XORTX Receives FDA Response on Orphan Drug Designation Application

● Pivotal Phase 2/3 Clinical Study in ADPKD Planned in 2019 ●

CALGARY, AB – November 26, 2018 **–** XORTX Therapeutics Inc. ("**XORTX**" or the "**Company**") (CSE:XRX; OTCQB:XRTXF), a biopharmaceutical company focused on developing innovative therapies to treat progressive kidney disease (PKD), is pleased to announce that the Company along with its collaborative partner, Cato Clinical Research, has received a response letter from the US Food and Drug Administration (FDA) regarding the recent Orphan Drug Designation (ODD) application for XORTX's XRx-008 program for the treatment of autosomal dominant polycystic kidney disease (ADPKD).

XORTX received a response from the FDA regarding the recently submitted ODD application submitted in September 2018 which clarified the additional information needed to obtain ODD for the use of XRx-008 as a treatment for ADPKD. Supplemental information will be filed with the FDA in 2019 to continue the process of obtaining ODD status for XRx-008.

Next Steps for development of XRx-008 include:

1/ Complete manufacturing of Clinical Study ready XRx-008
2/ Respond to and complete IND filing with FDA
3/ Characterize improved bio-availability of XRx-008 in man
4/ Submit pivotal phase 2/3 protocol, discuss special protocol approval (SPA) with FDA and initiate clinical trial.

Dr. Allen Davidoff, XORTX's CEO commented, "XRx-008 holds clinically meaningful promise as a therapy for PKD in ADPKD patients. During the past two quarters, we have focused our efforts toward initiating communications with the FDA through a pre-IND application, a pre-IND meeting with the FDA and ODD applications to clarify critical path steps required to efficiently develop this program through marketing approval. Feedback and discussions with the FDA provided a clear set of steps to accelerate and focus our priorities, staff, and funding in the future. Over the next year XORTX will focus on executing on the critical path steps that position the Company for a pivotal phase 2/3 clinical trial in 2019 and we will continue to communicate with the FDA regarding a SPA for that trial."

XORTX is focused on advancing XRx-008 through a phase 2/3 pivotal clinical trial for the treatment of ADPKD. Strong scientific and clinical evidence suggests that in this patient population, uric acid concentration can promote progression of kidney disease. Managing purine and uric acid levels in patients shows promise as a therapy to slow the rate at which filtering capacity in kidneys decreases. Importantly, for patients, only one FDA approved therapeutic option currently exists to treat PKD, but does not address the harmful effects of uric acid.

Orphan Drug programs in the United States – programs for the treatment of rare disease – were passed into law in 1983 to facilitate development of orphan drugs – drugs for rare diseases such as ADPKD, Huntington's disease, ALS and muscular dystrophy. These rare diseases typically have fewer than 200,000 patients living in the US and due to small patient numbers would not be considered economically feasible without government programs to support their economic viability. ODD does not indicate that the therapeutic

is either safe and effective or legal to manufacture and market in the United States. That process is handled through other offices in the FDA, however an ODD designation would qualify XORTX for a number of benefits from the US federal government, such as reduced taxes and grants to fund future clinical trial work – a potentially substantial non-dilutive funding benefit to shareholders. Similar programs for rare diseases exist in European Union, Japan and other countries. Orphan drugs generally follow the same regulatory development path as any other pharmaceutical product, in which testing focuses on pharmacokinetics and pharmacodynamics, dosing, stability, safety and efficacy, however some statistical burdens are lessened in an effort to maintain development momentum. As a result of world wide support for the development of therapeutic solutions to disease, orphan programs are some of the most successful, time and cost effective programs to develop.

For more information on ODD program fundamentals, see:
www.optum.com/resources/library/world-of-orphan-drugs.html

For more information on the robust market for Orphan Drug programs globally, see:
http://info.evaluategroup.com/rs/607-YGS-364/images/EPOD17.pdf

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 www.xortx.com.

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