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Form 20-F [X] Â Â Â Â Form 40-F [Â] Â SIGNATURE Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized. Â Â XORTX Therapeutics Inc. Â Â Â Â Â Â (Registrant) Â Â Â Â Â Â Date: January 6, 2025 Â By: Â Â Â Â /s/ Allen Davidoff Â Â Â Â Â Name: Â Allen Davidoff Â Â Title: Â Chief Executive Officer Â Â EXHIBIT INDEX Â 99.1 Â News release dated January 6, 2025 Â EX-99.1 2 exh_991.htm PRESS RELEASE Edgar Filing EXHIBIT 99.1 XORTX Adds Late Stage Gout Program to Pipeline XORTX to focus on late stage allopurinol intolerant gout program; discussion with FDA planned for first half 2025 regarding NDA filing CALGARY, Alberta, Jan. 06, 2025 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (NASDAQ: XRTX | TSXV: XRTX | Frankfurt: ANU), a late stage clinical pharmaceutical company focused on developing innovative therapies to treat progressive kidney disease, announces the launch of a new late stage program to treat gout. The new drug development program - XRx-026 - will focus on the treatment of individuals who have gout and are intolerant to allopurinol. With the clinical development of XORLOTM 1 having advanced sufficiently, including completion of a pivotal program, XORTX is initiating discussions for the XRx-026 program with the US Food and Drug Administration ("FDA") regarding preparation of a New Drug Application ("NDA"). Pending FDA feedback, the Company will also seek FDA orphan drug designation ("ODD") and NDA marketing approval for the XRx-026 program. Previously, oxypurinol was granted ODD for allopurinol intolerant gout. Dr. Allen Davidoff commented, "Oxypurinol has been demonstrated to be safe and effective in clinical studies focused on the treatment of individuals with gout who are intolerant to allopurinol. Intolerance to allopurinol remains an important issue for many patients and physicians and the XRx-026 program has demonstrated the potential to address this unmet medical need. XORTX will consult with the FDA during the first half of 2025, regarding requirements to file a NDA." About Hyperuricemia, Gout and Health Consequences The breakdown of nucleotides in the blood occurs through purine metabolism and results in the formation of uric acid by the xanthine oxidase enzyme. However, chronically high blood uric acid concentrations (hyperuricemia) have been associated with health consequences including gout, kidney stones, diabetes, cardiovascular disease, and renal failure. Worldwide, approximately 14% of individuals have hyperuricemia and an estimated 1 to 2% have gout. Lowering blood levels of uric acid in gout patients is strongly correlated with improved health outcomes. Addressable Gout Market Opportunity In North America, approximately 3.5 million people suffer from gout due to elevated uric acid levels in blood. The therapeutic options to lower uric acid levels include three major classes of drugs: (i) oral uricosurics that are used to decrease the reabsorption of uric acid by the kidney; (ii) intravenous uricase enzymes that are used to metabolize uric acid in the blood for excretion; and (iii) oral xanthine oxidase inhibitors ("XOIs") that are used to inhibit the production of uric acid. XOIs are the preferred first-line treatment for gout. Allopurinol is the most commonly prescribed XOI, with approximately 3 million prescriptions written per year in North America, however 3 to 5% of patients cannot tolerate allopurinol. An alternative XOI, Febuxostat, launched in the US in 2009 with the hope of treating allopurinol intolerant patients, however while Febuxostat achieved peak sales of approximately US\$450 million², it now carries a Black Box warning due to its associated risk of sudden cardiovascular death and its use has declined significantly. This decline in Febuxostat use has created an opportunity for a novel XOI to address the underlying unmet medical need which the XRx-026 program aims to fill. About XORTX Therapeutics Inc. XORTX is a pharmaceutical company with three clinically advanced products in development: 1) our lead, XRx-008 program for ADPKD; 2) our XRx-026 program for the treatment of allopurinol intolerant gout; and 3) our secondary program in XRx-101 for acute kidney and other acute organ injury associated with Coronavirus / COVID-19 infection. In addition, XRx-225 is a pre-clinical stage program for Type 2 Diabetic Nephropathy. XORTX is working to advance its clinical development stage products that target aberrant purine metabolism and xanthine oxidase to decrease or inhibit production of uric acid. At XORTX, we are dedicated to developing medications to improve the quality of life and health of kidney disease patients and individuals with gout. Additional information on XORTX is available at www.xortx.com. For more information, please contact: Allen Davidoff, CEO Nick Rigopoulos, Director of Communications adavidoff@xortx.com or +1 403 455 7727 nick@alpineequityadv.com or +1 617 901 0785 Neither the TSX Venture Exchange nor Nasdaq has approved or disapproved the contents of this news release. No stock exchange, securities commission or other regulatory authority has approved or disapproved the information contained herein. Forward Looking Statements This press release contains express or implied forward-looking statements pursuant to applicable securities laws. These forward-looking statements include, but are not limited to, the Company's beliefs, plans, goals, objectives, expectations, assumptions, estimates, intentions, future performance, other statements that are not historical facts and statements identified by words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates" or words of similar meaning. These forward-looking statements and their implications are based on the current expectations of the management of XORTX only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks, uncertainties, and other factors include, but are not limited to, our ability to obtain additional financing; the accuracy of our estimates regarding expenses, future revenues and capital requirements; the success and timing of our preclinical studies and clinical trials; the performance of third-party manufacturers and contract research organizations; our plans to develop and commercialize our product candidates; our plans to advance research in other kidney disease applications; and, our ability to obtain and maintain intellectual property protection for our product candidates. Except as otherwise required by applicable law and stock exchange rules, XORTX undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. More detailed information about the risks and uncertainties affecting XORTX is contained under the heading "Risk Factors" in XORTX's Annual Report on Form 20-F filed with the SEC, which is available on the SEC's website, www.sec.gov (including any documents forming a part thereof or incorporated by reference therein), as well as in our reports, public disclosure documents and other filings with the securities commissions and other regulatory bodies in Canada, which are available on www.sedarplus.ca. 1 XORLOTM is

XORTX®'s proprietary formulation of oxypurinol, that has granted US and EU patents. 2 Source: Takeda Pharmaceutical Company 2018 Annual Report.