

## XORTX Provides Overview and Announces \$5 Million Financing to Advance Clinical Trials

# Pivotal Registration Clinical Study with XRx-008 and Phase 2b Clinical Study with TMX-049 Planned in 2020

CALGARY, Alberta, April 29, 2019 (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, confirms that the Company has filed its audited financial statements and related management's discussion and analysis for the year ended December 31, 2018. The Company's MD&A highlights the significant milestones accomplished by XORTX in its first year as a listed public company. Both of XORTX's advanced clinical programs are focused on treating progressive kidney disease through the lowering of serum uric acid as highlighted below in this press release.

Dr. Allen Davidoff, Founder and CEO of XORTX stated:

"We are encouraged by the advancements made by XORTX in 2018 and thus far in 2019 and in particular, the validation of our efforts to develop uric acid lowering agents to slow or reverse progressive kidney disease has been multi-faceted, with acknowledgment by the PKD Foundation, and most notably by two recent published studies by the TODAY study team and Dr. Petter Bjornstad (see press release of April 16, 2019) and the Pilemann-Lyberg et al study published in the American Diabetes Association Journal (see press release of March 25, 2019). Both of these studies reveal that serum uric acid levels significantly affect the progression of kidney disease in adolescents with T2 diabetes and patients with T1 diabetes, respectively. Our recently announced agreement with Teijin further expands the Company's product offerings beyond XRx-008 to include TMX-049 for type 2 diabetic nephropathy ("T2DN"), a large and rapidly growing unaddressed medical need."

"We are highly optimistic about the future of our XRx-008 program which is poised to advance to a pivotal phase 3 clinical trial in 10 months and our secondary program in T2DN planned to enter phase 2b proof of concept testing in 14 months. XORTX plans to undertake a non-brokered financing of up to \$5 million of units priced at \$0.20, with each unit comprising one common share and one-half common share purchase warrant exercisable at \$0.40 for a one year term to fund the advancement of these two important clinical trials."

The Company anticipates that the private placement will be completed by May 31, 2019 and notes that the private placement is subject to regulatory approval and all securities issued will be subject to a statutory hold period of four months.

The following summarizes the advancements made in 2018 to date in XORTX's two programs:

#### XRx-008 for Autosomal Dominant Polycystic Kidney Disease (ADPKD):

- Formal recognition by the Polycystic Kidney Disease (PKD) Foundation of America (the "PKD Foundation") as a leader advancing the development of treatments for PKD and specifically rare diseases such as ADPKD and an ongoing cooperative working relationship.
- Preparation and filing Pre-IND documents with the FDA related to the development of XRx-008 – an oxypurinol formulation - for the treatment of autosomal dominant polycystic kidney disease ("ADPKD").
- Filing of Orphan Drug Designation ("ODD") documents with the FDA for XRx-008 for the treatment of ADPKD and FDA clarification of additional information required to obtain ODD status for XRx-008.
- Meeting and discussion with the FDA regarding XRx-008 Clinical Development Plan resulting in an accelerated clinical development plan composed of a bioavailability study of XRx-008 in man, then a single phase 3 registration clinical trial (under a special protocol assessment (SPA)).
- Thereafter submission of a New Drug Application (NDA) for marketing approval.

### XRx-221 (TMX-049) for Type 2 Diabetic Nephropathy (T2DN):

- Negotiated and signed a Letter of Intent for the co-development of TMX-049 with Teijin Pharma Limited ("Teijin"). This agreement would provide XORTX with exclusive global rights (excluding Japan) to develop TMX-049, a new generation of xanthine oxidoreductase inhibitor, for the treatment of T2DN. Teijin has already devoted considerable time, funding and resources to the development of TMX-049 in T2DN. At present, a Phase 2a study in T2DN patients in the US, has completed enrollment and anticipated to report topline results in Q3 2019.
- After execution of the definitive agreement contemplated by the LOI, XORTX and Teijin will work together on the development of the phase 2b clinical program for the treatment of T2DN. For further information, refer to the Company's press release of March 12, 2019.

#### **About XORTX Therapeutics Inc.**

XORTX Therapeutics Inc. is a biopharmaceutical company focused on developing innovative therapies to treat progressive kidney disease. XORTX has lead programs to develop treatments for progressive kidney disease due to diabetes, diabetic nephropathy and polycystic kidney disease. 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 <a href="https://www.xortx.com">www.xortx.com</a>.

The CSE has 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.

This news release includes forward looking statements that are subject to assumptions, risks and uncertainties. Statements in this news release which are not purely historical are forward looking statements, including without limitation any statements concerning the Company's intentions, plans, estimates, beliefs or expectations regarding the future. Although the Company believes that any such intentions, plans, estimates, beliefs and expectations in this news release are reasonable, there can be no assurance that any such intentions, plans, beliefs and expectations will prove to be accurate. The Company cautions readers that all forward looking statements, including without limitation those relating to the Company's future operations and business prospects, are based on assumptions none of which can be assured, and are subject to certain risks and uncertainties that could cause actual events or results to differ materially from those indicated in the forward looking statements. Readers are advised to rely on their own evaluation of such risks and uncertainties and should not place undue reliance on forward looking statements. Any forward looking statements are made as of the date of this news release, and the Company assumes no obligation to update the forward looking statements, or to update the reasons why actual events or results could or do differ from those projected in the forward looking statements. The Company assumes no obligations to update any forward looking statements, whether as a result of new information, future events or otherwise.



Source: XORTX Therapeutics Inc.