December 29, 2020

XORTX Announces Grant of European Patent

● Patent supporting Autosomal Dominant Polycystic Kidney Disease Granted – XRx-008 Program ●

CALGARY, Alberta, Dec. 29, 2020 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (CSE: XRX) (OTCQB: XRTXF), a biopharmaceutical company focused on developing innovative therapies to treat progressive kidney disease, is pleased to announce receipt of notification that the patent "Formulations of Xanthine Oxidase Inhibitors" will be granted by the European Patent Office. The patent covers compositions and methods of using XORTX's proprietary formulations of xanthine oxidase for, renal and other diseases where aberrant purine metabolism has been implicated in disease progression.

Dr. Allen Davidoff, CEO of XORTX stated, "This newly granted patent, covers compositions of formulations key to XORTX's platform technology and this issuance strengthens our intellectual property portfolio in the EU. Importantly, this European patent grant protects our first-in-class program for autosomal dominant polycystic kidney disease (ADPKD). Grant of this patent provides the protection to expand our clinical trials, commercialization and partnering opportunities throughout Europe. Including this newly allowed patent, XORTX now has four granted patents in the US and/or EU covering compositions and uses of uric acid lowering agents to treat and prevent kidney disease, hypertension, insulin resistance, diabetic nephropathy (DN)."

XORTX's XRx-008, for ADPKD, is a proprietary combination of uric acid lowering agents and other excipients. At present, there are few therapeutic options available to treat progressing kidney disease due to ADPKD or DN. The 20-year protection afforded by this patent will permit XORTX's first-in-class ADPKD therapy to address unmet medical needs in Europe. Market size estimates for Europe, the United States and Globally are estimated 160,000, 150,000 and 3 M[i], respectively. ADPKD is a rare disease with orphan disease programs in EU, US and Japan of protecting market exclusivity for 10, seven and 10 year periods respectively.

About Polycystic Kidney Disease and XRx-008

Polycystic kidney disease (PKD) is considered a rare disease with two main types - autosomal dominant PKD (ADPKD) and autosomal recessive PDK (ARPKD), with prevalence of 1:800 and 1:20,000, respectively. PKD is a disorder that originates due to genetic changes, and results in numerous fluid-filled cysts that can form in the kidneys. This genetic disorder tends to worsen with progressing age and is characterized by increasing cyst number and size that changes the shape of kidneys making them much larger. Progression of this disease reduces kidney function and may lead to kidney failure and the need for transplant or dialysis. Statistically, greater than 50% of individuals reach end stage

kidney failure by the age of 60 years. Typically, diagnosis of ADPKD occurs between the ages of 30 and 50, when signs and symptoms begin to appear. Progression of PKD is frequently accompanied by high blood pressure, hyperuricemia, gout, kidney stones, proteinuria, abdominal pain, hematuria and declining GFR. Like many progressing kidney diseases the rate of filtering capacity accelerates with time leading to end stage kidney failure and the need for kidney transplant or dialysis.

Recently, non-clinical and clinical evidence has accumulated showing that high serum uric acid concentration may mediate disease progression in ADPKD including:

1. Individuals with ADPKD have high reported incidences of hyperuricemia (>60%) and clinical gout (24%) and, conditions that are associated with uric acid crystal formation in the kidneys such as low serum and urine pH[1,2,3].

2. A high prevalence of kidney stones of approximately equal uric acid composition or oxalate composition[4].

3. High serum uric acid is an independent risk factor for cyst genesis, cyst growth and declining filtering capacity of kidneys[1].

4. Xanthine oxidase inhibition in ADPKD patients may reverse progression of glomerular filtration rate decline[5].

At the present time, few therapeutic options to treat, stabilize or slow this progressing kidney disease are available. At the present time, only a single drug is approved to date - Tolvaptan. Although helpful for slowing cyst growth, the need to develop of therapeutic options that slow progressive decline of filtering capacity remains, as is the critical to improve quality of life and kidney health for individuals facing this disease. XRx-008 represents a first-in-class opportunity to help individuals with decreasing renal filtering capacity and slow or prevent end stage renal disease and the need for dialysis.

References:

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3. Errasti P, Et al., Autosomal-dominant polycystic kidney disease: Transplant Proc, 2003, 35(5)1717 &
4. Idrizi A, et al Prevalence of Nephrolithiasis in polycystic kidney disease Cent Eur J Med 6(4):497_2011
5. Han M, et al., Hyperuricemia and Deterioration of Renal function in ADPKD, BMC Nephrol 15:63-2014

About XORTX Therapeutics Inc.

XORTX Therapeutics Inc. is a biopharmaceutical company with three clinically advanced products in development – XRx-008 for Autosomal Dominant Polycystic Kidney Disease

(ADPKD), XRx-101 for Coronavirus / COVID-19 infection and XRx-221 is a clinical stage program for Type 2 Diabetic Nephropathy (T2DN). The Company has strong intellectual property rights and established proof of concept through independent clinical studies. XORTX is working to advance its clinical development stage products that target uric acid lowering as a method of treating progressive kidney disease. At XORTX Therapeutics, we are dedicated to developing medications to improve the quality of life and future of patients with kidney disease. Additional information on XORTX Therapeutics is available at www.xortx.com.

For further information,
please contact:

Allen Davidoff, CEO
adavidoff@xortx.com or +1 403 455 7727

Bruce Rowlands, Chairman
browlands@xortx.com or +1 416 230 7260

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[i] Source: The National Center for Biotechnology Information, a branch of the US National Institutes of Health and the PKD International Association.

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