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XORTX Appoints Lonza for GMP Manufacturing and Formulation of XRx-101 (Oxypurinol) for Coronavirus / COVID-19 Clinical Trials

CALGARY, Alberta, April 30, 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 announces that it has granted the manufacturing contract for the active pharmaceutical ingredient for XRx-101 (Oxypurinol) and XRx-008 to Lonza Pharma & Biotech ("Lonza"). The urgent clinical need for therapies to suppress the severity of coronavirus / COVID-19 infection as a means of supporting the most vulnerable is a high priority for XORTX. In response to the need, and appeal from a variety of global clinical centers, XORTX has activated the manufacturing of Oxypurinol. Stepwise manufacturing of Oxypurinol to support the drug development and clinical trial process is expected to commence in May as the Company initiates regulatory discussions. In addition, the Company has applied for, and continues to apply for non-dilutive grants to support advancement of the important coronavirus / COVID-19 indication.

The launch of Oxypurinol manufacturing for both the coronavirus / COVID-19 (XRx-101) and autosomal dominant kidney disease programs (ADPKD: XRx-008) phase is the first step to advance these programs toward clinical testing. Both programs require regulatory approvals throughout the development process as well as late stage pivotal clinical testing. These development steps are essential to establish safety and efficacy prior to filing for regulatory marketing approval. At the present time neither XRx-101 for COVID-19 or XRx-008 for ADPKD have regulatory approvals for marketing. Simultaneous with the initiation of manufacturing, XORTX is prioritizing regulatory discussions with regulatory agencies from several nations regarding development status of XRx-101 (Oxypurinol) for coronavirus / COVID-19 infection and XRx-008 for ADPKD. Further guidance on progress of manufacturing and regulatory timing and acceptance will be provided when available.

"We are pleased to be working with Lonza on the manufacture of Oxypurinol, formulation development, new patentable technology advances and drug product for clinical and commercial supply by leveraging their integrated services. This is a key first step in advancing XRx-101 and XRx-008 towards clinical trials," stated Dr. Allen Davidoff, CEO of XORTX, who added, "XORTX believes strongly that the combined effect of the anti-viral properties, inhibition of xanthine oxidase and kidney protective effects of XRx-101 in coronavirus / COVID-19 infection will lessen the severity of infection and potentially the morbidity and mortality associated with this serious virus infection. For patients and the medical system, a therapy that decreases the severity of acute kidney and lung injury associated with COVID-19, could yield clinically meaningful results."

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 Lonza Group

Lonza is a leading global supplier to the pharmaceutical, biotech and specialty ingredients markets. The company works to promote a healthier lifestyle and prevent illness by supporting customers to deliver innovative medicines that help treat or even cure a wide range of diseases. This is complemented by a broad range of microbial control solutions, which help to create and maintain a healthy environment.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 100 sites and offices and approximately 15,500 full-time employees worldwide (at the end of 2019). The company generated sales of CHF 5.9 billion in 2019 with a CORE EBITDA of CHF 1.6 billion. Find out more at www.lonza.com.

About XRx-101 (Oxypurinol)

Oxypurinol was initially developed by Welcome 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. Although the anti-inflammatory, fibrosis and anti-viral properties have not described for COVID-19 infection, recent studies suggest that xanthine oxidase inhibition can lessen the symptoms and morbidity of viral infections such as influenza or herpes.

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.

In mouse models of influenza infection, a syndrome similar to TLS has been described, that results in a rapid rise of serum uric acid levels and this event is associated with a poor prognosis. Massive cell lysis results in the release of large amounts of uric acid, potassium and phosphate as well as cytokines into the systemic circulation, akin to Systemic Inflammatory Response Syndrome (SIRS)[3]. induced by viral infection. Both hyperuricemia and hyperphosphatasemia potentiate the risk of acute kidney injury by way of uric acid precipitation and calcium phosphate deposition in the renal tubules, further aggravating the electrolyte imbalance [1]. Additionally, the products of cell lysis trigger the release of cytokines, resulting in a systemic inflammatory response syndrome and frequently multiorgan failure[2].

Recently, accumulating evidence suggests that a subgroup of patients with severe COVID-19 might have a cytokine release syndrome. In some regards, this may be analogous to the mouse influenza scenario, where both tissue lysis and cytokine release produces the most severe form of COVID-19 infection, symptoms and poor survival prognosis.

References:

1 Howard, SC., Jopnes DP., Pui C-H. The Tumor Lysis Syndrome, N Engl J Med, 364(19)1844-1854, 2011

2 Jaffer U, Wade R.G. Gourlay T, Cytokines in the systemic inflammatory response syndrome, 2(3): 161-175, 2010

3 Khomich OA et al, Redox Biology of Respiratory Viruses, Viruses, 10, 394, 2018

About XORTX Therapeutics Inc.

XORTX Therapeutics Inc. is a biopharmaceutical company with three clinically advanced products in development – XRx-008 for Autosomal Dominant Polycystic Kidney Disease (ADPKD), XRx-101 for Coronavirus / COVID-19 infection and XRx-221, under a letter of intent to establish a co-development program with Teijin Pharma Limited, 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 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. 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.

XORTX THERAPEUTICS INC.

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