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XORTX Receives Small and Medium Enterprise Status for the European Union

CALGARY, Alberta, April 20, 2022 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (NASDAQ: XRTX | TSXV: XRTX | Frankfurt: ANU), a pharmaceutical company focused on developing innovative therapies to treat progressive kidney disease, is pleased to announce receipt of Small and Medium Enterprise ("SME") status for the European Union (the "EU"). This status is applicable for European Medicines Agency ("EMA") related interactions and confirmed by the SME office – Regulatory Science and Innovation Task Force. SME status provides reduced costs to the Company as it initiates discussions with the US Food and Drug Administration ("FDA") and EMA regarding the upcoming XR-008 phase 3 registration trial for XR-008 and other clinical programs.

SME status allows XORTX to benefit from significant financial incentives such as a 90% EMA fee reduction for scientific advice, clinical study protocol design, endpoint and statistical considerations, quality inspections and fee waivers for future EMA pre and post-authorization regulatory filings such as Orphan Drug Designation.

"This is an important step in our regulatory strategy which includes consultation with the EMA as we continue to develop our European development strategy," stated Dr. Allen Davidoff, CEO.

XORTX is currently conducting its clinical trial - XR-008 - a "bridging pharmacokinetics" study. This study is a three-part, single-dose; fed or fasted; then, multi-dose crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. It is designed to permit XORTX to characterize the safety and relative bioavailability of the XR-008 formulation. Knowledge gained during the conduct of this trial will provide guidance regarding the oral dose of XR-008 for the Company's planned registration trial in autosomal dominant polycystic kidney disease ("ADPKD"). Additionally, this study will provide data to support future New Drug Application ("NDA") submissions to the FDA and the EMA. This study is planned to start in the second quarter of 2022.

XR-008 Registration trial in ADPKD. XR-008 is a multi-site, multi-national, placebo controlled, study in ADPKD patients with progressing kidney disease. The objective of this study is to evaluate the safety and effectiveness of XR-008 over a 24-month period and study the ability of xanthine oxidase inhibition to decrease the rate of decline of glomerular filtration rate. An estimated 350 patients will be enrolled. This study is planned to start in the second half of 2022, subject to SPA (special protocol assessment) negotiations with the FDA.

About SME

The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.

https://ec.europa.eu/regional_policy/sources/conferences/state-aid/sme/smedefinitionguide_en.pdf

About EMA

The European Medicines Agency 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.

The EMA plays a central role in facilitating the development and authorization of medicines across Europe. The SME initiative promotes innovation from smaller companies such as XORTX. The company will be included in EMA's public SME register. One of the objectives of this online register is to facilitate and promote interaction, partnering and networking between SMEs.

<https://www.ema.europa.eu/en>

About XORTX Therapeutics Inc.

XORTX is a pharmaceutical company with two clinically advanced products in development: 1) our lead program in XRx-008 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.

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.