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XORTX Commences Gout Program NDA Discussions with the FDA

• Type C Meeting Requested to Accelerate XRx-026 for Gout to NDA •

CALGARY, Alberta, Feb. 24, 2025 (GLOBE NEWSWIRE) -- XORTX Therapeutics Inc. ("XORTX" or the "Company") (NASDAQ: XRTX | TSXV: XRTX | Frankfurt: ANUA), a late stage clinical pharmaceutical company focused on developing innovative therapies to treat progressive kidney disease and gout, announces that it has submitted a Type C meeting request with the US Food and Drug Administration (the "FDA") regarding the Company's XRx-026 program for the treatment of gout. Development of XORLO™¹, the Company's proprietary drug formulation of oxypurinol, has advanced to the point where a Type C meeting and discussion with the FDA is warranted. The purpose of this meeting is to review the XRx-026 program and its readiness for submission of a New Drug Application ("NDA") to gain marketing approval for XORLO™ in the US using the FDA's 505(b)2 development pathway.

Dr. Allen Davidoff, XORTX's CEO, commented, "The key elements of the XRx-026 program have advanced sufficiently to warrant a robust program review with the FDA. Having completed the work the FDA requested be conducted on oxypurinol in an approval letter issued previously, this Type C meeting will determine the FDA's position prior to submitting a NDA for final marketing approval. The meeting is expected to be held within 75 days of the FDA's receipt of the request. The prospect of helping individuals with gout that have otherwise few therapeutic options, combined with the fact that this program may be revenue positive within the next two years, is compelling."

The Company will provide updates on the progress of the XRx-026 gout program when additional information is available.

About Gout

In the US, approximately 44 million individuals have circulating uric acid above the normal range⁽¹⁾ and approximately 9.2 million individuals have symptomatic gout. Gout is an inflammatory arthritis that is triggered by the crystallization of uric acid in tissues, particularly the joints. Gout flares cause severe pain, reduced quality of life⁽²⁾, decreased physical function⁽²⁾⁽³⁾, increased healthcare costs⁽⁴⁾, and lost economic productivity⁽⁵⁾. Furthermore, gout is strongly associated with other serious conditions such as myocardial infarction⁽⁶⁾⁽⁷⁾, type 2 diabetes⁽⁸⁾, chronic kidney disease⁽⁹⁾, and premature mortality⁽⁶⁾⁽¹⁰⁾⁽¹¹⁾.

About the XRx-026 Program and XORLO™

The XRx-026 program is developing XORLO™ – a proprietary formulation of oxypurinol to

treat individuals suffering from gout. At present, oral xanthine oxidase inhibitors (“XOIs”) are the preferred therapeutic option used to inhibit the production of uric acid and decrease high uric acid levels in gout patients. Allopurinol is the most commonly prescribed XOI, with approximately 3.3 million prescriptions written annually in the US. Although effective, 3 to 5% of patients cannot tolerate allopurinol. An alternative XOI, Febuxostat, was launched in 2009 in the US with the hope of treating individuals with gout, and particularly those that were allopurinol-intolerant. While Febuxostat achieved peak sales of approximately US\$450 million², it was issued a Black Box warning due to its associated risk of sudden cardiovascular death, and its use declined significantly. Additionally, XORLO™ can address the unmet medical needs of allopurinol-intolerant patients and accelerating its NDA approval is now XORTX’s priority.

References:

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XORTX is a pharmaceutical company with three clinically advanced products in development: 1) our lead program 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. 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. Additional information on XORTX is available at www.xortx.com.

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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 XORLO™ is XORTX's proprietary formulation of oxypurinol, that has granted US and EU patents.

² Source: Takeda Pharmaceutical Company 2018 Annual Report.



Source: XORTX Therapeutics Inc.