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XORTX Announces Positive Topline Results from Part 2 Pharmacokinetics Bridging Study

Clinical Trial Shows Substantially Increased Bioavailability with Food and a Clean Safety and Pharmacologic Profile

CALGARY, Alberta, Aug. 22, 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 positive topline results from its Pharmacokinetics Bridging Study – XRX-OXY-101 – Part 2– ("Part 2") showing a substantial increase in oral bioavailability of XORTX's proprietary oxypurinol formulation provided with food compared to the fasted state. In addition, accompanying the improved bioavailability findings in Part 2 was a clean safety and pharmacologic profile with no drug related adverse or serious adverse events related to oral administration of oxypurinol.

Part 2 of this Study required successful recruitment, administration of a single oral dose of drug formulation in individuals who were fasted or fed a meal. Subsequently, blood sampling and bioanalytical evaluation were conducted in Part 2 of this Study to characterize the pharmacokinetics and bioavailability of a unique proprietary formulation of oxypurinol administered in advance of the Company's planned Phase 3 registration clinical trial in autosomal dominant polycystic kidney disease ("ADPKD").

XRX-OXY-101 Bridging Pharmacokinetic 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 to be used in the planned Phase 3 registration trial, with initiation of patient dosing scheduled for the first half 2023.

Part 2 of the XRX-OXY-101 Study achieved the following purposes:

1) Confirmed an increase of bioavailability of XORTX formulation when co-administered with food;
2) Supplemented additional key data to the XORTX pharmacokinetics data set characterizing oral bioavailability of the proprietary formulation; and
3) Built upon the pharmacokinetic and safety database of safety for oxypurinol and XORTX's

proprietary formulation

Dr. Allen Davidoff, CEO of XORTX, stated, “Successful completion of Part 1 and now part 2 of the XRX-OXY-101 study provides key data and knowledge for selecting the clinical dose and formulation for future oral dosing for our planned phase 3 registration trial in ADPKD. Results from arising from this study support the XRx-008 program, understanding of absorption, distribution, metabolism and excretion (ADME) of oxypurinol in our formulation. These four key ADME criteria influence drug levels,kinetics of drug exposure, performance and pharmacologic activity of the drug. Pharmacokinetic modeling of both of these data sets will provide key information regarding the safe and effective administration of oxypurinol and guide decision making as we plan and execute development of the XRx-008 program clinical and commercial development. We look forward to the initiation of dosing of Part 3 of the XRX-OXY-101 in the near future.”

About XRX-OXY-101 - a “Bridging Pharmacokinetics” Study. Part 1 of the study involved dosing under fasted conditions. Part 2 measured the effect of food on pharmacokinetics and Part 3 of the XRX-OXY-101 clinical trial is a multiple dose pharmacokinetics evaluation that will be undertaken in the second half of 2022. Safety evaluation is also an important aspect of the XRX-OXY-101 clinical trial. The Study is designed to permit XORTX to characterize the safety and relative bioavailability of the XRx-008 program formulations. Knowledge gained during the conduct of this trial is now providing critical guidance regarding the oral dosing for our planned registration trial in ADPKD.

Previously, Part 1 of the XRX-OXY-101 study achieved the following purposes:

1) Confirmed improved human bioavailability of XORTX formulations of oxypurinol for future development;
2) Established a pharmacokinetics data set characterizing oral bioavailability of XORTX formulations for future population based pharmacokinetic modeling; and
3) Confirmed the unique proprietary formulation innovations from recently granted US and EU patents that provide for increased circulating concentrations of oxypurinol.

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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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 Statement

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.