November 16, 2026

XORTX Completes Manufacturing of Clinical Drug Supply

● Clinical Drug Supply and Packaging completed in preparationfor the XRX-OXY-102 Clinical Study ●

CALGARY, Alberta, Nov. 16, 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 announce that manufacturing and packaging of clinical drug supply for the XRX-OXY-102 clinical trial has been completed. Production of XORTX's clinical drug supply is based on proprietary synthetic pathway for production of high yield pure oxypurinol, then formulated using our proprietary and patented formulation of this drug. This process to produce the formulation and tablet format the Company aims to advance through marketing approval is a key step forward for the XRx-026 program for the treatment of gout.

The XRx-026 program is our lead program focused on the treatment of individuals with symptoms of gout. In parallel with the manufacturing processes, method development and validation of tablet, drug development team activities include the preparation of the Clinical Trial Application ("**CTA**") for filing with Health Canada. Validation data from this manufacturing process will be included in the CTA. 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 Investigational New Drug ("**IND**") application filing with the US Food and Drug Administration ("**FDA**").

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 commercial tablet form. Part 1 of the study will characterizing the steady state pharmacokinetics of XORLO™, XORTX's commercial form of oxypurinol tablet. Part 2 of the study will evaluate the therapeutic equivalence of XORLO compared to allopurinol in gout patients. Data generated during this study will support the planned marketing application ("**NDA**") submission to the FDA. XORTX intends to advance this drug to marketing approval pending favorable clinical study results and its FDA discussions. Once completed, a commercial drug supply is a pre-requisite for FDA approval for marketing of XORLO™.

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[*].

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,” “may,” “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 payment of the registration fee for, and the registration and issuance of, the Japanese Patent; the anticipated term, expiry date and scope of the Japanese Patent, including the availability of any patent term extension; the protection the Japanese Patent may provide for the XRx-101 program and the Company’s other product candidates; the size, composition and strength of the Company’s patent portfolio and its plans to continue to build that portfolio; the Company’s evaluation of, and the potential for, partnering or licensing arrangements for the XRx-101 program and its other programs; the potential for xanthine oxidase inhibition to attenuate increases in uric acid and acute kidney injury associated with respiratory viral infection; and the advancement of the Company’s XRx-101 and XRx-026 programs, 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 risk that the registration fee is not paid or that the Japanese Patent is otherwise not registered and issued as anticipated, or at all; the risk that the Japanese Patent, once issued, is challenged, narrowed, invalidated or held unenforceable, including in post-grant opposition or invalidation proceedings before the JPO; the risk that the claims of the Japanese Patent do not cover competing products or provide meaningful commercial protection; the risk that no patent term extension is available for the Japanese Patent; the risk that the Company’s pending patent applications do not issue as patents, or issue with claims narrower than those sought; the Company’s ability to obtain, maintain, defend and enforce its intellectual property rights in Japan and other jurisdictions, including its ability to fund annuity and maintenance fees; the Company’s need for, and ability to obtain, additional capital to fund its development programs and operations; the risk that the XRx-101 program, which is not the Company’s lead program, is not further developed, partnered or approved in

Japan or any other jurisdiction; the risk that the Company does not enter into any partnering or licensing arrangement on acceptable terms, or at all; the risk that xanthine oxidase inhibition does not prove to be safe or effective in treating or preventing acute kidney injury or other acute organ injury associated with viral infection; 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, Canada and Japan; 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.

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

Source: XORTX Therapeutics Inc.