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XORTX Announces Submission to European Medicines Agency

Scientific Advice from EMA Committee for Medicinal Products for Human Use Requested

CALGARY, Alberta, July 19, 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, announces submission of a request for "scientific advice review" to the European Medicines Agency (the "EMA") and more specifically the Committee for Medicinal Products for Human Use (the "CHMP") regarding the XRx-008 program. This submission for CHMP/EMA review is intended to initiate discussions regarding the status of XORTX's XRx-008 program for autosomal dominant polycystic kidney disease ("ADPKD"), plans for its global phase 3 registration trial, and includes scientific advice pertaining to marketing approval in the EU.

To date, the Company has successfully completed the research and development activities leading to this request and is advancing its XRx-008 program for the treatment of ADPKD. R&D activities during the past year leading to this request included manufacturing clinical quality GMP oxypurinol, finalizing formulation of drug product, and characterizing improved oral bio-availability of oxypurinol in animal models.

Having previously received approval from both the FDA and Health Canada to commence its OXY-XRX-101 bridging pharmacokinetics study, the Company recently reported topline results showing substantially increased bioavailability of XRx-008 formulation candidates in humans. These important milestones have positioned XORTX for the next important step – initiating a scientific review process with the EMA CHMP regarding its scientific status, developmental assumptions and plans for recruiting individuals in the upcoming phase 3 registration trial.

Dr. Allen Davidoff, XORTX CEO stated, "This request is a critical component of our global regulatory plan to enhance the potential for approvability of our drug candidate which includes a potential Special Protocol Assessment discussion with the US Food and Drug Administration."

About the European Medicines Agency

The EMA is an agency of the European Union in charge of the evaluation and supervision of medicinal products. Prior to 2004, it was known as the European Agency for the Evaluation of Medicinal Products or European Medicines Evaluation Agency.

About the Committee for Medicinal Products for Human Use

The Committee for Medicinal Products for Human Use, formerly known as Committee for Proprietary Medicinal Products, is the EMA's committee responsible for elaborating the agency's opinions on all issues regarding medicinal products for human use.

About ADPKD

ADPKD is a rare disease that affects more that 10 million individuals worldwide.[1,2] ADPKD is typically diagnosed based upon the demonstration fluid-filled cysts in the kidneys and a family history of ADPKD. 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, dietary restrictions, and, for a limited percentage of suitable patients, pharmacotherapy.[4] New, more broadly applicable therapies to effectively 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, XRx-008 program 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.