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XORTX Receives No Objection Letter from Health Canada

Bridging Pharmacokinetics Study Autosomal Dominant Polycystic Kidney Disease – XRx-008 Program

CALGARY, Alberta, April 12, 2022 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (NASDAQ: XRTX | TSXV: XRTX | Frankfurt: ANU), a pharmaceutical company focused on developing innovative therapies to treat progressive kidney disease, is pleased to announce receipt of a no objection letter (NOL) from Health Canada regarding the Company's upcoming XRX-OXY-101 clinical 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) to determine the effect of food on the bioavailability of this formulation; and 3) to determine 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, CEO of XORTX stated, "We are pleased to receive the NOL from Health Canada earlier than expected. This important milestone provides regulatory approval for dosing of subjects with our novel proprietary product candidates. The XRX-OXY-101 study is designed to characterize the enhanced bioavailability of our novel proprietary xanthine oxidase formulation and is an important step forward in the development of XRx-008 program through the US FDA 505(b)2 development, our future phase 3 registration trial and eventually toward marketing approval for the treatment of individuals with progressive kidney disease due to ADPKD."

About ADPKD

ADPKD is a rare disease that affects more that 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.[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. 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, 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 date 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.