XORTX Announces Positive Phase 2 Results in Type 2 Diabetic Nephropathy (T2DN)

● TMX-049 Results Show Beneficial Decrease of Urinary Albumin in T2DN ●

CALGARY, AB – September 19, 2019 **–** 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 share, in conjunction with Teijin Pharma Limited ("Teijin"), the positive, statistically significant results from a recently completed U.S. phase 2 clinical trial (TMX-049DN-201) in individuals with type 2 diabetic nephropathy. This study achieved the primary endpoint for the efficacy of this study and TMX-049 was well tolerated. The study was entitled – "A Randomized, Placebo-Controlled, Double-Blind, Multicenter, Phase 2 Study to Assess Safety, Tolerability, and Renal Effects of TMX-049 in Subjects with Type 2 Diabetes and Albuminuria". This study was designed to test whether the inhibition of XO using TMX-049 over a 12 week treatment period, would decrease uric acid levels, and would provide a safe and effective therapeutic approach to decreasing albuminuria.

Dr. Allen Davidoff stated, "In the opinion of XORTX, TMX-049 is the leading next generation candidate xanthine oxidase inhibitor with a desirable combination of strong clinical safety record and potent uric acid lowering capability. The opportunity to co-develop TMX-049 for type 2 diabetic nephropathy, with Teijin, and the results of this study, substantially increase the probability of advancing a first in class and best in class drug to slow and reverse progression of kidney disease in individuals with type 2 diabetic nephropathy. We are very encouraged by the solid safety record in this trial and this outstanding positive result and look forward to furthering the development of this molecule."

In healthy individuals, Albumin is a type of protein that is normally found in the blood, but not in urine. When Albumin protein is found in urine it is called "albuminuria" or "proteinuria" and is interpreted by physicians as a sign of kidney disease. One of the primary functions of kidneys is to filter blood to remove metabolic/ waste products and manage/balance the excretion of water in the circulatory system. If kidneys are damaged, protein can leak out of the kidneys and into the urine, appearing as albuminuria. A urine albumin level that stays the same or decreases may mean that treatments are working, while increasing albuminuria is a sign of worsening kidney health.

Approximately 35-40% of patients with type 1 or type 2 diabetes mellitus develop diabetic kidney disease. This is a clinical syndrome characterized in its early stages by persistent protienuria, then followed by a relentless, decline in glomerular filtration rate (GFR). One of the first clinical signs of kidney disease is moderately increased urine albumin. If untreated, albuminuria will gradually worsen and untreated microalbuminuria will gradually worsen, reaching clinical proteinuria or severely increased albuminuria (albuminuria grade A3) over five to 15 years. Importantly, proteinuria of increasing severity is associated with a faster rate of renal decline, regardless of baseline eGFR.[1] As GFR then begins to decline and, without treatment, end-stage renal failure is likely to result in five to seven years.[2]

Diabetic kidney disease is a progressive chronic kidney disease that develops with diabetes and is reported to be the most common cause of dialysis. When chronic kidney disease progresses and dialysis is initiated, not only does the patient's quality of life significantly deteriorate, but the social burden of medical care costs increases. There is a rapidly growing need for treatments that improve, slow or reverse chronic kidney disease, including diabetic kidney disease, and that suppress the introduction of dialysis.

TMX-049 is a novel non-purine type xanthine oxidase inhibitor discovered by Teijin and currently under an exclusive negotiation of co-development agreement with XORTX as outlined in the letter of intent announced by XORTX on March 12, 2019. TMX-049 can inhibit uric acid production strongly by selectively inhibiting the enzyme, xanthine oxidase.

Study TMX-049DN-201 was a randomized, double-blind, placebo-controlled study in subjects with type 2 diabetes and albuminuria. The objective of the study was to assess the efficacy and safety of TMX-049 administered once daily for 12 weeks. Change in log-transformed urinary albumin-to-creatinine ratio was set as the primary outcome measure.

Highlights of the results of this study showed that in patients with T2DN:

1. TMX-049 could be safely administered to individuals with T2DN in the tested dose range and was well tolerated;

2. Oral daily doses of TMX-049 could substantially and significantly decrease serum uric acid (SUA).

3. Oral daily doses of TMX-049 decrease Urinary Albumin (UA) proteinuria to a substantial and statistically significant degree.

As a result, TMX-049 showed a statistically significant improvement compared to the placebo group, achieving the primary endpoint. No new concerns about the safety were observed. Details of the study design can be found at: https://clinicaltrials.gov/ct2/show/NCT03449199?term=TMX-049&cond=type+2+diabetic+nephropathy&rank=1

References:

1. Turin T C, Protienuria and Rate or change in Kidney Function, J. Am. Soc Nephrol Oct; 24(10):1661, 2013
2. Persson F., and Rossing P., Diagnosis of diabetic kidney disease: state of the art and future perspective, Kid Int Suppl v.8(1):2-7, 2018

About XORTX Therapeutics Inc.

XORTX Therapeutics Inc. is a biopharmaceutical company focused on developing innovative therapies to treat progressive kidney disease. XORTX has two lead programs to develop treatments for progressive kidney disease due to diabetes, diabetic nephropathy and polycystic kidney disease**.** XORTX's XRx-008 (a proprietary reformulation of Oxypurinol) is a late stage drug development program to treat autosomal dominant polycystic kidney disease (ADPKD). TMX-049, is a late phase 2b stage program in treat type 2 diabetic nephropathy (T2DN), under a Letter of Intent, that proposes a co-development agreement with Japan's Teijin Pharma Limited. Secondary programs focus on developing therapies for health consequences that accompany pre-diabetes, diabetes and cardiovascular disease. Additional information on XORTX Therapeutics is available at www.xortx.com.

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