July 7, 2022

XORTX Announces Pre-Phase 3 Meeting Request with US Food and Drug Administration (FDA)

CALGARY, Alberta, July 07, 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 that a type B pre-Phase 3 meeting request with the FDA was submitted on Wednesday, July 6, 2022. The meeting is expected to be held in approximately 70 days from today.

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 autosomal dominant polycystic kidney disease (ADPKD). R&D activities during the past year leading to this meeting request included manufacturing clinical quality GMP oxypurinol, finalizing formulation of drug product, and characterizing improved oral bio-availability of oxypurinol in animal models. We have achieved successful regulatory filings with the FDA and Health Canada and have commenced our OXY-XRX-101 bridging pharmacokinetics study. These important milestones have positioned XORTX for the next important step – a pre-Phase 3 meeting with the FDA.

Dr. Allen Davidoff, CEO of XORTX stated, “We look forward to this meeting with the FDA as well as the critical path steps necessary to finalize our registration trial protocol and initiate our global Phase 3 clinical trial. This meeting request provides an opportunity to open discussions with the FDA regarding the registration trial and key information needed to characterize the benefit of xanthine oxidase inhibition in individuals with ADPKD. This pre-Phase 3 meeting and upcoming Special Protocol Assessment negotiations with the FDA are anticipated to clarify the optimal path forward to support a New Drug Application (NDA) for marketing approval of XORTX’s lead product and to provide much needed therapy to slow the decline of renal function in patients with ADPKD and hyperuricemia.”

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, 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 patients with progressive kidney disease including those with ADPKD are needed.

About XORTX Therapeutics Inc.

XORTX is a pharmaceutical company with two clinically advanced products in development – XRx-008 for ADPKD, XRx-101 for acute kidney and other acute organ injury associated with Coronavirus / COVID-19 infection and 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, 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., Bergmann 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.