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XORTX Announces Completion of Screening and Enrollment in Bridging Pharmacokinetics Study

XRX-OXY-101 Study will inform the dose choice in the upcoming Phase 3 Clinical Trial

CALGARY, Alberta, Nov. 28, 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 successful screening and enrollment of the last remaining subjects into the XRX-OXY-101 Bridging Pharmacokinetics Study (the "Study"), including initiation of dosing of all subjects enrolled in Part 4 of the Study. The Study has been designed to characterize the improved bioavailability of various formulations, to assess the impact of dose on exposure, as well as the safety and pharmacokinetic properties of multiple doses of the Company's proprietary formulation of oxypurinol.

Dr. Allen Davidoff, CEO of XORTX stated, "Advancements, this year related to manufacturing of our proprietary formulations of oxypurinol as well as key regulatory interactions with Health Canada, the US Food and Drug Administration (FDA) and the Europeans Medicines Agency (EMA), led by our seasoned R&D team has permitted the timely completion of enrollment of subjects in the final two parts of this clinical trial. The Company anticipates completion of dosing in the XRX-OXY-101 clinical trial in the coming weeks and additional announcements of topline results of the final two parts of the Study in the near future. The key data emerging from this Study will be essential to our pharmacokinetic modeling and selection of a safe dose for individuals in the planned XRX-OXY-301 phase 3 clinical trial."

About the XRX-OXY-101 Study

XRX-OXY-101 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

XORTX's lead program XRx-008 is designed to deliver the xanthine oxidase inhibitor 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. Oxypurinol is a purine based xanthine oxidase inhibitor 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, thereby attenuate the mechanism of injury and accelerating effect of XO on progressing disease.

2/ XORTX's proprietary formulation of oxypurinol provides substantially increased absorption of oxypurinol. Because metabolism of oxypurinol is minimal and thereafter excreted unchanged, superior tolerability of this xanthine oxidase inhibitor results.
Building upon these key attributes is expected to provides an effective, well tolerated therapy for the XRx-008 program and the opportunity to provide a 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.

In other news, the Company announces that it has granted in accordance with the Company's stock option plan an aggregate of 70,000 options to purchase common shares of the Company to certain officers and consultants of the Company. The options granted are exercisable at $1.38 for a period of five years.

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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Neither the TSX Venture Exchange nor Nasdaq has approved or disapproved the contents of this news release. No stock exchange, securities commission or other regulatory authority has approved or disapproved the information contained herein.

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.