November 24, 2026

XORTX Advances Planned Health Canada and FDA Submissions for XORLO™ Clinical Trial, Targeted for Year End 2026

● Clinical Trial Application and Investigational New Drug application on trackfor submission in the fourth quarter of 2026 ●

CALGARY, Alberta, Nov. 24, 2026 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("**XORTX**" or the "**Company**") (NASDAQ: XRTX), a late-stage clinical pharmaceutical company focused on developing innovative therapies to treat gout and progressive kidney disease, is pleased to provide an update on the planned regulatory submissions for its lead XRx-026 program for the treatment of gout. Building on the completion of manufacturing and packaging of clinical drug supply for the XRX-OXY-102 clinical trial, announced on November 16, 2026, the Company's drug development team has been working closely with its regulatory, clinical and manufacturing partners to finalize the Clinical Trial Application ("**CTA**") for filing with Health Canada and the Investigational New Drug ("**IND**") application for filing with the U.S. Food and Drug Administration ("**FDA**"). Both submissions are on track for the fourth quarter of 2026, consistent with the IND timeline previously communicated by the Company.

The CTA and IND are expected to incorporate validation data from the clinical manufacturing process, together with the Company's clinical development plan for XORLO™, its proprietary formulation of oxypurinol. Conducting the first part of the XRX-OXY-102 clinical study in Canada is expected to enable the Company to accelerate the delivery of key clinical data in support of its planned New Drug Application ("**NDA**") filing with the FDA. This study is anticipated to add to the previously reported positive clinical results of the XRX-OXY-101 study.

"With clinical drug supply in hand, our team is focused on executing the CTA and IND submissions this quarter," said Dr. Allen Davidoff, Co-Chief Executive Officer of XORTX. "These filings are expected to be the next defining step for the XRx-026 program as we advance XORLO™ into the clinic and toward an NDA."

XORTX looks forward to providing further updates as its regulatory submissions progress.

About the XRX-OXY-102 program

Part 1 of the XRX-OXY-102 clinical trial builds upon the previously reported positive clinical results for the proprietary XORLO™ formulation and extends characterization of the intended commercial tablet form. Part 1 of the study is designed to characterize the steady state pharmacokinetics of XORLO™, XORTX's intended commercial form of oxypurinol tablet. Part 2 of the study is designed to evaluate the therapeutic equivalence of XORLO™

compared to allopurinol in gout patients. Data generated during this study are intended to support the planned NDA submission to the FDA. XORTX intends to seek marketing approval for XORLO™, subject to favorable clinical study results and its discussions with the FDA.

About Hyperuricemia and Gout

In the United States, approximately **44 million individuals** have uric acid levels above the normal range, with **9.2 million individuals living with gout**[1]. Gout is associated with severe pain, reduced quality of life[2], decreased physical function[3], increased healthcare costs[4], and lost economic productivity[5]. It is also strongly associated with metabolic syndrome[5], myocardial infarction[6,7], Type 2 diabetes mellitus[8], chronic kidney disease[9], and premature mortality[6,10,11]. Importantly, the global prevalence of gout is increasing, with cases expected to increase 70% over the next 25 years[*].

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[*] https://pubmed.ncbi.nlm.nih.gov/38996590/

About the XRx-026 Program and XORLO™

The XRx-026 program is developing XORLO™, the Company's proprietary formulation of oxypurinol, to treat individuals with gout. Oral xanthine oxidase inhibitors ("**XOIs**") are the current standard of care for treating hyperuricemia-associated gout. Allopurinol is the recommended first-line therapy for gout; however, limitations remain: approximately 3–5% of patients cannot tolerate allopurinol. An alternative XOI, febuxostat, at one time achieved annual peak net sales >US$450 million, and now carries a boxed warning for cardiovascular risk which has substantially decreased its use and sales. XORLO™ is designed to address this unmet need by providing an alternative therapeutic option with a potentially differentiated safety and efficacy profile. Advancement of XRx-026 through the planned CTA, IND and NDA filings is a strategic priority for XORTX.

References

1. Chen-Xu M, et al. Prevalence of Gout and Hyperuricemia in the US.*Arthritis Rheumatol.* 2019;71(6):991–999.
2. Singh JA. Quality of life and quality of care for patients with gout.*Curr Rheumatol Rep.* 2009;11(2):154–60.
3. Burke BT, et al. Physical Function, Hyperuricemia, and Gout in Older Adults.*Arthritis Care Res.* 2015;67(12):1730–8.
4. Rai SK, et al. The economic burden of gout: a systematic review.*Semin Arthritis Rheum.* 2015;45(1):75–80.
5. Choi HK, et al. Prevalence of the metabolic syndrome in individuals with hyperuricemia. *Am J Med.* 2007;120(5):442–7.
6. Choi HK, Curhan G. Independent impact of gout on mortality and risk for coronary heart disease. *Circulation.* 2007;116(8):894–900.
7. Liu S-C, et al. Gout and Risk of Myocardial Infarction: A Systematic Review.*PLoS ONE.* 2015;10(7):e0134088.
8. Choi HK, et al. Gout and the risk of type 2 diabetes among men with high

cardiovascular risk profile. *Rheumatology.* 2008;47(10):1567–70.
9. Roughley MJ, et al. Gout and risk of chronic kidney disease and nephrolithiasis: meta-analysis. *Arthritis Res Ther.* 2015;17(1).
10. Kuo C-F, et al. Gout: an independent risk factor for all-cause and cardiovascular mortality. *Rheumatology.* 2010;49(1):141–6.
11. Fisher MC, et al. Premature mortality gap in gout: a general population-based study. *Ann Rheum Dis.* 2017;76(7):1289–94.

About XORTX Therapeutics Inc.

XORTX is a pharmaceutical company with three clinically advanced products in development: 1) our lead XRx-026 program for the treatment of gout; 2) XRx-008 program for ADPKD; and 3) XRx-101 for acute kidney and other acute organ injury associated with respiratory virus infections. In addition, the Company is developing XRx-225, a pre-clinical stage program for Type 2 diabetic nephropathy, and the recently acquired VB4-P5 program, which is currently at the pre-IND stage of development and targets both rare and prevalent forms of kidney disease. XORTX is working to advance 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 that improve the quality of life and health of individuals with gout and other important diseases.

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Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, as well as “forward-looking information” within the meaning of applicable Canadian securities laws. Forward-looking statements may be identified by the use of words such as “anticipate,” “believe,” “expect,” “estimate,” “plan,” “intend,” “will,” “may,” “potential,” “on track,” “looks forward,” and similar expressions, and include all statements that are not statements of historical fact. These forward-looking statements include, but are not limited to, statements regarding the anticipated content and timing of the submission of the CTA to Health Canada and the IND to the FDA; the review of the CTA and IND by Health Canada and the FDA; the anticipated initiation, design, conduct, timing and results of the XRX-OXY-102 clinical trial; the expectation that conducting Part 1 of the XRX-OXY-102 clinical trial in Canada will accelerate the delivery of clinical data; the planned NDA submission to the FDA and its timing; the advancement of XORLO™ and the XRx-026 program toward marketing approval; and the advancement of the Company’s other development programs and its strategy.

Forward-looking statements are based on the Company’s current expectations and assumptions and are subject to known and unknown risks, uncertainties, and other factors that could cause actual results, performance, or achievements to differ materially from those expressed or implied by such statements. Such risks and uncertainties include, among others: the risk that the CTA or IND is not finalized or submitted on the anticipated timeline,

or at all; the risk that Health Canada or the FDA requires additional information, objects to the CTA, places the IND on clinical hold or otherwise delays or prevents the initiation of the XRX-OXY-102 clinical trial; the risk that manufacturing, validation or stability data do not support the regulatory submissions or the clinical trial as anticipated; the Company's reliance on third-party contract research, manufacturing and regulatory service providers; the risk that the XRX-OXY-102 clinical trial does not commence, enroll or complete as planned, or does not produce favorable results, or that data generated in Canada are not accepted by the FDA in support of an NDA; the Company's need for, and ability to obtain, additional capital to fund its development programs and operations; the Company's ability to advance, and obtain regulatory approval for, the XRx-026 program and its other product candidates on the timelines currently anticipated, or at all; the evolving regulatory environment applicable to the Company's business in the United States and Canada; the Company's ability to maintain the listing of its common shares on the Nasdaq Capital Market; and the Company's ability to attract and retain qualified personnel.

For a more detailed discussion of these and other risks and uncertainties, investors should review the disclosures contained under the heading "Risk Factors" in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2025, and in the Company's subsequent Reports of Foreign Private Issuer on Form 6-K, each as filed with or furnished to the U.S. Securities and Exchange Commission (the "**SEC**") and available at www.sec.gov, as well as in the Company's continuous disclosure documents filed with the Canadian securities regulatory authorities and available at www.sedarplus.ca.

The forward-looking statements in this press release speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise. Readers are cautioned not to place undue reliance on these forward-looking statements.

Source: XORTX Therapeutics Inc.