



XORTX Receives Positive Feedback from FDA on COVID-19 Related Acute Kidney Injury

• Clear Development Path Forward for XRx-101 •

CALGARY, AB – October 8, 2020 – XORTX Therapeutics Inc. ("XORTX" or the "Company") (CSE: XRX) (OTCQB: XRTXF), a clinical stage pharmaceutical company focused on developing innovative therapies to treat progressive kidney disease, is pleased to announce that the Company has received a positive response from the U.S. Food and Drug Administration ("FDA") regarding its recent submission of a COVID-19 coronavirus pre-investigational new drug ("pre-IND") meeting package providing the Company with a clear development path forward for XRx-101. XORTX's submission to the FDA summarized current data supporting the XRx-101 program, XORTX's plans to rapidly advance into clinical trials and further included questions related to XORTX's development program details including proposed manufacturing, non-clinical and clinical steps. The FDA response provided clear feedback on the proposed plan and outlined the critical steps to test XRx-101 in patients with COVID-19 infection to treat acute kidney injury ("AKI").

"We are very pleased with the collaborative feedback and tone of responses provided by the FDA and believe that we now have a robust understanding of the FDA's requirement for clinical trial testing of XRx-101, NDA submission, and the focus of their review", stated Dr. Allen Davidoff, CEO of XORTX, who added, "Based on responses from the FDA to our pre-IND package, we have clear guidance and the confidence in our decision to advance XRx-101 toward late stage clinical trial testing."

Looking to the near future, the Company anticipates results from the study currently being undertaken in partnership with Dr. Steven Coca, lead investigator and Associate Professor of Medicine at the Icahn School of Medicine and researchers at Mount Sinai in New York (*see August 4, 2020 press release*). The results of this study will guide future clinical trial design and conduct.

The Company is not making any express or implied claims that it has the ability to eliminate, cure or contain the COVID-19 coronavirus at this time.

About AKI

Acute Kidney Injury (AKI) or Acute Renal Failure (ARF) refer to a stark decrease in kidney function, increased blood nitrogenous waste products and urea, as well as a dysfunction of blood volume and electrolyte balance. The acronyms AKI and ARF increasingly recognize that small decreases in kidney function that do not result in overt organ failure are of substantial clinical relevance and are associated with increased occurrence of symptoms and rate of death*.

Coronavirus disease-19 (COVID-19) infection by SARS-CoV2 virus and the associated clinical disease symptoms, have resulted in more than 34 million infections worldwide and estimated mortality of ~3.9%. When first discovered, COVID-19 was described as a respiratory disease, however current understanding includes infection and injury to kidneys, heart, blood vessels, and the neurological system. AKI is a common complication affecting 40% of patients hospitalized with COVID-19, and injuring 20% sufficiently that acute dialysis is required. Of great concern is the finding that only 42% of patients with COVID-19 and AKI recovered baseline kidney function during hospitalization – a finding that may be a harbinger of a coming post-COVID kidney disease epidemic. (*M. Fisher, et al, AKI in hospitalized patients with and without COVID-19: A comparison study. J. Am. Soc. Nephrol. (2020)*).

* Source: <https://www.uptodate.com/contents/definition-and-staging-criteria-of-acute-kidney-injury-in-adults>).



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About XRx-101

XORTX Therapeutics has developed XRx-101 a novel proprietary formulation of xanthine oxidase inhibitor for the treatment of COVID-19 induced AKI. XRx-101 can act to inhibit xanthine oxidase expression due to hypoxia, or tissue destruction, thereby preventing increased serum uric acid (SUA) concentration from reaching saturation levels at which uric acid crystals could trigger acute organ injury. In concept, XRx-101 may ameliorate the severity of COVID-19 infection comorbidity, mortality, and damage to kidneys.

About XORTX Therapeutics Inc.

XORTX Therapeutics Inc. is a biopharmaceutical company with three clinically advanced products in development – XRx-008 for Autosomal Dominant Polycystic Kidney Disease (ADPKD), XRx-101 for Coronavirus / COVID-19 infection and XRx-221 is a clinical stage program for Type 2 Diabetic Nephropathy (T2DN). The Company has strong intellectual property rights and established proof of concept through independent clinical studies. XORTX is working to advance its clinical development stage products that target xanthine oxidase to inhibit production of uric acid. At XORTX Therapeutics, we are dedicated to developing medications to improve the quality of life and future of patients. Additional information on XORTX Therapeutics is available at www.xortx.com.

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