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XORTX Launches XRx-101, A New Program to Treat Coronavirus COVID-19 Infection

• XRx-101 – a triple action approach to suppressing COVID-19 Injury •

CALGARY, Alberta, March 16, 2020 (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, with late stage clinical programs, announces that it is exploring the potential of using XRx-101 (a new formulation of Oxypurinol) as a novel treatment for acute kidney and lung injury accompanying Coronavirus infection and specifically for the COVID-19 infection. The Company has reviewed recent studies characterizing the outbreak of COVID-19 in mainland China. These published reports clearly illustrate that acute kidney injury and acute pulmonary injury are key factors in the most serious cases of COVID-19 hospitalization and death.

In addition, studies of Coronavirus infections show that SARS and MERS and specifically COVID-19 can be frequently accompanied by pneumonia, acute kidney injury, proteinuria and hematuria^{1,2}. Acute kidney injury ("AKI") has been identified as an independent risk factor for patients' in-hospital mortality due to COVID-19 as well as other Coronavirus infections². Early reports suggested a lower incidence (between 3% to 9%) of AKI in those with COVID-19 infection^{2,6,8}. Recent reports, however, have shown a higher frequency of renal abnormalities. A study of 59 patients with COVID-19 found that 34% of patients developed massive albuminuria on the first day of admission and 63% developed proteinuria during their stay in hospital⁹.

Based on these recent studies, the Company believes that its Oxypurinol formulation, XRx-101, has the potential to be a front-line treatment for severe cases of Coronavirus and the ability to decrease morbidity and mortality in hospitalized patients. Coronavirus infections have high mortality rates¹ with SARS, MERS and COVID-19 having rates of 10%, 37% and 4%, respectively. While the COVID-19 mortality rate is currently reported to be lower than SARS and MERS, COVID-19 is more contagious than SARS and MERS. Management's belief that XRx-101 is a possible treatment for COVID-19 is based upon its potential anti-viral properties, and historic animal and human data that show that acute tissue injury can lead to rapid accumulation of uric acid and uric acid crystals that aggregate in kidneys and induce acute kidney injury^{3,4}. When acute kidney injury accompanies pneumonia, post-discharge outcomes are worse than either diagnosis alone. Patients who survive a pneumonia hospitalization and develop acute kidney injury are at high risk for major adverse kidney events including death and should receive careful follow-up⁴. Perhaps more importantly, Oxypurinol has been previously studied for anti-viral properties¹⁰, a characteristic that may

decrease morbidity and mortality of COVID-19. Importantly, Oxypurinol has in the past received an “Approval Letter” from the US FDA, potentially accelerating development for this purpose.

In concept, the triple action of XRx-101, as an anti-viral therapy, to decrease the production of uric acid and to increase aqueous solubility of uric acid will decrease uric acid crystal formation associated with tumor lysis “like” syndrome due to Coronavirus infection. Any agent that decreases the severity of primary or secondary pneumonia leading to acute kidney injury is potentially highly relevant.

XORTX believes that XRx-101 (a formulation of Oxypurinol) could be relevant and important for decreasing kidney and lung associated health consequences of the Coronavirus infection. Indeed, Xanthine oxidase inhibitors (XOI) have been reported to have a potent antiviral effect against influenza-A virus⁵, suggesting a third potential therapeutic method for suppressing the Coronavirus infection.

XORTX is preparing to manufacture and submit final investigative new drug (IND) applications for XRx-008 for the Company’s planned phase 3 clinical trial in Autosomal Dominant Polycystic Kidney Disease (ADPKD).

“XORTX has begun a comprehensive review of the potential for XRx-101 to be a novel treatment for Coronavirus infection and its health consequences,” commented Dr. Allen Davidoff, CEO, XORTX Therapeutics who added, “Oxypurinol is a well studied drug that is known to be clinically safe and effective at decreasing production of uric acid, as well as a potential anti-viral agent. Owing to its advanced development status, Oxypurinol could be quickly developed to help treat those most severely affected by COVID-19.”

XORTX has filed new intellectual property rights for XRx-101 for the treatment of respiratory and kidney disease due to viral infection.

About XORTX Therapeutics Inc.

XORTX Therapeutics Inc. is a biopharmaceutical company focused on developing innovative therapies to treat progressive kidney disease. XORTX has two lead programs to develop treatments for progressive kidney disease due to diabetes, diabetic nephropathy and polycystic kidney disease. XORTX’s XRx-008 (a proprietary reformulation of Oxypurinol) is a late stage drug development program to treat autosomal dominant polycystic kidney disease (ADPKD). TMX-049, is a late phase 2b stage program in treat type 2 diabetic nephropathy (T2DN), under a Letter of Intent, that proposes a co-development agreement with Japan’s Teijin Pharma Limited. 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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References:

1 Saraladevi Naicker, Chih-Wei Yang, Shang-Jyh Hwang, Bi-Cheng Liu, Jiang-Hua Chen, Vivekanand Jha, The Novel Coronavirus 2019 Epidemics and Kidneys, Kidney International March 2, 2020. [https://www.kidney-international.org/article/S0085-2538\(20\)30251-9/pdf](https://www.kidney-international.org/article/S0085-2538(20)30251-9/pdf)

2 Cheng, Y, Luo R., Wang K., Zhang M., Wang Z., Dong L., Li J., Yao Y., Ge S., Xu g., Kidney Impairment is associated with in-hospital deal of Covid-19 patients, medRxiv, March 04_2020 <https://www.medrxiv.org/content/10.1101/2020.02.18.20023242v1>

3 Wilson FP., Tumor Lysis Syndrome, Adv Chronic Kidney Dis, 21(1)18, 2014 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4017246/>

4 Chawla LS., Amdur RL., Faselis C., Kimmel PL., Palant CE., Impact of Acute Kidney Injury in Patients Hospitalized with Pneumonia, Crit Care Med, 45(4)600-606, 2017 <https://www.ncbi.nlm.nih.gov/pubmed/28291091>

5 Perez-Mazliah D et al, Allopurinol reduced antigen-specific and polyclonal activation of human T-cells, Frontiers in Immunology, Sept 2012

6 Wang D, Hu B, Hu C, et al. Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. JAMA,2020,doi:10.1001/jama.2020.1585.

7 Chen N, Zhou M, Dong X, et al. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study[J]. Lancet, 2020, 395(10223): 507-513.

8 Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of 2019 novel coronavirus infection in China. medRxiv preprint first posted online Feb. 9, 2020. <https://doi.org/10.1101/2020.02.06.20020974>Li Z,

9 Wu M, Guo J, et al. Caution on Kidney Dysfunctions of 2019-nCoV Patients. medRxiv preprint doi: <https://doi.org/10.1101/2020.02.08.20021212>.

10 El-Farrash, Youssef JM., and El-Mongy SE., Allopurinol as a potential therapeutic agent for recurrent herpes labialis, J Med Dent Sci, Jun 50(2):147-154

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