

January 19, 2021



XORTX Provides Corporate Update

• Synopsis of 2020 Achievements and Key Activities for 2021 •

CALGARY, Alberta, Jan. 19, 2021 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (CSE: XRX) (OTCQB: XRTXF), a biopharmaceutical company focused on developing innovative therapies to treat progressive kidney disease, is pleased to provide a synopsis of 2020 achievements and guidance on key activities for 2021.

2020 represented a pivotal year for XORTX and a year that provided several key milestones for the Company. The advent of the COVID crisis in March produced a worldwide impact on individuals and across a wide variety of industries. Presented with this new challenge XORTX undertook an internal strategic assessment of programs. Simultaneously, our robust knowledge of the uric acid lowering agent class of drugs and more specifically xanthine oxidase inhibition (XOI) permitted a new focus on potential therapeutic solutions to treat and prevent Acute Kidney Injury (AKI) associated with COVID-19 infection. Additionally, an understanding of acute kidney pathology presented an opportunity to initiate development of therapeutic approaches to aid individuals infected with moderate to severe COVID-19 and accompanied by AKI.

Key activities during 2020 resulted in the achievement of a number of important milestones including:

February 2020 – XORTX completed fundraising of ~\$2,500,000.

March 2020 – XORTX filed a provisional patent focused on the treatment and prevention of the health consequences of COVID-19 infection, and specifically AKI.

July 2020 - XORTX and Icahn School of Medicine at Mount Sinai entered into a research partnership to determine the role of high uric acid associated with AKI and other organ injury during COVID-19 infection. Preliminary data of hospitalized patients suggests high, early increased serum uric acid concentrations in these patients suggestive of AKI seen in "tumor lysis syndrome" observed in cancer patients.

August through October 2020 – Pre-IND filing for XRx-101 led to positive FDA guidance on clinical program design for treatment and prevention of AKI in connection with COVID-19 infection.

November 2020 - Topline results from Mount Sinai Research partnership revealed a concerning, prevalent, early increase in serum uric acid concentrations in patients hospitalized with COVID-19 infections. Early dose dependent association of high uric acid concentration and AKI suggested a viral "tissue lysis syndrome" may contribute to hyperuricemia, acute kidney and acute organ injury during COVID-19 infection in individuals.

December 2020 – XORTX received notice of grant of European patent for compositions of

formulations key to XORTX's platform technology. This European patent grant strengthens the Company's intellectual property portfolio in the EU. Importantly, this European patent grant protects our first-in-class program for autosomal dominant polycystic kidney disease (ADPKD).

XORTX is poised to build upon the results from 2020 and continue to advance its activities in both XRx-008 for ADPKD and XRx-101 for AKI due to COVID-19 infection.

Key activities planned for 2021 focus key value creation activities and catalysts for the year:

- Complete fundraising of between \$2,000,000 and \$3,000,000;
- Continue to increase exposure of XORTX's late clinical stage programs to pharma partner candidates and investors;
- Advance Pharma partnership interest and licensing discussions for both of XORTX's first in class opportunities in AKI (XRx-101) and in ADPKD (XRx-008);
- Advance and expand XORTX's program technologies by advancing key critical path development steps, including:
 - Manufacturing drug supply for both upcoming phase 3 "registration" clinical trials;
 - Completing our regulatory filings with FDA and EMA;
 - Characterizing bioavailability of XRx-008 and other formulations of uric acid lowering agents;
 - Complete orphan drug designation filing for the XRx-008 ADPKD program;
 - Negotiating the special protocol assessment (SPA) for ADPKD phase 3 registration clinical trial;
 - Preparing and filing additional provisional patent applications in both XRx-008 and XRx-101 programs; and
 - Grant of pending patent applications in US and Europe.
- XORTX also intends to seek an uplisting for its shares in the United States.

Dr. Allen Davidoff, CEO of XORTX stated, "2021 will be an important year for advancing our first-in-class therapeutics for both chronic and acute kidney injury. Executing on the path described in this market guidance illustrates the important key catalysts for XORTX as we strive to reach a larger audience with technologies that have the potential to redefine how kidney disease is treated in the future."

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 Polycystic Kidney Disease and XRx-008

Polycystic kidney disease (PKD) is considered a rare disease with two main types - autosomal dominant PKD (ADPKD) and autosomal recessive PDK (ARPKD), with prevalence of 1:800 and 1:20,000, respectively. PKD is a disorder that originates due to genetic changes, and results in numerous fluid-filled cysts that can form in the kidneys. This

genetic disorder tends to worsen with progressing age and is characterized by increasing cyst number and size that changes the shape of kidneys making them much larger. Progression of this disease reduces kidney function and may lead to kidney failure and the need for transplant or dialysis. Statistically, greater than 50% of individuals reach end stage kidney failure by the age of 60 years. Typically, diagnosis of ADPKD occurs between the ages of 30 and 50, when signs and symptoms begin to appear. Progression of PKD is frequently accompanied by high blood pressure, hyperuricemia, gout, kidney stones, proteinuria, abdominal pain, hematuria and declining GFR. Like many progressing kidney diseases, the rate of filtering capacity accelerates with time leading to end stage kidney failure and the need for kidney transplant or dialysis.

XORTX's XRx-008, for ADPKD, is a proprietary combination of uric acid lowering agents and other excipients. At present, there are few therapeutic options available to treat progressing kidney disease due to ADPKD or DN. The 20-year protection afforded by this patent will permit XORTX's first-in-class ADPKD therapy to address unmet medical needs in Europe. Market size estimates for Europe, the United States and Globally are estimated 160,000, 150,000 and 3 M¹, respectively. ADPKD is a rare disease with orphan disease programs in EU, US and Japan of protecting market exclusivity for 10, 7 and 10-year periods respectively.

Recently, non-clinical and clinical evidence has accumulated showing that high serum uric acid concentration may mediate disease progression in ADPKD including:

1. Individuals with ADPKD have high reported incidences of hyperuricemia (>60%) and clinical gout (24%) and, conditions that are associated with uric acid crystal formation in the kidneys such as low serum and urine pH^{1,2,3}.
2. A high prevalence of kidney stones of approximately equal uric acid composition or oxalate composition⁴.
3. High serum uric acid is an independent risk factor for cyst genesis, cyst growth and declining filtering capacity of kidneys¹.
4. Xanthine oxidase inhibition in ADPKD patients may reverse progression of glomerular filtration rate decline⁵.

At the present time, few therapeutic options to treat, stabilize or slow this progressing kidney disease are available. At the present time, only a single drug is approved to date - Tolvaptan. Although helpful for slowing cyst growth, the need to develop of therapeutic options that slow progressive decline of filtering capacity remains, as is the critical to improve quality of life and kidney health for individuals facing this disease. XRx-008 represents a first-in-class opportunity to help individuals with decreasing renal filtering capacity and slow or prevent end stage renal disease and the need for dialysis.

References:

1. Helal I, Nephrol Dial Transplant 28:380 ,2013
2. Jacob A.Torres, Mina Rezaei, Caroline Broderick, Louis Lin, Xiaofang Wang, Bernd Hoppe, Benjamin D. Cowley, Vincenzo Savica, Vincente E Torres, Saeed Khan, Ross P Holmes, Michael Mrug, Thomas Weimbs, Crystal deposition triggers tubule dilation that accelerated cystogenesis in polycystic kidney disease, J Clin Invest, 2019
3. Errasti P, Et al., Autosomal-dominant polycystic kidney disease: Transplant Proc,

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4. Idrizi A, et al Prevalence of Nephrolithiasis in polycystic kidney disease Cent Eur J Med 6(4):497_2011
5. Han M, et al., Hyperuricemia and Deterioration of Renal function in ADPKD, BMC Nephrol 15:63-2014

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 uric acid lowering as a method of treating progressive kidney disease. At XORTX, we are dedicated to developing medications to improve the quality of life and future of patients with kidney disease. Additional information on XORTX is available at www.xortx.com.

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¹ Source: The National Center for Biotechnology Information, a branch of the US National Institutes of Health and the PKD International Association.



Source: XORTX Therapeutics Inc.