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## **XORTX Announces Filing of FDA pre-IND Meeting Request Letter**

CALGARY, Alberta, June 08, 2018 (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 the Company along with Cato Clinical Research has filed its pre-IND meeting request letter with the FDA. The request for a pre-IND (Investigational New Drug) meeting was accompanied by pre-IND documents and initiates formal communications with the FDA regarding development of XR<sub>x</sub>-008 for the treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD). The meeting with the FDA has been scheduled for September 10, 2018. A further press release regarding the meeting outcome will be issued by the Company.

XORTX is focused on advancing XR<sub>x</sub>-008 through phase 2 clinical trials for the treatment of ADPKD. At the present time, despite considerable effort, very few approved therapeutic options exist to treat progressive kidney disease (PKD). There is reason for hope, however, based on recent clinical study evidence that managing purine metabolism and serum uric acid concentrations can positively affect the kidney health and outcomes of patients with PKD.

Dr. Allen Davidoff, XORTX's CEO added, "We are excited to take this important first regulatory step in the development of the XR<sub>x</sub>-008 program for ADPKD. This request initiates the process of establishing communication and discussion with the FDA regarding our phase 2 clinical trial plans and defining the critical path for clinical development and marketing approval of this therapy for PKD patients."

Before initiating a clinical trial program a number of steps are involved in preparation for this process. These steps include preparation of pre-IND documentation to support communications, meetings and discussion with the FDA. At these meetings, program status, development plans and questions are discussed, then final revision of the formal IND document is submitted and in parallel a Phase 2 clinical trial protocol.

### **About Polycystic Kidney Disease**

PKD is an inherited, genetic disease that causes multiple cysts to form in the kidneys and sometimes in other organs. There are two forms of polycystic kidney disease, Autosomal Dominant Polycystic Kidney Disease (ADPKD) and Autosomal Recessive PKD (ARPKD). Polycystic kidneys become very large and can contain many fluid filled cysts. A number of symptoms are associated PKD including high blood pressure, kidney pain, development of kidney stones, urinary tract and kidney infections and progressive kidney disease leading to kidney failure. As cysts grow and expand they create pressure compressing normal kidney tissue further injuring the kidney. ADPKD is reported to affect approximately 1:1000 and

1:2400 individuals while ARPKD is much rarer. Current treatments include blood pressure lowering drugs and Tolvaptan a vasopressin receptor antagonist.

### **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](http://www.XORTX.com).

For further information, please contact:

Allen Davidoff, CEO  
[adavidoff@xortx.com](mailto:adavidoff@xortx.com) or +1 403 455 7727

or Erik Matthews, Corporate Communications & Investor Relations  
[erik@xortx.com](mailto:erik@xortx.com) or +1 747 203 5240

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Source: XORTX Therapeutics Inc.