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XORTX Receives Further No Objection Letter from Health Canada

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

CALGARY, Alberta, Oct. 26, 2022 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (NASDAQ: XRTX | TSXV: XRTX | Frankfurt: ANU), a late stage clinical pharmaceutical company focused on developing innovative therapies to treat progressive kidney disease, is pleased to announce receipt of a further no objection letter (NOL) from Health Canada regarding the Company's ongoing XRX-OXY101 clinical bridging pharmacokinetics study (the "Study"). The Study was originally designed as a three part study and a NOL was received by Health Canada in April (see April 12, 2022 press release). XORTX has successfully completed parts 1 and 2 of the Study, has modified part 3 and has added an additional part 4 as outlined below.

XRX-OXY-101 Bridging Pharmacokinetics Study. XRX-OXY-101 was originally designed with three 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. After completion of parts 1 and 2, XORTX redesigned part 3 to include an additional characterization of food effect and added a fourth objective - part 4 - to characterize the proportion of oxypurinol absorbed with three increasing doses of XRx-008. 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 ("FDA") and the European Medicines Agency.

Dr. Allen Davidoff, CEO of XORTX stated, "We are pleased to receive the NOL from Health Canada for the amended pharmacokinetic Study. The Study to date has produced clear evidence of substantially increased bioavailability of XRx-008, XORTX's novel proprietary xanthine oxidase formulation This Health Canada NOL confirms that the Part 3 and 4 design can proceed. These two parts of the Study will be conducted in parallel. Notably, successful screening for part 3 has been completed and dosing will commence imminently, with part 4 screening underway. Parts 3 and 4 will dose individuals with tablets similar to those to be used in our phase 3 registration trial. Completion of the Study will support the XRx-008 program through the 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 Clinical Trial Applications

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

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.

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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.