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XORTX Therapeutics Announces Submission of Clinical Trial Application to Conduct Bridging Pharmacokinetics Study

Bridging Pharmacokinetic Study Initiated

CALGARY, Alberta, March 14, 2022 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (NASDAQ: XRTX | TSXV: XRTX | Frankfurt: ANU), a pharmaceutical therapeutics company focused on developing innovative therapies to treat progressive kidney disease, today announces that it submitted a clinical trial application (CTA) with Health Canada for a XRX-OXY-101 bridging pharmacokinetics study.

XRX-OXY-101 Bridging Pharmacokinetics Study. XRX-OXY-101 has been designed with three important objectives: 1) to determine which of XORTX's novel formulations results in the best circulating oxypurinol concentrations; 2) the effect of food on the bioavailability of this formulation; and 3) the safety and pharmacokinetics of multiple doses of this selected formulation. Knowledge gained during the conduct of this trial will provide guidance regarding the future oral dosing of oxypurinol formulations in support of the Company's planned phase 3 registration trial in Autosomal Dominant Polycystic Kidney Disease ("ADPKD"). Additionally, this study will provide data to support future NDA (New Drug Application) marketing submissions to the United States Food and Drug Administration and the European Medicines Agency.

Dr. Allen Davidoff stated, "XORTX is pleased to have made this regulatory filing step to initiate the launch of the XRX-OXY-101 bridging pharmacokinetic study. While only several months in duration, this XRX-OXY-101 study is an important first clinical step in our 505(b)2 clinical and regulatory plan for 2022 and will support the XRx-008 program for ADPKD as well as the planned phase 3 registration trial. This clinical trial initiated in Canada will provide key information to be used for the development of XRx-008 through the US FDA 505(b)2 marketing approval process."

About Autosomal Dominant Polycystic Kidney Disease ("ADPKD")

ADPKD is a rare disease that affects more than 10 million individuals worldwide.^{1,2} ADPKD is typically diagnosed based upon expansion of fluid-filled cysts in the kidneys. Over time, the increasing number and size of cysts can contribute to structural and functional changes to kidneys and is frequently accompanied by chronic pain which is a common problem for patients with ADPKD.³ Expansion of cysts is thought to compress healthy functioning tissue surrounding the cysts and contribute to further loss of kidney function, fibrosis, impaired nutrient exchange and impaired kidney function, accompanied later by end-stage renal disease (ESRD).¹ For individuals with progressing ADPKD, treatment recommendations

include anti-hypertensive treatment and dietary restrictions.⁴ New therapies to slow decline of kidney function in ADPKD are needed.

About XORTX Therapeutics Inc.

XORTX is a pharmaceutical company with two clinically advanced products in development: 1) our lead program in XRx-008 for ADPKD; and 2) our secondary program in XRx-101 for acute kidney and other acute organ injury associated with Coronavirus / COVID-19 infection. In addition, XRx-225 is a pre-clinical stage program for Type 2 Diabetic Nephropathy (T2DN). XORTX is working to advance its clinical development stage products that target aberrant purine metabolism and xanthine oxidase to decrease or inhibit production of uric acid. At XORTX Therapeutics, we are dedicated to developing medications to improve the quality of life and future health of patients. Additional information on XORTX is available at www.xortx.com.

About Clinical Trial Applications

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/applications.html>

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The TSX Venture Exchange and Nasdaq have neither approved nor disapproved the contents of this news release. No stock exchange, securities commission or other regulatory authority has approved or disapproved the information contained herein.

References:

1. Wiley C., Kamat S., Stelhorn R., Blais J., Analysis of nationwide data to determine the incidence and diagnosis of autosomal dominant polycystic kidney disease in the USA, *Kidney Disease*, 5(2): 107-117, 2019
2. Bergmann C., Guay-Woodford L.M., Harris P.C., Horie S., Peters D.J., Torres V.E., Polycystic Kidney Disease, *Nat Rev Dis Primers*. 4(1): 50, 2018
3. <https://pkdcure.org/living-with-pkd/chronic-pain-management/>
4. Gimpel C., Bermann C., Bockenhauer D., et al., International consensus statement of the diagnosis and management of autosomal dominant polycystic kidney disease in children and young people, *Nat Rev Nephrol* 15(11):713-726, 2019

Forward Looking Statements

This press release may contain express or implied forward-looking statements pursuant to Canadian and U.S. Federal securities laws. These forward-looking statements and their implications are based on the current reasonable expectations of the management of XORTX only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in such forward-looking statements. Except as otherwise required by law, XORTX undertakes no obligation to publicly release

any revisions or updates to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. More detailed information about the risks and uncertainties affecting XORTX is contained in the Company's most recently filed Annual Information Form and the Management Discussion and Analysis for its most recent financial reporting period filed on the Company's SEDAR profile (www.sedar.com) and under the heading "Risk Factors" in XORTX's Registration Statement on Form F-1 filed with the Securities and Exchange Commission ("SEC") available on the SEC's website, www.sec.gov.



Source: XORTX Therapeutics Inc.