XORTX Files U.S. FDA Pre-IND Meeting Request for XRx-101 (Oxypurinol) COVID-19 Program and Pre-IND Meeting Submission

● Potential of Acute Kidney Injury Emerging as a Serious Consequence of COVID-19 ●

CALGARY, AB - August 31, 2020 – XORTX Therapeutics Inc. (CSE : XRX) (OTCQB : XRTXF) (FRANKFURT : ANU1) (the "**Company**" or "**XORTX**") a late clinical stage pharmaceutical development company focused on kidney disease, is pleased to announce that the Company has filed its pre-IND (Investigational New Drug) meeting request with the U.S. FDA. This filing initiates formal communications with the U.S. FDA regarding development of the Company's proprietary formulation of XRx-101 (Oxypurinol) for the treatment and prevention of acute kidney injury (AKI) associated with COVID-19 coronavirus infection. The request for a pre-IND meeting was accompanied by the complete pre-IND briefing document.

The application includes discussion of the clinical development plan and requests for guidance regarding the novel proprietary formulation of Oxypurinol specifically designed to treat individuals at risk of AKI associated with COVID-19 coronavirus infection.

This application with the U.S. FDA, opens discussions regarding the critical path plan to bring XRx-101 to patients with COVID-19. The pre-IND package presents current data showing that:

1. COVID-19 is frequently accompanied by pneumonia, acute kidney injury, proteinuria, and hematuria[1,2] which can lead to multiple organ failure and death.
2. Though early reports suggested a low incidence (between 3% to 9%) of AKI in those with COVID-19 infection[2,3,4], data from the U.S. indicates that 25-35% of patients hospitalized with COVID-19 develop AKI.[5-7]
3. Up to 20% of those need renal replacement therapy (RRT), and the mortality rate in patients that experience AKI in the setting of COVID-19 is several-fold higher than patients without AKI.[6]
4. AKI has been identified as an independent risk factor for patients' in-hospital mortality due to COVID-19[2].
5. In a study of hospitalized patients with AKI, a hypercatabolic phenotype in a significant proportion of patients with AKI, manifested by extremely high serum uric acid levels[8].

"This submission is an important step for the Company and the XRx-101 program and we move forward with a strong belief, verified by human data, that XRx-101 (Oxypurinol) may be an effective treatment for acute kidney injury that accompanies coronavirus (COVID-19)," stated Dr. Allen Davidoff, CEO of XORTX Therapeutics, who added, "The focus and dedication of the XORTX team and our clinical development partners made the rapid development of this pre-IND package and meeting request possible. We will provide updates regarding discussions with the U.S. FDA."

Currently, the US has accounted for nearly 6 million COVID-19 infections, with an estimated 330,000 hospitalizations, close to 180,000 deaths, 65,000 individuals that are now permanently on dialysis, and nearly 44% (~80,000) of those released from hospital have ongoing acute kidney injury. In the absence of a viable vaccine, during the next 12 months these numbers could grow two to three-fold, and could give rise to a kidney disease crisis with substantial future socio-economic cost. A therapy to decrease the risk of acute kidney injury due to COVID-19 infection would address the rapidly growing medical need.

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 XRX-101 (Oxypurinol)

XORTX Therapeutics has developed XRx-101 (active ingredient Oxypurinol) a xanthine oxidase inhibitor for the treatment of COVID-19 induced AKI. Two key studies (one in a mouse model of influenza and another in herpes infection) have shown that XRx-101's active ingredient, Oxypurinol, can act as (1) an anti-viral, (2) uric acid lowering treatment, and (3) organ-protective therapy. Specifically, in the setting of serious viral infection and tissue damage, 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. Additionally, excipients in the formulation such as L-arginine, a basic amino acid and nitric oxide source, can increase the aqueous solubility of uric acid, thereby also decreasing uric acid crystal formation associated with tumor lysis-like syndrome due to COVID-19 infection. L-arginine is also reported to protect against kidney injury, in the setting of ischemia reperfusion injury. In concept, XRx-101 may ameliorate the severity of COVID-19 infection comorbidity, mortality, and damage to kidneys. This, in turn, could increase COVID-19 survival rates, especially in vulnerable populations such as the elderly and those with underlying medical conditions, while also lessening dependence on medical infrastructure and medical services.

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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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