

May 19, 2020



XORTX Provides Program Update Regarding XRx-008 for ADPKD and XRx- 101 for Coronavirus / COVID-19 Programs

CALGARY, Alberta, May 19, 2020 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (CSE: XRX) (OTCQB: XRTXF) (FRANKFURT: ANU1), a biopharmaceutical company focused on developing innovative therapies to treat kidney disease, is pleased to provide the following update on its clinical stage programs to treat chronic autosomal dominant polycystic kidney disease (ADPKD) - XRx-008 and acute kidney injury (AKI) associated with COVID-19 Infection – XRx-101.

XORTX continues to monitor the emerging health crisis associated with COVID-19 involving AKI and the long-term projected burden on individuals and the health care system. Recent key publications (links below) continue to aid in this process suggest that:

- the COVID-19 pandemic and infections are likely to continue for a least 12-24 months;
- the COVID-19 infection affects multiple organs during the course of infection, including lungs and kidneys, leaving individuals who survive infection with long-term recovery challenges;
- nearly 60% of individuals who are hospitalized with COVID-19 present with proteinuria – marker of kidney involvement, 37% of these patients have evidence of acute kidney injury and 90% of patients requiring respiratory ventilation have acute kidney failure requiring dialysis; and
- an estimate of the current US infection rates suggests that in the first two and a half months of COVID-19, approximately 73,000 US citizens now have AKI with an additional ~12,000 now requiring dialysis. During the next year these numbers are anticipated to increase substantially.

<https://www.sciencemag.org/news/2020/04/how-does-coronavirus-kill-clinicians-trace-ferocious-rampage-through-body-brain-toes>

<https://www.msn.com/en-us/health/health-news/coronavirus-destroys-lungs-but-doctors-are-finding-its-damage-in-kidneys-hearts-and-elsewhere/ar-BB12F0de?li=BBnb7Kz>

<https://www.reuters.com/article/us-health-coronavirus-kidney/kidney-injury-seen-in-more-than-a-third-of-hospitalized-covid-19-patients-u-s-study-idUSKBN22Q0U7>

With a focus on advancing both the ADPKD program as well as the COVID-19 program, XORTX has initiated a number of activities:

- Selection of LONZA Group as manufacturer of Oxypurinol, the active ingredient for both XRx-008 and XRx-101. LONZA will also perform formulation work and provide clinical supplies for future clinical trials in both programs.

- Submitted to the FDA Coronavirus Treatment Accelerated Program (CTAP) a development and data plan regarding a COVID-19 package and received guidance to submit a pre-IND package for review. Pre-IND submission preparations are underway – <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>.
- XORTX has also initiated discussions with the US Medical Countermeasures Group associated with the U.S. Government's Biomedical Advanced Research and Development Authority (BARDA) and separately with the National Institute of Health (NIH). These communications with BARDA and NIH are expected to further aid development of XORTX's XRx-101 program.
- XORTX continues to seek non-dilutive funding for XRx-008 and XRx-101 programs with several granting agencies.

As previously stated in the Company's prior press releases. The rationale for developing XRx-101 was made based on various in vivo studies showing that xanthine oxidase inhibition may confer suppression of viral infection and decrease symptoms of coronavirus COVID-19 infection and importantly improve survivability, and most importantly to protect the kidneys from AKI.

"The Company's activities in the past month to advance both the XRx-008, for ADPKD and XRx-101 for acute kidney injury due to COVID-19 have accelerated as we focus on applications for non-dilutive funding opportunities for these programs. A number of discussions with granting agencies, regulatory agencies such as the FDA and partnership discussions are proceeding in an effort to help those individuals with kidney disease." said Dr. Allen Davidoff, CEO of XORTX Therapeutics Inc.

This news release contains forward-looking information relating to, among other things, statements with respect to the potential for XRx-101 as a treatment to suppress the severity of the coronavirus / COVID-19 infection. 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.

About FDA CTAP

FDA has created a special emergency program for possible therapies, the Coronavirus Treatment Acceleration Program (CTAP). It uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful. We continue to support clinical trials that are testing new treatments for COVID so that we gain valuable knowledge about their safety and effectiveness.

<https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>

About BARDA

Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response, was established to aid in securing the U.S. from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI) and emerging infectious diseases (EID). BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile. BARDA's support includes funding, technical assistance and core services, ranging from a clinical research organization network to Centers for Innovation in Advanced Development and Manufacturing, and a fill-finish manufacturing network. To-date, BARDA has supported 42 FDA approvals for products addressing CBRN, PI, and EID threats.

BARDA's mission is accomplished through successful public-private partnerships with industry to share risk, improve efficiency and accelerate development all while sustaining a marketplace that guarantees continued access to countermeasures vital to our national security.

<https://www.phe.gov/about/BARDA/Pages/default.aspx>

About the National Institute of Health (NIH)

<https://www.nih.gov/about-nih>

About XRx-101 (Oxypurinol)

Oxypurinol was initially developed by Wellcome in the 1960's as an anti-cancer agent. In the 2000's Cardiome Pharma Corp. developed Oxypurinol for the treatment of "allopurinol intolerant gout" and submitted their program as an NDA (New Drug Application) for marketing approval and in 2005 received an "approvable letter" from the FDA for this purpose. XORTX Therapeutic filed a PCT patent application for a formulation of Oxypurinol in 2014 that is currently being developed for XRx-008 in ADPKD. Recently, XORTX announced that it had filed a prophetic patent application for a unique formulation of Oxypurinol for the XRx-101 program for COVID-19 / coronavirus infection with the intention to prosecute this application on a global scale.

Oxypurinol is a xanthine oxidase inhibitor that specifically decreases production of uric acid. Purine xanthine oxidase inhibitors such as Oxypurinol have also exhibited the ability to decrease free oxygen radical production, inflammatory cytokine expression, fibrosis and in addition have anti-viral properties.

Uric acid produced by xanthine oxidase is the primary excretory by product of nucleoside and nucleotide breakdown. In the acute setting, for example tumor lysis syndrome (TLS), xanthine oxidase inhibition can block acute organ and more specifically acute kidney injury. Tumor cell lysis releases DNA, cytokines, phosphate, and potassium. DNA is metabolized into adenosine and guanosine, which are then converted into xanthines. Xanthines are oxidized by xanthine oxidase into uric acid, which is then excreted through the kidneys. TLS develops when the accumulation of xanthine, uric acid, potassium, and phosphorus exceeds the kidney's capacity to excrete them. Cytokines cause hypotension, inflammation, and kidney injury, and worsen the kidney's excretory capacity. Damage to the kidneys also occurs by renal precipitation of uric acid, xanthine, and calcium phosphate. A rapid and

acute rise in uric acid levels and severely harm kidneys. Acute renal injury is the most common cause of mortality associated with TLS in solid tumors.

About XORTX Therapeutics Inc.

XORTX Therapeutics Inc. is a biopharmaceutical company with three clinically advanced products in development – XR_x-008 for Autosomal Dominant Polycystic Kidney Disease (ADPKD), XR_x-101 for Coronavirus / COVID-19 infection in addition to ongoing in licensing activity relating to potential therapies 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 xanthine oxidase to inhibit production of uric acid. At XORTX Therapeutics, we are dedicated to developing medications to improve the quality of life and future of patients. Additional information on XORTX Therapeutics is available at www.xortx.com.

In assessing opportunities, XORTX relies upon Company scientific expertise and its clinical advisory board composed of industry thought leaders and scientific publications within peer and non-peer reviewed publications to evaluate and advise on drug development programs. XORTX is led by Dr. Allen W. Davidoff, PhD who prior to founding XORTX had 15 years drug development experience with Stem Cell Therapeutics Corp. (co-founder, Chief Scientific Officer and Vice President, Product Development) and Cardiome Pharma Corp. (Senior Scientist and Head of Pharmacology). Dr. Davidoff has a broad range of clinical and regulatory experience in pharmaceutical R&D including two investigational new drug ("IND") applications or supplemental IND's, two phase 1 studies (4 multi-country), seven phase 2 studies, and one NDA.

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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. In particular, this news release contains forward-looking information relating to, among other things, statements with respect to the potential for XR_x-101 as a treatment to suppress the severity of the coronavirus / COVID-19 infection. 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 including that the products

developed by the Company will require approval from Health Canada and equivalent organizations in other countries before their sale can be authorized. These risks and uncertainties 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.