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RenovoRx Announces Orphan Drug Designation Granted for Treating Bile Duct Cancer

TIGeR-PaC -- a Phase III Clinical Trial Continues Enrolling Pancreatic Cancer Patients in U.S. and Europe

LOS ALTOS, Calif., June 2, 2020 /PRNewswire/ --RenovoRx, an innovator in targeted cancer therapy, today announced the U.S. Food and Drug Administration (FDA) has granted the Company orphan drug designation for treating bile duct cancer ---- also known as cholangiocarcinoma --- with intra-arterial gemcitabine. The Company's proprietary FDA cleared medical device system, RenovoCath®, employs a dual-balloon infusion catheter, enabling the Trans-Arterial Micro-Perfusion (TAMP™) approach for targeted delivery of gemcitabine to the tumor site.

In April 2018, RenovoRx received FDA orphan drug designation for treatment of pancreatic cancer with intra-arterial gemcitabine. RenovoRx's proprietary TAMP delivery of gemcitabine is being utilized in the TIGeR-PaC Phase III trial evaluating extended median survival and improved Quality of Life for pancreatic cancer patients.

In the United States, more than 8,000 people develop cholangiocarcinoma annually[i]. However, research suggests the incidence is higher due to misdiagnosis.[ii] The disease is nearly five times more common in Asia and the Mideast, largely due to parasitic liver fluke infections.[iii,iv]

According to Cancer.net, the 5-year survival rate ranges between 2 and 24%, depending on when the cancer is found. Two-thirds of patients are 65 or older.

"Receiving a second orphan drug designation from the FDA is a significant milestone as we build the TAMP platform for solid tumor treatment. This new orphan drug indication builds on the momentum of the TIGeR-PaC Phase III clinical trial currently treating pancreatic cancer patients in the U.S. and Europe," said RenovoRx CEO Shaun Bagai. "To help bile duct cancer patients, we are designing a Phase I/II clinical trial that will launch by early next year. This expansion of the RenovoRx platform, beyond pancreatic cancer, could improve outcomes for more cancer patients."

Bagai added, "Our team is evaluating market opportunities in Asia since it is estimated more than 100,000 patients are diagnosed annually with bile duct cancer that could be treated with RenovoRx's TAMP delivery of intra-arterial gemcitabine."

The FDA's Office of Orphan Drug Products grants orphan status to support development of medicines for underserved patient populations, or rare disorders, affecting fewer than

200,000 people in the U.S. Orphan drug designation provides RenovoRx certain benefits, including market exclusivity upon regulatory approval if received, exemption of FDA application fees and tax credits for qualified clinical trials.

About RenovoRx, Inc.

RenovoRx, headquartered in Silicon Valley, California, is developing innovative solutions for targeted delivery of fluids, including diagnostic and therapeutic agents such as chemotherapy, to specific sites in the body. Delivering these concentrated agents through the Trans-Arterial Micro-Perfusion (TAMP) method with RenovoCath safely and without transmission to non-targeted areas, is the focus of RenovoRx technology. Learn more by visiting the RenovoRx website or following us on Facebook, LinkedIn and Twitter.

The randomized TIGeR-PaC trial is enrolling newly diagnosed, unresectable locally-advanced pancreatic cancer patients in the United States and Europe. To learn more, visit https://renovorx.com/clinical-trial/.

This press release contains forward-looking statements regarding RenovoRx's future expectations, plans and prospects and are based on RenovoRx's current expectations and speak only as of the date hereof. RenovoRx disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise.

[i] Bile Duct Cancer (Cholangiocarcinoma): Statistics. Cancer.net, accessed May 28, 2020

[ii] CCA: The Statistics. worldcholangiocarcinomaday.org, accessed May 28, 2020.

[iii] Cholangiocarcinoma: Epidemiology and risk factors. Liver International, accessed May 28, 2020.

[iv] Bile Duct Cancer (Cholangiocarcinoma) and Liver Fluke Infection. US Department of Veteran Affairs, accessed May 28, 2020.