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# XORTX Announces Initiation of Clinical and Commercial Manufacturing of XORLO™

- **Contract manufacturing of GMP drug substance and commercial-scale tablets to support the XR<sub>x</sub>-OXY-102 clinical study and future US FDA marketing approval •**

CALGARY, Alberta, Sept. 10, 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, announces the launch of production of drug material and tablet manufacturing to support the Company's XR<sub>x</sub>-026 program for the treatment of gout. This manufacturing supports a planned two-part clinical study of XORLO™, the Company's proprietary formulation of oxypurinol, a xanthine oxidase inhibitor. The clinical trial, XR<sub>x</sub>-OXY-102, is being advanced based on positive and supportive prior clinical trial results and discussions with the US Food and Drug Administration (the "FDA").

The two-part clinical study will require production of GMP drug and clinical supply tablets representative of material intended for FDA marketing approval. Contract production of pure oxypurinol drug substance, the active pharmaceutical ingredient in XORLO™, using the Company's proprietary synthetic pathway, has begun.

XORTX is now working closely with its contract manufacturing partner toward the manufacture of commercial drug batches. Validation and stability data from this work is expected to provide key support for FDA marketing approval in the future.

"Advancing our clinical manufacturing and the work underway with our commercial manufacturing partner is a foundational step toward bringing XORLO™ to patients," stated Dr. Allen Davidoff, Co-Chief Executive Officer of XORTX, who added, "This progress provides the material we require for the XR<sub>x</sub>-OXY-102 clinical trial and builds the validation and stability record that we expect will support our NDA filing."

This manufacturing progress is one part of the Company's broader plan to advance XR<sub>x</sub>-026 toward FDA marketing approval, and XORTX looks forward to providing further updates on its regulatory and clinical strategy in the coming weeks.

## 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**<sup>1</sup>. Gout is associated with severe pain, reduced quality of life<sup>2</sup>, decreased physical function<sup>3</sup>, increased healthcare costs<sup>4</sup>, and lost economic productivity<sup>5</sup>. It is also strongly associated with metabolic syndrome<sup>5</sup>,

myocardial infarction<sup>6,7</sup>, Type 2 diabetes mellitus<sup>8</sup>, chronic kidney disease<sup>9</sup>, and premature mortality<sup>6,10,11</sup>. 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™, a proprietary formulation of oxypurinol, to treat individuals with gout. Oral xanthine oxidase inhibitors (XOIs) are the current standard of care, but limitations remain: approximately 3–5% of patients cannot tolerate allopurinol, and febuxostat, while once achieving >US\$450 million in annual sales, now carries a boxed warning for cardiovascular risk. 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 NDA filing is a strategic priority for XORTX.

### References

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9. Roughley MJ, et al. Gout and risk of chronic kidney disease and nephrolithiasis: meta-analysis. *Arthritis Res Ther*. 2015;17(1).
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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.

For more information, please contact:

Allen Davidoff, Co-CEO

[adavidoff@xortx.com](mailto:adavidoff@xortx.com)

+1 403 455 7727

Mika Grasso, Co-CEO

[mgrasso@xortx.com](mailto:mgrasso@xortx.com)

+1 949 244 6011

## 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," "positions," 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 initiation and completion of manufacturing of GMP oxypurinol drug substance and clinical and commercial-scale supply of XORLO™ tablets; the timing, design, and conduct of the planned XRx-OXY-102 clinical study; the expected contribution of validation and stability data to a future NDA filing and FDA marketing approval; 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 Company's reliance on third-party contract manufacturers, and the risk of delays, failures, or increased costs in the production of GMP drug substance and clinical or commercial supply tablets; the risk that validation and stability data do not support an NDA filing or FDA marketing approval; the Company's ability to initiate, conduct, and complete the planned XRx-OXY-102 clinical study on the timelines currently anticipated, or at all; 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; 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](http://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](http://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.