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XORTX Announces Completion of Dosing in XRX-OXY-101 Clinical Study

CALGARY, Alberta, Dec. 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, is pleased to announce the completion of dosing in the XRX-OXY-101 pharmacokinetics bridging study (the "Study"). Dosing of XORTX's proprietary oral oxypurinol formulation, XORLO™, in each of Part 1 through 4 included: Part 1 - Single dose pharmacokinetics; Part 2 - Single dose in food effect pharmacokinetics; Part 3 - Single dose proportionality pharmacokinetics; and Part 4 - Multi-dose pharmacokinetics in both fasted and fed state. Previously topline results from Part 1 and 2 have been reported in the Company's press releases of July 13 and August 22, 2022. Plasma sample analysis and topline results from both part 3 and part 4 are expected within the next several weeks. Consolidated topline results from each part are anticipated to be reported in January 2023.

Dr. Allen Davidoff, CEO of XORTX stated, "We are pleased to have reached this key milestone regarding the development of the XRx-008 program for the treatment of autosomal dominant polycystic kidney disease (ADPKD). Much of the credit for the rapid advancement of the XRx-008 program can be attributed to the skill and experience of our Chemistry, Manufacturing and Controls group, and the Clinical and Regulatory teams who have worked meticulously to reach this point. The characterization of XORTX's proprietary oxypurinol formulation, XORLO™, (US and EU formulation patents granted) will provide key information for dose selection, guide population pharmacokinetic modeling, and importantly provide foundational information for partnering discussions and future FDA submissions for marketing approval of this XORLO™ product in ADPKD."

About the XRX-OXY-101 Bridging Pharmacokinetics Study

XORTX's lead program XRx-008 is designed to deliver the xanthine oxidase inhibitor ("XOI") oxypurinol at concentrations sufficient to substantially inhibit aberrant purine metabolism in the kidneys of individuals with progressing kidney disease due to ADPKD, as well as inhibit production of uric acid in the circulation. Secondarily, this Study in healthy individuals is designed to provide data to perform pharmacokinetic modeling that will guide optimally safe administration of oxypurinol prior to initiation of XORTX's planned phase 3 registration trial in subjects with ADPKD.

The XRX-OXY-101 Bridging Pharmacokinetics Study is designed with four important objectives: 1) To determine which of XORTX's novel formulations results in the greatest circulating oxypurinol concentrations and oxypurinol exposure; 2) to determine the effect of food on the bioavailability of the selected formulation; 3) to determine the effect of a range of increasing doses on the bioavailability of the selected formulation; and 4) to determine the safety and pharmacokinetics of multiple doses of the selected formulation. Knowledge

gained during the conduct of this clinical trial will provide guidance regarding the formulation selected and the oral dosing regimen necessary to reach and maintain the target circulating concentration of oxypurinol.

About the XRx-008 program

Oxypurinol is a purine-based XOI with important pharmacologic characteristics ideal for administration to individuals with ADPKD. Key pharmacologic attributes include:

1/ the ability to act in the circulation, kidney and cardiovascular tissue and inhibit the production of uric acid and so attenuate the mechanism of injury and accelerating effect of XO on progressing diseases.

2/ XORTX's proprietary formulation of oxypurinol, XORLO™, provides substantially increased absorption of oxypurinol. Metabolism of oxypurinol is minimal and it is excreted unchanged. This approach provides an effective, well tolerated drug with an extensive clinical safety experience suggests this XRx-008 program has the capacity to provide superior xanthine oxidase inhibitor to slow the accelerating decline kidney function during ADPKD progression.

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 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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3. https://pkdcure.org/living-with-pkd/chronic-pain-management/
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Forward Looking Statements

This press release contains express or implied forward-looking statements pursuant to U.S. Federal securities laws. These forward-looking statements and their implications are based on the current 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 the forward-looking statements. Except as otherwise required by law, XORTX undertakes no obligation to publicly release any revisions 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 under the heading “Risk Factors” in XORTX’s Registration Statement on Form F-1 filed with the SEC, which is available on the SEC's website, www.sec.gov (including any documents forming a part thereof or incorporated by reference therein), as well as in our reports, public disclosure documents and other filings with the securities commissions and other regulatory bodies in Canada, which are available on www.sedar.com.

Source: XORTX Therapeutics Inc.