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XORTX Outlines Anticipated Health Canada Clinical Trial Application for XRx-026 for Gout

- **Clinical Trial Application planned for filing with Health Canada, extending the Company's international regulatory strategy for gout program XRx-026 •**

CALGARY, Alberta, Oct. 08, 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 outline of its anticipated Clinical Trial Application ("**CTA**") submission to Health Canada for the XRx-026 gout program. The filing supports the Company's planned two-part clinical study, XRx-OXY-102, evaluating XORLO™, the Company's proprietary formulation of oxypurinol, a xanthine oxidase inhibitor, for the treatment of gout. 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 U.S. Food and Drug Administration (the "**FDA**") for marketing approval.

Recent drug development team activities have included parallel preparation of the CTA for filing with Health Canada. The application describes the Company's clinical development plan for XRx-026 and its intention to advance the program toward regulatory approval in Canada in parallel with its planned NDA filing with the FDA. Part one 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 commercial tablet form.

"Advancing our Clinical Trial Application with Health Canada is expected to enable more efficient clinical plan execution and extends our regulatory strategy for XRx-026 globally," said Dr. Allen Davidoff, Co-Chief Executive Officer of XORTX, who added, "Gout is a growing global burden, and approaches that make more efficient use of our capital, personnel and time are expected to accelerate the availability of XORLO™ to patients wherever the need exists. This, in turn, is anticipated to enhance the overall value of the XRx-026 program for the Company and its shareholders."

As the XRx-026 program has advanced, the Company has received increased inquiries from potential commercialization partners in a number of jurisdictions. The Company has not entered into any agreement with any such party, and there can be no assurance that any of these discussions will result in a transaction. XORTX looks forward to providing further updates regarding the XRx-026 drug development program as it advances toward the planned CTA and NDA filings.

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 life², decreased physical function³, increased healthcare costs⁴, and lost economic productivity⁵. It is also strongly associated with metabolic syndrome⁵, myocardial infarction^{6,7}, Type 2 diabetes mellitus⁸, chronic kidney disease⁹, 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*.

* <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 differentiated safety and efficacy profile. Advancement of XRx-026 through the planned CTA and NDA filings is a strategic priority for XORTX.

References

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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,” “designed to,” “enable,” “accelerate,” “extend,” “potential,” “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 preparation, timing, content and submission of the Company’s planned CTA to Health Canada for the XRx-026 program; the design, initiation, conduct and completion of the planned two-part XRr-OXY-102 clinical study, including the Company’s plan to conduct the first part of the study in Canada; the Company’s expectation that conducting the first part of the study in Canada will accelerate the delivery of clinical data in support of its planned NDA filing with the FDA; the Company’s regulatory strategy in the United States, Canada and other jurisdictions, including the timing and content of its planned regulatory submissions to the FDA and its intention to advance the XRx-026 program toward regulatory approval in Canada; the Company’s expectations regarding the more efficient use of its capital, personnel and time and the potential to accelerate the availability of XORLO™ to patients; interest from, and the potential for arrangements with, commercialization partners; statements regarding the prevalence of hyperuricemia and gout and the projected growth in the prevalence of gout, which are based on third-party data; and the advancement of the Company’s XRx-026 program, its 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 Company’s need for, and ability to obtain, additional capital to fund its development programs and operations; the risk that the Company’s CTA submission to

Health Canada is delayed or, once submitted, is not accepted by Health Canada, is subject to objection or to requests for additional information or data, or is otherwise not permitted to proceed; the risk that the Company's regulatory submissions to the FDA are delayed or not accepted, or that the planned XRX-OXY-102 clinical study is placed on clinical hold or otherwise not permitted to proceed by the FDA; the Company's ability to initiate, conduct, and complete the planned XRX-OXY-102 clinical study, in Canada and elsewhere, on the timelines currently anticipated, or at all, and the risk that the results of that study are not positive, are not accepted by the FDA, or do not support an NDA submission; the risk that Health Canada or the FDA does not agree with the Company's proposed clinical development plan or regulatory pathway, or requires additional studies or data; the Company's reliance on third-party contract research organizations and contract manufacturers; the risk that discussions with potential commercialization partners do not result in any agreement on acceptable terms, or at all; the risk that third-party data regarding the prevalence of hyperuricemia and gout, and projections of future prevalence, prove to be inaccurate; competition from existing and future therapies for gout; 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 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.