun Bagai, CEO, RenovoRx. "This data will notably include PFS from the Phase III study, which has historically been used as a registrational endpoint in FDA New Drug Applications both in accelerated and traditional approvals. We look forward to continued engagement with leading oncologists in the field as we advance RenovoGem and our delivery platform's potential to benefit cancer patients."

**Presentation Details:**

**Abstract Title:** “The Phase 3 study Targeted Intra-Arterial Gemcitabine vs. Continuation of IV Gemcitabine plus Nab-Paclitaxel following Induction with Sequential IV Gemcitabine plus Nab-Paclitaxel and Radiotherapy for Locally Advanced Pancreatic Cancer (TIGeR-PaC) trend toward a survival benefit at its first interim analysis”

**Abstract Number:** LBA-1

**Presenting Author:** Michael Jon Pishvaian, M.D., Ph.D., Director of Gastrointestinal, Developmental Therapeutics and Clinical Research Programs, Associate Professor of Oncology, John Hopkins School of Public Health

**Presentation Date and Time:** Thursday, June 29, 2023, at 8:50 – 9:00 AM CEST

Data presented at the conference will be available to view in the [Clinicians](#) section of the RenovoRx website following the ESMO GI Conference.

The treatment of LAPC remains a clinical challenge with a median survival of 15-18 months from diagnosis. RenovoGem™ delivers gemcitabine directly to the tumor site, enhancing the therapeutic effectiveness while potentially minimizing the systemic side effects commonly associated with traditional chemotherapy intravenous administration, and potentially improving patient outcomes. RenovoGem is currently under investigation for the intra-arterial delivery of gemcitabine and has not been approved for commercial sale.

TIGeR-PaC is currently enrolling unresectable LAPC patients at several sites across the US. To learn more about the study and the participating clinical trial sites, visit <https://renovorx.com/clinical-trial/>.

### **About RenovoRx, Inc.**

RenovoRx is a clinical-stage biopharmaceutical company developing targeted combination therapies for high unmet medical needs. The Company's proprietary Trans-Arterial Micro-Perfusion (TAMP™) therapy platform is designed to bypass traditional systemic delivery methods and ensure precise therapeutic delivery to a target tissue, while minimizing a therapy's systemic toxicities. RenovoRx's unique approach to drug-delivery offers the potential for increased treatment safety, tolerance, and wider therapeutic windows. The Company's lead product candidate, RenovoGem™, combines gemcitabine with the company's patented delivery system and is regulated by FDA under its 505(b)2 pathway. RenovoGem is currently in a Phase III clinical trial (TIGeR-PaC) for the treatment of LAPC. RenovoRx is committed to transforming the lives of patients by delivering innovative solutions to change the current paradigm of cancer care. For more information, visit [www.renovorx.com](http://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 RenovoTAMP®, RenovoCath® or RenovoGem™ 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 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; 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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